```
*************************************************************************************************;
**  Program Name    :  adc19ef-ve-cov-7pd2-eval.sas                                    **;
**  Date Created    :  22Mar2021                                                   **;
**  Programmer Name :  WUY169                                                      **;
**  Purpose         :  Create adc19ef-ve-cov-7pd2-eval                             **;
**  Input data      :  adc19ef                                                 **;
**  Output data     :  adc19ef-ve-cov-7pd2-eval.html                               **;
*************************************************************************************************;
options mprint mlogic symbolgen mprint symbolgen mlogic nocenter missing=" ";
title;
footnote;

proc datasets library=WORK kill nolist nodetails;
quit;

%let prot=/Volumes/app/cdars/prod/sites/cdars4/prjC459/nda2_unblinded_esub/bla_esub_adam/saseng/cdisc3_0;
libname datvprot "&prot./data_vai" access=readonly;

%let codename=adc19ef-ve-cov-7pd2-eval;
%let outlog=&prot./analysis/esub/logs/&codename..log;
%let outtable=&prot./analysis/esub/output/&codename..html;

proc printto log="&outlog" new;
run;

/*** Population Flag **/

proc sql;
  create table popf as select distinct usubjid, evaleffl, trt01pn, trt01p, aai2effl
  from datvprot.adsl
  where EVALEFFL='Y' and MULENRFL ne "Y" and PHASEN ne 1 and HIVFL = 'N'
  order by usubjid;
quit;

proc sql;
  create table adc19ef as select *
  from datvprot.adc19ef
  order by usubjid;
quit;

data tpop;
  merge adc19ef (in = a) popf (in = b);
  by usubjid;
  if a*b;
run;

/***** Total Population ****/

proc sql;
  create table dsin as select distinct subjid, trt01pn, trt01p, paramn, paramcd, param, CDCRMUFL, CDP27FL,
PDRMUPFL,
  aval, avalc, evaleffl, PDP27FL, pdrmufl, ILD27FL, filocrfl, usubjid, aai2effl, PDP214FL, ILD214FL, CDRMUPFL,
adt, dvstdt
```

```
  from tpop;
quit;

proc sql noprint;
  select bign into :n1 - :n2
  from (select count(distinct usubjid) as bign, trt01pn
  from dsin
  group by trt01pn)
  order by trt01pn;
quit;

%let n1 = &n1.;
%let n2 = &n2.;

%put &n1 &n2.;

/*** Subjects at Risk ****/

proc sql;
  create table riskp as select distinct usubjid, trt01pn, trt01p, aval
  from dsin
  where PDRMUPFL = "N" and paramcd in ("ST27PD") and aval > 0;
quit;

proc sql;
  create table n2 as select count(distinct usubjid) as n2, trt01pn
  from riskp
  group by trt01pn
  order by trt01pn;
quit;

/***** Events (n1) ****/

proc sql;
  create table evnts as select distinct usubjid, param, avalc, trt01pn
  from dsin
  where paramcd in ("C19ONST") and upcase(ILD27FL) = "Y" and upcase(FILOCRFL) = "Y" and ((not
missing(DVSTDT) and adt <= DVSTDT) or missing(DVSTDT))
  and usubjid in (select distinct usubjid from riskp)
  order by usubjid;
quit;

proc sql;
  create table evtn as select count(distinct usubjid) as smln, trt01pn
  from evnts
  group by trt01pn
  order by trt01pn;
quit;

/**** Make sure All treatment arms are present in EVTN dataset (with 0 cases) *****/
proc sql noprint;
  create table trt_u as
  select distinct trt01pn
  from dsin
```

```
  order by trt01pn;
quit;

data evtn;
  merge evtn (in=a) trt_u (in=b);
  by trt01pn;
  if b;
  if missing(smln) then smln = 0;
run;

/*** Surveillance Time ****/

proc sql;
  create table st as select distinct usubjid, aval, trt01pn, trt01p, paramcd
  from dsin
  where paramcd in ("ST27PD") and
  usubjid in (select distinct usubjid from riskp);
quit;

proc sql;
  create table riskn as select a.*, b.ptyrs, pty
  from  n2 a inner join
  (select (sum(aval)/365.25/1000) as ptyrs, sum(aval)/365.25 as pty, trt01pn
  from st group by trt01pn) b on a.trt01pn = b.trt01pn;
quit;

proc sql;
  create table pt as select strip(put(a.smln,best.)) as evtn, b.*, smln/ptyrs as ir,
  a.smln, (put(ptyrs, 7.3) || " (" || strip(put(n2,best.))) || ")" as ptyb
  from evtn a inner join
  riskn b on a.trt01pn = b.trt01pn;
quit;

/**** Total cases ****/
proc sql noprint;
  select sum(smln) into :ncases
  from pt;
quit;

%let ncases = &ncases.;

/***** Cases in Vacination Group ****/

proc sql noprint;
   select smln into :nv1-:nv2 from pt;
quit;

%let nv1 = &nv1;
%let nv2 = &nv2;
%let ncases = &ncases;
%let ve = 0.3;

%put No. of Cases in Vacination group are &nv1.;
%put Total No. of Cases in the trial are &ncases.;
```

```
proc transpose data = pt out = tr prefix = trt;
  var ptyrs;
  id trt01pn;
run;

data tr;
 set tr;
 *IRR=trt8/trt9;
 n_p = &ncases - &nv1.;
 r = trt8/trt9;
 P = R*(1-&VE)/(1+R*(1-&VE));
 IR_V=&nv1/trt8;
 IR_P=n_p/trt9;
 alpha = 0.05;
 length VE lcl ucl $25.;
 VE=strip(put(100*(1-IR_V/IR_P),7.1));
 pr = put(CDF('BETA',p,0.700102+&nv1,1+&ncases-&nv1),7.4);
 pr_n = CDF('BETA',p,0.700102+&nv1,1+&ncases-&nv1);
 qh_theta = quantile('BETA',0.975,0.700102+&nv1,1+&ncases-&nv1);
 ql_theta = quantile('BETA',0.025,0.700102+&nv1,1+&ncases-&nv1);
 QH = round (100*(R - qL_theta*(R+1))/(R*(1-qL_theta)), 0.01);
 QL = round (100*(R - qH_theta*(R+1))/(R*(1-qH_theta)), 0.01);

 *** Use Clopper-Pearson Method to display CI ****;
 fu = finv( 1- alpha/2, 2*(&nv1.+1), 2*N_P);
 ucl_pi = (&nv1 +1)*fu/(N_P + (&nv1.+1)*fu);
 fl = finv(1-alpha/2, 2*(N_P+1), 2*&nv1.);
 if &nv1 = 0 then lcl_pi = 0;
 else lcl_pi = &nv1./(&nv1. + fl*(N_P+1));
 ucl_theta = ucl_pi/(r*(1-ucl_pi));
 lcl_theta = lcl_pi/(r*(1-lcl_pi));
 qu = 100*(1 - lcl_theta);
 ql = 100*(1 - ucl_theta);
 if not missing(ql) then lcl = strip(put(ql,8.1));
 else lcl = "-(*ESC*){unicode 221e}";
 if not missing(qu) then ucl = strip(put(qu,8.1));
 else ucl = 'NE';
 vci = "(" || strip(lcl) || ", " || strip(ucl) || ")";
 **** END ****;

 text = "First COVID-19 occurrence from 7 days after Dose 2";
 /**** If probablity is 0 then show <0.0001' and if its 1 then then show >0.9999 *****/
 if pr_n < 0.0001 then pr = '<0.0001';
 else if pr_n > 0.9999 then pr = '>0.9999';
 /**** If VE is missing then show Infinity symbol ****/
 if strip(ve) = '.' then do; ve = "-(*ESC*){unicode 221e}"; vci = "(NA, NA)"; end;
run;

proc transpose data = pt out = trn prefix = trtn;
  var evtn;
  id trt01pn;
run;
```

```
proc transpose data = pt out = try prefix = trty;
  var ptyb;
  id trt01pn;
run;

proc sql;
  create table final as select a.*, b.*, c.*
  from trn (drop = _name_) a,
  try (drop = _name_) b,
  tr (drop = _name_) c;
quit;

********* Set up Report *******;
ods escapechar="~";

ods html file="&outtable.";

title1 "Vaccine Efficacy (*ESC*){unicode 2013} First COVID-19 Occurrence From 7 Days After Dose 2";
title2 "(*ESC*){unicode 2013} Blinded Placebo-Controlled Follow-up Period";
title3 "(*ESC*){unicode 2013} Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 (*ESC*)
{unicode 2013} Evaluable Efficacy (7 Days) Population";
footnote1 "Abbreviation: VE = vaccine efficacy.";
footnote2 "a.(*ESC*){nbspace 5}N = number of subjects in the specified group. ~nb.(*ESC*){nbspace 5}n1 = Number
of subjects meeting the endpoint definition.";
footnote3 "c.(*ESC*){nbspace 5}Total surveillance time in 1000 person-years for the given endpoint across all subjects
within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the
end of the surveillance period.";
footnote4 "d.(*ESC*){nbspace 5}n2 = Number of subjects at risk for the endpoint.";
footnote5 "e.(*ESC*){nbspace 5}Confidence interval (CI) for VE is derived based on the Clopper and Pearson method
adjusted for surveillance time.";
footnote6 "f.(*ESC*){nbspace 5}Posterior probability (Pr) was calculated using a beta-binomial model with prior beta
(0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.";
;

proc report data = final nowd headline headskip split = "*" style(report)=[];
column (text ("Vaccine Group (as Randomized)~{line}" ("BNT162b2 (30 ~{unicode 03BC}g)*(N~{super a}=&n1.)"
trtn8 trty8) ("Placebo*(N~{super a}=&n2.)" trtn9 trty9)) ve vci pr);
define text / "Efficacy Endpoint" flow style(header)=[just=l] style(column)=[cellwidth=3in just=l];
define trtn8 / " n1~{super b}" style(column)=[cellwidth=0.8in just=c];
define trty8 / "Surveillance*Time~{super c} (n2~{super d})" style(column)=[cellwidth=1.5in just=c];
define trtn9 / " n1~{super b}" style(column)=[cellwidth=0.8in just=c];
define trty9 / "Surveillance*Time~{super c} (n2~{super d})" style(column)=[cellwidth=1.5in just=c];
define ve / "  VE (%)" style(column)=[cellwidth=0.5in just=c];
define vci / " (95% CI~{super e})" style(column)=[cellwidth=0.5in just=c];
define pr / "Pr (VE >30% | data)~{super f}" style(column)=[cellwidth=0.5in just=c];
run;

ods HTML close;

proc printto;
run;
```

```
*************************************************************************************************;
**  Program Name    :  adc19ef-ve-sev-cov-7pd2-eval.sas                                          **;
**  Date Created    :  22Mar2021                                                                 **;
**  Programmer Name :  WUY169                                                                    **;
**  Purpose         :  Create adc19ef-ve-sev-cov-7pd2-eval                                       **;
**  Input data      :  adc19ef                                                                   **;
**  Output data     :  adc19ef-ve-sev-cov-7pd2-eval.html                                         **;
*************************************************************************************************;
options mprint mlogic symbolgen mprint symbolgen mlogic nocenter missing=" ";
title;
footnote;

proc datasets library=WORK kill nolist nodetails;
quit;

%let prot=/Volumes/app/cdars/prod/sites/cdars4/prjC459/nda2_unblinded_esub/bla_esub_adam/saseng/cdisc3_0;
libname datvprot "&prot./data_vai" access=readonly;

%let codename=adc19ef-ve-sev-cov-7pd2-eval;
%let outlog=&prot./analysis/esub/logs/&codename..log;
%let outtable=&prot./analysis/esub/output/&codename..html;

proc printto log="&outlog" new;
run;

/*** Population Flag **/

proc sql;
  create table popf as select distinct usubjid, evaleffl, trt01pn, trt01p, aai2effl
  from datvprot.adsl
  where EVALEFFL='Y' and MULENRFL ne "Y" and PHASEN ne 1 and HIVFL = 'N'
  order by usubjid;
quit;

proc sql;
  create table adc19ef as select *
  from datvprot.adc19ef
  order by usubjid;
quit;

data tpop;
  merge adc19ef (in = a) popf (in = b);
  by usubjid;
  if a*b;
run;

/***** Total Population ****/

proc sql;
  create table dsin as select distinct subjid, trt01pn, trt01p, paramn, paramcd, param, CDCRMUFL, CDP27FL,
PDRMUPFL,
  aval, avalc, evaleffl, PDP27FL, pdrmufl, ILD27FL, filocrfl, usubjid, aai2effl, PDP214FL, ILD214FL, CDRMUPFL,
adt, dvstdt
```

```
  from tpop;
quit;

proc sql noprint;
  select bign into :n1 - :n2
  from (select count(distinct usubjid) as bign, trt01pn
  from dsin
  group by trt01pn)
  order by trt01pn;
quit;

%let n1 = &n1.;
%let n2 = &n2.;

%put &n1 &n2.;

/*** Subjects at Risk ****/

proc sql;
  create table riskp as select distinct usubjid, trt01pn, trt01p, aval
  from dsin
  where PDRMUPFL = "N" and paramcd in ("ST27SE") and aval > 0;
quit;

proc sql;
  create table n2 as select count(distinct usubjid) as n2, trt01pn
  from riskp
  group by trt01pn
  order by trt01pn;
quit;

/***** Events (n1) ****/

proc sql;
  create table evnts as select distinct usubjid, param, avalc, trt01pn
  from dsin
  where paramcd in ("SEVCONST") and upcase(ILD27FL) = "Y" and upcase(FILOCRFL) = "Y" and ((not
missing(DVSTDT) and adt <= DVSTDT) or missing(DVSTDT))
  and usubjid in (select distinct usubjid from riskp)
  order by usubjid;
quit;

proc sql;
  create table evtn as select count(distinct usubjid) as smln, trt01pn
  from evnts
  group by trt01pn
  order by trt01pn;
quit;

/**** Make sure All treatment arms are present in EVTN dataset (with 0 cases) *****/
proc sql noprint;
  create table trt_u as
  select distinct trt01pn
  from dsin
```

```
  order by trt01pn;
quit;

data evtn;
  merge evtn (in=a) trt_u (in=b);
  by trt01pn;
  if b;
  if missing(smln) then smln = 0;
run;

/*** Surveillance Time ****/

proc sql;
  create table st as select distinct usubjid, aval, trt01pn, trt01p, paramcd
  from dsin
  where paramcd in ("ST27SE") and
  usubjid in (select distinct usubjid from riskp);
quit;

proc sql;
  create table riskn as select a.*, b.ptyrs, pty
  from  n2 a inner join
  (select (sum(aval)/365.25/1000) as ptyrs, sum(aval)/365.25 as pty, trt01pn
  from st group by trt01pn) b on a.trt01pn = b.trt01pn;
quit;

proc sql;
  create table pt as select strip(put(a.smln,best.)) as evtn, b.*, smln/ptyrs as ir,
  a.smln, (put(ptyrs, 7.3) || " (" || strip(put(n2,best.))) || ")" as ptyb
  from evtn a inner join
  riskn b on a.trt01pn = b.trt01pn;
quit;

/**** Total cases ****/
proc sql noprint;
  select sum(smln) into :ncases
  from pt;
quit;

%let ncases = &ncases.;

/***** Cases in Vacination Group ****/

proc sql noprint;
   select smln into :nv1-:nv2 from pt;
quit;

%let nv1 = &nv1;
%let nv2 = &nv2;
%let ncases = &ncases;
%let ve = 0.3;

%put No. of Cases in Vacination group are &nv1.;
%put Total No. of Cases in the trial are &ncases.;
```

```
proc transpose data = pt out = tr prefix = trt;
  var ptyrs;
  id trt01pn;
run;

data tr;
 set tr;
 *IRR=trt8/trt9;
 n_p = &ncases - &nv1.;
 r = trt8/trt9;
 P = R*(1-&VE)/(1+R*(1-&VE));
 IR_V=&nv1/trt8;
 IR_P=n_p/trt9;
 alpha = 0.05;
 length VE lcl ucl $25.;
 VE=strip(put(100*(1-IR_V/IR_P),7.1));
 pr = put(CDF('BETA',p,0.700102+&nv1,1+&ncases-&nv1),7.4);
 pr_n = CDF('BETA',p,0.700102+&nv1,1+&ncases-&nv1);
 qh_theta = quantile('BETA',0.975,0.700102+&nv1,1+&ncases-&nv1);
 ql_theta = quantile('BETA',0.025,0.700102+&nv1,1+&ncases-&nv1);
 QH = round (100*(R - qL_theta*(R+1))/(R*(1-qL_theta)), 0.01);
 QL = round (100*(R - qH_theta*(R+1))/(R*(1-qH_theta)), 0.01);

 *** Use Clopper-Pearson Method to display CI ****;
 fu = finv( 1- alpha/2, 2*(&nv1.+1), 2*N_P);
 ucl_pi = (&nv1 +1)*fu/(N_P + (&nv1.+1)*fu);
 fl = finv(1-alpha/2, 2*(N_P+1), 2*&nv1.);
 if &nv1 = 0 then lcl_pi = 0;
 else lcl_pi = &nv1./(&nv1. + fl*(N_P+1));
 ucl_theta = ucl_pi/(r*(1-ucl_pi));
 lcl_theta = lcl_pi/(r*(1-lcl_pi));
 qu = 100*(1 - lcl_theta);
 ql = 100*(1 - ucl_theta);
 if not missing(ql) then lcl = strip(put(ql,8.1));
 else lcl = "-(*ESC*){unicode 221e}";
 if not missing(qu) then ucl = strip(put(qu,8.1));
 else ucl = 'NE';
 vci = "(" || strip(lcl) || ", " || strip(ucl) || ")";
 **** END ****;

 text = "First severe COVID-19 occurrence from 7 days after Dose 2";
 /**** If probablity is 0 then show <0.0001' and if its 1 then then show >0.9999 *****/
 if pr_n < 0.0001 then pr = '<0.0001';
 else if pr_n > 0.9999 then pr = '>0.9999';
 /**** If VE is missing then show Infinity symbol ****/
 if strip(ve) = '.' then do; ve = "-(*ESC*){unicode 221e}"; vci = "(NA, NA)"; end;
run;

proc transpose data = pt out = trn prefix = trtn;
  var evtn;
  id trt01pn;
run;
```

```
proc transpose data = pt out = try prefix = trty;
  var ptyb;
  id trt01pn;
run;

proc sql;
  create table final as select a.*, b.*, c.*
  from trn (drop = _name_) a,
  try (drop = _name_) b,
  tr (drop = _name_) c;
quit;

********* Set up Report *******;
ods escapechar="~";

ods html file="&outtable.";

title1 "Vaccine Efficacy (*ESC*){unicode 2013} First Severe COVID-19 Occurrence From 7 Days After Dose 2";
title2 "(*ESC*){unicode 2013} Blinded Placebo-Controlled Follow-up Period";
title3 "(*ESC*){unicode 2013} Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 (*ESC*)
{unicode 2013} Evaluable Efficacy (7 Days) Population";
footnote1 "Abbreviation: VE = vaccine efficacy.";
footnote2 "a.(*ESC*){nbspace 5}N = number of subjects in the specified group. ~nb.(*ESC*){nbspace 5}n1 = Number
of subjects meeting the endpoint definition.";
footnote3 "c.(*ESC*){nbspace 5}Total surveillance time in 1000 person-years for the given endpoint across all subjects
within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the
end of the surveillance period.";
footnote4 "d.(*ESC*){nbspace 5}n2 = Number of subjects at risk for the endpoint.";
footnote5 "e.(*ESC*){nbspace 5}Confidence interval (CI) for VE is derived based on the Clopper and Pearson method
adjusted for surveillance time.";
footnote6 "f.(*ESC*){nbspace 5}Posterior probability (Pr) was calculated using a beta-binomial model with prior beta
(0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.";
;


proc report data = final nowd headline headskip split = "*" style(report)=[];
column (text ("Vaccine Group (as Randomized)~{line}" ("BNT162b2 (30 ~{unicode 03BC}g)*(N~{super a}=&n1.)"
trtn8 trty8) ("Placebo*(N~{super a}=&n2.)" trtn9 trty9)) ve vci pr);
define text / "Efficacy Endpoint" flow style(header)=[just=l] style(column)=[cellwidth=3in just=l];
define trtn8 / " n1~{super b}" style(column)=[cellwidth=0.8in just=c];
define trty8 / "Surveillance*Time~{super c} (n2~{super d})" style(column)=[cellwidth=1.5in just=c];
define trtn9 / " n1~{super b}" style(column)=[cellwidth=0.8in just=c];
define trty9 / "Surveillance*Time~{super c} (n2~{super d})" style(column)=[cellwidth=1.5in just=c];
define ve / "  VE (%)" style(column)=[cellwidth=0.5in just=c];
define vci / " (95% CI~{super e})" style(column)=[cellwidth=0.5in just=c];
define pr / "Pr (VE >30% | data)~{super f}" style(column)=[cellwidth=0.5in just=c];
run;

ods HTML close;

proc printto;
run;
```

```
*************************************************************************************************;
**  Program Name    :  adc19ef-ve-sev-cov-7pd2-wo-eval.sas                          **;
**  Date Created    :  22Mar2021                                                    **;
**  Programmer Name :  WUY169                                                       **;
**  Purpose         :  Create adc19ef-ve-sev-cov-7pd2-wo-eval                       **;
**  Input data      :  adc19ef                                                      **;
**  Output data     :  adc19ef-ve-sev-cov-7pd2-wo-eval.html                         **;
*************************************************************************************************;
options mprint mlogic symbolgen mprint symbolgen mlogic nocenter missing=" ";
title;
footnote;

proc datasets library=WORK kill nolist nodetails;
quit;

%let prot=/Volumes/app/cdars/prod/sites/cdars4/prjC459/nda2_unblinded_esub/bla_esub_adam/saseng/cdisc3_0;
libname datvprot "&prot./data_vai" access=readonly;

%let codename=adc19ef-ve-sev-cov-7pd2-wo-eval;
%let outlog=&prot./analysis/esub/logs/&codename..log;
%let outtable=&prot./analysis/esub/output/&codename..html;

proc printto log="&outlog" new;
run;

/*** Population Flag **/

proc sql;
  create table popf as select distinct usubjid, evaleffl, trt01pn, trt01p, aai2effl
  from datvprot.adsl
  where EVALEFFL='Y' and MULENRFL ne "Y" and PHASEN ne 1 and HIVFL = 'N'
  order by usubjid;
quit;

proc sql;
  create table adc19ef as select *
  from datvprot.adc19ef
  order by usubjid;
quit;

data tpop;
  merge adc19ef (in = a) popf (in = b);
  by usubjid;
  if a*b;
run;

/***** Total Population ****/

proc sql;
  create table dsin as select distinct subjid, trt01pn, trt01p, paramn, paramcd, param, CDCRMUFL, CDP27FL,
PDRMUPFL,
  aval, avalc, evaleffl, PDP27FL, pdrmufl, ILD27FL, filocrfl, usubjid, aai2effl, PDP214FL, ILD214FL, CDRMUPFL,
adt, dvstdt
```

```
  from tpop;
quit;

proc sql noprint;
  select bign into :n1 - :n2
  from (select count(distinct usubjid) as bign, trt01pn
  from dsin
  where PDP27FL = "Y"
  group by trt01pn)
  order by trt01pn;
quit;

%let n1 = &n1.;
%let n2 = &n2.;

%put &n1 &n2.;

/*** Subjects at Risk ****/

proc sql;
  create table riskp as select distinct usubjid, trt01pn, trt01p, aval
  from dsin
  where PDRMUPFL = "N" and PDP27FL = "Y" and paramcd in ("ST27SE") and aval > 0;
quit;

proc sql;
  create table n2 as select count(distinct usubjid) as n2, trt01pn
  from riskp
  group by trt01pn
  order by trt01pn;
quit;

/***** Events (n1) ****/

proc sql;
  create table evnts as select distinct usubjid, param, avalc, trt01pn
  from dsin
  where paramcd in ("SEVCONST") and upcase(ILD27FL) = "Y" and upcase(FILOCRFL) = "Y" and ((not
missing(DVSTDT) and adt <= DVSTDT) or missing(DVSTDT))
  and usubjid in (select distinct usubjid from riskp)
  order by usubjid;
quit;

proc sql;
  create table evtn as select count(distinct usubjid) as smln, trt01pn
  from evnts
  group by trt01pn
  order by trt01pn;
quit;

/**** Make sure All treatment arms are present in EVTN dataset (with 0 cases) *****/
proc sql noprint;
  create table trt_u as
  select distinct trt01pn
```

```
  from dsin
  order by trt01pn;
quit;

data evtn;
  merge evtn (in=a) trt_u (in=b);
  by trt01pn;
  if b;
  if missing(smln) then smln = 0;
run;

/*** Surveillance Time ****/

proc sql;
  create table st as select distinct usubjid, aval, trt01pn, trt01p, paramcd
  from dsin
  where paramcd in ("ST27SE") and
  usubjid in (select distinct usubjid from riskp);
quit;

proc sql;
  create table riskn as select a.*, b.ptyrs, pty
  from  n2 a inner join
  (select (sum(aval)/365.25/1000) as ptyrs, sum(aval)/365.25 as pty, trt01pn
  from st group by trt01pn) b on a.trt01pn = b.trt01pn;
quit;

proc sql;
  create table pt as select strip(put(a.smln,best.)) as evtn, b.*, smln/ptyrs as ir,
  a.smln, (put(ptyrs, 7.3) || " (" || strip(put(n2,best.))) || ")" as ptyb
  from evtn a inner join
  riskn b on a.trt01pn = b.trt01pn;
quit;

/**** Total cases ****/
proc sql noprint;
  select sum(smln) into :ncases
  from pt;
quit;

%let ncases = &ncases.;

/***** Cases in Vacination Group ****/

proc sql noprint;
   select smln into :nv1-:nv2 from pt;
quit;

%let nv1 = &nv1;
%let nv2 = &nv2;
%let ncases = &ncases;
%let ve = 0.3;

%put No. of Cases in Vacination group are &nv1.;
```

```
%put Total No. of Cases in the trial are &ncases.;

proc transpose data = pt out = tr prefix = trt;
  var ptyrs;
  id trt01pn;
run;

data tr;
 set tr;
 *IRR=trt8/trt9;
 n_p = &ncases - &nv1.;
 r = trt8/trt9;
 P = R*(1-&VE)/(1+R*(1-&VE));
 IR_V=&nv1/trt8;
 IR_P=n_p/trt9;
 alpha = 0.05;
 length VE lcl ucl $25.;
 VE=strip(put(100*(1-IR_V/IR_P),7.1));
 pr = put(CDF('BETA',p,0.700102+&nv1,1+&ncases-&nv1),7.4);
 pr_n = CDF('BETA',p,0.700102+&nv1,1+&ncases-&nv1);
 qh_theta = quantile('BETA',0.975,0.700102+&nv1,1+&ncases-&nv1);
 ql_theta = quantile('BETA',0.025,0.700102+&nv1,1+&ncases-&nv1);
 QH = round (100*(R - qL_theta*(R+1))/(R*(1-qL_theta)), 0.01);
 QL = round (100*(R - qH_theta*(R+1))/(R*(1-qH_theta)), 0.01);

 *** Use Clopper-Pearson Method to display CI ****;
 fu = finv( 1- alpha/2, 2*(&nv1.+1), 2*N_P);
 ucl_pi = (&nv1 +1)*fu/(N_P + (&nv1.+1)*fu);
 fl = finv(1-alpha/2, 2*(N_P+1), 2*&nv1.);
 if &nv1 = 0 then lcl_pi = 0;
 else lcl_pi = &nv1./(&nv1. + fl*(N_P+1));
 ucl_theta = ucl_pi/(r*(1-ucl_pi));
 lcl_theta = lcl_pi/(r*(1-lcl_pi));
 qu = 100*(1 - lcl_theta);
 ql = 100*(1 - ucl_theta);
 if not missing(ql) then lcl = strip(put(ql,8.1));
 else lcl = "-(*ESC*){unicode 221e}";
 if not missing(qu) then ucl = strip(put(qu,8.1));
 else ucl = 'NE';
 vci = "(" || strip(lcl) || ", " || strip(ucl) || ")";
 **** END ****;

 text = "First severe COVID-19 occurrence from 7 days after Dose 2";
 /**** If probablity is 0 then show <0.0001' and if its 1 then then show >0.9999 *****/
 if pr_n < 0.0001 then pr = '<0.0001';
 else if pr_n > 0.9999 then pr = '>0.9999';
 /**** If VE is missing then show Infinity symbol ****/
 if strip(ve) = '.' then do; ve = "-(*ESC*){unicode 221e}"; vci = "(NA, NA)"; end;
run;

proc transpose data = pt out = trn prefix = trtn;
  var evtn;
  id trt01pn;
run;
```

```
proc transpose data = pt out = try prefix = trty;
  var ptyb;
  id trt01pn;
run;

proc sql;
  create table final as select a.*, b.*, c.*
  from trn (drop = _name_) a,
  try (drop = _name_) b,
  tr (drop = _name_) c;
quit;

********* Set up Report *******;
ods escapechar="~";

ods html file="&outtable.";

title1 "Vaccine Efficacy (*ESC*){unicode 2013} First Severe COVID-19 Occurrence From 7 Days After Dose 2";
title2 "(*ESC*){unicode 2013} Blinded Placebo-Controlled Follow-up Period";
title3 "(*ESC*){unicode 2013} Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 (*ESC*){unicode 2013} Evaluable Efficacy (7 Days) Population";
footnote1 "Abbreviations: N-binding = SARS-CoV-2 nucleoprotein(*ESC*){unicode 2013}binding; NAAT = nucleic acid amplification test; ~nSARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.";
footnote2 "Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.";
footnote3 "a.(*ESC*){nbspace 5}N = number of subjects in the specified group. ~nb.(*ESC*){nbspace 5}n1 = Number of subjects meeting the endpoint definition.";
footnote4 "c.(*ESC*){nbspace 5}Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.";
footnote5 "d.(*ESC*){nbspace 5}n2 = Number of subjects at risk for the endpoint.";
footnote6 "e.(*ESC*){nbspace 5}Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.";
footnote7 "f.(*ESC*){nbspace 5}Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.";
;

proc report data = final nowd headline headskip split = "*" style(report)=[];
column (text ("Vaccine Group (as Randomized)~{line}" ("BNT162b2 (30 ~{unicode 03BC}g)*(N~{super a}=&n1.)" trtn8 trty8) ("Placebo*(N~{super a}=&n2.)" trtn9 trty9)) ve vci pr);
define text / "Efficacy Endpoint" flow style(header)=[just=l] style(column)=[cellwidth=3in just=l];
define trtn8 / " n1~{super b}" style(column)=[cellwidth=0.8in just=c];
define trty8 / "Surveillance*Time~{super c} (n2~{super d})" style(column)=[cellwidth=1.5in just=c];
define trtn9 / " n1~{super b}" style(column)=[cellwidth=0.8in just=c];
define trty9 / "Surveillance*Time~{super c} (n2~{super d})" style(column)=[cellwidth=1.5in just=c];
define ve / "  VE (%)" style(column)=[cellwidth=0.5in just=c];
define vci / " (95% CI~{super e})" style(column)=[cellwidth=0.5in just=c];
define pr / "Pr (VE >30% | data)~{super f}" style(column)=[cellwidth=0.5in just=c];
run;

ods HTML close;
```

```
proc printto;
run;
```

```
*************************************************************************************************;
**  Program Name    :  addv.sas                                                                  **;
**  Date Created    :  09Mar2021                                                                 **;
**  Programmer Name :  XIONGR03                                                                  **;
**  Purpose         :  Create addv dataset                                                       **;
**  Input data      :  dv suppdv adsl                                                            **;
**  Output data     :  addv.sas7bdat                                                             **;
*************************************************************************************************;
options mprint mlogic symbolgen mprint symbolgen mlogic nocenter missing=" ";

proc datasets library=WORK kill nolist nodetails;
quit;

**Setup the environment**;
%let
oprot=/Volumes/app/cdars/prod/sites/cdars4/prjC459/nda2_unblinded_esub/bla_euaext_esub_sdtm/saseng/cdisc3_0;
%let prot=/Volumes/app/cdars/prod/sites/cdars4/prjC459/nda2_unblinded_esub/bla_esub_adam/saseng/cdisc3_0;
libname dataprot "&oprot./data" access=readonly;
libname datvprot "&prot./data_vai";

proc printto print="&prot./analysis/esub/output/addv.rpt"
      log="&prot./analysis/esub/logs/addv.log" new;
run;

proc sort data=dataprot.suppdv out=suppdv;
   by usubjid idvarval qnam;
run;

proc transpose data=suppdv out=suppdv1(drop=_NAME_ _LABEL_);
   by usubjid idvarval;
   var qval;
   id qnam;
   idlabel qlabel;
run;

data suppdv1;
   set suppdv1;
   dvseq=input(idvarval, best.);
run;

proc sort;
   by usubjid dvseq;
run;

proc sort data=dataprot.dv out=dv;
   by usubjid dvseq;
run;

data _dv1;
   merge dv suppdv1;
   by usubjid dvseq;

proc sort;
```

```
   by usubjid;
run;

proc sort data=datvprot.adsl out=adsl;
   by usubjid;
run;

data _dv2;
   merge _dv1(in=a) adsl(in=b);
   by usubjid;

   if a;
run;

data _dv3;
   set _dv2;
   format ASTDT date9. aphasdt date9. aphaedt date9.;
   length aphase $40. aperiodc $20.;
   label ASTDT='Analysis Start Date' APHASE='Phase' APERIOD='Period'
      APERIODC='Period (C)' PREFL='Pre-treatment Flag' TRPFL='On Treatment Flag';
   p2dt=min(VAX201DT, unblnddt);

   if dvstdtc ne "" then
      astdt=input(dvstdtc, yymmdd10.);

   if brthdt<=astdt<=(trtsdt-1) then
      do;
         aphase='PRE-TREATMENT';
      end;
   else if (.<trtsdt<=astdt and p2dt=.) or (p2dt ne . and .<trtsdt<=astdt<p2dt)
      then
         do;
         aphase='TREATMENT 01';
      end;
   else if .<p2dt<=astdt<trtedt+365 then
      do;
         aphase='TREATMENT 02';
      end;

   if (trtsdt ne . and .<astdt and p2dt=.) or (trtsdt ne . and p2dt
      ne . and .<astdt<p2dt) then
         do;
         aperiod=1;
         aperiodc='Period 01';
      end;
   else if .<p2dt<=astdt<=trtsdt+365 then
      do;
         aperiod=2;
         aperiodc='Period 02';
      end;

   if astdt<trtsdt then
      prefl='Y';
```

```
   if substr(aphase, 1, 9)='TREATMENT' then
      TRPFL='Y';
   else
      TRPFL='N';
run;

data final;
   retain studyid usubjid domain subjid siteid age sex race trtsdt trtedt arm
      armcd actarm actarmcd trt01p trt01a trt01pn trt01an agegr1 agegr1n dvseq
      dvspid dvterm dvterm1 dvdecod epoch actsite desgtor cape dvcat dvstdtc dvstdy
      astdt prefl trpfl randfl phase phasen trtarn trtar trtprn trtpr COHORT
      COHORTN DOSALVL DOSALVLN DOSPLVL DOSPLVLN DS3KFL AGEGR3N AGEGR3 AGEGR4N
      AGEGR4 HIVFL AGETR01 TRTSDTM TRTEDTM TR01SDTM TR01EDTM TR02SDTM TR02EDTM
      VAX101 VAX102 VAX10U VAX201 VAX202 VAX20U VAX20UDT UNBLNDDT MULENRFL RAND1FL;
   set _dv3;
   keep studyid usubjid domain subjid siteid age sex race trtsdt trtedt arm armcd
      actarm actarmcd trt01p trt01a trt01pn trt01an agegr1 agegr1n dvseq dvspid
      dvterm dvterm1 dvdecod epoch actsite desgtor cape dvcat dvstdtc dvstdy astdt
      prefl trpfl randfl phase phasen trtarn trtar trtprn trtpr COHORT COHORTN
      DOSALVL DOSALVLN DOSPLVL DOSPLVLN DS3KFL AGEGR3N AGEGR3 AGEGR4N AGEGR4 HIVFL
      AGETR01 TRTSDTM TRTEDTM TR01SDTM TR01EDTM TR02SDTM TR02EDTM VAX101 VAX102
      VAX10U VAX201 VAX202 VAX20U VAX20UDT UNBLNDDT MULENRFL RAND1FL;
run;
proc sort data=final
      out=datvprot.addv(label='Protocol Deviations Analysis Dataset');
   by USUBJID ASTDT;
run;

proc printto;
run;
```

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** COHORT SELECTION
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Cohort Selection		
DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.		
1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Informed Consent		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/7/2020

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Demography		
1.	Subject ID	[10551006]
2.	Birth Date:	(b) (6)/1955
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Aug/7/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** INCLUSION/EXCLUSION CRITERIA

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met		
1.	Description of Inclusion Criterion Not Met	Not Applicable
Exclusion Criteria Met		
2.	Description of Exclusion Criterion Met	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Screening		
1.	Date of Completion/Discontinuation/Death	Aug/7/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Keratoconus, bilateral eyes]
	Start Date:	UNK/UNK/1969
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal allergies]
	Start Date:	UNK/UNK/1958
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Benign Pulmonary Granulomas]
	Start Date:	UNK/UNK/2009
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Osteoarthritis, bilateral thumbs]
	Start Date:	UNK/UNK/2002
	Ongoing:	YES

1.e

Line/MH Number:	[5]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hyperlipidemia]
Start Date:	Sep/UNK/2018
Ongoing:	YES

~~1.f~~

Line/MH Number:	[~~6~~]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[~~Intermittent urinary tract infections~~]
Start Date:	~~UNK/UNK/1973~~
Ongoing:	~~YES~~

1.g

Line/MH Number:	[7]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Rosacea]
Start Date:	UNK/UNK/2010
Ongoing:	YES

1.h

Line/MH Number:	[8]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[GERD]
Start Date:	Sep/UNK/1993
Ongoing:	YES

1.i

Line/MH Number:	[9]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Lactose intolerance]
Start Date:	UNK/UNK/1993
Ongoing:	YES

1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypothyroid]
	Start Date:	Sep/UNK/1988
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Post-menopausal]
	Start Date:	Dec/UNK/2010
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Sulfite allergy]
	Start Date:	UNK/UNK/1999
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs		
1.	Date:	Aug/7/2020
2.	Weight:	[61.0]
3.	Unit:	kg
4.	Height:	[158.0]
5.	Unit:	cm
6.	Body Mass Index:	[24.4]

Vital Signs Details

7.a		
	Record Identifier:	1
	Temperature:	[36.7]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis			
1.	Lab Panel:		
2.	Lab Sub-Panel:		
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	[ ]	
5.	Specimen Type:		

Lab Result		
6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	
	Not Done:	NOT DONE

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition		
1.	Randomization Date :	Aug/7/2020
2.	Randomization Number:	[223587]
3.	Randomization Group:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/7/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP6S51]
5.b	Sample ID	[BP6S52]
5.c	Sample ID	[BP6S53]
5.d	Sample ID	[BPFTRZ]
5.e	Sample ID	[BPFTS0]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/7/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP6S4Z]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/7/2020 10:31
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** REACTOGENICITY DIARY
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Reactogenicity Diary		
1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT

Header Text: c4591001	
Visit: V2_VAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Aug/26/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO

2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

2.g	Symptom:	NEW OR WORSENED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs		
1.	Date:	Aug/26/2020

Vital Signs Details		
2.a	Record Identifier:	1
	Temperature:	[36.2]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments
eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	Not Applicable	Comments
2.	Lab Sub-Panel:	Not Applicable	Comments
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable [ ]	Comments
5.	Specimen Type:	Not Applicable	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Not Applicable Choriogonadotropin Beta_PX113	
	Result:	Not Applicable	Comments
	Not Done:	Not Applicable	Comments

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/26/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP6RXN]

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/26/2020 10:08
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/24/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO

2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Sep/6/2020
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	YES Ongoing? NO Stop Date: Sep/6/2020
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/24/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BPV09L]
5.b	Sample ID	[BPV09M]
5.c	Sample ID	[BPFTKC]
5.d	Sample ID	[BPFTKD]

Header Text: c4591001	
Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** DATE OF VISIT - ILLNESS ONSET
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Form Version: 20-Feb-2021 02:17	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Signs and Symptoms		
1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	
Symptoms		
4.	Symptoms:	
	Was symptom present?	
Symptoms - Other		
5.	Symptoms - Other Text:	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** HEALTH CARE UTILIZATION
Form Version: 20-Feb-2021 02:19	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[ ]

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	

Header Text: c4591001	
Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Illness Details		
1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Unplanned Assessments		
1.	Assessments	

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation/Death :	Sep/24/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: Follow-Up - Unscheduled | **Form:** DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Disposition - Follow-Up		
1.	Date of Completion/Discontinuation/Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit	**Form:** DATE OF VISIT - REPEAT SWAB
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001
Visit: Logs **Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Urinary Tract Infection	Sep/1/2020 22:01	NO End Date Time: Sep/6/2020 08:00	Repeating Pages
2.	ADVERSE EVENT	2	Injection site pain	Dec/22/2020 09:02	NO End Date Time: Dec/24/2020 08:00	Repeating Pages
3.	ADVERSE EVENT	3	injection site pain	Jan/11/2021 14:00	NO End Date Time: Jan/12/2021 18:00	Repeating Pages
4.	ADVERSE EVENT	4	chills	Jan/11/2021 19:00	NO End Date Time: Jan/11/2021 20:00	Repeating Pages
5.	ADVERSE EVENT	5	fatigue	Jan/12/2021 12:00	NO End Date Time: Jan/12/2021 15:00	Repeating Pages
6.	ADVERSE EVENT	6	lymph node swelling	Jan/12/2021 12:00	NO End Date Time: Jan/12/2021 15:00	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Urinary Tract Infection]
4.	Start Date Time:	Sep/1/2020 22:01
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/6/2020 08:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Bacterial Infection]

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection site pain]
4.	Start Date Time:	Dec/22/2020 09:02
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/24/2020 08:00
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[injection site pain]
4.	Start Date Time:	Jan/11/2021 14:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/12/2021 18:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[chills]
4.	Start Date Time:	Jan/11/2021 19:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/11/2021 20:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[fatigue]
4.	Start Date Time:	Jan/12/2021 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/12/2021 15:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[lymph node swelling]
4.	Start Date Time:	Jan/12/2021 12:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/12/2021 15:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001
Visit: Logs **Form:** MEDICATION ERROR
Form Version: 17-Jul-2020 21:54
Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Medication Error		
1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Influenza Vaccine	Sep/20/2020	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Concomitant Medications		
1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Influenza Vaccine]
5.	Date:	Sep/20/2020

Header Text: c4591001
Visit: Logs **Form:** CONCOMITANT MEDICATIONS - PROHIBITED
Form Version: 22-Apr-2020 21:03
Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

Header Text: c4591001

Visit: Logs **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Radiation Treatment		
1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** TRANSFUSIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1.	Transfusion Type:	
2.	Date of Transfusion:	//

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Vital Signs		
1.	Date:	//

Vital Signs Details		
2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Lab Urinalysis		
1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

Lab Result		
6.	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Dec/16/2020
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Further Vaccination Confirmation		
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2

Header Text: c4591001	
Visit: V101_VAX3	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Dec/22/2020
2.	Erroneous Visit	

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INFORMED CONSENT - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Informed Consent - Further Vaccination		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Dec/22/2020

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met		
1.	Description of Inclusion Criterion Not Met	Not Applicable
Exclusion Criteria Met		
2.	Description of Exclusion Criterion Met	Not Applicable

Header Text: c4591001

Visit: V101_VAX3 **Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Screening for Further Vaccination		
1.	Date of Completion/Discontinuation/Death :	Dec/22/2020
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments
eCRF Audit Trail History

Lab Urinalysis			
1.	Lab Panel:	Not Applicable	Comments
2.	Lab Sub-Panel:	Not Applicable	Comments
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable [ ]	Comments
5.	Specimen Type:	Not Applicable	Comments

Lab Result			
6.a	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Not Applicable Choriogonadotropin Beta_PX113	
	Result:	Not Applicable	Comments
	Not Done:	Not Applicable	Comments

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2PLR]
5.b	Sample ID	[BS3B2Z]
5.c	Sample ID	[BS3B30]

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Dec/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2PLN]

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Dec/22/2020 09:02
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** TREATMENT UNBLINDED
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Treatment Unblinded		
1.	Date Treatment Unblinded :	Dec/17/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Withdrawal Of Consent		
1.	Withdrawal of Consent Date :	//

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** DEATH DETAILS CODED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Death Details		
1.	Date of Collection / Notification of Death:	//

Cause of Death		
2.	Cause of Death Status:	
	Cause of Death:	[ ]

Header Text: c4591001

Visit: V102_VAX4 **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/11/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments
eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	Not Applicable	Comments
2.	Lab Sub-Panel:	Not Applicable	Comments
3.	Collection Date:	Not Applicable //	Comments
4.	Laboratory Name and Address (Derived)	Not Applicable [ ]	Comments
5.	Specimen Type:	Not Applicable	Comments

Lab Result

6.a	Sponsor ID:	Not Applicable [ ]	Comments
	Test:	Not Applicable Choriogonadotropin Beta_PX113	
	Result:	Not Applicable	Comments
	Not Done:	Not Applicable	Comments

Header Text: c4591001

Visit: V102_VAX4 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2PNW]

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/11/2021 09:00
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V103_MONTH1 **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Feb/12/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1 **Form:** CONTACT OUTCOME

Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Contact Outcome		
1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Feb/12/2021
3.	Comments:	[ ]

Header Text: c4591001	
Visit: V104_MONTH6	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6 **Form:** CONTACT OUTCOME

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: V105_MONTH18 **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18 **Form:** CONTACT OUTCOME

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001	
Visit: FURTHER_VACCINATION_EOT - Unscheduled	**Form:** DISPOSITION - TREATMENT
Form Version: 10-Dec-2020 02:29	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation/Death :	Feb/12/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001	
Visit: Subject Status - Unscheduled	**Form:** SUBJECT STATUS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Subject Status		
1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Sep/24/2020

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Casebook Signature Form		
1.	Casebook Signature	Click Here to Enable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Audit Trail

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Mar-01-2021 16:27:45 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** INCLUSION/EXCLUSION CRITERIA - Comments

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
Form	Aug-07-2020 12:25:25 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
3	Aug-07-2020 12:29:37 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
Form	Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe.mpastores)	Not Applicable Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
1	Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe mpastores)	Not Applicable Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
2	Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe mpastores)	Not Applicable --- Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
3	Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe mpastores)	Not Applicable Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
4	Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe mpastores)	Not Applicable Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
5	Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe mpastores)	Not Applicable Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
6.a	Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe mpastores)	Not Applicable --- Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
6.a	Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe mpastores)	Not Applicable --- Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
6.a	Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe mpastores)	Not Applicable --- Not Applicable

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
Form	Dec-22-2020 10:08:53 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
Form	Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001	
Visit: V101_VAX3	**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments
Form Version: 10-Dec-2020 02:23	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
1	Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
2	Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001	
Visit: V101_VAX3	**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments
Form Version: 10-Dec-2020 02:23	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
3	Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
4	Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
5	Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
6.a	Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001	
Visit: V101_VAX3	**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments
Form Version: 10-Dec-2020 02:23	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
6.a	Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
6.a	Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
Form	Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
1	Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001	
Visit: V102_VAX4	**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments
Form Version: 10-Dec-2020 02:23	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
2	Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
3	Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001	
Visit: V102_VAX4	**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments
Form Version: 10-Dec-2020 02:23	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
4	Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
5	Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001	
Visit: V102_VAX4	**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments
Form Version: 10-Dec-2020 02:23	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
6.a	Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
6.a	Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001	
Visit: V102_VAX4	**Form:** LAB URINALYSIS - PREGNANCY TEST - Comments
Form Version: 10-Dec-2020 02:23	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
6.a	Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

This form requires signing by a member of each of the following signature groups:
- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Mar-01-2021 16:27:45 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Megan Pastores	N/A	Mar-01-2021 15:21:53 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Feb-17-2021 07:51:38 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Julie Glazier	N/A	Feb-16-2021 16:44:04 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Feb-12-2021 15:40:02 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Elle Billman	N/A	Feb-12-2021 10:55:39 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Jan-20-2021 16:25:48 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Elle Billman	N/A	Dec-18-2020 15:14:48 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Nov-02-2020 13:17:04 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Julie Glazier	N/A	Nov-02-2020 11:49:05 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Oct-12-2020 08:40:16 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Megan Pastores	N/A	Sep-24-2020 10:16:54 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Sep-10-2020 09:53:32 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Header Text: c4591001

Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-07-2020 12:24:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-07-2020 12:24:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Aug-07-2020 12:24:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** OBTAINED Date Written Consent Obtained Aug/7/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Subject ID

Date	Location	User	Value	Reason
Aug-07-2020 12:24:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10551006	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:24:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6)/1955	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-07-2020 12:24:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-07-2020 12:24:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-07-2020 12:24:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Aug-07-2020 12:25:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/7/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-07-2020 12:25:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/7/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-07-2020 12:25:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-07-2020 12:25:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551006
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1.a

Date	Location	User	Value	Reason
Aug-07-2020 12:45:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 1 **Medical History Term:** Keratoconus, bilateral eyes **Start Date:** UNK/UNK/1969 **Ongoing:** YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:45:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-07-2020 12:45:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Keratoconus, bilateral eyes	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:45:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** UNK/UNK/1969	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:45:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-07-2020 12:45:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 2 **Medical History Term:** Seasonal allergies **Start Date:** UNK/UNK/1958 **Ongoing:** YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:45:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-07-2020 12:45:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Seasonal allergies	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:45:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** UNK/UNK/1958	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:45:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

1.c

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551006
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-07-2020 12:46:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 3 **Medical History Term:** Benign Pulmonary Granulomas **Start Date:** UNK/UNK/2009 **Ongoing:** YES	Initial Entry

1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Benign Pulmonary Granulomas	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** UNK/UNK/2009	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

1.d

Date	Location	User	Value	Reason
Aug-07-2020 12:46:29	ACV0PFEINFP6000	auto calc	**Data Entry:**	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)		(autocalc)	**Line/MH Number:** 4 **Medical History Term:** Osteoarthritis, bilateral thumbs **Start Date:** UNK/UNK/2002 **Ongoing:** YES	

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Osteoarthritis, bilateral thumbs	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** UNK/UNK/2002	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Aug-07-2020 12:46:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 5 **Medical History Term:** Hyperlipidemia	Initial Entry

			Start Date: Sep/UNK/2018 **Ongoing:** YES	

1.e Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Hyperlipidemia	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/UNK/2018	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:46:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

1.f

Date	Location	User	Value	Reason
Nov-02-2020 11:49:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Line/MH Number:** ~~6~~ **Medical History Term:** ~~Intermittent urinary tract infections~~ **Start Date:** ~~UNK/UNK/1973~~ **Ongoing:** ~~YES~~	Changed Information **(DELETED)**

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Aug-07-2020 12:47:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Line/MH Number:** 6 **Medical History Term:** Intermittent urinary tract infections **Start Date:** UNK/UNK/1973 **Ongoing:** YES	Changed Information
Aug-07-2020 12:47:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 6 **Medical History Term:** Occasional urinary tract infections **Start Date:** UNK/UNK/1973 **Ongoing:** YES	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551006
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

1.f Line/MH Number:

Date	Location	User	Value	Reason
Nov-02-2020 11:49:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** ~~6~~	Changed Information **(DELETED)**
Aug-07-2020 12:47:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 6	Initial Entry

1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Nov-02-2020 11:49:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** ~~Intermittent urinary tract infectio ns~~	Changed Information **(DELETED)**
Aug-13-2020 22:37:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Katherine Liau (pfe.liaukf)	Query 1: Closed	Response satisfies query
Aug-13-2020 11:50:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	Original value is correct
Aug-12-2020 06:56:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	GPD Clin: Per IC3 and Criteria for Temporary Delay of Enrolment (Protocol 5.5), please confirm stability of symptoms within 6 weeks of enrolment and no acute event within 48h before study intervention administration
Aug-07-2020 12:47:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Intermittent urinary tract infectio ns	Changed Information
Aug-07-2020 12:47:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Occasional urinary tract infectio ns	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

1.f Start Date:

Date	Location	User	Value	Reason
Nov-02-2020 11:49:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** ~~UNK/UNK/1973~~	Changed Information **(DELETED)**
Aug-07-2020 12:47:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** UNK/UNK/1973	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Nov-02-2020 11:49:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** ~~YES~~	Changed Information **(DELETED)**
Aug-07-2020 12:47:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

1.g

Date	Location	User	Value	Reason
Aug-07-2020 12:47:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 7 **Medical History Term:** Rosacea **Start Date:** UNK/UNK/2010 **Ongoing:** YES	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551006
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

1.g Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:47:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 7	Initial Entry

1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-07-2020 12:47:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Rosacea	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:47:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** UNK/UNK/2010	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:47:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

1.h

Date	Location	User	Value	Reason
Aug-07-2020 12:48:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 8 **Medical History Term:** GERD **Start Date:** Sep/UNK/1993 **Ongoing:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

1.h Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:48:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 8	Initial Entry

1.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-07-2020 12:48:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** GERD	Initial Entry

1.h Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:48:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/UNK/1993	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:48:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551006
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1.i

Date	Location	User	Value	Reason
Aug-07-2020 12:48:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 9 **Medical History Term:** Lactose intolerance **Start Date:** UNK/UNK/1993 **Ongoing:** YES	Initial Entry

1.i Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:48:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 9	Initial Entry

1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-07-2020 12:48:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Lactose intolerance	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:48:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** UNK/UNK/1993	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:48:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

1.j

Date	Location	User	Value	Reason
Aug-07-2020 12:49:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 10 **Medical History Term:** Hypothyroid **Start Date:** Sep/UNK/1988 **Ongoing:** YES	Initial Entry

1.j Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10	Initial Entry

1.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Hypothyroid	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/UNK/1988	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

1.k

Date	Location	User	Value	Reason

Aug-07-2020 12:49:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 11 **Medical History Term:** Post-menopausal **Start Date:** Dec/UNK/2010 **Ongoing:** YES	Initial Entry

1.k Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 11	Initial Entry

1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Post-menopausal	Initial Entry

1.k Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Dec/UNK/2010	Initial Entry

1.k Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

1.l

Date	Location	User	Value	Reason
Aug-07-2020 12:49:51 (UTC-08:00) Pacific	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:**	Initial Entry

Time (US & Canada)			**Line/MH Number:** 12 **Medical History Term:** Sulfite allergy **Start Date:** UNK/UNK/1999 **Ongoing:** YES	

1.l Line/MH Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 12	Initial Entry

1.l Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sulfite allergy	Initial Entry

1.l Start Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** UNK/UNK/1999	Initial Entry

1.l Ongoing:

Date	Location	User	Value	Reason
Aug-07-2020 12:49:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/7/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 61.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 158.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 24.4	Initial Entry

Time (US & Canada)				

7.a

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 36.7 **Temperature Unit:** C **Temperature Location::** FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 36.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-07-2020 12:26:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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3. Collection Date:

Date	Location	User	Value	Reason
Aug-07-2020 12:29:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-07-2020 12:28:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113 **Test::** Choriogonadotropin Beta_PX113 **Result::** **Not Done::** NOT DONE	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-07-2020 12:28:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-07-2020 12:28:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-07-2020 12:28:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT DONE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-07-2020 12:30:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/7/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-07-2020 12:30:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 223587	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-07-2020 12:36:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-07-2020 12:36:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-07-2020 12:36:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-07-2020 12:36:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-07-2020 12:36:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Date of Collection: Aug/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-07-2020 12:36:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BP6S51	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 12:36:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP6S51	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-07-2020 12:36:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BP6S52	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 12:36:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP6S52	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-07-2020 12:37:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BP6S53	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 12:37:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP6S53	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-07-2020 12:37:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BPFTRZ	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.d Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 12:37:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BPFTRZ	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-07-2020 12:37:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BPFTS0	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 12:37:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BPFTS0	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-07-2020 12:38:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-07-2020 12:38:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-07-2020 12:38:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-07-2020 12:38:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-07-2020 12:38:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Date of Collection: Aug/7/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-07-2020 12:38:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BP6S4Z	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Aug-07-2020 12:38:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP6S4Z	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-07-2020 12:32:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-07-2020 12:32:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-07-2020 12:32:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-07-2020 12:32:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/7/2020 10:31	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-07-2020 12:32:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-07-2020 12:32:45 (UTC-08:00) Pacific	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** LEFT	Initial Entry

Time (US & Canada)				

7. Route:

Date	Location	User	Value	Reason
Aug-07-2020 12:32:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-07-2020 12:32:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-07-2020 12:32:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-07-2020 12:33:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES - REACTOGENICITY E-D IARY COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Aug-26-2020 11:11:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Aug/26/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Symptom::** FEVER **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Aug-27-2020 09:24:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Symptom::** FATI	Transcription Error

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?: GUE NO	
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Symptom::** FATIGUE **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** YES Ongoing? NO Stop Date: Aug/11/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

2.b Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-27-2020 14:07:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Closed	Response satisfies query
Aug-27-2020 09:24:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-27-2020 09:24:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Transcription Error
Aug-27-2020 08:04:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Isaac Arasavalli (pfe.arasai)	Query 1: Opened	eDiary: Per eDiary records, FATIGUE is not reported on Last day (Day 7) however the last day in inform is entered as 'Yes' for the same. Please verify and update. Else, clarify. Thanks.
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** YES Ongoing? NO Stop Date: Aug/11/2020	Initial Entry

2.c

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-27-2020 09:24:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Symptom::** HE AD AC HE **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Transcription Error
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Symptom::** HEADACHE **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** YES Ongoing? NO Stop Date: Aug/12/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

2.c Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-27-2020 14:07:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Erik Sundgaard (pfe.sundgaardea)	Query 1: Closed	Response satisfies query
Aug-27-2020 09:24:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Aug-27-2020 09:24:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Transcription Error
Aug-27-2020 08:05:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Isaac Arasavalli (pfe.arasai)	Query 1: Opened	eDiary: Per eDiary records, HEADACHE is not reported on Last day (Day 7) however the last day in inform is entered as 'Yes' for the same. Please verify and update. Else, clarify. Thanks.
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** YES Ongoing? NO Stop Date: Aug/12/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

2.d

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Symptom::** CHILLS **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

2.d Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

2.e

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Symptom::** VOMITING **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Symptom::** DIARRHEA **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Symptom::** NEW OR WORSENED MUSCLE PAIN **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NEW OR WORSENED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Symptom::** NEW OR WORSENED JOINT PAIN	Initial Entry

			Were fever or syste mic symptoms prese nt on the last day th e Subject Diary was completed?: NO	

2.h Symptom:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NEW OR WORSENED JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Injection Site Reaction::** RE DN ESS	Initial Entry

			Were injection site reacti ons present on the last d ay the Subject Diary was completed?: NO	

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Injection Site Reaction::** SW ELL ING **Were injection site react ions present on the last day the Subject Diary w as completed?:** NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Injection Site Reaction::** PAIN AT INJECTION SITE **Were injection site reactions present on the last day the Subject Diary was completed?:** NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Aug-26-2020 11:40:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Aug-26-2020 11:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Aug/26/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Aug-26-2020 11:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 36.2 **Temperature Unit:** C **Temperature Location::** FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Aug-26-2020 11:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Aug-26-2020 11:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 36.2	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Aug-26-2020 11:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** C	Initial Entry

2.a Temperature Location:

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-26-2020 11:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Not Applicable	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-27-2020 09:00:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-27-2020 09:00:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-27-2020 09:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-27-2020 09:00:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-27-2020 09:00:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Collection: Aug/26/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-27-2020 09:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP6RXN	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 09:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP6RXN	Initial Entry

Header Text: c4591001
Visit: V2_VAX2_L
Form: VACCINATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551006
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-26-2020 11:42:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-26-2020 11:42:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Aug/26/2020 10:08	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:18 (UTC-08:00) Pacific	ACV0PFEINFP6000	Megan Pastores	**Data Entry:** LEFT	Initial Entry

Time (US & Canada)		(pfe.mpastores)		

7. Route:

Date	Location	User	Value	Reason
Aug-26-2020 11:42:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-26-2020 11:42:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED O BSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-26-2020 11:42:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Sep-24-2020 10:16:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** Sep/24/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Symptom::** FEVER **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Symptom::** FATIGUE	Initial Entry

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?: YES Ongoing? NO Stop Date: Sep/6/2020	

2.b Symptom:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** YES Ongoing? NO Stop Date: Sep/6/2020	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Symptom::** HEADACHE	Initial Entry

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	

2.c Symptom:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Symptom::** CHILLS **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** YES Ongoing? NO Stop Date: Sep/6/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

2.d Symptom:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** YES Ongoing? NO Stop Date: Sep/6/2020	Initial Entry

2.e

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Symptom::** VOMITING **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Initial Entry

2.f

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Symptom::** DIARRHEA **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

2.f Symptom:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Symptom::** NEW OR WORSENED MUSCLE PAIN **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

2.g Symptom:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NEW OR WORSENED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Symptom::** NEW OR WORSENED JOINT PAIN	Initial Entry

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	

2.h Symptom:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NEW OR WORSENED JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Injection Site Reaction::** RE DN ESS	Initial Entry

			Were injection site reacti ons present on the last d ay the Subject Diary was completed?: NO	

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Injection Site Reaction::** SW ELL ING **Were injection site react ions present on the last day the Subject Diary w as completed?:** NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Injection Site Reaction::** PAIN AT INJECTION SITE **Were injection site reactions present on the last day the Subject Diary was completed?:** NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-24-2020 13:26:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-24-2020 15:27:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-24-2020 15:27:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-24-2020 15:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-24-2020 15:27:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-24-2020 15:27:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Date of Collection: Sep/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-24-2020 15:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BPV09L	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 15:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BPV09L	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-24-2020 15:28:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BPV09M	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 15:28:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BPV09M	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-24-2020 15:28:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BPFTKC	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 15:28:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BPFTKC	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-24-2020 15:28:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BPFTKD	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.d Sample ID

Date	Location	User	Value	Reason
Sep-24-2020 15:28:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BPFTKD	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Sep-24-2020 10:55:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** Sep/24/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-24-2020 10:55:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-24-2020 10:55:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT - Audit Trail
Form Version: 22-Apr-2020 21:02	**Form Status:**
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551006	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-03-2020 04:14:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	MH deleted
Nov-02-2020 11:49:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	AE of UTI is new occurrence and not part of baseline medical history
Nov-01-2020 21:23:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Derrick Newton (pfe newtod07)	Query 1: Opened	The AE Urinary Tract Infection was reported but is also listed in Medical History. Please clarify if this is a worsening of the baseline condition, and if so, please consider adding "worsening" to the AE term.
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** Urinary Tract Infection	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** Sep/1/2020 22:01	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO End Date Time: Sep/6/2020 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NOT RELATED If Not Related to study treatme nt(s), this event is due to: OTHER *If Other, specify:* Bacterial Infection	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-24-2020 13:16:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Injection site pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Dec/22/2020 09:02	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO End Date Time: Dec/24/2020 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason

Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551006
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-11-2021 10:04:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** injection site pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/11/2021 14:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-16-2021 16:44:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO End Date Time: Jan/12/2021 18:00	Transcription Error
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO End Date Time:	Initial Entry

			Jan/12/2021 08:00	

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NOT APPLICABLE	Initial Entry

Time (US & Canada)				

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-12-2021 10:59:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** chills	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/11/2021 19:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO End Date Time: Jan/11/2021 20:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason

Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Frozen
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551006
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-12-2021 11:00:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** fatigue	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/12/2021 12:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO End Date Time: Jan/12/2021 15:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason

Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason

Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-12-2021 11:01:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 6	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** lymph node swelling	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/12/2021 12:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO End Date Time: Jan/12/2021 15:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason

Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Frozen
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551006
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-12-2021 11:03:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Sep-24-2020 15:50:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. What is the medication identifier?

Date	Location	User	Value	Reason
Sep-24-2020 15:50:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Sep-24-2020 15:50:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Sep-24-2020 15:50:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Sep-24-2020 15:50:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** Influenza Vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Sep-24-2020 15:50:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** Sep/20/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Dec-18-2020 15:14:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Dec/16/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Dec-18-2020 15:15:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-18-2020 15:15:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Dec-18-2020 15:15:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Participant is willing to return f or Vaccination 3 Participant is: eligible per local/national rec ommendations and confirme d to have received only place bo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Dec-22-2020 10:08:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Dec/22/2020	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Dec-22-2020 10:08:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** OBTAINED Date Written Consent Obtained Dec/22/2020	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Dec-22-2020 10:09:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Dec/22/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-22-2020 10:09:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Dec-22-2020 10:09:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Dec-22-2020 10:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Dec-22-2020 15:50:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-22-2020 15:50:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-22-2020 15:50:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-22-2020 15:50:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-22-2020 15:50:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES Date of Collection: Dec/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-22-2020 15:50:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:** BR2PLR	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 15:50:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BR2PLR	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-22-2020 15:50:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:** BS3B2Z	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 15:50:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BS3B2Z	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-22-2020 15:51:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:** BS3B30	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 15:51:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BS3B30	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Dec-22-2020 16:08:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-22-2020 16:08:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-22-2020 16:09:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-22-2020 16:08:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-22-2020 16:08:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES Date of Collection: Dec/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-22-2020 16:09:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:** BR2PLN	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 16:09:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BR2PLN	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Dec-22-2020 10:11:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Dec-22-2020 10:11:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Dec-22-2020 10:11:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Dec-22-2020 10:11:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Dec/22/2020 09:02	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Dec-22-2020 10:11:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Dec-22-2020 10:11:26 (UTC-08:00) Pacific	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** LEFT	Initial Entry

Time (US & Canada)				

7. Route:

Date	Location	User	Value	Reason
Dec-22-2020 10:11:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Dec-22-2020 10:11:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Dec-22-2020 10:11:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Dec-22-2020 10:11:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Dec-22-2020 10:11:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Mar-01-2021 15:21:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** Dec/17/2020	Transcription Error
Dec-18-2020 15:15:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Dec/16/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-18-2020 15:15:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V102_VAX4 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Jan-11-2021 09:57:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/11/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

6.a

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:23 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sponsor-Defined Identifier:** Not Applicable **Test::** Not Applicable **Result::** Not Applicable **Not Done::** Not Applicable	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

6.a Not Done:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Jan-11-2021 15:09:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-11-2021 15:09:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-11-2021 15:10:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-11-2021 15:09:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-11-2021 15:09:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES Date of Collection: Jan/11/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-11-2021 15:10:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:** BR2PNW	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551006

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Jan-11-2021 15:10:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BR2PNW	Initial Entry

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-11-2021 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-11-2021 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/11/2021 09:00	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:48 (UTC-08:00) Pacific	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** LEFT	Initial Entry

Time (US & Canada)				

7. Route:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-11-2021 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-11-2021 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-11-2021 10:00:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V103_MONTH1 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Feb-12-2021 10:55:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Feb/12/2021	Initial Entry

Header Text: c4591001

Visit: V103_MONTH1 **Form:** CONTACT OUTCOME - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Contact Type:

Date	Location	User	Value	Reason
Feb-12-2021 10:56:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Feb-12-2021 10:56:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES Date of Contact: Feb/12/2021	Initial Entry

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT - Unscheduled | **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-16-2021 03:44:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Ashwini Devi Subhash (pfe.subhaa)	Query 1: Closed	incorrect
Feb-12-2021 19:11:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW7250357;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate.
Feb-12-2021 10:56:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry :** Feb/12/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-12-2021 10:56:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-12-2021 10:56:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Subject Status

Date	Location	User	Value	Reason
Sep-24-2020 10:55:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** FOLLOW-UP	Initial Entry
Aug-07-2020 12:30:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Aug-07-2020 12:25:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Sep-24-2020 10:55:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Sep/24/2020	Initial Entry
Aug-07-2020 12:30:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/7/2020	Initial Entry
Aug-07-2020 12:25:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/7/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551006 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Casebook Signature

Date	Location	User	Value	Reason
Sep-10-2020 08:38:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Click Here to Enable	Initial Entry

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** COHORT SELECTION
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/10/2020

Header Text: c4591001

Visit: COHORT_SELECTION **Form:** DEMOGRAPHY

Form Version: 06-Jul-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Demography		
1.	Subject ID	[10551012]
2.	Birth Date:	(b) (6)/1988
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Aug/10/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** INCLUSION/EXCLUSION CRITERIA
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Screening		
1.	Date of Completion/Discontinuation /Death	Aug/10/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** GENERAL MEDICAL HISTORY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Asthma]
	Start Date:	Jan/1/1996
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Seasonal allergies]
	Start Date:	Jan/1/1993
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hypothyroid]
	Start Date:	Mar/6/2000
	Ongoing:	YES

1.d

Line/MH Number:	[4]
Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Zithromax allergy]
Start Date:	Dec/UNK/1998
Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Aug/10/2020
2.	Weight:	[59.6]
3.	Unit:	kg
4.	Height:	[156.0]
5.	Unit:	cm
6.	Body Mass Index:	[24.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.8]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/10/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a

Sponsor ID:	[113]
Test:	Choriogonadotropin Beta_PX113
Result:	NEGATIVE
Not Done:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L **Form:** RANDOMIZATION

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition		
1.	Randomization Date :	Aug/10/2020
2.	Randomization Number:	[43756]
3.	Randomization Group:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/10/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP6S5W]
5.b	Sample ID	[BP6S5X]
5.c	Sample ID	[BP6S5Y]
5.d	Sample ID	[BPFTSC]
5.e	Sample ID	[BPFTSD]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/10/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP6S5S]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/10/2020 12:10
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** REACTOGENICITY DIARY
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Reactogenicity Diary		
1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/1/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE

4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

Header Text: c4591001

Visit: V2_VAX2_L	**Form:** VITAL SIGNS - TEMP
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Sep/1/2020

Vital Signs Details

2.a

Record Identifier:	1
Temperature:	[34.6]
Unit:	C
Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/1/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/1/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP91S9]

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/1/2020 14:31
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/29/2020
2.	Erroneous Visit	

Header Text: c4591001	
Visit: V3_MONTH1_POSTVAX2_L	**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES
Form Version: 30-Jul-2020 21:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination Symptoms Diary - Symptom Resolved Dates

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.g	Symptom:	NEW OR WORSENED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE

4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/29/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BPV0CJ]
5.b	Sample ID	[BPV0CK]
5.c	Sample ID	[BPFTLC]
5.d	Sample ID	[BPFTLD]

Header Text: c4591001

Visit: V4_MONTH6_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Feb/23/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/23/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2P7G]
5.b	Sample ID	[BS3BBR]
5.c	Sample ID	[BS3BBP]

Header Text: c4591001	
Visit: V5_MONTH12_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: V6_MONTH24_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** DATE OF VISIT - ILLNESS ONSET
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Form Version: 20-Feb-2021 02:17	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Signs and Symptoms		
1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	
Symptoms		
4.	Symptoms:	
	Was symptom present?	
Symptoms - Other		
5.	Symptoms - Other Text:	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** HEALTH CARE UTILIZATION
Form Version: 20-Feb-2021 02:19	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[ ]

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Illness Details		
1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit	**Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Unplanned Assessments		
1.	Assessments	

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	Sep/29/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: Follow-Up - Unscheduled | **Form:** DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit | **Form:** DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: Logs **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Left supraclavicular adenopathy	Sep/2/2020 07:00	NO End Date Time: Sep/3/2020 07:00	Repeating Pages
2.	ADVERSE EVENT	2	Shingles	Feb/8/2021 19:00	YES	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Left supraclavicular adenopathy]
4.	Start Date Time:	Sep/2/2020 07:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/3/2020 07:00
6.	Toxicity Grade:	1

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[2]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Shingles]	Comments
4.	Start Date Time:	Feb/8/2021 19:00	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	2	

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [viral infection]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Medication Error		
1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	influenza vaccine	Sep/30/2020	Repeating Pages

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Concomitant Medications		
1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[influenza vaccine]
5.	Date:	Sep/30/2020

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - PROHIBITED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

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Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

Header Text: c4591001

Visit: Logs **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** RADIATION TREATMENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

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Radiation Treatment		
1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** TRANSFUSIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

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1.	Transfusion Type:	
2.	Date of Transfusion:	//

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** VITAL SIGNS - TEMP
Form Version: 20-Feb-2021 02:16	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Vital Signs		
1.	Date:	//

Vital Signs Details

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

Lab Result

6.

Sponsor ID:	[ ]
Test:	
Result:	
Not Done:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 1
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 6
Form Version: 10-Oct-2020 16:01	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE
Form Version: 14-Jan-2021 02:29	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Informed Consent - Asymptomatic Surveillance		
1.	Consent Was:	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/25/2021
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete, Frozen
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Further Vaccination Confirmation		
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** TREATMENT UNBLINDED
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Treatment Unblinded		
1.	Date Treatment Unblinded :	Jan/25/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Withdrawal Of Consent		
1.	Withdrawal of Consent Date :	//

Header Text: c4591001

Visit: Disposition - Unscheduled	**Form:** DEATH DETAILS CODED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Death Details

1.	Date of Collection / Notification of Death:	//

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[ ]

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Subject Status		
1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Sep/29/2020

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Casebook Signature Form		
1.	Casebook Signature	Click Here to Enable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Audit Trail

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Feb-25-2021 16:22:18 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** INCLUSION/EXCLUSION CRITERIA - Comments

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
Form	Aug-10-2020 13:16:12 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Comments

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
3	Feb-25-2021 10:29:31 (UTC-08:00) Pacific Time (US & Canada)	Lana Norman (pfe.lnorman)	one dermatome and no prior history of shingles

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Feb-25-2021 16:22:18 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Lana Norman	N/A	Feb-25-2021 10:29:31 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Feb-24-2021 08:03:52 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Header Text: c4591001

Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Elle Billman	N/A	Feb-23-2021 15:53:47 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Feb-23-2021 15:02:24 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Elle Billman	N/A	Feb-23-2021 10:58:29 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Jan-27-2021 17:04:55 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Julie Glazier	N/A	Jan-27-2021 13:04:05 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Oct-12-2020 08:49:52 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Header Text: c4591001

Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Julie Glazier	N/A	Sep-29-2020 13:12:29 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Sep-10-2020 09:56:14 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: COHORT_SELECTION	**Form:** COHORT SELECTION - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-10-2020 13:15:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-10-2020 13:15:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Aug-10-2020 13:15:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** OBTAINED Date Written Consent Obtained Aug/10/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Subject ID

Date	Location	User	Value	Reason
Aug-10-2020 13:15:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10551012	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-10-2020 13:15:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6) 1988	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-10-2020 13:15:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Aug-10-2020 13:15:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-10-2020 13:15:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Aug-10-2020 13:16:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/10/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-10-2020 13:16:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/10/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-10-2020 13:16:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-10-2020 13:16:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1.a

Date	Location	User	Value	Reason
Aug-10-2020 13:20:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 1 **Medical History Term:** Asthma **Start Date:** Jan/1/1996 **Ongoing:** YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-10-2020 13:20:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-13-2020 22:38:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Katherine Liau (pfe.liaukf)	Query 1: Closed	Response satisfies query

Aug-13-2020 11:50:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	Original value is correct
Aug-12-2020 04:58:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	GPD Clin: Per IC3, please confirm stability of symptoms prior to study enrolment; that no significant change in therapy or hospitalization for worsening of disease within 6 weeks of enrolment. Also, confirm EC13 reviewed (systemic corticosteroid use)
Aug-10-2020 13:20:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Asthma	Initial Entry

1.a Start Date:

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-10-2020 13:20:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Jan/1/1996	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-10-2020 13:20:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

1.b

Date	Location	User	Value	Reason
Aug-10-2020 13:21:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 2 **Medical History Term:** Seasonal allergies **Start Date:** Jan/1/1993 **Ongoing:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Seasonal allergies	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Jan/1/1993	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:06	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)				

1.c

Date	Location	User	Value	Reason
Aug-10-2020 13:21:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 3 **Medical History Term:** Hypothyroid **Start Date:** Mar/6/2000 **Ongoing:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Hypothyroid	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Mar/6/2000	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:32	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)				

1.d

Date	Location	User	Value	Reason
Aug-10-2020 13:21:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 4 **Medical History Term:** Zithromax allergy **Start Date:** Dec/UNK/1998 **Ongoing:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Zithromax allergy	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Dec/UNK/1998	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-10-2020 13:21:59	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/10/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 59.6	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason

Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 156.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 24.5	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 36.8	Initial Entry

			Temperatur e Unit: C **Temperatur e Location::** FORE HEAD	

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 36.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** C	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:28	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/10/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason

Aug-10-2020 13:17:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-10-2020 13:17:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113 **Test::** Choriogonadotropin Beta_PX113 **Result::** NEGATIVE **Not Done ::**	Initial Entry

6.a Sponsor ID:

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-10-2020 13:17:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NEGATIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Randomization Date :

Date	Location	User	Value	Reason
Aug-10-2020 13:17:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/10/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-10-2020 13:17:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 43756	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-10-2020 15:09:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-10-2020 15:09:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-10-2020 15:09:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-10-2020 15:09:43 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-10-2020 15:09:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Date of Collection: Aug/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-10-2020 15:09:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID :** BP6S5W	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:09:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP6S5W	Initial Entry

5.b

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Aug-10-2020 15:09:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID :** BP6S5X	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:09:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP6S5X	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-10-2020 15:10:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID :** BP6S5Y	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:10:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP6S5Y	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.d

Date	Location	User	Value	Reason
Aug-10-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BPFTSC	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BPFTSC	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-10-2020 15:10:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BPFTSD	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

5.e Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:10:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BPFTSD	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-10-2020 15:11:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-10-2020 15:11:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-10-2020 15:11:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-10-2020 15:11:02 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-10-2020 15:11:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Date of Collection: Aug/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-10-2020 15:11:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID :** BP6S5S	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-10-2020 15:11:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP6S5S	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-10-2020 13:18:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-10-2020 13:18:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-10-2020 13:18:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason

Aug-10-2020 13:18:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/10/2020 12:10	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-10-2020 13:18:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-10-2020 13:18:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-10-2020 13:18:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-10-2020 13:18:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-10-2020 13:18:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-10-2020 13:18:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Sep-01-2020 15:31:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/1/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Symptom::** FEVER **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Symptom::** FATIGUE **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

2.b Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Symptom::** HE AD AC HE	Initial Entry

			Were fever or s ystemic sympto ms present on t he last day the Subject Diary was completed? : NO	

2.c Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Symptom::** C	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)			**Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** HILLS NO	

2.d Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2.e

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Symptom::** VOMITING **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

2.f

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Symptom::** DIARRHEA **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

2.f Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Symptom::** NEW OR WORSENED MUSCLE PAIN	Initial Entry

			Were fever o NO **r systemic sy mptoms pre sent on the l ast day the S ubject Diary was complet ed?:**	

2.g Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NEW OR WORSENED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-01-2020	ACV0PFEINFP6000	Julie Glazier	**Data Entry:**	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L	**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

15:31:58 (UTC-08:00) Pacific Time (US & Canada)		(pfe.jglazier)	**Symptom::**	NEW OR WORSENED JOINT PAIN	
			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	NO	

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

2.h Symptom:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NEW OR WORSENED JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Injection Site Reaction::** REDNESS **Were injection site reactions present on the last day the Subject Diary was completed?:** NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Injection Site Reaction::** SWELLING **Were injection site reactions present on the last day the Subject Diary was completed?:** NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:30

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Injection Site Reaction::** PAIN AT INJECTION SITE	Initial Entry

			Were injection site reactions present on the last day the Subject Diary was completed?: NO	

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-01-2020 15:31:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Sep-01-2020 15:32:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/1/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-01-2020 15:32:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 34.6 **Temperature Unit:** C **Temperature Location::** FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-01-2020 15:32:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

2.a Temperature:

Date	Location	User	Value	Reason
Sep-02-2020 01:49:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 1: Closed	As per site confirmation
Sep-01-2020 15:32:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	correct as entered, not clinically significant
Sep-01-2020 15:32:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 34.6 C is outside of Normal Range 36.1 - 37.5 C.
Sep-01-2020 15:32:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 34.6	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-01-2020 15:32:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** C	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-01-2020 15:32:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-01-2020 15:32:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-01-2020 15:32:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-01-2020 15:32:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/1/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason

Sep-01-2020 15:32:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-01-2020 15:32:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-01-2020 15:32:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113 **Test::** Choriogonadotropin Beta_PX113 **Result::** NEGATIVE **Not Done ::**	Initial Entry

6.a Sponsor ID:

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:27

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-01-2020 15:32:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-01-2020 15:32:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-01-2020 15:32:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NEGATIVE	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-01-2020 15:57:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-01-2020 15:57:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-01-2020 15:57:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-01-2020 15:57:26 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-01-2020 15:57:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Date of Collection: Sep/1/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-01-2020 15:57:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BP91S9	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-01-2020 15:57:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP91S9	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-01-2020 15:34:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-01-2020 15:34:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-01-2020 15:34:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason

Sep-01-2020 15:34:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/1/2020 14:31	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-01-2020 15:34:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-01-2020 15:34:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-01-2020 15:34:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-01-2020 15:34:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-01-2020 15:34:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-29-2020 13:12:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/29/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Symptom::** FEVER **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

2.a Symptom:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FEVER	Initial Entry

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2.b

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Symptom::** FATIGUE **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

2.b Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Symptom::** HE AD AC HE	Initial Entry

			Were fever or s ystemic sympto ms present on t he last day the Subject Diary was completed? : NO	

2.c Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** HEADACHE	Initial Entry

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2.d

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Symptom::** C	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)			**Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** CHILLS NO	

2.d Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** CHILLS	Initial Entry

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2.e

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Symptom::** VOMITING **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

2.e Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** VOMITING	Initial Entry

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

2.f

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Symptom::** DIARRHEA **Were fever or systemic symptoms present on the last day the Subject Diary was completed?:** NO	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

2.f Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** DIARRHEA	Initial Entry

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2.g

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Symptom::** NEW OR WORSENED MUSCLE PAIN	Initial Entry

			Were fever o NO **r systemic sy mptoms pre sent on the l ast day the S ubject Diary was complet ed?:**	

2.g Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NEW OR WORSENED MUSCLE PAIN	Initial Entry

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2.h

Date	Location	User	Value	Reason
Sep-29-2020	ACV0PFEINFP6000	Julie Glazier	**Data Entry:**	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

13:14:12 (UTC-08:00) Pacific Time (US & Canada)		(pfe.jglazier)	**Symptom::**	NEW OR WORSENED JOINT PAIN	
			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	NO	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

2.h Symptom:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NEW OR WORSENED JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason

Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** LEFT	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Injection Site Reaction::** REDNESS **Were injection site reactions present on the last day the Subject Diary was completed?:** NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Injection Site Reaction::** SWELLING **Were injection site reactions present on the last day the Subject Diary was completed?:** NO	Initial Entry

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Injection Site Reaction::** PAIN AT INJECTION SITE	Initial Entry

			Were injection site reactions present on the last day the Subject Diary was completed?: NO	

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-29-2020 13:14:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-29-2020 15:19:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-29-2020 15:19:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-29-2020 15:19:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-29-2020 15:19:45 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-29-2020 15:19:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Collection: Sep/29/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-29-2020 15:19:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BPV0CJ	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 15:19:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPV0CJ	Initial Entry

5.b

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-29-2020 15:20:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BPV0CK	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 15:20:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPV0CK	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-29-2020 15:20:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BPFTLC	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 15:20:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPFTLC	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-29-2020 15:20:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BPFTLD	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-29-2020 15:20:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPFTLD	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-23-2021 10:58:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Feb/23/2021	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Feb-23-2021 15:53:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-23-2021 15:53:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-23-2021 15:53:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-23-2021 15:53:47 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Feb-23-2021 15:53:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES Date of Collection : Feb/23/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-23-2021 15:53:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID :** BR2P7G	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 15:53:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BR2P7G	Initial Entry

5.b

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-23-2021 15:54:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:** BS3BBR	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 15:54:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BS3BBR	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-23-2021 15:54:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:** BS3BBP	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 15:54:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BS3BBP	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Sep-29-2020 13:19:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/29/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-29-2020 13:19:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-29-2020 13:19:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Left supraclavicular a denopathy	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason

Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/2/2020 07:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO End Date Time: Sep/3/2020 07:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT APPLICABLE	Initial Entry

Pacific Time (US & Canada)				

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-29-2020 13:18:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-25-2021 12:15:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Closed	Response satisfies query
Feb-25-2021 10:29:08	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Query 1: Answered	one dermatome

(UTC-08:00) Pacific Time (US & Canada)				and no prior history of shingles
Feb-25-2021 06:34:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Opened	clinical: pls advise if one or more than one dermatome involved, and if subject has prior history of shingles.
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Shingles	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Feb/8/2021 19:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-23-2021 11:04:15	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)				

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** 2	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-23-2021 13:33:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NOT RELATED If Not Related to s tudy treatment(s), this event is due to : OTHER *If Other, specif y:* viral infection	New Information
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NOT RELATED If Not Related to s tudy treatment(s), this event is due to : OTHER	Initial Entry

10. Latest Action Taken with Study Treatment:

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-25-2021 12:14:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Closed	Response satisfies query
Feb-25-2021 10:16:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Query 1: Answered	none of the meds taken for this event were steroids
Feb-25-2021 06:36:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Opened	clinical: did subject receive steroids? if so please advise of dose and duration.Thanks
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NOT RECOVERED /NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-23-2021 11:04:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Feb-23-2021 11:02:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. What is the medication identifier?

Date	Location	User	Value	Reason
Feb-23-2021 11:02:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-23-2021 11:02:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-23-2021 11:02:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Feb-23-2021 11:02:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** influenza vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Feb-23-2021 11:02:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Sep/30/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Jan-27-2021 13:04:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Jan/25/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete, Frozen
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551012	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Jan-27-2021 13:04:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-27-2021 13:04:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-27-2021 13:04:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vac	Initial Entry

			cination 1/2	

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-27-2021 13:04:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Jan/25/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-27-2021 13:04:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551012 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Subject Status

Date	Location	User	Value	Reason
Sep-29-2020 13:19:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** FOLLOW-UP	Initial Entry
Aug-10-2020 13:17:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Aug-10-2020 13:16:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Sep-29-2020 13:19:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Sep/29/2020	Initial Entry
Aug-10-2020 13:17:44	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/10/2020	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)				
Aug-10-2020 13:16:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/10/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551012

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Casebook Signature

Date	Location	User	Value	Reason
Sep-10-2020 08:39:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Click Here to Enable	Initial Entry

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** COHORT SELECTION
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/20/2020

Header Text: c4591001

Visit: COHORT_SELECTION **Form:** DEMOGRAPHY

Form Version: 06-Jul-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Demography		
1.	Subject ID	[10551084]
2.	Birth Date:	(b) (6)1989
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	ASIAN
6.	Racial Designation:	

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Aug/20/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** INCLUSION/EXCLUSION CRITERIA
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Screening		
1.	Date of Completion/Discontinuation /Death	Aug/20/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** GENERAL MEDICAL HISTORY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments

Medical History Details

1.

Line/MH Number:	Not Applicable [ ]
Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	Not Applicable [ ]
Start Date:	Not Applicable //
Ongoing:	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs		
1.	Date:	Aug/20/2020
2.	Weight:	[80.4]
3.	Unit:	kg
4.	Height:	[171.2]
5.	Unit:	cm
6.	Body Mass Index:	[27.4]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.9]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition		
1.	Randomization Date :	Aug/20/2020
2.	Randomization Number:	[59409]
3.	Randomization Group:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/20/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP6RSR]
5.b	Sample ID	[BP6RSS]
5.c	Sample ID	[BP6RST]
5.d	Sample ID	[BPFTY5]
5.e	Sample ID	[BPFTY6]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/20/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP6RSH]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/20/2020 13:33
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** REACTOGENICITY DIARY
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Reactogenicity Diary		
1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/8/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L	**Form:** VITAL SIGNS - TEMP
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Sep/8/2020

Vital Signs Details

2.a

Record Identifier:	1
Temperature:	[36.7]
Unit:	C
Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/8/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP9233]

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/8/2020 12:00
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001	
Visit: V3_MONTH1_POSTVAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Oct/8/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/8/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BPV0JM]
5.b	Sample ID	[BPV0JN]
5.c	Sample ID	[BPFTR9]
5.d	Sample ID	[BPFTRB]

Header Text: c4591001

Visit: V4_MONTH6_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Mar/2/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/2/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2P8C]
5.b	Sample ID	[BSG7K5]
5.c	Sample ID	[BSG7K6]

Header Text: c4591001	
Visit: V5_MONTH12_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001	
Visit: V6_MONTH24_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** DATE OF VISIT - ILLNESS ONSET
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Form Version: 20-Feb-2021 02:17	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Signs and Symptoms		
1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	
Symptoms		
4.	Symptoms:	
	Was symptom present?	
Symptoms - Other		
5.	Symptoms - Other Text:	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Health Care Utilization		
1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	
Health Care Utilization Other		
2.	Other Type of Practitioner Specify:	[ ]
Health Care Utilization		
3.	Has the subject been hospitalized due to potential COVID-19 illness?	

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit	**Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Unplanned Assessments		
1.	Assessments	

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	Oct/8/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: Follow-Up - Unscheduled | **Form:** DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit | **Form:** DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: Logs **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Warm feeling of neck and head	Aug/20/2020 14:05	NO End Date Time: Aug/21/2020 09:00	Repeating Pages
2.	ADVERSE EVENT	2	Fatigue	Aug/20/2020 15:30	NO End Date Time: Aug/21/2020 08:00	Repeating Pages
3.	ADVERSE EVENT	3	Low grade fever	Sep/8/2020 14:00	NO End Date Time: Sep/9/2020 07:00	Repeating Pages
4.	ADVERSE EVENT	4	Fatigue	Sep/8/2020 14:00	NO End Date Time: Sep/9/2020 07:00	Repeating Pages
5.	ADVERSE EVENT	5	Exposure during pregnancy	Feb/4/2021 UNK:UNK	YES	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Warm feeling of neck and head]
4.	Start Date Time:	Aug/20/2020 14:05
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/21/2020 09:00
6.	Toxicity Grade:	1

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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eCRF Audit Trail History
Form Audit Trail

Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fatigue]
4.	Start Date Time:	Aug/20/2020 15:30
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/21/2020 08:00
6.	Toxicity Grade:	1

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Low grade fever]
4.	Start Date Time:	Sep/8/2020 14:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/9/2020 07:00
6.	Toxicity Grade:	1

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fatigue]
4.	Start Date Time:	Sep/8/2020 14:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/9/2020 07:00
6.	Toxicity Grade:	1

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[5]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Exposure during pregnancy]	
4.	Start Date Time:	Feb/4/2021 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	Comments

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [sexual intercourse]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	UNKNOWN
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Medication Error		
1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Flu Vaccine	Oct/9/2020	Repeating Pages

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

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eCRF Audit Trail History
Form Audit Trail

Concomitant Medications		
1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Flu Vaccine]
5.	Date:	Oct/9/2020

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - PROHIBITED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

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Concomitant Medications

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

Header Text: c4591001

Visit: Logs **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Radiation Treatment		
1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** TRANSFUSIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

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1.	Transfusion Type:	
2.	Date of Transfusion:	//

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** VITAL SIGNS - TEMP
Form Version: 20-Feb-2021 02:16	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Vital Signs

1.	Date:	//

Vital Signs Details

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Vaccination

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 1
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 6
Form Version: 10-Oct-2020 16:01	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE
Form Version: 14-Jan-2021 02:29	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Informed Consent - Asymptomatic Surveillance		
1.	Consent Was:	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Dec/17/2020
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Further Vaccination Confirmation		
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** TREATMENT UNBLINDED
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Treatment Unblinded		
1.	Date Treatment Unblinded :	Dec/17/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Withdrawal Of Consent		
1.	Withdrawal of Consent Date :	//

Header Text: c4591001

Visit: Disposition - Unscheduled	**Form:** DEATH DETAILS CODED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Death Details

1.	Date of Collection / Notification of Death:	//

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[ ]

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Subject Status		
1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/8/2020

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Casebook Signature Form		
1.	Casebook Signature	Click Here to Enable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Audit Trail

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Mar-12-2021 09:53:05 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Aug-20-2020 15:38:21 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe.mpastores)	Not Applicable Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - Comments

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
Form	Aug-20-2020 15:41:23 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe.mpastores)	Not Applicable Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Comments

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
6	Mar-10-2021 11:46:42 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Mar-12-2021 09:53:05 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Julie Glazier	N/A	Mar-11-2021 13:29:58 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Mar-10-2021 18:48:00 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Julie Glazier	N/A	Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Mar-02-2021 19:21:41 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Megan Pastores	N/A	Mar-02-2021 10:00:24 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Jan-20-2021 16:59:46 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Elle Billman	N/A	Dec-17-2020 13:35:41 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Oct-21-2020 16:44:39 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Header Text: c4591001

Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: COHORT_SELECTION	**Form:** COHORT SELECTION - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-20-2020 15:34:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-20-2020 15:34:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Aug-20-2020 15:34:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** OBTAINED Date Written Consent Obtained Aug/20/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Subject ID

Date	Location	User	Value	Reason
Aug-20-2020 15:33:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10551084	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-20-2020 15:33:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6)/1989	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-20-2020 15:36:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Aug-20-2020 15:36:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NOT HISPANIC O R LATINO(A) OR OF SPANISH ORI GIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-20-2020 15:36:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** ASIAN	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Aug-20-2020 15:38:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Aug/20/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-20-2020 15:39:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Aug/20/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-20-2020 15:39:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-20-2020 15:39:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Aug/20/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 80.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason

Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 171.2	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 27.4	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 36.9	Initial Entry

			Temperature Unit: C **Temperature Location::** FOREHEAD	

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 36.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** C	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:28 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-20-2020 15:42:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-20-2020 15:43:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Aug/20/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-20-2020 15:43:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 59409	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-21-2020 09:08:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-21-2020 09:08:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-21-2020 09:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-21-2020 09:08:42 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-21-2020 09:08:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Collection: Aug/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-21-2020 09:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP6RSR	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 09:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP6RSR	Initial Entry

5.b

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-21-2020 09:09:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP6RSS	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 09:09:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP6RSS	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-21-2020 09:09:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP6RST	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 09:09:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP6RST	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-21-2020 09:09:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BPFTY5	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 09:09:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPFTY5	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-21-2020 09:10:16	ACV0PFEINFP6000	Megan Pastores	**Data Entry:** **Sample ID:** BPFTY	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)		(pfe.mpastores)	**D:** 6	

5.e Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 09:10:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPFTY6	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-21-2020 08:51:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-21-2020 08:51:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-21-2020 08:51:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-21-2020 08:51:34 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-21-2020 08:51:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Collection: Aug/20/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-21-2020 08:51:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP6RSH	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-21-2020 08:51:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP6RSH	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-20-2020 15:44:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-20-2020 15:44:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-20-2020 15:44:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Aug-20-2020 15:44:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Aug/20/2020 13:33	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-20-2020 15:44:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-20-2020 15:44:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-20-2020 15:44:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-20-2020 15:44:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-20-2020 15:44:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-20-2020 15:44:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Sep-08-2020 13:12:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/8/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Sep-08-2020 13:12:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/8/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-08-2020 13:12:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 36.7 **Temperature Unit:** C **Temperature Location::** FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-08-2020 13:12:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

2.a Temperature:

Date	Location	User	Value	Reason
Sep-08-2020 13:12:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 36.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-08-2020 13:12:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-08-2020 13:12:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-08-2020 16:47:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-08-2020 16:47:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-08-2020 16:47:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-08-2020 16:47:27 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-08-2020 16:47:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Date of Collection: Sep/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-08-2020 16:47:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BP9233	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-08-2020 16:47:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP9233	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-08-2020 13:13:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-08-2020 13:13:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-08-2020 13:13:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Sep-08-2020 13:13:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/8/2020 12:00	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-08-2020 13:13:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-08-2020 13:13:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-08-2020 13:13:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-08-2020 13:13:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-08-2020 13:13:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-08-2020 12:09:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Oct/8/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Oct-08-2020 15:39:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-08-2020 15:39:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-08-2020 15:39:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-08-2020 15:39:10 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-08-2020 15:39:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Collection: Oct/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-08-2020 15:39:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BPV0JM	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 15:39:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPV0JM	Initial Entry

5.b

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-08-2020 15:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BPV0JN	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 15:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPV0JN	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-08-2020 15:39:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BPFTR9	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 15:39:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPFTR9	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-08-2020 15:39:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BPFTRB	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-08-2020 15:39:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPFTRB	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Mar-02-2021 10:00:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Mar/2/2021	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Mar-02-2021 15:49:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-02-2021 15:49:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-02-2021 15:49:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-02-2021 15:49:31 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Mar-02-2021 15:49:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Collection: Mar/2/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-02-2021 15:49:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BR2P8C	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 15:49:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BR2P8C	Initial Entry

5.b

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Mar-02-2021 15:49:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BSG7K5	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 15:49:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BSG7K5	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-02-2021 15:50:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BSG7K6	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 15:50:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BSG7K6	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-08-2020 12:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Oct/8/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-08-2020 12:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-08-2020 12:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Warm feeling of neck and head	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason

Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/20/2020 14:05	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO End Date Time: Aug/21/2020 09:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT APPLICABLE	Initial Entry

Pacific Time (US & Canada)				

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-08-2020 13:17:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Transcription Error
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

Pacific Time (US & Canada)				

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-08-2020 13:15:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Fatigue	Initial Entry

4. Start Date Time:

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/20/2020 15:30	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO End Date Time: Aug/21/2020 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason

Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-08-2020 13:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Low grade fever	Initial Entry

4. Start Date Time:

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/8/2020 14:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO End Date Time: Sep/9/2020 07:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason

Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-08-2020 12:28:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-08-2020 12:28:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Transcription Error
Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Did the adverse event cause the subject to be discontinued from the study?' is Yes but neither DISPOSITION - TREATMENT form nor DISPOSITION - FOLLOW-UP has Status as "ADVERSE EVENT". Please review and update as appropriate.

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Oct-08-2020 12:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Fatigue	Initial Entry

4. Start Date Time:

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/8/2020 14:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO End Date Time: Sep/9/2020 07:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason

Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551084	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-08-2020 12:27:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Exposure during pregnancy	Initial Entry

4. Start Date Time:

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Mar-11-2021 13:29:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Feb/4/2021 UNK:UNK	Changed Information
Mar-10-2021 14:25:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Jan/28/2021 UNK:UNK	New Information
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Jan/21/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-10-2021 11:46:42	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Not Applicable	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)				

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-10-2021 12:25:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason

Mar-10-2021 12:25:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT RELATED If Not Related to st udy treatment(s), th is event is due to: OTHER *If Other, specify :* sexual interco urse	New Information
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-10-2021	ACV0PFEINFP6000	Julie Glazier	**Data Entry:**	Initial Entry

11:46:17 (UTC-08:00) Pacific Time (US & Canada)		(pfe.jglazier)	NO	

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-11-2021 01:14:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Rose Madelein (pfe.rosem19)	Query 1: Closed	Response satisfies query
Mar-10-2021 12:26:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	correct as entered per guidance given regarding this situation
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Exposure during pregnancy:

& Canada)				Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** UNKNOWN	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Mar-10-2021 11:46:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Mar-02-2021 10:30:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. What is the medication identifier?

Date	Location	User	Value	Reason
Mar-02-2021 10:30:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Mar-02-2021 10:30:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Mar-02-2021 10:30:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in

the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Mar-02-2021 10:30:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Flu Vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Mar-02-2021 10:30:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Oct/9/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Dec-17-2020 13:35:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Dec/17/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Jan-08-2021 09:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Transcription Error
Dec-17-2020 13:37:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Dec-17-2020 13:37:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Dec/17/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-17-2020 13:37:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551084 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Subject Status

Date	Location	User	Value	Reason
Oct-08-2020 12:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** FOLLOW-UP	Initial Entry
Aug-20-2020 15:43:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Aug-20-2020 15:39:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-08-2020 12:10:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Oct/8/2020	Initial Entry
Aug-20-2020 15:43:17	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/20/2020	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)				
Aug-20-2020 15:39:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/20/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551084

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-21-2020 15:16:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Click Here to Enable	Initial Entry

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** COHORT SELECTION
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/24/2020

Header Text: c4591001

Visit: COHORT_SELECTION **Form:** DEMOGRAPHY

Form Version: 06-Jul-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Demography		
1.	Subject ID	[10551092]
2.	Birth Date:	(b) (6)/1972
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Aug/24/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** INCLUSION/EXCLUSION CRITERIA
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Screening		
1.	Date of Completion/Discontinuation /Death	Aug/24/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** GENERAL MEDICAL HISTORY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments

Medical History Details

1.

Line/MH Number:	Not Applicable [ ]
Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	Not Applicable [ ]
Start Date:	Not Applicable //
Ongoing:	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Aug/24/2020
2.	Weight:	[70.0]
3.	Unit:	kg
4.	Height:	[174.5]
5.	Unit:	cm
6.	Body Mass Index:	[23.0]

Vital Signs Details

7.a

Record Identifier:	1
Temperature:	[36.5]
Unit:	C
Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V1_DAY1_VAX1_L **Form:** RANDOMIZATION

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition		
1.	Randomization Date :	Aug/24/2020
2.	Randomization Number:	[61282]
3.	Randomization Group:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/24/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP6RTV]
5.b	Sample ID	[BP6RTW]
5.c	Sample ID	[BP6RTX]
5.d	Sample ID	[BPFTYP]
5.e	Sample ID	[BPFTYR]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/24/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP6RTN]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/24/2020 11:38
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** REACTOGENICITY DIARY
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Reactogenicity Diary		
1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L	**Form:** VITAL SIGNS - TEMP
Form Version: 15-Sep-2020 21:54	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Sep/15/2020

Vital Signs Details

2.a

Record Identifier:	1
Temperature:	[36.9]
Unit:	C
Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/15/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP922D]

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/15/2020 14:13
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001	
Visit: V3_MONTH1_POSTVAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Oct/13/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/13/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2PBP]
5.b	Sample ID	[BR2PBR]
5.c	Sample ID	[BS89X1]
5.d	Sample ID	[BS89X2]

Header Text: c4591001

Visit: V4_MONTH6_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Mar/11/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2P9D]
5.b	Sample ID	[BSG7LS]
5.c	Sample ID	[BSG7LT]

Header Text: c4591001	
Visit: V5_MONTH12_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: V6_MONTH24_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** DATE OF VISIT - ILLNESS ONSET
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Form Version: 20-Feb-2021 02:17	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Signs and Symptoms		
1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	
Symptoms		
4.	Symptoms:	
	Was symptom present?	
Symptoms - Other		
5.	Symptoms - Other Text:	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Health Care Utilization		
1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	
Health Care Utilization Other		
2.	Other Type of Practitioner Specify:	[ ]
Health Care Utilization		
3.	Has the subject been hospitalized due to potential COVID-19 illness?	

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit	**Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Unplanned Assessments		
1.	Assessments	

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	Oct/13/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: Follow-Up - Unscheduled | **Form:** DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit | **Form:** DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: Logs **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Injection Site Pain	Aug/24/2020 17:00	NO End Date Time: Aug/26/2020 08:00	Repeating Pages
2.	ADVERSE EVENT	2	Injection site pain	Sep/15/2020 17:00	NO End Date Time: Sep/17/2020 17:00	Repeating Pages
3.	ADVERSE EVENT	3	Headache	Sep/16/2020 08:00	NO End Date Time: Sep/16/2020 10:00	Repeating Pages
4.	ADVERSE EVENT	4	Exposure during pregnancy	Feb/3/2021 UNK:UNK	YES	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection Site Pain]
4.	Start Date Time:	Aug/24/2020 17:00
5.	Is the adverse event still ongoing?	NO End Date Time: Aug/26/2020 08:00
6.	Toxicity Grade:	1

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection site pain]
4.	Start Date Time:	Sep/15/2020 17:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/17/2020 17:00
6.	Toxicity Grade:	1

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Headache]
4.	Start Date Time:	Sep/16/2020 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/16/2020 10:00
6.	Toxicity Grade:	1

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[4]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Exposure during pregnancy]	
4.	Start Date Time:	Feb/3/2021 UNK:UNK	
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	Not Applicable	Comments

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [sexual intercourse]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	UNKNOWN
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Medication Error		
1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Flu vaccine	Oct/14/2020	Repeating Pages

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

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eCRF Audit Trail History
Form Audit Trail

Concomitant Medications		
1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Flu vaccine]
5.	Date:	Oct/14/2020

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - PROHIBITED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

Header Text: c4591001

Visit: Logs **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Radiation Treatment		
1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** TRANSFUSIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1.	Transfusion Type:	
2.	Date of Transfusion:	//

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** VITAL SIGNS - TEMP
Form Version: 20-Feb-2021 02:16	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Vital Signs

1.	Date:	//

Vital Signs Details

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 1
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 6
Form Version: 10-Oct-2020 16:01	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE
Form Version: 14-Jan-2021 02:29	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Informed Consent - Asymptomatic Surveillance		
1.	Consent Was:	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Mar/11/2021
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Further Vaccination Confirmation		
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** TREATMENT UNBLINDED
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Treatment Unblinded		
1.	Date Treatment Unblinded :	Mar/11/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Withdrawal Of Consent		
1.	Withdrawal of Consent Date :	//

Header Text: c4591001

Visit: Disposition - Unscheduled	**Form:** DEATH DETAILS CODED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Death Details

1.	Date of Collection / Notification of Death:	//

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[ ]

Header Text: c4591001	
Visit: Subject Status - Unscheduled	**Form:** SUBJECT STATUS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Subject Status		
1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/13/2020

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Casebook Signature Form		
1.	Casebook Signature	Click Here to Enable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Audit Trail

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Mar-12-2021 14:14:35 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** INCLUSION/EXCLUSION CRITERIA - Comments
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
Form	Aug-24-2020 14:28:20 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - Comments

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
Form	Aug-24-2020 14:32:53 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Comments

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
6	Mar-11-2021 15:34:34 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Mar-12-2021 14:14:35 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Julie Glazier	N/A	Mar-12-2021 10:31:13 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Mar-12-2021 09:54:26 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Header Text: c4591001

Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Julie Glazier	N/A	Mar-11-2021 15:30:59 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Oct-21-2020 16:48:44 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: COHORT_SELECTION	**Form:** COHORT SELECTION - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-24-2020 14:24:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-24-2020 14:24:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Aug-24-2020 14:24:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** OBTAINED Date Written Consent Obtained Aug/24/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Subject ID

Date	Location	User	Value	Reason
Aug-24-2020 14:24:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10551092	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-24-2020 14:24:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6)/1972	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-24-2020 14:24:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Aug-24-2020 14:24:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-24-2020 14:24:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Aug-24-2020 14:28:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/24/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-24-2020 14:28:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/24/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-24-2020 14:28:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-24-2020 14:28:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/24/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 70.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason

Aug-24-2020 16:43:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 174.5	Transcription Error
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 189.2	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-24-2020 16:43:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 23.0	Transcription Error
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 19.6	Initial Entry

& Canada)				

7.a

Date	Location	User	Value	Reason
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 36.5 **Temperature Unit:** C **Temperature Location::** FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 36.5	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

7.a Unit:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-24-2020 14:30:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/24/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 61282	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-25-2020 08:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-25-2020 08:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-25-2020 08:09:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 08:09:31 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 08:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Collection: Aug/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-25-2020 08:09:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP6RTV	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 08:09:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP6RTV	Initial Entry

5.b

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-25-2020 08:09:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP6RTW	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 08:09:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP6RTW	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-25-2020 08:09:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP6RTX	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 08:09:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP6RTX	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-25-2020 08:10:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BPFTYP	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 08:10:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPFTYP	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-25-2020 08:10:10	ACV0PFEINFP6000	Megan Pastores	**Data Entry:** **Sample ID:** BPFTY	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)		(pfe.mpastores)	**D:** R	

5.e Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 08:10:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPFTYR	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-25-2020 07:56:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-25-2020 07:56:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-25-2020 07:56:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 07:56:09 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 07:56:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Collection: Aug/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-25-2020 07:56:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP6RTN	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 07:56:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP6RTN	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-24-2020 14:30:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-24-2020 14:30:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Aug-24-2020 14:30:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/24/2020 11:38	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-24-2020 14:30:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-24-2020 14:30:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-24-2020 14:30:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-24-2020 14:31:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Sep-16-2020 08:39:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/15/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Sep-16-2020 08:39:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/15/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-16-2020 08:39:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 36.9 **Temperature Unit:** C **Temperature Location::** FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-16-2020 08:39:56 (UTC-08:00) Pacific Time (US	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 1	Initial Entry

& Canada)				

2.a Temperature:

Date	Location	User	Value	Reason
Sep-16-2020 08:39:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 36.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-16-2020 08:39:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-16-2020 08:39:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-16-2020 09:07:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-16-2020 09:07:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-16-2020 09:07:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-16-2020 09:07:27 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-16-2020 09:07:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Collection: Sep/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-16-2020 09:07:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP922D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-16-2020 09:07:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP922D	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-16-2020 08:40:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-16-2020 08:40:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-16-2020 08:40:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason

Sep-16-2020 08:40:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/15/2020 14:13	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-16-2020 08:40:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-16-2020 08:40:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-16-2020 08:40:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-16-2020 08:40:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-16-2020 08:40:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-13-2020 15:59:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Oct/13/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Oct-13-2020 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-13-2020 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-13-2020 15:23:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-13-2020 15:23:24 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-13-2020 15:23:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Collection: Oct/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-13-2020 15:23:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BR2PBP	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 15:23:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BR2PBP	Initial Entry

5.b

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-13-2020 15:23:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BR2PBR	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 15:23:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BR2PBR	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-13-2020 15:23:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BS89X1	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 15:23:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BS89X1	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-13-2020 15:24:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BS89X2	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-13-2020 15:24:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BS89X2	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-11-2021 15:30:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Mar/11/2021	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Mar-11-2021 15:53:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-11-2021 15:53:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-11-2021 15:56:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-11-2021 15:53:49 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Mar-11-2021 15:53:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Collection: Mar/11/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-11-2021 15:56:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BR2P9D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 15:56:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BR2P9D	Initial Entry

5.b

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Mar-11-2021 15:56:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BSG7LS	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 15:56:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BSG7LS	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-11-2021 15:56:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BSG7LT	Initial Entry

Header Text: c4591001

Visit: V4_MONTH6_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Mar-11-2021 15:56:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BSG7LT	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-13-2020 15:59:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Oct/13/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-13-2020 15:59:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-13-2020 15:59:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Injection Site Pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason

Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Aug/24/2020 17:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO End Date Time: Aug/26/2020 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NOT APPLICABLE	Initial Entry

Pacific Time (US & Canada)				

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-16-2020 08:44:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Injection site pain	Initial Entry

4. Start Date Time:

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/15/2020 17:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO End Date Time: Sep/17/2020 17:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to

prevent above outcomes).

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason

Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-13-2020 16:00:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Headache	Initial Entry

4. Start Date Time:

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/16/2020 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO End Date Time: Sep/16/2020 10:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to

prevent above outcomes).

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason

Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-13-2020 16:01:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Exposure during pregnancy	Initial Entry

4. Start Date Time:

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Feb/3/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-11-2021 15:34:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Not Applicable	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to

prevent above outcomes).

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT RELATED If Not Related to stu dy treatment(s), this event is due to: OTHER *If Other, specify:* sexual intercour	Initial Entry

			se	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason

Mar-12-2021 20:06:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Rose Madelein (pfe.rosem19)	Query 1: Closed	Response satisfies query
Mar-12-2021 10:30:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	correct as entered per sponsor guidance
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE Exposure during pregnancy: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** UNKNOWN	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Mar-11-2021 15:34:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Mar-12-2021 10:31:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. What is the medication identifier?

Date	Location	User	Value	Reason
Mar-12-2021 10:31:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Mar-12-2021 10:31:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Mar-12-2021 10:31:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Mar-12-2021 10:31:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Flu vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Mar-12-2021 10:31:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Oct/14/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-11-2021 15:32:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Mar/11/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Mar-11-2021 15:33:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-11-2021 15:32:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Mar-11-2021 15:32:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vac	Initial Entry

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

			cination 1/2	

Header Text: c4591001

Visit: Disposition - Unscheduled	**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551092	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Mar-11-2021 15:33:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Mar/11/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-11-2021 15:33:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551092 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Subject Status

Date	Location	User	Value	Reason
Oct-13-2020 15:59:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** FOLLOW-UP	Initial Entry
Aug-24-2020 14:30:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Aug-24-2020 14:28:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-13-2020 15:59:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Oct/13/2020	Initial Entry
Aug-24-2020 14:30:34	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/24/2020	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)				
Aug-24-2020 14:28:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/24/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551092

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-21-2020 15:20:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Click Here to Enable	Initial Entry

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** COHORT SELECTION
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Informed Consent		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/24/2020

Header Text: c4591001

Visit: COHORT_SELECTION **Form:** DEMOGRAPHY

Form Version: 06-Jul-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Demography		
1.	Subject ID	[10551094]
2.	Birth Date:	(b) (6)/1964
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Aug/24/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** INCLUSION/EXCLUSION CRITERIA
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Screening		
1.	Date of Completion/Discontinuation /Death	Aug/24/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** GENERAL MEDICAL HISTORY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Medical History Details

1.a

Line/MH Number:	[1]
Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Dermatomyositis]
Start Date:	UNK/UNK/1995
Ongoing:	NO End Date: UNK/UNK/1998

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs		
1.	Date:	Aug/24/2020
2.	Weight:	[75.4]
3.	Unit:	kg
4.	Height:	[167.0]
5.	Unit:	cm
6.	Body Mass Index:	[27.0]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[35.9]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 21-Aug-2020 02:49 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/24/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a

Sponsor ID:	[113]
Test:	Choriogonadotropin Beta_PX113
Result:	NEGATIVE
Not Done:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L **Form:** RANDOMIZATION

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition		
1.	Randomization Date :	Aug/24/2020
2.	Randomization Number:	[238378]
3.	Randomization Group:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/24/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP6RV3]
5.b	Sample ID	[BP6RV4]
5.c	Sample ID	[BP6RV5]
5.d	Sample ID	[BPFTYV]
5.e	Sample ID	[BPFTYW]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/24/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP6RTY]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/24/2020 12:32
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** REACTOGENICITY DIARY

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT

Header Text: c4591001

Visit: V2_VAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/14/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L	**Form:** VITAL SIGNS - TEMP
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Sep/14/2020

Vital Signs Details

2.a

Record Identifier:	1
Temperature:	[35.1]
Unit:	C
Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L	**Form:** LAB URINALYSIS - PREGNANCY TEST
Form Version: 21-Aug-2020 02:49	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/14/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP9212]

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/14/2020 10:53
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001	
Visit: V3_MONTH1_POSTVAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Oct/12/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/12/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BPV0KK]
5.b	Sample ID	[BPV0KL]
5.c	Sample ID	[BS89WF]
5.d	Sample ID	[BS89WG]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Nov/10/2020
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	COVID_A

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Signs and Symptoms

1.	Date of Assessment:	Nov/10/2020
2.	Date of First Symptom Started:	Nov/8/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Nov/12/2020

Symptoms

4.a	Symptoms:	FEVER
	Was symptom present?	NO
4.b	Symptoms:	NEW OR INCREASED COUGH
	Was symptom present?	NO
4.c	Symptoms:	NEW OR INCREASED SHORTNESS OF BREATH
	Was symptom present?	NO
4.d	Symptoms:	CHILLS
	Was symptom present?	NO
4.e	Symptoms:	NEW OR INCREASED MUSCLE PAIN
	Was symptom present?	NO

4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	NO
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

Symptoms - Other

5.a	Symptoms - Other Text:	[fatigue]

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form
Form Comments
eCRF Audit Trail History

Microbiology Specimen

1.	Actual Date of Collection:	Not Applicable //	Comments
2.	Specimen Type:	Not Applicable	Comments
3.	Specimen Collection Location:	Not Applicable	Comments
4.	Assay Code and Description:	Not Applicable	Comments
5.	Device Type:	Not Applicable	Comments
6.	Trade Name:	Not Applicable	Comments
7.	Test Result:	Not Applicable	Comments
8.	Comments/Findings /Details:	Not Applicable [ ]	Comments
9.	Trade Name Other, Specify:	Not Applicable [ ]	Comments

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Nov/10/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[CV00576]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[Telehealth visit]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Health Care Utilization

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	NO
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	NO
1.e	Physician or Healthcare Professional:	TELEPHONE CONSULTATION
	Occurrence of Visits or Contacts:	NO

1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[ ]

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	NO

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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Respiratory Treatment		
1.	What is the treatment Identifier?	[ ]
2.	Concomitant Non-drug Treatment Pre-specified:	
3.	Treatment:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020 | **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Illness Details		
1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	1

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					Repeating Pages

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020	**Form:** ILLNESS DETAILS - SEVERE
Form Version: 17-Jul-2020 21:55	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

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Illness Details		
1.	Category of Clinical Event:	
2.	Subcategory of Clinical Event:	
3.	Was a diagnosis obtained?	
4.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result:	
1.								Repeating Pages

Header Text: c4591001	
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020	**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Form Version: 21-Aug-2020 02:49	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Lab Chemistry Details		
1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result		
5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result:	
1.								Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020	**Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Form Version: 21-Aug-2020 02:51	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

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Laboratory Data Hematology

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

Lab Result

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** VITAL SIGNS - COVID
Form Version: 21-Aug-2020 02:50
Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Date:	Vital Signs Details			Form Instance
		Record Identifier:	Systolic:	Diastolic:	
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020 | **Form:** VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Vital Signs

1.	Date:	//

Vital Signs Details

2.	Record Identifier:	
	Systolic:	[ ]
	Diastolic:	[ ]
	Respiratory Rate in respirations/minute:	[ ]
	Heart Rate in beats/minute:	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Date:	Vital Signs Details		Form Instance
1.		**Record Identifier:**	**Oxygen Saturation**	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020 | **Form:** VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Vital Signs		
1.	Date:	//

Vital Signs Details		
2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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Oxygenation Parameters		
1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[ ]
3.	FiO2 (Fraction of Inhaled Oxygen):	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020	**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Form Version: 06-Jul-2020 21:55	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: POT_COVID_ILL 1 **Form:** IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020 | **Form:** IMAGING

Form Version: 06-Jul-2020 21:53 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Imaging		
1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/22/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Dec/22/2020
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	COVID_A1

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/22/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2PLT]
5.b	Sample ID	[BS3B33]
5.c	Sample ID	[BS3B34]

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Unplanned Assessments		
1.	Assessments	

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	Oct/12/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: Follow-Up - Unscheduled | **Form:** DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit **Form:** DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001
Visit: Logs **Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Injection Site Pain	Sep/15/2020 UNK:UNK	NO End Date Time: Sep/16/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	Headache	Sep/15/2020 UNK:UNK	NO End Date Time: Sep/16/2020 UNK:UNK	Repeating Pages
3.	ADVERSE EVENT	3	injection site soreness	Jan/22/2021 04:00	NO End Date Time: Jan/23/2021 06:00	Repeating Pages
4.	ADVERSE EVENT	4	Injection Site Pain	Feb/11/2021 16:00	NO End Date Time: Feb/13/2021 07:00	Repeating Pages
5.	ADVERSE EVENT	5	Headache	Feb/12/2021 06:00	NO End Date Time: Feb/13/2021 06:00	Repeating Pages

Header Text: c4591001

Visit: Logs **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
6.	ADVERSE EVENT	6	Left Axillary Adenopathy	Feb/12/2021 06:00	NO End Date Time: Feb/15/2021 06:00	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection Site Pain]
4.	Start Date Time:	Sep/15/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/16/2020 UNK:UNK
6.	Toxicity Grade:	1

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Headache]
4.	Start Date Time:	Sep/15/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/16/2020 UNK:UNK
6.	Toxicity Grade:	1

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[injection site soreness]
4.	Start Date Time:	Jan/22/2021 04:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/23/2021 06:00
6.	Toxicity Grade:	1

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection Site Pain]
4.	Start Date Time:	Feb/11/2021 16:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/13/2021 07:00
6.	Toxicity Grade:	1

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Headache]
4.	Start Date Time:	Feb/12/2021 06:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/13/2021 06:00
6.	Toxicity Grade:	1

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Left Axillary Adenopathy]
4.	Start Date Time:	Feb/12/2021 06:00
5.	Is the adverse event still ongoing?	NO End Date Time: Feb/15/2021 06:00
6.	Toxicity Grade:	1

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Medication Error		
1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Date:	//

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - PROHIBITED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Concomitant Medications

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

Header Text: c4591001

Visit: Logs **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Radiation Treatment		
1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** TRANSFUSIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

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1.	Transfusion Type:	
2.	Date of Transfusion:	//

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** VITAL SIGNS - TEMP
Form Version: 20-Feb-2021 02:16	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Vital Signs

1.	Date:	//

Vital Signs Details

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

Lab Result

6.

Sponsor ID:	[ ]
Test:	
Result:	
Not Done:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 1
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 6
Form Version: 10-Oct-2020 16:01	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/15/2021
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete, Frozen
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Further Vaccination Confirmation		
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Treatment Unblinded		
1.	Date Treatment Unblinded :	Jan/20/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Withdrawal Of Consent		
1.	Withdrawal of Consent Date :	//

Header Text: c4591001

Visit: Disposition - Unscheduled	**Form:** DEATH DETAILS CODED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Death Details

1.	Date of Collection / Notification of Death:	//

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[ ]

Header Text: c4591001

Visit: V101_VAX3 **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/21/2021
2.	Erroneous Visit	

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INFORMED CONSENT - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Informed Consent - Further Vaccination		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/21/2021

Header Text: c4591001

Visit: V101_VAX3	**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable

Header Text: c4591001

Visit: V101_VAX3	**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Screening for Further Vaccination		
1.	Date of Completion/Discontinuation /Death :	Jan/21/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 14-Jan-2021 02:21 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/21/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a

Sponsor ID:	[113]
Test:	Choriogonadotropin Beta_PX113
Result:	NEGATIVE
Not Done:	

Header Text: c4591001

Visit: V101_VAX3	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/21/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2P2F]
5.b	Sample ID	[BS3B7W]
5.c	Sample ID	[BS3B7V]

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/21/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2P2D]

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/21/2021 14:54
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V102_VAX4 **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Feb/11/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 14-Jan-2021 02:21 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/11/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

Header Text: c4591001

Visit: V102_VAX4 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/11/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2P63]

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/11/2021 12:04
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001	
Visit: V103_MONTH1	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Mar/11/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1 **Form:** CONTACT OUTCOME

Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Contact Outcome		
1.	Contact Type:	TELEPHONE VISIT
2.	Was contact made?	YES Date of Contact: Mar/11/2021
3.	Comments:	[ ]

Header Text: c4591001	
Visit: V104_MONTH6	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6 **Form:** CONTACT OUTCOME

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: V105_MONTH18	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18 **Form:** CONTACT OUTCOME

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	Mar/11/2021
2.	Phase of Disposition:	OPEN LABEL TREATMENT
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Subject Status		
1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/12/2020

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Casebook Signature Form		
1.	Casebook Signature	Click Here to Enable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Audit Trail

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Mar-12-2021 14:16:22 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** INCLUSION/EXCLUSION CRITERIA - Comments

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
Form	Aug-24-2020 14:43:35 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
Form	Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
1	Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
2	Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
3	Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020 | **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
4	Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
5	Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
6	Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
7	Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020 | **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
8	Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
9	Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments
Form Version: 10-Dec-2020 02:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
Form	Jan-21-2021 15:34:02 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Mar-12-2021 14:16:22 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Megan Pastores	N/A	Mar-12-2021 11:40:58 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Feb-17-2021 15:58:13 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Header Text: c4591001

Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Elle Billman	N/A	Feb-17-2021 12:09:26 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Feb-12-2021 15:45:23 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Elle Billman	N/A	Feb-11-2021 14:39:40 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
Helen Stacey	Approved	Feb-11-2021 14:26:33 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
Affidavit: By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject. Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature. To this I do attest by supplying my user name and password and clicking the button marked Submit below.				
Elle Billman	N/A	Feb-11-2021 13:08:40 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
Helen Stacey	Approved	Jan-25-2021 12:09:49 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Header Text: c4591001

Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Elle Billman	N/A	Jan-25-2021 11:32:28 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Jan-21-2021 18:29:27 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Elle Billman	N/A	Jan-21-2021 15:18:23 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Jan-20-2021 17:02:55 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Elle Billman	N/A	Dec-22-2020 15:46:32 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Nov-13-2020 10:53:55 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Header Text: c4591001

Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Elle Billman	N/A	Nov-12-2020 15:16:55 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Nov-10-2020 13:26:41 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Elle Billman	N/A	Nov-10-2020 12:38:02 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Oct-21-2020 16:49:36 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: COHORT_SELECTION	**Form:** COHORT SELECTION - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-24-2020 14:42:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-24-2020 14:42:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Aug-24-2020 14:42:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** OBTAINED Date Written Consent Obtained Aug/24/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Subject ID

Date	Location	User	Value	Reason
Aug-24-2020 14:42:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10551094	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-24-2020 14:42:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6)/1964	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-24-2020 14:43:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Aug-24-2020 14:43:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-24-2020 14:43:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Aug-24-2020 14:43:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/24/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-24-2020 14:43:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/24/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-24-2020 14:43:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-24-2020 14:43:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1.a

Date	Location	User	Value	Reason
Aug-24-2020 14:47:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 1 **Medical History Term:** Dermatomyositis **Start Date:** UNK/UNK/1995 **Ongoing:** NO End Date: UNK/UNK/1998	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-24-2020 14:47:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-24-2020 14:47:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Dermatomyositis	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-24-2020 14:47:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** UNK/UNK/1995	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-24-2020 14:47:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO End Date: UNK/UNK/1998	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/24/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 75.4	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason

Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 167.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 27.0	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 35.9	Initial Entry

			Temperatur e Unit: C **Temperatur e Location::** FORE HEAD	

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-25-2020 01:05:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 1: Closed	As per site confirmation
Aug-24-2020 14:44:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	Original value is correct
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 35.9 C is outside of Normal Range

& Canada)				36.1 - 37.5 C.
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 35.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/24/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason

Aug-24-2020 14:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-24-2020 14:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113 **Test::** Choriogonadotropin Beta_PX113 **Result::** NEGATIVE **Not Done ::**	Initial Entry

6.a Sponsor ID:

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-24-2020 14:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-24-2020 14:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NEGATIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-24-2020 14:45:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/24/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-24-2020 14:45:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 238378	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-25-2020 08:11:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-25-2020 08:11:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-25-2020 08:12:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 08:11:51 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 08:11:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Collection: Aug/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-25-2020 08:12:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP6RV3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 08:12:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP6RV3	Initial Entry

5.b

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-25-2020 08:12:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP6RV4	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 08:12:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP6RV4	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-25-2020 08:12:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP6RV5	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 08:12:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP6RV5	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-25-2020 08:14:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BPFTYV	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 08:14:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPFTYV	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-25-2020 08:14:24	ACV0PFEINFP6000	Megan Pastores	**Data Entry:** **Sample ID:** BPFTY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)		(pfe.mpastores)	**D:** W	

5.e Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 08:14:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPFTYW	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-25-2020 07:56:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-25-2020 07:56:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-25-2020 07:57:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 07:56:57 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 07:56:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Collection: Aug/24/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-25-2020 07:57:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP6RTY	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 07:57:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP6RTY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-24-2020 14:45:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-24-2020 14:45:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-24-2020 14:45:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Aug-24-2020 14:45:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/24/2020 12:32	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-24-2020 14:45:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-24-2020 14:45:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-24-2020 14:45:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-24-2020 14:45:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-24-2020 14:45:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-24-2020 14:45:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Sep-14-2020 12:03:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/14/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Sep-14-2020 12:04:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/14/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-14-2020 12:04:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 35.1 **Temperature Unit:** C **Temperature Location::** FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-14-2020 12:04:32 (UTC-08:00) Pacific Time (US	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 1	Initial Entry

& Canada)				

2.a Temperature:

Date	Location	User	Value	Reason
Sep-15-2020 23:39:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 2: Closed	Response satisfies query
Sep-15-2020 10:10:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 2: Answered	not clinically significant
Sep-15-2020 01:27:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 2: Opened	DM :Kindly confirm the temperature 35.1 C recorded is clinically significant or not, thank you.
Sep-15-2020 01:26:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe.ks66)	Query 1: Closed	DM :Kindly confirm the temperature 35.1 C recorded is clinically significant or not, thank you.

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Sep-14-2020 12:06:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Query 1: Answered	Original value is correct
Sep-14-2020 12:04:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 35.1 C is outside of Normal Range 36.1 - 37.5 C.
Sep-14-2020 12:04:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 35.1	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-14-2020 12:04:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-14-2020 12:04:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-14-2020 12:05:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-14-2020 12:05:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-14-2020 12:05:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/14/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason

Sep-14-2020 12:05:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-14-2020 12:05:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-14-2020 12:05:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113 **Test::** Choriogonadotropin Beta_PX113 **Result::** NEGATIVE **Not Done ::**	Initial Entry

6.a Sponsor ID:

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-14-2020 12:05:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-14-2020 12:05:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-14-2020 12:05:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NEGATIVE	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-14-2020 15:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-14-2020 15:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-14-2020 15:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-14-2020 15:39:26 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-14-2020 15:39:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Date of Collection: Sep/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-14-2020 15:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BP9212	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-14-2020 15:39:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP9212	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-14-2020 12:11:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-14-2020 12:11:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-14-2020 12:11:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Sep-14-2020 12:11:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/14/2020 10:53	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-14-2020 12:11:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-14-2020 12:11:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-14-2020 12:11:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-14-2020 12:11:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-14-2020 12:11:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-12-2020 13:10:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Oct/12/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Oct-12-2020 16:02:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-12-2020 16:02:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-12-2020 16:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-12-2020 16:02:04 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-12-2020 16:02:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Collection: Oct/12/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-12-2020 16:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BPV0KK	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 16:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPV0KK	Initial Entry

5.b

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-12-2020 16:02:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BPV0KL	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 16:02:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPV0KL	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-12-2020 16:02:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BS89WF	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 16:02:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BS89WF	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-12-2020 16:02:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BS89WG	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Oct-12-2020 16:02:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BS89WG	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Nov-10-2020 12:40:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Nov-10-2020 12:38:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Nov-10-2020 12:38:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal

				Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Nov-10-2020 12:38:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Nov/10/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** COVID_A	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date of Assessment:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Nov/10/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Nov/8/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Jan-25-2021 11:32:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO Date of Last Symptom Resolved: Nov/12/2020	New Information
Nov-10-2020 12:38:43	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)				

4.a

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Symptoms:** FEVER **Symptom Present:** NO	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

4.b

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Symptoms:** NEW OR INCREASED COUGH **Symptom Present:** NO	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

4.c

Date	Location	User	Value	Reason
Nov-10-2020	ACV0PFEINFP6000	Elle Billman	**Data Entry:**	Initial Entry

12:38:43 (UTC-08:00) Pacific Time (US & Canada)		(pfe.ebillman)	**Symptoms:** NEW OR INCREASED SHORTNESS OF BREATH **Symptom Present:** NO	

4.c Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Symptoms:** CHIL	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)			**Symptom Present:** LS NO	

4.d Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Symptoms:** NEW OR INCREASED MUSCLE PAIN	Initial Entry

			Symptom Present: NO	

4.e Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Symptoms:** NEW LOSS OF TASTE OR SMELL	Initial Entry

			Sympt om Pr esent: NO	

4.f Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NEW LOSS OF TA STE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

4.g

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Symptoms:** NEW OR I NCREASE D SORE TH ROAT	Initial Entry

			Symptom Present: YES	

4.g Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Symptoms:** DIARRHEA **Symptom Present:** NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

4.h Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Symptoms:** VOMITING **Symptom Present:** NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Nov-10-2020 12:38:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-10-2020 12:38:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Symptoms - Other:** fatigue	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Nov-10-2020 12:38:57	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** fatigue	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020	**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History
Form Version: 10-Oct-2020 16:02	**Form Status:** Data Complete, Frozen
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Actual Date of Collection:

Date	Location	User	Value	Reason
Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason

Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-10-2020 12:40:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Nov-10-2020 12:40:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-10-2020 12:40:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-12-2020 15:16:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-11-2020 07:33:25 (UTC-08:00)	ACV0PFEINFP6000	Carrie Nedrick (pfe.nedrickc)	Query 1: Opened	DM: 'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Nov-10-2020 12:40:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-10-2020 12:40:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES Date of Collection : Nov/10/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-12-2020 15:16:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:** CV00576	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Nov-12-2020 15:16:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** CV00576	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Nov-10-2020 12:40:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-10-2020 12:40:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-10-2020 12:40:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Nov-10-2020 12:40:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Telehealth visit	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1.a

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Type of Practitioner:** SPECIALIST **Occurrence of Visits or Contacts:** NO	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

1.b

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Type of Practitioner:** EMERGENCY ROOM **Occurrence of Visits or Contacts:** NO	Initial Entry

1.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** EMERGENCY ROOM	Initial Entry

1.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

1.c

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Type of Practitioner:** PRIMARY CARE PHYSICIAN **Occurrence of Visits or Contacts:** NO	Initial Entry

1.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** PRIMARY CARE PHYSICIAN	Initial Entry

1.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

1.d

Date	Location	User	Value	Reason

Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Type of Practitioner:** URGENT CARE **Occurrence of Visits or Contacts:** NO	Initial Entry

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

1.e

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Type of Practition** TELEPHONE CO	Initial Entry

Pacific Time (US & Canada)			**er:** NSULTATION **Occurrence of Visits or Contacts:** NO	

1.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** TELEPHONE CONSULTATION	Initial Entry

1.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

1.f

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Type of Practitioner:** OTHER	Initial Entry

& Canada)			**Occurrence of** NO **Visits or Cont acts:**	

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Nov-10-2020 12:41:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/10/2020

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category of Clinical Event:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Nov-10-2020 12:41:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-10-2020 12:41:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** 1	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/22/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Dec-22-2020 15:46:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Dec/22/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Dec-22-2020 15:46:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** COVID_A1	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/22/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Dec-22-2020 15:54:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-22-2020 15:54:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-22-2020 15:54:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-22-2020 15:54:44 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Dec-22-2020 15:54:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES Date of Collection : Dec/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-22-2020 15:54:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID :** BR2PLT	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 15:54:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BR2PLT	Initial Entry

5.b

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/22/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Dec-22-2020 15:55:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID :** BS3B33	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 15:55:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BS3B33	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-22-2020 15:56:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID :** BS3B34	Initial Entry

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/22/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Dec-22-2020 15:56:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BS3B34	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-12-2020 13:10:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Oct/12/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-12-2020 13:10:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-12-2020 13:10:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Injection Site Pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason

Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/15/2020 UNK: UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO End Date Time: Sep/16/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NOT APPLICABLE	Initial Entry

Pacific Time (US & Canada)				

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-12-2020 13:16:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Headache	Initial Entry

4. Start Date Time:

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/15/2020 UNK: UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO End Date Time: Sep/16/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason

Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-12-2020 13:27:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** injection site sorenes s	Initial Entry

4. Start Date Time:

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-17-2021 12:09:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/22/2021 04:00	Transcription Error
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/22/2021 16:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO End Date Time: Jan/23/2021 06:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** RELATED	Initial Entry

& Canada)				

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-11-2021 13:10:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Injection Site Pain	Initial Entry

4. Start Date Time:

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Feb/11/2021 16:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO End Date Time: Feb/13/2021 07:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason

Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Mar-12-2021 11:45:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Headache	Initial Entry

4. Start Date Time:

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Feb/12/2021 06:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO End Date Time: Feb/13/2021 06:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason

Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Mar-12-2021 11:51:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 6	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Left Axillary Adeno pathy	Initial Entry

4. Start Date Time:

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Feb/12/2021 06:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO End Date Time: Feb/15/2021 06:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason

Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Mar-12-2021 11:52:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Jan-20-2021 14:55:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/15/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Jan-20-2021 14:55:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 14:55:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-20-2021 14:55:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to	Initial Entry

			have received o nly placebo at V accination 1/2	

Header Text: c4591001

Visit: Disposition - Unscheduled	**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-20-2021 14:55:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/20/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-20-2021 14:55:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Jan-21-2021 15:18:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/21/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Jan-21-2021 15:18:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** OBTAINED Date Written Consent Obtained Jan/21/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-21-2021 15:18:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/21/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-21-2021 15:18:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-21-2021 15:18:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 | **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Jan-21-2021 15:33:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-21-2021 15:33:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-21-2021 15:33:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/21/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason

Jan-21-2021 15:33:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-21-2021 15:33:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-21-2021 15:33:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113 **Test::** Choriogonadotropin Beta_PX113 **Result::** NEGATIVE **Not Done ::**	Initial Entry

6.a Sponsor ID:

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Jan-21-2021 15:33:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-21-2021 15:33:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-21-2021 15:33:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NEGATIVE	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Jan-21-2021 15:19:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-21-2021 15:19:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-21-2021 15:20:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-21-2021 15:19:41 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-21-2021 15:19:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES Date of Collection : Jan/21/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-21-2021 15:20:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID :** BR2P2F	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-21-2021 15:20:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BR2P2F	Initial Entry

5.b

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Jan-21-2021 15:20:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:** BS3B7W	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-21-2021 15:20:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BS3B7W	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-21-2021 15:20:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:** BS3B7V	Initial Entry

Header Text: c4591001

Visit: V101_VAX3	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Jan-21-2021 15:20:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BS3B7V	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Jan-21-2021 15:19:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-21-2021 15:19:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-21-2021 15:19:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-21-2021 15:19:14 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-21-2021 15:19:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES Date of Collection : Jan/21/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-21-2021 15:19:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID :** BR2P2D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-21-2021 15:19:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BR2P2D	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-21-2021 15:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-21-2021 15:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-21-2021 15:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Jan-21-2021 15:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/21/2021 14:54	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-21-2021 15:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-21-2021 15:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-21-2021 15:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-21-2021 15:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-21-2021 15:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-21-2021 15:24:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-21-2021 15:24:48	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V101_VAX3	**Form:** VACCINATION - eCRF Audit Trail History
Form Version: 10-Dec-2020 02:26	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				

Header Text: c4591001

Visit: V102_VAX4 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Feb-11-2021 13:08:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Feb/11/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4 | **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Feb-11-2021 13:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-11-2021 13:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-11-2021 13:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Feb/11/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V102_VAX4 | **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Feb-11-2021 13:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-11-2021 13:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-11-2021 13:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113 **Test::** Choriogonadotropin Beta_PX113 **Result::** NEGATIVE **Not Done ::**	Initial Entry

6.a Sponsor ID:

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-11-2021 13:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-11-2021 13:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-11-2021 13:08:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NEGATIVE	Initial Entry

Header Text: c4591001

Visit: V102_VAX4 | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Feb-11-2021 14:39:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-11-2021 14:39:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-11-2021 14:39:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-11-2021 14:39:40 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Feb-11-2021 14:39:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES Date of Collection : Feb/11/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-11-2021 14:39:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID :** BR2P63	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-11-2021 14:39:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BR2P63	Initial Entry

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-11-2021 13:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-11-2021 13:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-11-2021 13:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason

Feb-11-2021 13:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Feb/11/2021 12:04	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-11-2021 13:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-11-2021 13:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-11-2021 13:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-11-2021 13:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-11-2021 13:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-11-2021 13:09:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Feb-11-2021 13:09:31	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES	Initial Entry

Header Text: c4591001	
Visit: V102_VAX4	**Form:** VACCINATION - eCRF Audit Trail History
Form Version: 10-Dec-2020 02:26	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551094	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				

Header Text: c4591001

Visit: V103_MONTH1 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Mar-12-2021 11:40:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Mar/11/2021	Initial Entry

Header Text: c4591001

Visit: V103_MONTH1 **Form:** CONTACT OUTCOME - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Contact Type:

Date	Location	User	Value	Reason
Mar-12-2021 11:41:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** TELEPHONE VISIT	Initial Entry

2. Was contact made?

Date	Location	User	Value	Reason
Mar-12-2021 11:41:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Contact: Mar/11/2021	Initial Entry

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Mar-12-2021 11:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Mar/11/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Mar-12-2021 11:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** OPEN LABEL TREATMENT	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Mar-12-2021 11:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551094 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Subject Status

Date	Location	User	Value	Reason
Oct-12-2020 13:10:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** FOLLOW-UP	Initial Entry
Aug-24-2020 14:45:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Aug-24-2020 14:43:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-12-2020 13:10:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Oct/12/2020	Initial Entry
Aug-24-2020 14:45:13	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/24/2020	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)				
Aug-24-2020 14:43:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/24/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551094

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-21-2020 15:23:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Click Here to Enable	Initial Entry

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** COHORT SELECTION
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Informed Consent		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/27/2020

Header Text: c4591001

Visit: COHORT_SELECTION **Form:** DEMOGRAPHY

Form Version: 06-Jul-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Demography		
1.	Subject ID	[10551128]
2.	Birth Date:	(b) (6)/1994
3.	Sex:	MALE
4.	Ethnicity:	HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	BLACK OR AFRICAN AMERICAN WHITE
6.	Racial Designation:	

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Aug/27/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** INCLUSION/EXCLUSION CRITERIA
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/27/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** GENERAL MEDICAL HISTORY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments

Medical History Details

1.

Line/MH Number:	Not Applicable [ ]
Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	Not Applicable [ ]
Start Date:	Not Applicable //
Ongoing:	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Aug/27/2020
2.	Weight:	[120.2]
3.	Unit:	kg
4.	Height:	[174.5]
5.	Unit:	cm
6.	Body Mass Index:	[39.5]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** RANDOMIZATION
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition		
1.	Randomization Date :	Aug/27/2020
2.	Randomization Number:	[69060]
3.	Randomization Group:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/27/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP6RZX]
5.b	Sample ID	[BP6RZY]
5.c	Sample ID	[BP6RZZ]
5.d	Sample ID	[BPFV13]
5.e	Sample ID	[BPFV14]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/27/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP6RZP]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/27/2020 13:05
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** REACTOGENICITY DIARY
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Reactogenicity Diary		
1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/17/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L	**Form:** VITAL SIGNS - TEMP
Form Version: 15-Sep-2020 21:54	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Sep/17/2020

Vital Signs Details

2.a

Record Identifier:	1
Temperature:	[36.7]
Unit:	C
Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/17/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BPV07H]

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/17/2020 10:59
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001	
Visit: V3_MONTH1_POSTVAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Oct/15/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/15/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2PCX]
5.b	Sample ID	[BS89YC]
5.c	Sample ID	[BS89YD]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** DATE OF VISIT - ILLNESS ONSET
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Form Version: 20-Feb-2021 02:17	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Signs and Symptoms		
1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	
Symptoms		
4.	Symptoms:	
	Was symptom present?	
Symptoms - Other		
5.	Symptoms - Other Text:	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[ ]

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit	**Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Unplanned Assessments		
1.	Assessments	

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	Oct/15/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: Follow-Up - Unscheduled	**Form:** DISPOSITION - FOLLOW-UP
Form Version: 15-Sep-2020 21:53	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit **Form:** DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: Logs **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	injection site pain	Jan/18/2021 09:47	NO End Date Time: Jan/21/2021 UNK:UNK	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[injection site pain]
4.	Start Date Time:	Jan/18/2021 09:47
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/21/2021 UNK:UNK
6.	Toxicity Grade:	1

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Medication Error		
1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Flu Vaccination	Sep/21/2020	Repeating Pages

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Concomitant Medications		
1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Flu Vaccination]
5.	Date:	Sep/21/2020

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - PROHIBITED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Concomitant Medications

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

Header Text: c4591001

Visit: Logs **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Radiation Treatment		
1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** TRANSFUSIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1.	Transfusion Type:	
2.	Date of Transfusion:	//

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** VITAL SIGNS - TEMP
Form Version: 20-Feb-2021 02:16	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Vital Signs

1.	Date:	//

Vital Signs Details

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 1
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 6
Form Version: 10-Oct-2020 16:01	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/6/2021
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Further Vaccination Confirmation		
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** TREATMENT UNBLINDED
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Treatment Unblinded		
1.	Date Treatment Unblinded :	Jan/13/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//

Header Text: c4591001

Visit: Disposition - Unscheduled	**Form:** DEATH DETAILS CODED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Death Details

1.	Date of Collection / Notification of Death:	//

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[ ]

Header Text: c4591001

Visit: V101_VAX3 **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/18/2021
2.	Erroneous Visit	

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INFORMED CONSENT - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Informed Consent - Further Vaccination		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/18/2021

Header Text: c4591001

Visit: V101_VAX3	**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable

Header Text: c4591001

Visit: V101_VAX3	**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Screening for Further Vaccination		
1.	Date of Completion/Discontinuation /Death :	Jan/18/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V101_VAX3	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BS3B6P]
5.b	Sample ID	[BS3B6R]
5.c	Sample ID	[BR2P19]

Header Text: c4591001

Visit: V101_VAX3	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/18/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2P17]
5.b	Sample ID	[ ]

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/18/2021 09:46
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001	
Visit: V102_VAX4	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Feb/8/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/8/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2P5C]

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/8/2021 09:31
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V103_MONTH1	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1 **Form:** CONTACT OUTCOME

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: V104_MONTH6	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6 **Form:** CONTACT OUTCOME

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001	
Visit: V105_MONTH18	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18	**Form:** CONTACT OUTCOME
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT - Unscheduled	**Form:** DISPOSITION - TREATMENT
Form Version: 20-Feb-2021 02:26	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

Header Text: c4591001	
Visit: Subject Status - Unscheduled	**Form:** SUBJECT STATUS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Subject Status		
1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/15/2020

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Casebook Signature Form		
1.	Casebook Signature	Click Here to Enable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Audit Trail

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Feb-09-2021 09:47:57 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** INCLUSION/EXCLUSION CRITERIA - Comments

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
Form	Aug-27-2020 14:55:21 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - Comments

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
Form	Aug-27-2020 14:58:37 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments
Form Version: 10-Dec-2020 02:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
Form	Jan-18-2021 10:40:39 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Feb-09-2021 09:47:57 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Elle Billman	N/A	Feb-08-2021 11:39:18 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Jan-20-2021 17:20:59 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Header Text: c4591001

Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Elle Billman	N/A	Jan-18-2021 10:39:32 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Nov-30-2020 14:20:09 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Megan Pastores	N/A	Nov-30-2020 11:58:28 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Oct-21-2020 17:02:19 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: COHORT_SELECTION	**Form:** COHORT SELECTION - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-27-2020 14:54:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-27-2020 14:54:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Aug-27-2020 14:54:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** OBTAINED Date Written Consent Obtained Aug/27/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Subject ID

Date	Location	User	Value	Reason
Aug-27-2020 14:54:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10551128	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-27-2020 14:54:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6)/1994	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: COHORT_SELECTION **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Aug-27-2020 14:55:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Nov-30-2020 11:58:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BLACK OR AFRICAN AMERICAN WHITE	Transcription Error
Aug-27-2020 14:55:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Aug-27-2020 14:55:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/27/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-27-2020 14:55:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/27/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/27/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 120.2	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason

Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 174.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 39.5	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 36.6	Initial Entry

			Temperatur e Unit: C **Temperatur e Location::** FORE HEAD	

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 36.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** C	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-27-2020 14:55:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-27-2020 14:56:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/27/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-27-2020 14:56:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 69060	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-28-2020 09:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-28-2020 09:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-28-2020 09:04:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 09:03:16 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-28-2020 09:03:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Collection: Aug/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 09:04:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP6RZX	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 09:04:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP6RZX	Initial Entry

5.b

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-28-2020 09:04:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP6RZY	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 09:04:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP6RZY	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-28-2020 09:04:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP6RZZ	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 09:04:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP6RZZ	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-28-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BPFV13	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 09:05:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPFV13	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-28-2020 09:05:26	ACV0PFEINFP6000	Megan Pastores	**Data Entry:** **Sample ID:** BPFV1	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)		(pfe.mpastores)	**D:** 4	

5.e Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 09:05:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPFV14	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-27-2020 16:58:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-27-2020 16:58:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-27-2020 16:58:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-27-2020 16:58:38 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-27-2020 16:58:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Date of Collection: Aug/27/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-27-2020 16:58:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BP6RZP	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-27-2020 16:58:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP6RZP	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-27-2020 14:56:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-27-2020 14:56:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-27-2020 14:56:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Aug-27-2020 14:56:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/27/2020 13:05	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-27-2020 14:56:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-27-2020 14:56:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-27-2020 14:56:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-27-2020 14:56:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-27-2020 14:56:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-27-2020 14:56:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Sep-17-2020 11:58:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/17/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Sep-17-2020 11:59:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/17/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-17-2020 11:59:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 36.7 **Temperature Unit:** C **Temperature Location::** FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-17-2020 11:59:34 (UTC-08:00) Pacific Time (US	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 1	Initial Entry

& Canada)				

2.a Temperature:

Date	Location	User	Value	Reason
Sep-17-2020 11:59:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 36.7	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-17-2020 11:59:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-17-2020 11:59:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-17-2020 14:19:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-17-2020 14:19:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-17-2020 14:19:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-17-2020 14:19:16 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-17-2020 14:19:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Collection: Sep/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-17-2020 14:19:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BPV07H	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 14:19:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPV07H	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-17-2020 12:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-17-2020 12:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-17-2020 12:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Sep-17-2020 12:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/17/2020 10:59	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-17-2020 12:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-17-2020 12:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-17-2020 12:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-17-2020 12:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-17-2020 12:00:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-15-2020 14:13:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Oct/15/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Oct-15-2020 15:29:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-15-2020 15:29:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-15-2020 15:29:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 15:29:25 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-15-2020 15:29:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Collection: Oct/15/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-15-2020 15:29:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BR2PCX	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 15:29:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BR2PCX	Initial Entry

5.b

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-15-2020 15:29:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BS89YC	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 15:29:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BS89YC	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-15-2020 15:30:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BS89YD	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Oct-15-2020 15:30:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BS89YD	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-15-2020 14:13:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Oct/15/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-15-2020 14:13:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-15-2020 14:13:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** injection site pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason

Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/18/2021 09:47	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO End Date Time: Jan/21/2021 UNK :UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NOT APPLICABLE	Initial Entry

Pacific Time (US & Canada)				

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-08-2021 11:41:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Oct-15-2020 15:11:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-15-2020 15:11:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-15-2020 15:11:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-15-2020 15:11:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in

the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-15-2020 15:11:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Flu Vaccination	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-15-2020 15:11:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/21/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Jan-18-2021 10:39:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/6/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Jan-18-2021 10:40:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 10:39:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-18-2021 10:39:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to	Initial Entry

			have received o nly placebo at V accination 1/2	

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-18-2021 10:40:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/13/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-18-2021 10:40:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Jan-18-2021 10:40:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/18/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Jan-18-2021 10:40:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** OBTAINED Date Written Consent Obtained Jan/18/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-18-2021 10:40:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/18/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-18-2021 10:40:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-18-2021 10:40:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Jan-18-2021 14:50:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-18-2021 14:50:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-18-2021 14:50:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 14:50:20 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-18-2021 14:50:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES Date of Collection : Jan/18/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-18-2021 14:50:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID :** BS3B6P	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-18-2021 14:50:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BS3B6P	Initial Entry

5.b

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Jan-18-2021 14:50:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID :** BS3B6R	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-18-2021 14:50:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BS3B6R	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-18-2021 14:50:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID :** BR2P19	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Jan-18-2021 14:50:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BR2P19	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Jan-18-2021 14:49:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-18-2021 14:49:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-18-2021 14:49:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 14:49:16 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-18-2021 14:49:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES Date of Collection : Jan/18/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-18-2021 14:49:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID :** BR2P17	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-18-2021 14:49:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BR2P17	Initial Entry

5.b

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Jan-18-2021 14:50:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:**	Transcription Error
Jan-18-2021 14:49:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:** BS3B6P	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-18-2021 14:50:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:**	Transcription Error
Jan-18-2021 14:49:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BS3B6P	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-18-2021 10:41:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-18-2021 10:41:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-18-2021 10:41:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason

Jan-18-2021 10:41:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/18/2021 09:46	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-18-2021 10:41:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-18-2021 10:41:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-18-2021 10:41:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-18-2021 10:41:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-18-2021 10:41:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-18-2021 10:41:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-18-2021 10:41:25	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V101_VAX3	**Form:** VACCINATION - eCRF Audit Trail History
Form Version: 10-Dec-2020 02:26	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551128	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				

Header Text: c4591001

Visit: V102_VAX4 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Feb-08-2021 11:39:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Feb/8/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4 | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Feb-08-2021 14:27:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-08-2021 14:27:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-08-2021 14:27:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-08-2021 14:27:09 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Feb-08-2021 14:27:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES Date of Collection : Feb/8/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-08-2021 14:27:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID :** BR2P5C	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-08-2021 14:27:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BR2P5C	Initial Entry

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-08-2021 11:40:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-08-2021 11:40:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-08-2021 11:40:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Feb-08-2021 11:40:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Feb/8/2021 09:31	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-08-2021 11:40:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-08-2021 11:40:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-08-2021 11:40:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-08-2021 11:40:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-08-2021 11:40:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-08-2021 11:40:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Feb-08-2021 11:40:12	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)				

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551128 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Subject Status

Date	Location	User	Value	Reason
Oct-15-2020 14:13:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** FOLLOW-UP	Initial Entry
Aug-27-2020 14:56:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Aug-27-2020 14:55:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-15-2020 14:13:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Oct/15/2020	Initial Entry
Aug-27-2020 14:56:07	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/27/2020	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)				
Aug-27-2020 14:55:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/27/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551128

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-21-2020 15:32:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Click Here to Enable	Initial Entry

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** COHORT SELECTION
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/28/2020

Header Text: c4591001

Visit: COHORT_SELECTION **Form:** DEMOGRAPHY

Form Version: 06-Jul-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Demography		
1.	Subject ID	[10551139]
2.	Birth Date:	(b) (6)/1967
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	ASIAN
6.	Racial Designation:	

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Aug/28/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** INCLUSION/EXCLUSION CRITERIA
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Screening		
1.	Date of Completion/Discontinuation /Death	Aug/28/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** GENERAL MEDICAL HISTORY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Medical History Details

1.a

Line/MH Number:	[1]
Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[Hypertension]
Start Date:	Dec/UNK/2016
Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Aug/28/2020
2.	Weight:	[65.3]
3.	Unit:	kg
4.	Height:	[161.5]
5.	Unit:	cm
6.	Body Mass Index:	[25.0]

Vital Signs Details

7.a

Record Identifier:	1
Temperature:	[36.9]
Unit:	C
Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 21-Aug-2020 02:49 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/28/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a

Sponsor ID:	[113]
Test:	Choriogonadotropin Beta_PX113
Result:	NEGATIVE
Not Done:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L **Form:** RANDOMIZATION

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition		
1.	Randomization Date :	Aug/28/2020
2.	Randomization Number:	[72367]
3.	Randomization Group:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/28/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP6S18]
5.b	Sample ID	[BP6S19]
5.c	Sample ID	[BP6S1B]
5.d	Sample ID	[BPFV1S]
5.e	Sample ID	[BPFV1T]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/28/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP6S15]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/28/2020 12:14
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** REACTOGENICITY DIARY

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Reactogenicity Diary

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT

Header Text: c4591001

Visit: V2_VAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/17/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L	**Form:** VITAL SIGNS - TEMP
Form Version: 15-Sep-2020 21:54	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Sep/17/2020

Vital Signs Details

2.a

Record Identifier:	1
Temperature:	[36.5]
Unit:	C
Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 21-Aug-2020 02:49 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/17/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/17/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BPV07R]

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/17/2020 14:21
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001	
Visit: V3_MONTH1_POSTVAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Oct/16/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/16/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2PD3]
5.b	Sample ID	[BS89YR]
5.c	Sample ID	[BS89YP]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** DATE OF VISIT - ILLNESS ONSET
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Form Version: 20-Feb-2021 02:17	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Signs and Symptoms		
1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	
Symptoms		
4.	Symptoms:	
	Was symptom present?	
Symptoms - Other		
5.	Symptoms - Other Text:	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Health Care Utilization		
1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	
Health Care Utilization Other		
2.	Other Type of Practitioner Specify:	[ ]
Health Care Utilization		
3.	Has the subject been hospitalized due to potential COVID-19 illness?	

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit	**Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Unplanned Assessments		
1.	Assessments	

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	Oct/16/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: Follow-Up - Unscheduled | **Form:** DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit | **Form:** DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: Logs **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	injection site soreness	Jan/20/2021 18:00	NO End Date Time: Jan/22/2021 08:00	Repeating Pages
2.	ADVERSE EVENT	2	chills	Jan/21/2021 14:00	NO End Date Time: Jan/22/2021 08:00	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[injection site soreness]
4.	Start Date Time:	Jan/20/2021 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/22/2021 08:00
6.	Toxicity Grade:	1

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[chills]
4.	Start Date Time:	Jan/21/2021 14:00
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/22/2021 08:00
6.	Toxicity Grade:	1

7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	NO

13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Medication Error		
1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Influenza vaccine	Oct/14/2020	Repeating Pages

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

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eCRF Audit Trail History
Form Audit Trail

Concomitant Medications		
1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Influenza vaccine]
5.	Date:	Oct/14/2020

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - PROHIBITED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Concomitant Medications

1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

Header Text: c4591001

Visit: Logs **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Radiation Treatment		
1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** TRANSFUSIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1.	Transfusion Type:	
2.	Date of Transfusion:	//

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** VITAL SIGNS - TEMP
Form Version: 20-Feb-2021 02:16	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Vital Signs

1.	Date:	//

Vital Signs Details

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** LAB URINALYSIS - PREGNANCY TEST
Form Version: 20-Feb-2021 02:14	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

Lab Result

6.

Sponsor ID:	[ ]
Test:	
Result:	
Not Done:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 1
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 6
Form Version: 10-Oct-2020 16:01	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/13/2021
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Further Vaccination Confirmation		
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** TREATMENT UNBLINDED
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Treatment Unblinded		
1.	Date Treatment Unblinded :	Jan/18/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Withdrawal Of Consent

1.	Withdrawal of Consent Date :	//

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** DEATH DETAILS CODED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Death Details		
1.	Date of Collection / Notification of Death:	//

Cause of Death		
2.	Cause of Death Status:	
	Cause of Death:	[ ]

Header Text: c4591001

Visit: V101_VAX3 **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/20/2021
2.	Erroneous Visit	

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INFORMED CONSENT - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Informed Consent - Further Vaccination		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Jan/20/2021

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met		
1.	Description of Inclusion Criterion Not Met	Not Applicable
Exclusion Criteria Met		
2.	Description of Exclusion Criterion Met	Not Applicable

Header Text: c4591001

Visit: V101_VAX3	**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Screening for Further Vaccination		
1.	Date of Completion/Discontinuation /Death :	Jan/20/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 14-Jan-2021 02:21 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Jan/20/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a

Sponsor ID:	[113]
Test:	Choriogonadotropin Beta_PX113
Result:	NEGATIVE
Not Done:	

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/20/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2P22]
5.b	Sample ID	[BS3B7J]
5.c	Sample ID	[BS3B7H]

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Jan/20/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2P20]

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Jan/20/2021 09:05
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V102_VAX4 **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Feb/10/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 14-Jan-2021 02:21 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/10/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a

Sponsor ID:	[113]
Test:	Choriogonadotropin Beta_PX113
Result:	NEGATIVE
Not Done:	

Header Text: c4591001

Visit: V102_VAX4 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/10/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2P5T]

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/10/2021 09:16
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	RIGHT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V103_MONTH1	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1 **Form:** CONTACT OUTCOME

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: V104_MONTH6	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6	**Form:** CONTACT OUTCOME
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: V105_MONTH18	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18	**Form:** CONTACT OUTCOME
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT - Unscheduled	**Form:** DISPOSITION - TREATMENT
Form Version: 20-Feb-2021 02:26	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

Header Text: c4591001	
Visit: Subject Status - Unscheduled	**Form:** SUBJECT STATUS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Subject Status		
1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/16/2020

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Casebook Signature Form		
1.	Casebook Signature	Click Here to Enable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Audit Trail

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Feb-10-2021 17:30:42 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
Form	Aug-28-2020 13:14:35 (UTC-08:00) Pacific Time (US & Canada)	Megan Pastores (pfe.mpastores)	Not Applicable Not Applicable

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments
Form Version: 10-Dec-2020 02:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
Form	Jan-20-2021 12:22:11 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Feb-10-2021 17:30:42 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Elle Billman	N/A	Feb-10-2021 10:12:08 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Jan-20-2021 17:24:44 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Header Text: c4591001

Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Elle Billman	N/A	Jan-18-2021 15:13:35 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Oct-21-2020 17:08:50 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: COHORT_SELECTION	**Form:** COHORT SELECTION - eCRF Audit Trail History
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-28-2020 13:12:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-28-2020 13:12:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Aug-28-2020 13:13:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** OBTAINED Date Written Consent Obtained Aug/28/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Subject ID

Date	Location	User	Value	Reason
Aug-28-2020 13:12:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10551139	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-28-2020 13:12:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6)/1967	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-28-2020 13:13:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Aug-28-2020 13:13:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NOT HISPANIC O R LATINO(A) OR OF SPANISH ORI GIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-28-2020 13:13:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** ASIAN	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Aug-28-2020 13:14:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Aug/28/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-28-2020 13:15:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Aug/28/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-28-2020 13:15:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-28-2020 13:15:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1.a

Date	Location	User	Value	Reason
Aug-28-2020 13:16:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 1 **Medical History Term:** Hypertension **Start Date:** Dec/UNK/2016 **Ongoing:** YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-28-2020 13:16:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-28-2020 13:16:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Hypertension	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

1.a Start Date:

Date	Location	User	Value	Reason
Aug-28-2020 13:16:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Dec/UNK/2016	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-28-2020 13:16:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Aug/28/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 65.3	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason

Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 161.5	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 25.0	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 36.9	Initial Entry

			Temperature Unit: C **Temperature Location::** FOREHEAD	

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 36.9	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** C	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History
Form Version: 21-Aug-2020 02:51	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Aug/28/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason

Aug-28-2020 13:19:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-28-2020 13:19:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113 **Test::** Choriogonadotropin Beta_PX113 **Result::** NEGATIVE **Not Done ::**	Initial Entry

6.a Sponsor ID:

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-28-2020 13:19:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-28-2020 13:19:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NEGATIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-28-2020 13:20:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Aug/28/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-28-2020 13:20:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 72367	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-28-2020 15:34:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-28-2020 15:34:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-28-2020 15:34:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 15:34:12 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-28-2020 15:34:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Collection: Aug/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 15:34:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP6S18	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:34:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP6S18	Initial Entry

5.b

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-28-2020 15:34:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP6S19	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:34:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP6S19	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-28-2020 15:34:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP6S1B	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:34:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP6S1B	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-30-2020 09:40:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BPFV1S	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 09:40:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPFV1S	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-30-2020 09:40:32	ACV0PFEINFP6000	Megan Pastores	**Data Entry:** **Sample ID:** BPFV1	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)		(pfe.mpastores)	**D:** T	

5.e Sample ID

Date	Location	User	Value	Reason
Sep-30-2020 09:40:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPFV1T	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-28-2020 15:24:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-28-2020 15:24:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-28-2020 15:24:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 15:24:02 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Aug-28-2020 15:24:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Collection: Aug/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 15:24:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BP6S15	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:24:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BP6S15	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-28-2020 13:21:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-28-2020 13:21:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-28-2020 13:21:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Aug-28-2020 13:21:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Aug/28/2020 12:14	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-28-2020 13:21:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-28-2020 13:21:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-28-2020 13:21:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-28-2020 13:21:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-28-2020 13:21:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-28-2020 13:21:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Sep-17-2020 15:09:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/17/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/17/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-17-2020 15:10:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 36.5 **Temperature Unit:** C **Temperature Location::** FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

2.a Temperature:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 36.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/17/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason

Sep-17-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-17-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113 **Test::** Choriogonadotropin Beta_PX113 **Result::** NEGATIVE **Not Done ::**	Initial Entry

6.a Sponsor ID:

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-17-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-17-2020 15:10:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NEGATIVE	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-17-2020 15:14:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-17-2020 15:14:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-17-2020 15:14:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-17-2020 15:14:01 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-17-2020 15:14:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Date of Collection: Sep/17/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-17-2020 15:14:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID :** BPV07R	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-17-2020 15:14:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BPV07R	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-17-2020 15:11:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-17-2020 15:11:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-17-2020 15:11:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Sep-17-2020 15:12:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/17/2020 14:21	Transcription Error
Sep-17-2020 15:11:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/17/2020 12:14	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-17-2020 15:11:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-17-2020 15:11:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason

Sep-17-2020 15:11:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-17-2020 15:11:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-17-2020 15:11:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Oct-16-2020 12:23:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Oct/16/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Oct-16-2020 15:48:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-16-2020 15:48:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-16-2020 15:48:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-16-2020 15:48:01 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Oct-16-2020 15:48:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Date of Collection: Oct/16/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-16-2020 15:48:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID :** BR2PD 3	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 15:48:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BR2PD3	Initial Entry

5.b

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Oct-16-2020 15:48:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BS89YR	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 15:48:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BS89YR	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-16-2020 15:48:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BS89YP	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 15:48:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BS89YP	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-16-2020 12:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Oct/16/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-16-2020 12:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-16-2020 12:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** injection site sorenes s	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason

Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/20/2021 18:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO End Date Time: Jan/22/2021 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NOT APPLICABLE	Initial Entry

Pacific Time (US & Canada)				

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-10-2021 10:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** chills	Initial Entry

4. Start Date Time:

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/21/2021 14:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO End Date Time: Jan/22/2021 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important

medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason

Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-10-2021 10:15:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Oct-16-2020 12:23:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-16-2020 12:23:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-16-2020 12:23:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-16-2020 12:23:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-16-2020 12:23:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Influenza vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-16-2020 12:23:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Oct/14/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Jan-18-2021 15:13:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/13/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Jan-18-2021 15:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-18-2021 15:13:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Jan-18-2021 15:13:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to	Initial Entry

			have received o nly placebo at V accination 1/2	

Header Text: c4591001

Visit: Disposition - Unscheduled	**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Jan-18-2021 15:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/18/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Jan-18-2021 15:13:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Jan-20-2021 12:21:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/20/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Jan-20-2021 12:22:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** OBTAINED Date Written Consent Obtained Jan/20/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-20-2021 12:22:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/20/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Jan-20-2021 12:22:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Jan-20-2021 12:22:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 | **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Jan-20-2021 12:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Jan-20-2021 12:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Jan-20-2021 12:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/20/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason

Jan-20-2021 12:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Jan-20-2021 12:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Jan-20-2021 12:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113 **Test::** Choriogonadotropin Beta_PX113 **Result::** NEGATIVE **Not Done ::**	Initial Entry

6.a Sponsor ID:

Header Text: c4591001

Visit: V101_VAX3 **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Jan-20-2021 12:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Jan-20-2021 12:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Jan-20-2021 12:22:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NEGATIVE	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Jan-20-2021 14:59:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-20-2021 14:59:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-20-2021 14:59:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 14:59:03 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-20-2021 14:59:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES Date of Collection : Jan/20/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-20-2021 14:59:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID :** BR2P22	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 14:59:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BR2P22	Initial Entry

5.b

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Jan-20-2021 14:59:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:** BS3B7J	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 14:59:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BS3B7J	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-20-2021 15:00:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:** BS3B7H	Initial Entry

Header Text: c4591001

Visit: V101_VAX3	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

5.c Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 15:00:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BS3B7H	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Jan-20-2021 14:58:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Jan-20-2021 14:58:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Jan-20-2021 14:58:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-20-2021 14:58:36 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-20-2021 14:58:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES Date of Collection : Jan/20/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Jan-20-2021 14:58:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID :** BR2P20	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Jan-20-2021 14:58:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BR2P20	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Jan-20-2021 12:23:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Jan-20-2021 12:23:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Jan-20-2021 12:23:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason

Jan-20-2021 12:23:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Jan/20/2021 09:05	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Jan-20-2021 12:23:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Jan-20-2021 12:23:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Jan-20-2021 12:23:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Jan-20-2021 12:23:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Jan-20-2021 12:23:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Jan-20-2021 12:23:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Jan-20-2021 12:23:04	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V101_VAX3	**Form:** VACCINATION - eCRF Audit Trail History
Form Version: 10-Dec-2020 02:26	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551139	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				

Header Text: c4591001

Visit: V102_VAX4 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-10-2021 10:12:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Feb/10/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4 | **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Feb/10/2021	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason

Feb-10-2021 10:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Feb-10-2021 10:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113 **Test::** Choriogonadotropin Beta_PX113 **Result::** NEGATIVE **Not Done ::**	Initial Entry

6.a Sponsor ID:

Header Text: c4591001

Visit: V102_VAX4 **Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-10-2021 10:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NEGATIVE	Initial Entry

Header Text: c4591001

Visit: V102_VAX4 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Feb-10-2021 15:06:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-10-2021 15:06:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-10-2021 15:07:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-10-2021 15:06:56 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

Pacific Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Feb-10-2021 15:06:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES Date of Collection : Feb/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-10-2021 15:07:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID :** BR2P5T	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-10-2021 15:07:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BR2P5T	Initial Entry

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-10-2021 10:12:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-10-2021 10:12:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Feb-10-2021 10:12:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Feb/10/2021 09:16	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** RIGHT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-10-2021 10:12:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-10-2021 10:12:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Feb-10-2021 10:12:52	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)				

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551139 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Subject Status

Date	Location	User	Value	Reason
Oct-16-2020 12:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** FOLLOW-UP	Initial Entry
Aug-28-2020 13:20:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Aug-28-2020 13:15:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-16-2020 12:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Oct/16/2020	Initial Entry
Aug-28-2020 13:20:07	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/28/2020	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)				
Aug-28-2020 13:15:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/28/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551139

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-21-2020 15:37:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Click Here to Enable	Initial Entry

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** COHORT SELECTION
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/28/2020

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Demography		
1.	Subject ID	[10551145]
2.	Birth Date:	(b) (6)/1985
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Aug/28/2020
2.	Erroneous Visit	

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** INCLUSION/EXCLUSION CRITERIA
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met		
1.	Description of Inclusion Criterion Not Met	Not Applicable
Exclusion Criteria Met		
2.	Description of Exclusion Criterion Met	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Screening		
1.	Date of Completion/Discontinuation /Death	Aug/28/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments

Medical History Details

1.	Line/MH Number:	Not Applicable [ ]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	Not Applicable [ ]
	Start Date:	Not Applicable //
	Ongoing:	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs		
1.	Date:	Aug/28/2020
2.	Weight:	[89.0]
3.	Unit:	kg
4.	Height:	[166.0]
5.	Unit:	cm
6.	Body Mass Index:	[32.3]

Vital Signs Details

7.a		
	Record Identifier:	1
	Temperature:	[36.6]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 21-Aug-2020 02:49 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Aug/28/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a

Sponsor ID:	[113]
Test:	Choriogonadotropin Beta_PX113
Result:	NEGATIVE
Not Done:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition		
1.	Randomization Date :	Aug/28/2020
2.	Randomization Number:	[73002]
3.	Randomization Group:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/28/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP6S21]
5.b	Sample ID	[BP6S22]
5.c	Sample ID	[BP6S23]
5.d	Sample ID	[BPFV25]
5.e	Sample ID	[BPFV26]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/28/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP6S1W]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/28/2020 14:35
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** REACTOGENICITY DIARY
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Reactogenicity Diary		
1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT

Header Text: c4591001	
Visit: V2_VAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/16/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP

Form Version: 10-Oct-2020 16:01 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Sep/16/2020

Vital Signs Details

2.a

Record Identifier:	1
Temperature:	[36.8]
Unit:	C
Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 21-Aug-2020 02:49 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis			
1.	Lab Panel:		
2.	Lab Sub-Panel:		
3.	Collection Date:	Not Done //	Comments
4.	Laboratory Name and Address (Derived)	[ ]	
5.	Specimen Type:		

Lab Result		
6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	
	Not Done:	NOT DONE

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[deferred as vaccine not administered]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments
eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	Not Applicable	Comments
2.	Treatment Name	Not Applicable [ ]	Comments
3.	Formulation:	Not Applicable	Comments
4.	Dose Date Time:	Not Applicable //	Comments
5.	Anatomical Location:	Not Applicable	Comments
6.	Body Side:	Not Applicable	Comments
7.	Route:	Not Applicable	Comments
8.	Actual Dose:	Not Applicable [ ]	Comments
9.	Unit:	Not Applicable	Comments
10.	Timeframe Subject Was Observed	Not Applicable	Comments
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	Not Applicable	Comments

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Oct/14/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/14/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2PCK]
5.b	Sample ID	[BR2PCL]
5.c	Sample ID	[BS89XX]
5.d	Sample ID	[BS89XY]

Header Text: c4591001

Visit: V4_MONTH6_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: V5_MONTH12_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: V6_MONTH24_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Form Version: 20-Feb-2021 02:17	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Signs and Symptoms		
1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	
Symptoms		
4.	Symptoms:	
	Was symptom present?	
Symptoms - Other		
5.	Symptoms - Other Text:	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001	
Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** HEALTH CARE UTILIZATION
Form Version: 20-Feb-2021 02:19	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[ ]

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	

Header Text: c4591001	
Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Illness Details		
1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Unplanned Assessments		
1.	Assessments	

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	Oct/14/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	ADVERSE EVENT
4.	Specify Status:	[ ]

Header Text: c4591001	
Visit: Follow-Up - Unscheduled	**Form:** DISPOSITION - FOLLOW-UP
Form Version: 15-Sep-2020 21:53	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Disposition - Follow-Up		
1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001
Visit: Logs **Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Dysphagia	Aug/UNK/2020 UNK:UNK	YES	Repeating Pages
2.	ADVERSE EVENT	2	Right upper extremity pain	Oct/10/2020 UNK:UNK	YES	Repeating Pages
3.	ADVERSE EVENT	3	Cerebral Capillary telangiectasia	Sep/26/2020 UNK:UNK	YES	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT	
2.	AE ID:	[1]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Dysphagia]	
4.	Start Date Time:	Aug/UNK/2020 UNK:UNK	Comments
5.	Is the adverse event still ongoing?	YES	
6.	Toxicity Grade:	1	
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO	
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO	
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [unknown, GI or neurological abnormality]	
10.	Latest Action Taken with Study Treatment:	DRUG WITHDRAWN	
11.	Was a Concomitant Medication given?	NO	

12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Right upper extremity pain]
4.	Start Date Time:	Oct/10/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Cause is being evaluated]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Cerebral Capillary telangiectasia]
4.	Start Date Time:	Sep/26/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [anatomical abnormality]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Medication Error		
1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	[ ]			[ ]		Repeating Pages

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

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Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Date:	//

Header Text: c4591001

Visit: Logs **Form:** CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

Header Text: c4591001

Visit: Logs **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Radiation Treatment		
1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1.	Transfusion Type:	
2.	Date of Transfusion:	//

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Vital Signs		
1.	Date:	//

Vital Signs Details		
2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 1
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001	
Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE
Form Version: 14-Jan-2021 02:29	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Informed Consent - Asymptomatic Surveillance		
1.	Consent Was:	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Feb/18/2021
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete, Frozen
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Further Vaccination Confirmation		
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** TREATMENT UNBLINDED
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Treatment Unblinded		
1.	Date Treatment Unblinded :	Feb/18/2021
2.	Primary Reason for Unblinding:	OTHER If other, specify: [Subject is not eligible due to medical issues. Wants to be unblinded to get vaccine elsewhere.]

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Withdrawal Of Consent		
1.	Withdrawal of Consent Date :	//

Header Text: c4591001

Visit: Disposition - Unscheduled	**Form:** DEATH DETAILS CODED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Death Details

1.	Date of Collection / Notification of Death:	//

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[ ]

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Subject Status		
1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Oct/14/2020

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Casebook Signature Form		
1.	Casebook Signature	Click Here to Enable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Audit Trail

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Feb-25-2021 16:28:59 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** INCLUSION/EXCLUSION CRITERIA - Comments

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Aug-28-2020 15:37:55 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - Comments

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Aug-28-2020 15:43:33 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST - Comments

Form Version: 21-Aug-2020 02:49 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
3	Oct-13-2020 15:21:52 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	deferred as vaccine not administered --- Not Done

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
Form	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
1	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
2	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
3	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
4	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
5	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
6	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
7	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
8	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
9	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
10	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - Comments

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
11	Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Comments

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
4	Oct-27-2020 16:44:04 (UTC-08:00) Pacific Time (US & Canada)	Lana Norman (pfe.lnorman)	no estimated start date can be provided other than late August

Header Text: c4591001
Visit: Investigator Signature - Unscheduled
Form: CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Signed, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551145
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

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This form requires signing by a member of each of the following signature groups:
- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Feb-25-2021 16:28:59 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Elle Billman	N/A	Feb-24-2021 11:19:23 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Feb-22-2021 13:56:23 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Elle Billman	N/A	Feb-22-2021 10:35:34 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Oct-27-2020 16:54:08 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551145	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-28-2020 15:37:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-28-2020 15:37:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Aug-28-2020 15:37:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** OBTAINED Date Written Consent Obtained Aug/28/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Subject ID

Date	Location	User	Value	Reason
Aug-28-2020 15:36:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10551145	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-28-2020 15:36:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6)/1985	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-28-2020 15:37:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-28-2020 15:37:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-28-2020 15:37:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Aug-28-2020 15:37:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/28/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-28-2020 15:38:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/28/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-28-2020 15:38:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-28-2020 15:38:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/28/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 89.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 166.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 32.3	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 36.6 **Temperature Unit:** C **Temperature Location::** FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 36.6	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Lab Panel:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/28/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Aug-28-2020 15:39:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Aug-28-2020 15:39:35 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:**	Initial Entry

(US & Canada)			**Sponsor-Defined Identifier:** 113 **Test::** Choriogonadotropin Beta_PX113 **Result::** NEGATIVE **Not Done::**	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Aug-28-2020 15:39:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NEGATIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-28-2020 15:40:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/28/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-28-2020 15:40:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 73002	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-28-2020 15:55:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-28-2020 15:55:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-28-2020 15:55:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 15:55:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-28-2020 15:55:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** YES Date of Collection: Aug/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 15:55:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Sample ID:** BP6S21	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:55:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** BP6S21	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-28-2020 15:55:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Sample ID:** BP6S22	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:55:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** BP6S22	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-28-2020 15:56:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Sample ID:** BP6S23	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:56:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** BP6S23	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-28-2020 15:56:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Sample ID:** BPFV25	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.d Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:56:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** BPFV25	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-28-2020 15:56:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Sample ID:** BPFV26	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:56:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** BPFV26	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-28-2020 15:58:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-28-2020 15:58:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-28-2020 15:58:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-28-2020 15:58:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-28-2020 15:58:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** YES Date of Collection: Aug/28/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Aug-28-2020 15:58:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Sample ID:** BP6S1W	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Aug-28-2020 15:58:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** BP6S1W	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: VACCINATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551145
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-28-2020 15:40:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-28-2020 15:40:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-28-2020 15:40:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-28-2020 15:40:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/28/2020 14:35	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-28-2020 15:40:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Aug-28-2020 15:40:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-28-2020 15:40:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-28-2020 15:40:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-28-2020 15:40:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-28-2020 15:40:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-13-2020 15:20:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 2: Deleted	Initial Entry
Oct-13-2020 15:20:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/16/2020	Initial Entry
Oct-10-2020 01:50:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe ks66)	Query 2: Reissued:Candidate	Visit 2 has not scheduled yet
Oct-09-2020 15:33:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Query 2: Answered	pending to be schedule as per PI discretion
Oct-08-2020 00:58:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sonal K (pfe ks66)	Query 2: Reissued:Opened	DM 1: Visit 1 was on 28/Aug/2020, however visit 2 is not happened yet, please confirm when is visit 2 expected to occur.
Oct-07-2020 10:42:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 2: Answered	visit has not occurred
Oct-05-2020 03:22:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Roshni Nair (pfe nairr29)	Query 2: Opened	DM: Kindly review and complete 'Date of Visit, Nasal Swab, Vaccination, Vital Signs' forms at this visit. Thank you.
Oct-01-2020 14:12:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jarred E Lee (pfe.leej299)	Query 2: Candidate	DM: Kindly review and complete 'Date of Visit, Nasal Swab, Vaccination, Vital Signs' forms at this visit. Thank you.

Header Text: c4591001
Visit: V2_VAX2_L
Form: DATE OF VISIT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551145
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Oct-01-2020 14:11:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Jarred E Lee (pfe.leej299)	Query 1: Closed	Reissued under Candidate status due to visit has not occurred yet.
Sep-26-2020 03:30:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (pfe.suryas18)	Query 1: Reissued:Opened	Kindly keep query in open status until visit is occurred. Thank you.
Sep-25-2020 12:25:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	visit has not occurred yet
Sep-24-2020 23:21:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe reddyr51)	Query 1: Opened	DM: Kindly review and complete 'Date of Visit, Nasal Swab, Pregnancy Test, Vaccination, Vital Signs' forms at this visit. Thank you.

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Oct-13-2020 15:21:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/16/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-13-2020 15:21:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 36.8 **Temperature Unit:** C **Temperature Location::** FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-13-2020 15:21:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Oct-13-2020 15:21:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 36.8	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Oct-13-2020 15:21:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** C	Initial Entry

2.a Temperature Location:

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-13-2020 15:21:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

3. Collection Date:

Date	Location	User	Value	Reason
Oct-13-2020 15:21:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Not Done	Initial Entry

6.a

Date	Location	User	Value	Reason
Oct-13-2020 15:22:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113 **Test::** Choriogonadotropin Beta_PX113 **Result::** **Not Done::** NOT DONE	Initial Entry
Oct-13-2020 15:21:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sponsor-Defined Identifier:** **Test::** Choriogonadotropin Beta_PX113 **Result::** **Not Done::**	Initial Entry

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-13-2020 15:22:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-13-2020 15:21:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

6.a Not Done:

Date	Location	User	Value	Reason
Oct-13-2020 15:22:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT DONE	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Oct-13-2020 15:22:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-13-2020 15:22:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-13-2020 15:22:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-13-2020 15:22:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** deferred as vaccine not administered	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Not Applicable	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Not Applicable	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Not Applicable	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Not Applicable	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Not Applicable	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Not Applicable	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Not Applicable	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Not Applicable	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Not Applicable	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Not Applicable	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Oct-13-2020 15:23:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Not Applicable	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-14-2020 15:18:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** Oct/14/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Oct-14-2020 15:48:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-14-2020 15:48:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-14-2020 15:49:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-14-2020 15:48:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-14-2020 15:48:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Date of Collection: Oct/14/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-14-2020 15:49:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BR2PCK	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.a Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 15:49:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BR2PCK	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-14-2020 15:49:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BR2PCL	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 15:49:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BR2PCL	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-14-2020 15:49:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BS89XX	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 15:49:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BS89XX	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-14-2020 15:49:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BS89XY	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.d Sample ID

Date	Location	User	Value	Reason
Oct-14-2020 15:49:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BS89XY	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-14-2020 15:18:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** Oct/14/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-14-2020 15:18:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-22-2020 09:47:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe rb01)	Query 1: Closed	Response satisfies query
Oct-22-2020 09:47:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe rb01)	Query 2: Closed	Response satisfies query
Oct-22-2020 08:31:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 2: Answered	Changed data per query
Oct-22-2020 08:30:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Status is reported as Adverse Event, but there is no Adverse Event with 'Did the adverse event cause the subject to be discontinued from the study' reported as YES. Please check and correct the data.
Oct-22-2020 08:30:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

Header Text: c4591001
Visit: End of Treatment - Unscheduled
Form: DISPOSITION - TREATMENT - eCRF Audit Trail History
Form Version: 15-Sep-2020 21:55
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551145
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Oct-22-2020 08:30:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** ADVERSE EVENT	Changed Information
Oct-21-2020 09:33:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (pfe rb01)	Query 1: Opened	Subject has not received vaccination 2, but status is entered as COMPLETED. Please verify and update accordingly, else clarify. Thank you.
Oct-14-2020 15:18:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551145
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-21-2020 04:18:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	to review again in line with start date update.
Sep-18-2020 08:57:44 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Query 1: Answered	Pending further evaluations
Sep-17-2020 08:50:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: There is no medical history entered for this subject. Please clarify if this remains correct or if any information has been obtained in the review of this event that may warrant updates.
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Dysphagia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason

Oct-28-2020 10:43:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	per site response
Oct-27-2020 16:43:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Query 1: Answered	no estimated start date can be provided other than late August
Oct-22-2020 13:42:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Reissued:Opened	CLINQUERY: Since V1 was on 28Aug20, please review if an estimate can be applied for the day in August that can be added into this field
Oct-22-2020 09:47:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	subject states late August, exact date unknown
Sep-21-2020 04:16:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Reissued:Opened	CLINQUERY: Please leave query in open state until further information obtained for start date.
Sep-18-2020 08:56:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Query 1: Answered	Pending further evaluations
Sep-17-2020 08:48:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: A complete start date for AEs is required. Per CRF guidelines, if an exact date is unknown please provide best estimate
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason

Oct-15-2020 12:07:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Oct-15-2020 10:04:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	still ongoing
Oct-14-2020 11:48:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: Please review if this event 'Dysphagia' remains ongoing or if any update to the subject's condition/data can be applied to the CRF.
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason

Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-16-2020 13:22:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER *If Other, specify:* unknown, GI or neurological abnormality	New Information
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-22-2020 08:31:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** DRUG WITHDRAWN	Changed Information
Sep-18-2020 13:42:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Query 1: Deleted	Initial Entry
Sep-18-2020 13:42:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NOT APPLICABLE	Initial Entry
Sep-18-2020 04:15:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kirti Bhangale (pfe.bhangk01)	Query 1: Reissued:Candidate	DM: Thank you for confirmation. Please consider responding this query only after data will be updated.
Sep-17-2020 14:48:49 (UTC-08:00) Pacific	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	pending further testing if 2nd

Time (US & Canada)				vaccine will be given, temporary delay at this time
Sep-17-2020 05:10:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe.reddyr51)	Query 1: Opened	DM: The response for "Latest Action Taken with Study Treatment" is missing? kindly review and update.

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-16-2020 13:19:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-15-2020 12:08:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Oct-15-2020 09:57:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-15-2020 09:57:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** Right upper extremity pain	Changed Information
Oct-15-2020 07:20:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: Please expand acronym (RUE) in order to permit coding
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** RUE pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason

Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** Oct/10/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-02-2020 10:18:53 (UTC-08:00) Pacific	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Closed	Response satisfies query

Time (US & Canada)				
Nov-02-2020 09:49:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Query 2: Answered	still pending
Oct-28-2020 07:49:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Opened	CLINQUERY: Is there any update to this entry 'Cause is being evaluated' that can be added to the CRF?
Oct-16-2020 11:04:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kirti Bhangale (pfe.bhangk01)	Query 1: Closed	Response satisfies query
Oct-15-2020 09:48:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Updated
Oct-15-2020 09:48:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NOT RELATED If Not Related to study treatme nt(s), this event is due to: OTHER *If Other, specify:* Cause is being evaluated	Updated
Oct-15-2020 01:13:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe reddyr51)	Query 1: Opened	DM: The response for "Is this event related to study treatment" Is reported as 'Not Related', however response for, 'Please indicate what this event is due to' is missing. Kindly review and update.
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551145
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-14-2020 15:22:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** NO	Initial Entry

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551145
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-19-2020 10:57:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Closed	Discrepancy has been closed.
Oct-19-2020 09:13:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-19-2020 09:13:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Cerebral Capillary telangiectasia	New Information
Oct-16-2020 22:33:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify CAPILLARY TELANGIECTASIA as follows...The term apperas incomplete. If reporting CEREBRAL CAPILLARY TELANGIECTASIA,

				update the verbatim term as such. Otherwise clarify and update the term as appropriate. Thank you.
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry :** Capillary tel angiectasia	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/26/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

Time (US & Canada)				

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-20-2020 05:10:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Ankita Thakur (pfe.thakua20)	Query 1: Closed	Response satisfies query.
Oct-19-2020 09:13:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Oct-19-2020 09:13:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT RELATED If Not Related to study treatme nt(s), this event is due to: OTHER *If Other, specify:* anatomical abnormality	New Information
Oct-19-2020 02:07:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Rajashekhar Reddy (pfe reddyr51)	Query 1: Opened	DM: The response for "If Not Related to study treatment(s), this event is due to is reported as "Other", however specify is missing? kindly review and update.
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT RELATED If Not Related to study treatme nt(s), this event is due to:	Initial Entry

			OTHER	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-16-2020 16:00:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Feb-22-2021 10:35:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Feb/18/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551145

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-22-2021 10:37:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Participant is NOT willing to retu rn for Vaccination 3 OR otherwise not eligible	Initial Entry

Header Text: c4591001
Visit: Disposition - Unscheduled
Form: TREATMENT UNBLINDED - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551145
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-22-2021 10:38:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Feb/18/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Mar-04-2021 23:53:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Amol Deshmukh (pfe.deshma24)	Query 2: Closed	Response satisfies query
Mar-04-2021 09:59:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 2: Answered	Original value is correct
Feb-25-2021 22:02:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Madhan Babu (pfe.babum05)	Query 2: Opened	IVRS Reconciliation: Other is selected as the primary reason for unblinding but matching blind break is not captured in IRT. Please correct primary reason in Inform or confirm as correct".
Feb-25-2021 00:57:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Closed	Auto closed by Validation Check: VC_DS001_35
Feb-24-2021 11:19:23 (UTC-08:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answere	Transcription Error

Pacific Time (US & Canada)			d	
Feb-24-2021 11:19:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** OTHER *If other, specify:* Subject is not eligible due to medical issues. Wants to be unblinded to get vaccine elsewhere.	Transcription Error

Feb-24-2021 00:49:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW7390884;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate.
Feb-22-2021 10:38:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

Header Text: c4591001
Visit: Subject Status - Unscheduled
Form: SUBJECT STATUS - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551145
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Subject Status

Date	Location	User	Value	Reason
Oct-22-2020 08:30:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DISCONTINUED	Changed Information
Oct-14-2020 15:18:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** FOLLOW-UP	Initial Entry
Aug-28-2020 15:40:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Aug-28-2020 15:38:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-22-2020 08:30:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Oct/14/2020	Changed Information
Oct-14-2020 15:18:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Oct/14/2020	Initial Entry
Aug-28-2020 15:40:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/28/2020	Initial Entry
Aug-28-2020 15:38:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/28/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551145 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Casebook Signature

Date	Location	User	Value	Reason
Oct-27-2020 13:01:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Click Here to Enable	Initial Entry

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** COHORT SELECTION
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/31/2020

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** DEMOGRAPHY
Form Version: 06-Jul-2020 21:55	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Demography		
1.	Subject ID	[10551153]
2.	Birth Date:	(b) (6) /1957
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	ASIAN
6.	Racial Designation:	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Aug/31/2020
2.	Erroneous Visit	

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** INCLUSION/EXCLUSION CRITERIA
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Aug/31/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diabetic neuropathy]
	Start Date:	Feb/UNK/2005
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hyperlipidemia]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Type 2 diabetes]
	Start Date:	UNK/UNK/2005
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs		
1.	Date:	Aug/31/2020
2.	Weight:	[68.8]
3.	Unit:	kg
4.	Height:	[173.8]
5.	Unit:	cm
6.	Body Mass Index:	[22.8]

Vital Signs Details

7.a

Record Identifier:	1
Temperature:	[36.4]
Unit:	C
Temperature Location:	FOREHEAD

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** RANDOMIZATION
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition		
1.	Randomization Date :	Aug/31/2020
2.	Randomization Number:	[247288]
3.	Randomization Group:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/31/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP6S3F]
5.b	Sample ID	[BP6S3G]
5.c	Sample ID	[BP6S3H]
5.d	Sample ID	[BPFV2P]
5.e	Sample ID	[BPFV2R]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/31/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP6S38]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/31/2020 13:30
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** REACTOGENICITY DIARY
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Reactogenicity Diary		
1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT

Header Text: c4591001	
Visit: V2_VAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/21/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L	**Form:** VITAL SIGNS - TEMP
Form Version: 15-Sep-2020 21:54	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Sep/21/2020

Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[35.9]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/21/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BPV088]

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/21/2020 12:00
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Oct/19/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/19/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BR2PDS]
5.b	Sample ID	[BS8B02]
5.c	Sample ID	[BS8B01]

Header Text: c4591001

Visit: V4_MONTH6_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: V5_MONTH12_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: V5_MONTH12_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: V6_MONTH24_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Form Version: 20-Feb-2021 02:17	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Signs and Symptoms		
1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	
Symptoms		
4.	Symptoms:	
	Was symptom present?	
Symptoms - Other		
5.	Symptoms - Other Text:	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001	
Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** HEALTH CARE UTILIZATION
Form Version: 20-Feb-2021 02:19	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Health Care Utilization

1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[ ]

Health Care Utilization

3.	Has the subject been hospitalized due to potential COVID-19 illness?	

Header Text: c4591001	
Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Illness Details		
1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Unplanned Assessments		
1.	Assessments	

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	Oct/19/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: Follow-Up - Unscheduled | **Form:** DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001
Visit: Logs **Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Perforated appendicitis	Aug/31/2020 19:00	NO End Date Time: Sep/16/2020 UNK:UNK	Repeating Pages
2. DELETED	ADVERSE EVENT	2	Appendicitis	Aug/UNK/2020 UNK:UNK	YES	Repeating Pages
3.	ADVERSE EVENT	3	Injection Site Pain	Aug/31/2020 18:00	NO End Date Time: Sep/3/2020 08:00	Repeating Pages
4.	ADVERSE EVENT	4	Injection site pain	Sep/22/2020 08:00	NO End Date Time: Sep/24/2020 08:00	Repeating Pages
5.	ADVERSE EVENT	5	Fatigue	Sep/21/2020 16:00	NO End Date Time: Sep/21/2020 20:00	Repeating Pages

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Perforated appendicitis]
4.	Start Date Time:	Aug/31/2020 19:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/16/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO

9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [bacterial infection]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020342548]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	~~ADVERSE EVENT~~
2.	AE ID:	[~~2~~]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[~~Appendicitis~~]
4.	Start Date Time:	~~Aug/UNK/2020 UNK:UNK~~
5.	Is the adverse event still ongoing?	~~YES~~
6.	Toxicity Grade:	~~3~~
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	~~NO~~
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	~~NO~~

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

9.	Is this event related to study treatment:	~~NOT RELATED~~ ~~If Not Related to study treatment(s), this event is due to:~~ ~~OTHER~~ ~~If Other, specify:~~ [~~possession of an appendix~~]
10.	Latest Action Taken with Study Treatment:	~~NOT APPLICABLE~~
11.	Was a Concomitant Medication given?	~~NO~~
12.	Was a Non-Drug Treatment given?	~~NO~~
13.	What was the outcome of this adverse event?:	~~NOT RECOVERED/NOT RESOLVED~~
14.	Did the adverse event cause the subject to be discontinued from the study?	~~NO~~
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection Site Pain]
4.	Start Date Time:	Aug/31/2020 18:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/3/2020 08:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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eCRF Audit Trail History
Form Audit Trail

Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[4]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Injection site pain]
4.	Start Date Time:	Sep/22/2020 08:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/24/2020 08:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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eCRF Audit Trail History
Form Audit Trail

Adverse Event Report		
1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Fatigue]
4.	Start Date Time:	Sep/21/2020 16:00
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/21/2020 20:00
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	RELATED

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001
Visit: Logs **Form:** MEDICATION ERROR
Form Version: 17-Jul-2020 21:54
Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Medication Error		
1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	[ ]			[ ]		Repeating Pages

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

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Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Date:	//

Header Text: c4591001
Visit: Logs **Form:** CONCOMITANT MEDICATIONS - PROHIBITED
Form Version: 22-Apr-2020 21:03
Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

Header Text: c4591001
Visit: Logs **Form:** RADIATION TREATMENT
Form Version: 22-Apr-2020 21:02
Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Radiation Treatment		
1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1.	Transfusion Type:	
2.	Date of Transfusion:	//

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** VITAL SIGNS - TEMP
Form Version: 20-Feb-2021 02:16	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Vital Signs

1.	Date:	//

Vital Signs Details

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 1
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 6
Form Version: 10-Oct-2020 16:01	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE
Form Version: 14-Jan-2021 02:29	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Informed Consent - Asymptomatic Surveillance		
1.	Consent Was:	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Further Vaccination Confirmation		
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Treatment Unblinded		
1.	Date Treatment Unblinded :	//
2.	Primary Reason for Unblinding:	

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Withdrawal Of Consent		
1.	Withdrawal of Consent Date :	//

Header Text: c4591001

Visit: Disposition - Unscheduled	**Form:** DEATH DETAILS CODED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Death Details

1.	Date of Collection / Notification of Death:	//

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[ ]

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Subject Status		
1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/19/2020

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Casebook Signature Form		
1.	Casebook Signature	Click Here to Enable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled
Form: CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Signed, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551153
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Audit Trail

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Oct-26-2020 15:26:11 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** INCLUSION/EXCLUSION CRITERIA - Comments

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
Form	Aug-31-2020 15:06:01 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled
Form: CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Signed, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551153
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

This form requires signing by a member of each of the following signature groups:
- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Oct-26-2020 15:26:11 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Aug-31-2020 15:05:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Aug-31-2020 15:05:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Aug-31-2020 15:05:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** OBTAINED Date Written Consent Obtained Aug/31/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Subject ID

Date	Location	User	Value	Reason
Aug-31-2020 15:05:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10551153	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Aug-31-2020 15:05:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6)/1957	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-31-2020 15:05:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Aug-31-2020 15:05:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Aug-31-2020 15:05:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** ASIAN	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Aug-31-2020 15:05:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/31/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Aug-31-2020 15:06:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/31/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1.a

Date	Location	User	Value	Reason
Aug-31-2020 15:09:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 1 **Medical History Term:** Diabetic neuropathy **Start Date:** Feb/UNK/2005 **Ongoing:** YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 15:09:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-31-2020 15:09:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Diabetic neuropathy	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 15:09:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Feb/UNK/2005	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 15:09:36	ACV0PFEINFP6000	Julie Glazier	**Data Entry:**	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)		(pfe.jglazier)	YES	

1.b

Date	Location	User	Value	Reason
Aug-31-2020 15:09:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 2 **Medical History Term:** Hyperlipidemia **Start Date:** UNK/UNK/2010 **Ongoing:** YES	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 15:09:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-31-2020 15:09:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Hyperlipidemia	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 15:09:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** UNK/UNK/2010	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 15:09:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

1.c

Date	Location	User	Value	Reason
Aug-31-2020 15:10:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 3 **Medical History Term:** Hypertension **Start Date:** UNK/UNK/2010 **Ongoing:** YES	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551153
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

1.c Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 15:10:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-31-2020 15:10:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Hypertension	Initial Entry

1.c Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 15:10:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** UNK/UNK/2010	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 15:10:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

1.d

Date	Location	User	Value	Reason
Aug-31-2020 15:10:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 4 **Medical History Term:** Type 2 diabetes **Start Date:** UNK/UNK/2005 **Ongoing:** YES	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551153
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

1.d Line/MH Number:

Date	Location	User	Value	Reason
Aug-31-2020 15:10:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Aug-31-2020 15:10:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Type 2 diabetes	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Aug-31-2020 15:10:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** UNK/UNK/2005	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Aug-31-2020 15:10:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/31/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 68.8	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 173.8	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason

Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 22.8	Initial Entry

7.a

Date	Location	User	Value	Reason
Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Record Identifier:** 1 **:** **Temperature:** 36.4 **Temperature Unit:** C **:** **Temperature Location::** FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 36.4	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Aug-31-2020 15:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Randomization Date :

Date	Location	User	Value	Reason
Aug-31-2020 15:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/31/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Aug-31-2020 15:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 247288	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Aug-31-2020 16:05:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-31-2020 16:05:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-31-2020 16:06:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 16:05:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-31-2020 16:05:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Date of Collection: Aug/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason

Aug-31-2020 16:06:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BP6S3F	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 16:06:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP6S3F	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-31-2020 16:06:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BP6S3G	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 16:06:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP6S3G	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-31-2020 16:06:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BP6S3H	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 16:06:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP6S3H	Initial Entry

5.d

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Aug-31-2020 16:06:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BPFV2P	Initial Entry

5.d Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 16:06:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BPFV2P	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-31-2020 16:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BPFV2R	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 16:06:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BPFV2R	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Aug-31-2020 15:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Aug-31-2020 15:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Aug-31-2020 15:55:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-31-2020 15:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-31-2020 15:55:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Date of Collection: Aug/31/2020	Initial Entry

5.a

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Aug-31-2020 15:55:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BP6S38	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Aug-31-2020 15:55:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP6S38	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: VACCINATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551153
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Aug-31-2020 15:07:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Aug-31-2020 15:07:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Aug-31-2020 15:07:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Aug-31-2020 15:07:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/31/2020 13:30	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Aug-31-2020 15:07:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: VACCINATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551153
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Aug-31-2020 15:07:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Aug-31-2020 15:07:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-31-2020 15:07:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Aug-31-2020 15:07:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Aug-31-2020 15:07:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO - REACTOGENICITY E-DIARY NOT COLLECTED F OR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Sep-21-2020 12:59:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/21/2020	Initial Entry

Header Text: c4591001
Visit: V2_VAX2_L
Form: VITAL SIGNS - TEMP - eCRF Audit Trail History
Form Version: 15-Sep-2020 21:54
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551153
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Sep-21-2020 14:05:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/21/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-21-2020 14:05:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Record Identifier ::** 1 **Temperature:** 35.9 **Temperature Unit:** C **Temperature Location::** FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-21-2020 14:05:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-22-2020 05:07:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kirti Bhangale (pfe.bhangk01)	Query 1: Closed	Response satisfies query
Sep-21-2020 14:05:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Query 1: Answered	Original value is correct
Sep-21-2020 14:05:11 (UTC-08:00) Pacific	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 35.9 C is outside of

Time (US & Canada)				Normal Range 36.1 - 37.5 C.
Sep-21-2020 14:05:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** 35.9	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-21-2020 14:05:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-21-2020 14:05:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-21-2020 12:59:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-21-2020 12:59:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-21-2020 12:59:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-21-2020 12:59:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-21-2020 12:59:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Date of Collection: Sep/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V2_VAX2_L	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551153	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Sep-21-2020 12:59:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BPV088	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-21-2020 12:59:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BPV088	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-21-2020 14:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-21-2020 14:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-21-2020 14:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-21-2020 14:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/21/2020 12:00	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-21-2020 14:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason

Sep-21-2020 14:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-21-2020 14:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-21-2020 14:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-21-2020 14:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-19-2020 13:15:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Oct/19/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551153

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Oct-19-2020 15:05:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-19-2020 15:05:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-19-2020 15:05:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-19-2020 15:05:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-19-2020 15:05:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Date of Collection: Oct/19/2020	Initial Entry

5.a

Date	Location	User	Value	Reason

Oct-19-2020 15:05:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BR2PDS	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 15:05:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BR2PDS	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-19-2020 15:05:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BS8B02	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 15:05:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BS8B02	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-19-2020 15:05:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BS8B01	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-19-2020 15:05:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BS8B01	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-19-2020 13:15:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Oct/19/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-19-2020 13:15:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-19-2020 13:15:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

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Date	Location	User	Value	Reason
Sep-09-2020 13:12:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Deleted	deleted as requested
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Category:

Date	Location	User	Value	Reason
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-16-2020 05:52:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	resolved
Sep-15-2020 10:27:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	term has been updated on form, will resend
Sep-11-2020 03:09:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020342548,the term in Safety database was updated to 'Appendicitis. Per PSSR, The SAE term reported on the SAE form is appendicitis. Please confirm correct term. If PERFORATED APPENDICITIS,please submit a follow-up SAE form.

Sep-10-2020 08:56:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Perforated appendicitis	Changed Information
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Perforated appendix	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/31/2020 19:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-19-2020 13:29:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO End Date Time: Sep/16/2020 UNK:UNK	New Information
Sep-22-2020 09:38:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Barialai Kakar (pfe.kakarb)	Query 2: Closed	Response satisfies query
Sep-15-2020 12:20:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 2: Answered	source has been updated, still ongoing
Sep-15-2020 11:58:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sholeh Majdi-Yazdi (pfe.majdis01)	Query 2: Opened	Please confirm and amend. Per source (AE/SAE log) the stop date is 01Sep2020.
Sep-11-2020 08:34:29 (UTC-08:00) Pacific	ACV0PFEINFP6000	Nandini Cossons	Query 1: Closed	Response satisfies query

Time (US & Canada)		(pfe.cossons_n)		
Sep-10-2020 08:56:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	still ongoing, subject still recovering
Sep-09-2020 09:48:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 1: Opened	GPD CLINQUERY: Please confirm whether adverse event of perforated appendix is still ongoing.
Sep-08-2020 09:08:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Changed Information
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO End Date Time: Sep/1/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Sep-07-2020 01:45:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551153
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Perforated appendix: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-14-2020 09:14:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Cavin van Schalkwyk (pfe.vanscc01)	Query 1: Closed	Response satisfies query
Oct-13-2020 14:39:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Query 1: Answered	data correct as recorded... appendicitis is a bacterial infection of the appendix. This is not a separate AE.
Oct-12-2020 08:59:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (pfe.PFESDQ_PROD)	Query 1: Opened	"If not related to study treatment other" = bacterial infection. Any symptoms, AEs or other key data should be collected on the appropriate page. Please confirm if this should be an AE or medhx and update

				accordingly. "[cefall01 SDQ=17106]"
Sep-10-2020 08:57:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* bacterial infe	Changed Information

			c ti o n	
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data E ntry:** NOT R ELATE D If Not Relat ed to study treat ment(s), thi s even t is du e to: OT HE R *If Ot her , s pe cif y:* a p p e n d i c it is	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-11-2020 19:16:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Oct-09-2020 14:11:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-09-2020 14:11:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	**Data Entry:** YES	Changed Information
Oct-08-2020 12:24:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL per SAE report, IV antibiotics were given for SAE; please review and update if required
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-11-2020 19:16:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Oct-09-2020 14:12:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information

Oct-09-2020 14:12:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	**Data Entry:** YES	Changed Information
Oct-08-2020 12:45:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL Per SAE report, subject had an appendectomy on 01 Sep 2020. Please review this non-drug treatment, and update accordingly
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-19-2020 13:29:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Oct-19-2020 13:29:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** RECOVERED/RESOLVED	Changed Information
Oct-19-2020 13:29:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	For AE Perforated appendicitis: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Sep-22-2020 09:38:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Barialai Kakar (pfe kakarb)	Query 3: Closed	Response satisfies query

Sep-15-2020 12:20:33 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 3: Answered	still ongoing
Sep-15-2020 12:00:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sholeh Majdi-Yazdi (pfe majdis01)	Query 3: Opened	Please confirm and amend. Per paper AE/SAE log, the event has been recovered/resolved.
Sep-09-2020 04:35:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Closed	issue resolved
Sep-08-2020 09:08:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Sep-08-2020 09:08:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Perforated appendix: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Sep-08-2020 09:08:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-08-2020 09:08:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** RECOVERING/RESOLVING	Changed Information
Sep-07-2020 01:53:21 (UTC-08:00)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	Query 1: Opened	SAE RECON:AER#2020342548 ,outcome was reported as

Pacific Time (US & Canada)				RECOVERING/RESOLVING in SAE form however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-04-2020 08:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Sep-07-2020 01:45:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	**Data Entry:** 2020342548	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

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1. Category:

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-09-2020 13:25:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Closed	Response satisfies query
Sep-09-2020 13:12:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	Changed data per query
Sep-09-2020 08:59:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sian Jones (pfe.jones111)	Query 1: Opened	clinical-pls remove AE of 'appendicitis' as this is subsumed within AE of perforated appendix. Thank you
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Appendicitis	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Aug/UNK/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26	ACV0PFEINFP6000	Julie Glazier	**Data Entry:**	Initial Entry

***** THIS REPEATING FORM HAS BEEN DELETED *****

(UTC-08:00) Pacific Time (US & Canada)		(pfe.jglazier)	NO	

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* possession of an appendix	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Deleted, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-04-2020 08:48:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Injection Site Pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Aug/31/2020 18:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO End Date Time: Sep/3/2020 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NOT APPLICABLE	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-21-2020 14:25:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Injection site pain	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-20-2020 12:30:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Oct-20-2020 11:04:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/22/2020 08:00	Transcription Error
Oct-20-2020 10:32:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-20-2020 10:32:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/21/2020 08:00	Transcription Error

Oct-20-2020 08:19:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: Start date of Injection Site Pain is reported prior to the study vaccination administration. Please review entries and amend as appropriate.
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/20/2020 08:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO End Date Time: Sep/24/2020 08:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

Time (US & Canada)				

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-19-2020 13:16:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Fatigue	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/21/2020 16:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO End Date Time: Sep/21/2020 20:00	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT APPLICABLE	Initial Entry

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Locked, Frozen
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551153
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Oct-19-2020 13:17:57 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Subject Status

Date	Location	User	Value	Reason
Oct-19-2020 13:15:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** FOLLOW-UP	Initial Entry
Aug-31-2020 15:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Aug-31-2020 15:06:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-19-2020 13:15:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Oct/19/2020	Initial Entry
Aug-31-2020 15:07:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/31/2020	Initial Entry
Aug-31-2020 15:06:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Aug/31/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551153 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-26-2020 14:57:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Helen Stacey (pfe hstacey)	**Data Entry:** Click Here to Enable	Initial Entry

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** COHORT SELECTION
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Informed Consent		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/3/2020

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Demography		
1.	Subject ID	[10551176]
2.	Birth Date:	(b) (6) /1970
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/3/2020
2.	Erroneous Visit	

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** INCLUSION/EXCLUSION CRITERIA
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met		
1.	Description of Inclusion Criterion Not Met	Not Applicable
Exclusion Criteria Met		
2.	Description of Exclusion Criterion Met	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Screening		
1.	Date of Completion/Discontinuation /Death	Sep/3/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal allergies]
	Start Date:	Apr/1/1982
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Angina]
	Start Date:	Mar/24/2010
	Ongoing:	NO End Date: Feb/4/2016
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Sinus tachycardia]
	Start Date:	Apr/1/2019
	Ongoing:	YES
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	Oct/1/2000
	Ongoing:	YES

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertriglyceridemia]
	Start Date:	Apr/1/2010
	Ongoing:	YES
1 f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Type 2 diabetes]
	Start Date:	Feb/1/2020
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coronary vasospasm]
	Start Date:	Mar/24/2010
	Ongoing:	NO End Date: Feb/4/2016
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Anomalous coronary artery]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Coronary artery bypass graft]
	Start Date:	UNK/UNK/2010
	Ongoing:	NO End Date: UNK/UNK/2010

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551176
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

1.j

Line/MH Number:	[10]
Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Redo of coronary bypass graft with re-implantation RCA and "unroofing of LAD bridge"]
Start Date:	UNK/UNK/2016
Ongoing:	NO End Date: UNK/UNK/2016

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs		
1.	Date:	Sep/3/2020
2.	Weight:	[104.3]
3.	Unit:	kg
4.	Height:	[170.0]
5.	Unit:	cm
6.	Body Mass Index:	[36.1]

Vital Signs Details		
7.a	Record Identifier:	1
	Temperature:	[36.8]
	Unit:	C
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 21-Aug-2020 02:49 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/3/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a

Sponsor ID:	[113]
Test:	Choriogonadotropin Beta_PX113
Result:	NEGATIVE
Not Done:	

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** RANDOMIZATION
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition		
1.	Randomization Date :	Sep/3/2020
2.	Randomization Number:	[80233]
3.	Randomization Group:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/3/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP91X8]
5.b	Sample ID	[BP91X9]
5.c	Sample ID	[BPFTDK]
5.d	Sample ID	[BPFTDL]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/3/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP91X4]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/3/2020 12:14
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** REACTOGENICITY DIARY
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Reactogenicity Diary		
1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT

Header Text: c4591001	
Visit: V2_VAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/23/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP

Form Version: 15-Sep-2020 21:54 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Sep/23/2020

Vital Signs Details

2.a

Record Identifier:	1
Temperature:	[36.5]
Unit:	C
Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 21-Aug-2020 02:49 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Lab Urinalysis

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/23/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

Lab Result

6.a	Sponsor ID:	[113]
	Test:	Choriogonadotropin Beta_PX113
	Result:	NEGATIVE
	Not Done:	

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/23/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BPV091]

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination		
1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/23/2020 10:18
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001	
Visit: V3_MONTH1_POSTVAX2_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Oct/22/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/22/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2PFY]
5.b	Sample ID	[BS8B20]
5.c	Sample ID	[BS8B1Z]

Header Text: c4591001

Visit: V4_MONTH6_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V4_MONTH6_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: V5_MONTH12_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V5_MONTH12_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: V6_MONTH24_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V6_MONTH24_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 20-Feb-2021 02:17 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Signs and Symptoms		
1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	

Symptoms		
4.	Symptoms:	
	Was symptom present?	

Symptoms - Other		
5.	Symptoms - Other Text:	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit **Form:** HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Health Care Utilization		
1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other		
2.	Other Type of Practitioner Specify:	[ ]

Health Care Utilization		
3.	Has the subject been hospitalized due to potential COVID-19 illness?	

Header Text: c4591001	
Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Illness Details		
1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Unplanned Assessments		
1.	Assessments	

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	Oct/22/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001	
Visit: Follow-Up - Unscheduled	**Form:** DISPOSITION - FOLLOW-UP
Form Version: 15-Sep-2020 21:53	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Follow-Up		
1.	Date of Completion/Discontinuation /Death :	Dec/18/2020
2.	Phase of Disposition:	FOLLOW-UP
3.	Status:	WITHDRAWAL BY SUBJECT
4.	Specify Status:	[subject withdrew from study prior to Subject receiving Covid-19 vaccine outside of study]

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001
Visit: Logs **Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still On going	Form Instance
1.	ADVERSE EVENT	1	Coronary vasospasm	Sep/25/2020 UNK:UNK	NO End Date Time: Sep/26/2020 UNK:UNK	Repeating Pages

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Locked, Frozen
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551176
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Coronary vasospasm]
4.	Start Date Time:	Sep/25/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/26/2020 UNK:UNK
6.	Toxicity Grade:	3
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [underlying cardiac disease]

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020375789]

Header Text: c4591001

Visit: Logs **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001
Visit: Logs - Unscheduled
Form: MEDICATION ERROR
Form Version: 17-Jul-2020 21:54
Form Status: Not Started
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551176
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

Medication Error		
1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Influenza vaccine	Oct/9/2020	Repeating Pages
2. DELETED	2	VACCINATIONS	NO	BNT162b2	Dec/18/2020	Repeating Pages
3. DELETED	3	VACCINATIONS	NO	BNT162b2	Jan/8/2021	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Concomitant Medications		
1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Influenza vaccine]
5.	Date:	Oct/9/2020

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form
eCRF Audit Trail History
Form Audit Trail

Concomitant Medications			
1.	What is the medication identifier?	[~~2~~]	
2.	Category:	~~VACCINATIONS~~	
3.	Concomitant Medications Pre-specified:	~~NO~~	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[~~BNT162b2~~]	Comments
5.	Date:	~~Dec/18/2020~~	Comments

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Deleted, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form
eCRF Audit Trail History
Form Audit Trail

Concomitant Medications		
1.	What is the medication identifier?	[~~3~~]
2.	Category:	~~VACCINATIONS~~
3.	Concomitant Medications Pre-specified:	~~NO~~
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[~~BNT162b2~~]
5.	Date:	~~Jan/8/2021~~

Header Text: c4591001

Visit: Logs **Form:** CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Concomitant Medications		
1.	What is the medication identifier?	[ ]
2.	Category:	
3.	Concomitant Medications Pre-specified:	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[ ]
5.	Dose:	[ ]
6.	Dose Unit:	
7.	Dose Frequency:	
8.	Route:	
9.	Start Date:	//
10.	Ongoing?	

Header Text: c4591001

Visit: Logs **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Radiation Treatment		
1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1.	Transfusion Type:	
2.	Date of Transfusion:	//

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Vital Signs		
1.	Date:	//

Vital Signs Details		
2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Lab Urinalysis

1.	Lab Panel:	
2.	Lab Sub-Panel:	
3.	Collection Date:	//
4.	Laboratory Name and Address (Derived)	[ ]
5.	Specimen Type:	

Lab Result

6.	Sponsor ID:	[ ]
	Test:	
	Result:	
	Not Done:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: V201_SURVEIL_CONSENT - Unscheduled	**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE
Form Version: 14-Jan-2021 02:29	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Informed Consent - Asymptomatic Surveillance		
1.	Consent Was:	

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Dec/14/2020
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Further Vaccination Confirmation		
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2

Header Text: c4591001	
Visit: V101_VAX3	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INFORMED CONSENT - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Informed Consent - Further Vaccination		
1.	Consent Was:	

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:30	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Inclusion Criteria Not Met		
1.	Description of Inclusion Criterion Not Met	

Exclusion Criteria Met		
2.	Description of Exclusion Criterion Met	

Header Text: c4591001

Visit: V101_VAX3 **Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Disposition - Screening for Further Vaccination		
1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** TREATMENT UNBLINDED
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Treatment Unblinded		
1.	Date Treatment Unblinded :	Dec/14/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Withdrawal Of Consent		
1.	Withdrawal of Consent Date :	//

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** DEATH DETAILS CODED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Death Details		
1.	Date of Collection / Notification of Death:	//

Cause of Death		
2.	Cause of Death Status:	
	Cause of Death:	[ ]

Header Text: c4591001	
Visit: Subject Status - Unscheduled	**Form:** SUBJECT STATUS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Subject Status		
1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Dec/18/2020

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Casebook Signature Form		
1.	Casebook Signature	Click Here to Enable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Audit Trail

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Feb-22-2021 14:00:05 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** INCLUSION/EXCLUSION CRITERIA - Comments

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Item	Date	User	Comment
Form	Sep-03-2020 13:40:29 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

Item	Date	User	Comment
4	Jan-13-2021 15:38:10 (UTC-08:00) Pacific Time (US & Canada)	Lana Norman (pfe.lnorman)	previously reported as Unspecified Covid-19 vaccine

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

Item	Date	User	Comment
5	Jan-13-2021 15:38:45 (UTC-08:00) Pacific Time (US & Canada)	Lana Norman (pfe.lnorman)	
5	Jan-13-2021 15:24:59 (UTC-08:00) Pacific Time (US & Canada)	Lana Norman (pfe.lnorman)	Unknown

Header Text: c4591001
Visit: Investigator Signature - Unscheduled
Form: CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Signed, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551176
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

This form requires signing by a member of each of the following signature groups:
- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Feb-22-2021 14:00:05 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
Affidavit: By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject. Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature. To this I do attest by supplying my user name and password and clicking the button marked Submit below.				
Elissa OConnor	N/A	Feb-22-2021 10:18:30 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
Helen Stacey	Approved	Feb-17-2021 08:55:01 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed
Affidavit: By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject. Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature. To this I do attest by supplying my user name and password and clicking the button marked Submit below.				
Elissa OConnor	N/A	Feb-16-2021 13:52:28 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated
Affidavit: N/A				
Helen Stacey	Approved	Feb-10-2021 17:31:57 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Header Text: c4591001
Visit: Investigator Signature - Unscheduled
Form: CASEBOOK SIGNATURE FORM - Signature History
Form Version: 22-Apr-2020 21:04
Form Status: Data Complete, Signed, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551176
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Elissa OConnor	N/A	Feb-10-2021 14:08:53 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Jan-27-2021 17:11:06 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Elissa OConnor	N/A	Jan-27-2021 08:08:46 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Jan-20-2021 17:59:33 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Julie Glazier	N/A	Dec-22-2020 13:28:16 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Dec-16-2020 15:53:26 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Elle Billman	N/A	Dec-16-2020 09:57:18 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Oct-27-2020 16:56:33 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-03-2020 13:39:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Sep-03-2020 13:39:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Sep-03-2020 13:39:48 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** OBTAINED Date Written Consent Obtained Sep/3/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Subject ID

Date	Location	User	Value	Reason
Sep-03-2020 13:37:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10551176	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-03-2020 13:37:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6)/1970	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-03-2020 13:39:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FEMALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-03-2020 13:39:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Date	Location	User	Value	Reason
Sep-03-2020 13:39:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Sep-03-2020 13:40:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/3/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-03-2020 13:40:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/3/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-03-2020 13:40:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-03-2020 13:40:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1.a

Date	Location	User	Value	Reason
Sep-03-2020 13:49:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 1 **Medical History Term:** Seasonal allergies **Start Date:** Apr/1/1982 **Ongoing:** YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 13:49:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-03-2020 13:49:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Seasonal allergies	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 13:49:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Apr/1/1982	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 13:49:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

1.b

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Sep-03-2020 13:50:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 2 **Medical History Term:** Angina **Start Date:** Mar/24/2010 **Ongoing:** NO End Date: Feb/4/2016	Initial Entry

1.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 13:50:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-30-2020 10:57:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Sep-30-2020 09:24:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	Changed data per query
Sep-29-2020 09:04:12 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	CLINICAL On review of SAE report: Coronary vasospasm, past Med Hx of coronary vasospasm (2010-6) and Anomalous coronary artery (CABG x2) were mentioned, yet do not appear in CRF. Please review for clinical relevance and update Med Hx as appropriate.
Sep-03-2020 13:50:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Angina	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 13:50:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Mar/24/2010	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551176
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Sep-03-2020 13:50:19 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO End Date: Feb/4/2016	Initial Entry

1.c

Date	Location	User	Value	Reason
Sep-08-2020 11:44:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Line/MH Number:** 3 **Medical History Term:** Sinus tachycardia **Start Date:** Apr/1/2019 **Ongoing:** YES	Changed Information
Sep-04-2020 08:58:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Line/MH Number:** 3 **Medical History Term:** Cardiac arrhythmia **Start Date:** Apr/1/2019 **Ongoing:** YES	Changed Information
Sep-03-2020 13:51:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 3 **Medical History Term:** Arrhythmia **Start Date:** Apr/1/2019 **Ongoing:** YES	Initial Entry

1.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 13:51:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-08-2020 12:04:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Sep-08-2020 11:44:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-08-2020 11:44:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sinus tachycardia	Changed Information
Sep-04-2020 10:17:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Reissued:Opened	CLINQUERY: Thank you for the update. However, could you clarify if any other description can be offered for the cardiac arrhythmia
Sep-04-2020 08:58:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Sep-04-2020 08:58:26 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Cardiac arrhythmia	Changed Information
Sep-04-2020 07:45:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: Please review if a more descriptive term can be applied to describe the 'Arrhythmia' reported.
Sep-03-2020 13:51:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Arrhythmia	Initial Entry

1.c Start Date:

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551176
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-03-2020 13:51:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Apr/1/2019	Initial Entry

1.c Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 13:51:00 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

1.d

Date	Location	User	Value	Reason
Sep-03-2020 13:51:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 4 **Medical History Term:** Hypertension **Start Date:** Oct/1/2000 **Ongoing:** YES	Initial Entry

1.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 13:51:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 4	Initial Entry

1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-03-2020 13:51:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Hypertension	Initial Entry

1.d Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 13:51:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Oct/1/2000	Initial Entry

1.d Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 13:51:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

1.e

Date	Location	User	Value	Reason
Sep-03-2020 13:51:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 5 **Medical History Term:** Hypertriglyceridemia **Start Date:** Apr/1/2010 **Ongoing:** YES	Initial Entry

1.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 13:51:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 5	Initial Entry

1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-03-2020 13:51:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Hypertriglyceridemia	Initial Entry

1.e Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 13:51:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Apr/1/2010	Initial Entry

1.e Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 13:51:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

1.f

Date	Location	User	Value	Reason
Sep-03-2020 13:52:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 6 **Medical History Term:** Type 2 diabetes **Start Date:** Feb/1/2020 **Ongoing:** YES	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551176
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

1.f Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 13:52:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 6	Initial Entry

1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-03-2020 13:52:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Type 2 diabetes	Initial Entry

1.f Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 13:52:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Feb/1/2020	Initial Entry

1.f Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 13:52:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

1.g

Date	Location	User	Value	Reason
Sep-30-2020 09:20:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 7 **Medical History Term:** Coronary vasospasm **Start Date:** Mar/24/2010 **Ongoing:** NO End Date: Feb/4/2016	Initial Entry

1.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-30-2020 09:20:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 7	Initial Entry

1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-30-2020 09:20:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Coronary vasospasm	Initial Entry

1.g Start Date:

Date	Location	User	Value	Reason
Sep-30-2020 09:20:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Mar/24/2010	Initial Entry

1.g Ongoing:

Date	Location	User	Value	Reason
Sep-30-2020 09:20:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO End Date: Feb/4/2016	Initial Entry

1.h

Date	Location	User	Value	Reason
Sep-30-2020 09:22:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 8 **Medical History Term:** Anomalous coronary artery **Start Date:** UNK/UNK/2010 **Ongoing:** YES	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551176
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

1.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-30-2020 09:22:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 8	Initial Entry

1.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-30-2020 09:22:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Anomalous coronary artery	Initial Entry

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551176
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

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1.h Start Date:

Date	Location	User	Value	Reason
Sep-30-2020 09:22:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** UNK/UNK/2010	Initial Entry

1.h Ongoing:

Date	Location	User	Value	Reason
Sep-30-2020 09:22:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

1.i

Date	Location	User	Value	Reason
Sep-30-2020 09:23:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 9 **Medical History Term:** Coronary artery bypass graft **Start Date:** UNK/UNK/2010 **Ongoing:** NO End Date: UNK/UNK/2010	Initial Entry

1.i Line/MH Number:

Date	Location	User	Value	Reason
Sep-30-2020 09:23:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 9	Initial Entry

1.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-30-2020 09:23:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Coronary artery bypass graft	Initial Entry

1.i Start Date:

Date	Location	User	Value	Reason
Sep-30-2020 09:23:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** UNK/UNK/2010	Initial Entry

1.i Ongoing:

Date	Location	User	Value	Reason
Sep-30-2020 09:23:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO End Date: UNK/UNK/2010	Initial Entry

1.j

Date	Location	User	Value	Reason
Sep-30-2020 09:24:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 10 **Medical History Term:** Redo of coronary bypass graft with re-implantation RCA and "unroofing of LAD bridge" **Start Date:** UNK/UNK/2016	Initial Entry

			Ongoing: NO End Date: UNK/UNK/2016	

1.j Line/MH Number:

Date	Location	User	Value	Reason
Sep-30-2020 09:24:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10	Initial Entry

1.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-30-2020 09:24:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Redo of coronary bypass graft with re-implantation RCA and "unroofing of LAD bridge"	Initial Entry

1.j Start Date:

Date	Location	User	Value	Reason
Sep-30-2020 09:24:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** UNK/UNK/2016	Initial Entry

1.j Ongoing:

Date	Location	User	Value	Reason
Sep-30-2020 09:24:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO End Date: UNK/UNK/2016	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/3/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 104.3	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 170.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 36.1	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 36.8 **Temperature Unit:** C **Temperature Location::** FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 36.8	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/3/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-03-2020 13:41:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-03-2020 13:41:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

			Test:: Choriogonadotropin Beta_PX113 **Result::** NEGATIVE **Not Done::**	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-03-2020 13:41:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NEGATIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Randomization Date :

Date	Location	User	Value	Reason
Sep-03-2020 13:42:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/3/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-03-2020 13:42:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 80233	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-03-2020 15:59:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-03-2020 15:59:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-03-2020 15:59:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 15:59:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-03-2020 15:59:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Date of Collection: Sep/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 15:59:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BP91X8	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Sep-03-2020 15:59:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP91X8	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-03-2020 15:59:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BP91X9	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 15:59:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP91X9	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-03-2020 15:59:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BPFTDK	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 15:59:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BPFTDK	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-03-2020 16:00:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BPFTDL	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.d Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:00:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BPFTDL	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-03-2020 16:00:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-03-2020 16:00:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-03-2020 16:00:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 16:00:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-03-2020 16:00:22 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Date of Collection: Sep/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 16:00:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BP91X4	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Sep-03-2020 16:00:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP91X4	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-03-2020 13:42:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-03-2020 13:42:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-03-2020 13:42:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-03-2020 13:42:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/3/2020 12:14	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-03-2020 13:42:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-03-2020 13:42:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-03-2020 13:42:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-03-2020 13:42:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBS ERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-03-2020 13:42:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-03-2020 13:42:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Sep-23-2020 11:37:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/23/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/23/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-23-2020 11:37:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 36.5 **Temperature Unit:** C **Temperature Location::** FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 36.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Sep-23-2020 11:37:24 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Lab Panel:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINALYSIS	Initial Entry

2. Lab Sub-Panel:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** PREGNANCY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/23/2020	Initial Entry

4. Laboratory Name and Address (Derived)

Date	Location	User	Value	Reason
Sep-23-2020 11:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** STUDY SITE	Initial Entry

5. Specimen Type:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** URINE	Initial Entry

6.a

Date	Location	User	Value	Reason
Sep-23-2020 11:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Sponsor-Defined Identifier:** 113	Initial Entry

			Test:: Choriogonadotropin Beta_PX113 **Result::** NEGATIVE **Not Done::**	

6.a Sponsor ID:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NEGATIVE	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-23-2020 15:06:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-23-2020 15:06:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-23-2020 15:06:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-23-2020 15:06:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-23-2020 15:06:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** YES Date of Collection: Sep/23/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-23-2020 15:06:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Sample ID:** BPV091	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Sep-23-2020 15:06:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** BPV091	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-23-2020 11:37:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-23-2020 11:37:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/23/2020 10:18	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-23-2020 11:37:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-23-2020 11:37:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBS ERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-23-2020 11:37:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-22-2020 12:29:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Oct/22/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Oct-22-2020 14:42:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-22-2020 14:42:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-22-2020 14:43:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-22-2020 14:42:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-22-2020 14:42:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** YES Date of Collection: Oct/22/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-22-2020 14:43:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Sample ID:** BR2PFY	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Oct-22-2020 14:43:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** BR2PFY	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-22-2020 14:43:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Sample ID:** BS8B20	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 14:43:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** BS8B20	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-22-2020 14:43:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** **Sample ID:** BS8B1Z	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-22-2020 14:43:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** BS8B1Z	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-22-2020 12:30:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Oct/22/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-22-2020 12:30:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-22-2020 12:30:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: Follow-Up - Unscheduled | **Form:** DISPOSITION - FOLLOW-UP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:53 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Jan-27-2021 08:08:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elissa OConnor (pfe.eoconnor)	**Data Entry:** Dec/18/2020	Changed Information
Dec-22-2020 13:28:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Dec/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Dec-22-2020 13:28:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** FOLLOW-UP	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-10-2021 14:33:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Closed	Response satisfies query
Feb-10-2021 14:08:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Feb-10-2021 14:08:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elissa OConnor (pfe.eoconnor)	**Data Entry:** WITHDRAWAL BY SUBJECT	Changed Information
Jan-27-2021 12:25:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Reissued:Opened	CLINQUERY: Thank you for clarifying, status can be amended to be WITHDRAWAL BY SUBJECT since subject is opting to receive vaccine off study
Jan-27-2021 08:09:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elissa OConnor (pfe.eoconnor)	Query 2: Answered	subject was discontinued prior to outside vaccination so it is not a PD

Jan-25-2021 07:21:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Gbenga Akinkunmi (pfe.akinkg)	Query 2: Opened	CLINQUERY: Since subject received a non-study covid-19 vaccine prior to discontinuing from study, please amend status to reflect PROTOCOL DEVIATION
Jan-25-2021 04:00:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Candidate	CLINQUERY: Since subject received a non-study covid-19 vaccine prior to discontinuing from study, please amend status to reflect PROTOCOL DEVIATION
Dec-22-2020 13:28:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Dec-22-2020 13:28:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is NO LONGER MEETS ELIGIBILITY CRITERIA but "Specify Status" is missing.
Dec-22-2020 13:28:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO LONGER MEETS ELIGIBILITY CRITERIA	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Feb-22-2021 10:44:41 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Closed	Response satisfies query
Feb-22-2021 10:18:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Feb-22-2021 10:18:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elissa OConnor (pfe.eoconnor)	**Data Entry:** subject withdrew from study prior t o Subject receiving Covid-19 vacci	Changed Information

			ne outside of study	
Feb-21-2021 22:47:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 2: Opened	CLINQUERY: In line with prior clarification "subject was discontinued prior to outside vaccination so it is not a PD" - please review entry in this field that suggests vaccine was received prior to study end
Feb-19-2021 10:14:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Candidate	CLINQUERY: In line with prior clarification "subject was discontinued prior to outside vaccination so it is not a PD" - please review entry in this field that suggests vaccine was received prior to study end
Jan-14-2021 13:20:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	non-study vax page updated
Jan-13-2021 15:25:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Query 1: Answered	pending data from a subject
Jan-06-2021 10:10:21 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Opened	CLINQUERY: Please capture the non-study vaccine in the CONMED VAX page under LOGS tab.
Dec-22-2020 13:29:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Subject received Covid-19 vaccine outside of study	Changed Information
Dec-22-2020 13:28:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Subject received Covid-19 vaccine study outside of study	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001
Visit: Logs - Unscheduled
Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02
Form Status: Data Complete, Locked, Frozen
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551176
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Coronary vasospasm	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/25/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO End Date Time: Sep/26/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-28-2020 14:41:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Oct-27-2020 20:23:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Oct-27-2020 09:24:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Query 2: Answered	Form was updated and faxed over on 10/26. Form is being uploaded to Florence.
Oct-23-2020 17:19:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	Clinical COVID testing has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020375789] to provide whether COVID testing was performed (yes/no) and if yes, the results.
Sep-29-2020 03:46:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Coronary vasospasm: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Is this serious event associated with congenital anomaly or birth defect? NO	Initial Entry

			Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO	

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-28-2020 14:41:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* underlying cardiac disease	New Information

Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-28-2020 13:38:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Sep-29-2020 03:46:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	**Data Entry:** 2020375789	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Oct-22-2020 12:32:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

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Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

Date	Location	User	Value	Reason
Feb-10-2021 14:24:34 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elissa OConnor (pfe.eoconnor)	Form Deleted	Changed Information
Jan-13-2021 15:24:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

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Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

Date	Location	User	Value	Reason
Feb-16-2021 13:52:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elissa OConnor (pfe.eoconnor)	Form Deleted	Removing per sponsor request
Jan-13-2021 15:39:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-22-2020 12:32:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-22-2020 12:32:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-22-2020 12:32:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-22-2020 12:32:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Influenza vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Oct-22-2020 12:32:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Oct/9/2020	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-13-2021 15:24:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-13-2021 15:24:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-13-2021 15:24:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Feb-10-2021 14:32:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Feb-10-2021 14:24:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elissa OConnor (pfe.eoconnor)	Query 1: Answered	ok will remove. since subject discontinued prior to receiving non-study vaccines
Jan-28-2021 07:00:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 1: Opened	CLINQUERY: Clarified at FUP page that subject discontinued from study prior to

***** THIS REPEATING FORM HAS BEEN DELETED *****

				receiving non-study vaccines. If correct, then these vaccines should not be captured in CRF as occurred post end of study
Jan-27-2021 12:31:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Candidate	CLINQUERY: Clarified at FUP page that subject discontinued from study prior to receiving non-study vaccines. If correct, then these vaccines should not be captured in CRF as occurred post end of study
Jan-13-2021 15:38:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	**Data Entry:** BNT162b2	Changed Information
Jan-13-2021 15:24:51 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	**Data Entry:** Unspecified Covid-19 vaccine	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Jan-13-2021 15:39:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	**Data Entry:** Dec/18/2020	Initial Entry
Jan-13-2021 15:38:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	**Data Entry:**	Initial Entry
Jan-13-2021 15:24:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	**Data Entry:** Unknown	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-13-2021 15:39:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-13-2021 15:39:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-13-2021 15:39:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Feb-16-2021 15:16:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Closed	Response satisfies query
Feb-16-2021 13:52:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Removing per sponsor request
Feb-10-2021 22:29:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Sathenapalli Suguna Srujan (pfe.srujas)	Query 1: Opened	CLINQUERY: Clarified at FUP page that subject discontinued from study prior to receiving non-study

***** THIS REPEATING FORM HAS BEEN DELETED *****

				vaccines. If correct, then these vaccines should not be captured in CRF as occurred post end of study
Feb-10-2021 14:23:50 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 1: Candidate	CLINQUERY: Clarified at FUP page that subject discontinued from study prior to receiving non-study vaccines. If correct, then these vaccines should not be captured in CRF as occurred post end of study
Jan-13-2021 15:39:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	**Data Entry:** BNT162b2	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Jan-27-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Mina Francisco (pfe francm73)	Query 1: Closed	Response satisfies query
Jan-27-2021 08:11:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elissa OConnor (pfe.eoconnor)	Query 1: Answered	we got a query on the final disposition CRF saying to add the vaccinations to the med log. Please advise
Jan-27-2021 02:02:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Malerato Moloi (pfe moloim)	Query 1: Reissued: Opened	DM: Thank you, please note that there cannot be a date that is after the date of disposition follow-up. Please update as appropriate.

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

Jan-26-2021 14:44:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	do you want the second vaccine removed then?
Jan-14-2021 17:41:03 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (pfe.DMW_QUERY)	Query 1: Opened	DMW6841692;'Start Date' is after 'Date of Completion/Discontinuation /Death' on the Disposition - Follow-up eCRF. Please clarify or correct.
Jan-13-2021 15:39:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Lana Norman (pfe.lnorman)	**Data Entry :** Jan/8/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Dec-16-2020 09:57:18 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Dec/14/2020	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-01-2021 06:11:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 3: Closed	guidance review being undertaken for subjects who never signed consent for V101
Jan-27-2021 12:27:08 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 3: Reissued:Opened	CLINQUERY: Understood - the page completion options below are to clarify in V101 folder that visit will not go ahead as planned. Pages need to be completed to finalise CRF
Jan-27-2021 08:15:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elissa OConnor (pfe.eoconnor)	Query 3: Answered	Subject never came in for V101 that is why the pages are not completed. they were discontinued in the study before then.
Jan-20-2021 05:21:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 3: Opened	CLINQUERY: Please complete the pages in the V101/Vax 3 folder. Date can be the date of contact/date deemed no further vax. Disp screening = No Longer Meets Eligibility. Capture the eligibility criterion not met in the IE page.
Jan-12-2021 14:23:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Closed	to review with updated guidelines
Jan-08-2021 09:38:55	ACV0PFEINFP6000	auto query	Query 2: Answered	Transcription Error

(UTC-08:00) Pacific Time (US & Canada)		(autoquery)		
Jan-08-2021 09:38:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Transcription Error
Jan-08-2021 03:58:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Reissued:Opened	CLINQUERY: Please clarify, was the subject's Rx arm unblinded before or after knowledge of receipt of non-study vaccine (and so was there intention to proceed with V101 on unblind)? This may alter data selections
Dec-29-2020 12:08:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Dec-29-2020 12:08:05 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe mpastores)	**Data Entry:** Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible	New Information
Dec-23-2020 08:17:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Hayley Wyper (pfe.wyperh)	Query 2: Opened	CLINQUERY: FUP status states subject had received a vaccine outside of the study, which would mean subject was ineligible for any further vaccination on study. Please clarify discrepancy in this entry vs FUP page.
Dec-16-2020 09:58:28 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551176

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

(US & Canada)				
Dec-16-2020 09:57:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Dec-16-2020 09:57:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled | **Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Dec-16-2020 09:58:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Dec/14/2020	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Dec-16-2020 09:58:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Subject Status

Date	Location	User	Value	Reason
Feb-10-2021 14:08:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DISCONTINUED	Changed Information
Dec-22-2020 13:28:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DISCONTINUED	Initial Entry
Oct-22-2020 12:30:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** FOLLOW-UP	Initial Entry
Sep-03-2020 13:42:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Sep-03-2020 13:40:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Feb-10-2021 14:08:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Dec/18/2020	Changed Information
Jan-27-2021 08:08:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Dec/18/2020	Changed Information
Dec-22-2020 13:28:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Dec/21/2020	Initial Entry
Oct-22-2020 12:30:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Oct/22/2020	Initial Entry
Sep-03-2020 13:42:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Sep/3/2020	Initial Entry
Sep-03-2020 13:40:46 (UTC-08:00) Pacific Time	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Sep/3/2020	Initial Entry

Header Text: c4591001	
Visit: Subject Status - Unscheduled	**Form:** SUBJECT STATUS - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551176	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

(US & Canada)				

Header Text: c4591001

Visit: Investigator Signature - Unscheduled | **Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Signed, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551176 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-27-2020 12:45:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Click Here to Enable	Initial Entry

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** COHORT SELECTION
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

1.	Select appropriate response - Protocol version	24 JUL 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001	
Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/3/2020

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Demography		
1.	Subject ID	[10551182]
2.	Birth Date:	(b) (6)/1958
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/3/2020
2.	Erroneous Visit	

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** INCLUSION/EXCLUSION CRITERIA
Form Version: 30-Jul-2020 21:29	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DISPOSITION - SCREENING

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Screening		
1.	Date of Completion/Discontinuation /Death	Sep/3/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** GENERAL MEDICAL HISTORY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Seasonal allergies]
	Start Date:	UNK/UNK/1970
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	UNK/UNK/2019
	Ongoing:	YES

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Sep/3/2020
2.	Weight:	[109.0]
3.	Unit:	kg
4.	Height:	[180.4]
5.	Unit:	cm
6.	Body Mass Index:	[33.5]

Vital Signs Details

7.a

Record Identifier:	1
Temperature:	[37.1]
Unit:	C
Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition		
1.	Randomization Date :	Sep/3/2020
2.	Randomization Number:	[251860]
3.	Randomization Group:	[ ]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/3/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP91XX]
5.b	Sample ID	[BP91XY]
5.c	Sample ID	[BPFTF1]
5.d	Sample ID	[BPFTF2]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/3/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BP91XV]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/3/2020 15:09
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001	
Visit: V1_DAY1_VAX1_L	**Form:** REACTOGENICITY DIARY
Form Version: 06-Jul-2020 21:53	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Reactogenicity Diary		
1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Sep/25/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP

Form Version: 15-Sep-2020 21:54 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vital Signs

1.	Date:	Sep/25/2020

Vital Signs Details

2.a

Record Identifier:	1
Temperature:	[36.5]
Unit:	C
Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/25/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BPV0BF]

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/25/2020 13:41
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	THE PROTOCOL SPECIFIED OBSERVATION PERIOD
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Oct/26/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/26/2020
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2PGK]
5.b	Sample ID	[BS8B38]
5.c	Sample ID	[BS8B37]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** DATE OF VISIT - ILLNESS ONSET
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Form Version: 20-Feb-2021 02:17	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Signs and Symptoms		
1.	Date of Assessment:	//
2.	Date of First Symptom Started:	//
3.	Symptoms Ongoing?	
Symptoms		
4.	Symptoms:	
	Was symptom present?	
Symptoms - Other		
5.	Symptoms - Other Text:	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit

Form: HEALTH CARE UTILIZATION

Form Version: 20-Feb-2021 02:19

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Health Care Utilization		
1.	Physician or Healthcare Professional:	
	Occurrence of Visits or Contacts:	

Health Care Utilization Other		
2.	Other Type of Practitioner Specify:	[ ]

Health Care Utilization		
3.	Has the subject been hospitalized due to potential COVID-19 illness?	

Header Text: c4591001

Visit: POT_COVID_ILL - New Unscheduled Visit	**Form:** ILLNESS DETAILS
Form Version: 06-Jul-2020 21:52	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Illness Details

1.	Category of Clinical Event:	
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	
3.	Toxicity Grade:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit	**Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Illness Visit		
3.	COVID-19 Illness Visit:	

Header Text: c4591001

Visit: POT_COVID_CONVA - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Unplanned - New Unscheduled Visit	**Form:** UNPLANNED VISIT
Form Version: 22-Apr-2020 21:04	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Unplanned Assessments		
1.	Assessments	

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	Oct/26/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: Follow-Up - Unscheduled | **Form:** DISPOSITION - FOLLOW-UP

Form Version: 15-Sep-2020 21:53 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Disposition - Follow-Up

1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

Header Text: c4591001	
Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit	**Form:** DATE OF VISIT - REPEAT SWAB
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	
COVID-19 Repeat Swab		
3.	COVID-19 Repeat Swab:	

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New Unscheduled Visit	**Form:** ELECTRONIC SAMPLE TRACKING - REPEAT SWAB
Form Version: 10-Oct-2020 15:57	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[ ]

Header Text: c4591001
Visit: Logs **Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02
Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Melanoma	Nov/16/2020 UNK:UNK	YES	Repeating Pages
2.	ADVERSE EVENT	2	skin lesion of scalp	Sep/25/2020 10:00	NO End Date Time: Nov/16/2020 UNK:UNK	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled	**Form:** ADVERSE EVENT REPORT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

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eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Melanoma]
4.	Start Date Time:	Nov/16/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event YES

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Sun exposure]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021036886]

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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eCRF Audit Trail History
Form Audit Trail

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[skin lesion of scalp]
4.	Start Date Time:	Sep/25/2020 10:00
5.	Is the adverse event still ongoing?	NO End Date Time: Nov/16/2020 UNK:UNK
6.	Toxicity Grade:	1
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO

8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [sun exposure]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Medication Error	Start Date	Is the medication error Still Ongoing	Study Medication Errors Action	Form Instance
1.						Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** MEDICATION ERROR

Form Version: 17-Jul-2020 21:54 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Medication Error		
1.	Category:	
2.	Medication Error (Type of Medication Error):	[ ]
3.	Start Date:	//
4.	Is the medication error still ongoing?	
5.	Latest Action Taken with Study Treatment:	
6.	Was a Concomitant Medication given?	
7.	Was a Non-Drug Treatment given?	
8.	Did the Medication Error cause the subject to be discontinued from the study?	
9.	Was this medication error associated with any adverse events?	
10.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	1	VACCINATIONS	NO	Flu vaccine.	Oct/14/2020	Repeating Pages
2. DELETED	2	VACCINATIONS	NO	Keytruda	Jan/UNK/2021	Repeating Pages
3.	3	VACCINATIONS	NO	Shingles virus vaccine	Jan/25/2021	Repeating Pages

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

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Concomitant Medications		
1.	What is the medication identifier?	[1]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Flu vaccine.]
5.	Date:	Oct/14/2020

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Deleted, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form
eCRF Audit Trail History
Form Audit Trail

Concomitant Medications		
1.	What is the medication identifier?	[~~2~~]
2.	Category:	~~VACCINATIONS~~
3.	Concomitant Medications Pre-specified:	~~NO~~
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[~~Keytruda~~]
5.	Date:	~~Jan/UNK/2021~~

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form
eCRF Audit Trail History
Form Audit Trail

Concomitant Medications		
1.	What is the medication identifier?	[3]
2.	Category:	VACCINATIONS
3.	Concomitant Medications Pre-specified:	NO
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Shingles virus vaccine]
5.	Date:	Jan/25/2021

Header Text: c4591001
Visit: Logs **Form:** CONCOMITANT MEDICATIONS - PROHIBITED
Form Version: 22-Apr-2020 21:03
Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Dose Description	Form Instance
1.	1	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	NO	Keytruda	unk	Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03 | **Form Status:** Incomplete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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eCRF Audit Trail History
Form Audit Trail

Concomitant Medications

1.	What is the medication identifier?	[1]	
2.	Category:	CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	
3.	Concomitant Medications Pre-specified:	NO	
4.	Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).	[Keytruda]	
5.	Dose:	[unk]	
6.	Dose Unit:	Unknown	Comments
7.	Dose Frequency:		Comments
8.	Route:	INTRAVENOUS	
9.	Start Date:	Jan/UNK/2021	
10.	Ongoing?	YES	

Header Text: c4591001
Visit: Logs **Form:** RADIATION TREATMENT
Form Version: 22-Apr-2020 21:02
Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Start Date	Form Instance
1.		[ ]		[ ]		Repeating Pages

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Radiation Treatment		
1.	Category:	
2.	What is the treatment Identifier?	[ ]
3.	Concomitant Non-drug Treatment Pre-specified:	
4.	Treatment:	[ ]
5.	Start Date:	//
6.	Ongoing?	

Header Text: c4591001

Visit: Logs **Form:** TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

#	Transfusion Type	Date of Transfusion	Form Instance
1.			Repeating Pages

Header Text: c4591001	
Visit: Logs - Unscheduled	**Form:** TRANSFUSIONS
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

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1.	Transfusion Type:	
2.	Date of Transfusion:	//

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Vital Signs		
1.	Date:	//

Vital Signs Details

2.	Record Identifier:	
	Temperature:	[ ]
	Unit:	
	Temperature Location:	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled | **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001	
Visit: Unplanned Vaccination - Unscheduled	**Form:** CONTACT OUTCOME - MONTH 6
Form Version: 10-Oct-2020 16:01	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Jan/14/2021
2.	Erroneous Visit	

Header Text: c4591001	
Visit: Potential ReVax Initial Contact - Unscheduled	**Form:** FURTHER VACCINATION CONFIRMATION
Form Version: 10-Dec-2020 02:25	**Form Status:** Data Complete, Frozen
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Further Vaccination Confirmation		
1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** TREATMENT UNBLINDED
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Treatment Unblinded		
1.	Date Treatment Unblinded :	Jan/14/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001	
Visit: Disposition - Unscheduled	**Form:** WITHDRAWAL OF CONSENT
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Withdrawal Of Consent		
1.	Withdrawal of Consent Date :	//

Header Text: c4591001

Visit: Disposition - Unscheduled	**Form:** DEATH DETAILS CODED
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Death Details

1.	Date of Collection / Notification of Death:	//

Cause of Death

2.	Cause of Death Status:	
	Cause of Death:	[ ]

Header Text: c4591001	
Visit: V101_VAX3	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Date of Visit		
1.	Date of Visit	Feb/23/2021
2.	Erroneous Visit	

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INFORMED CONSENT - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/23/2021

Header Text: c4591001	
Visit: V101_VAX3	**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION
Form Version: 10-Dec-2020 02:30	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Form Comments

Inclusion Criteria Not Met

1.	Description of Inclusion Criterion Not Met	Not Applicable

Exclusion Criteria Met

2.	Description of Exclusion Criterion Met	Not Applicable

Header Text: c4591001

Visit: V101_VAX3	**Form:** DISPOSITION - SCREENING FOR FURTHER VACCINATION
Form Version: 10-Dec-2020 02:31	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Disposition - Screening for Further Vaccination		
1.	Date of Completion/Discontinuation /Death :	Feb/23/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V101_VAX3 | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/23/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2P7L]
5.b	Sample ID	[BS3BBY]
5.c	Sample ID	[BS3BBX]

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Electronic Sample Tracking		
1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/23/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]

Aliquot		
Please enter barcode for each aliquot.		
5.a	Sample ID	[BR2P7J]

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/23/2021 12:12
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

Header Text: c4591001

Visit: V102_VAX4 **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V102_VAX4	**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Form Version: 22-Apr-2020 21:03	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Electronic Sample Tracking		
1.	Data Origin	
2.	Sample Type	
3.	Sample Collected?	
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[ ]
Aliquot		
Please enter barcode for each aliquot.		
5.	Sample ID	[ ]

Header Text: c4591001

Visit: V102_VAX4 **Form:** VACCINATION

Form Version: 10-Dec-2020 02:26 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Vaccination		
1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

Header Text: c4591001	
Visit: V103_MONTH1	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1 **Form:** CONTACT OUTCOME

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001	
Visit: V104_MONTH6	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6 **Form:** CONTACT OUTCOME

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001	
Visit: V105_MONTH18	**Form:** DATE OF VISIT
Form Version: 22-Apr-2020 21:02	**Form Status:** Not Started
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Date of Visit		
1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18 **Form:** CONTACT OUTCOME

Form Version: 22-Apr-2020 21:04 **Form Status:** Not Started

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Contact Outcome		
1.	Contact Type:	
2.	Was contact made?	
3.	Comments:	[ ]

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT - Unscheduled | **Form:** DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26 | **Form Status:** Not Started

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Disposition - Treatment		
1.	Date of Completion/Discontinuation /Death :	//
2.	Phase of Disposition:	
3.	Status:	
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Subject Status		
1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/26/2020

Header Text: c4591001	
Visit: Investigator Signature - Unscheduled	**Form:** CASEBOOK SIGNATURE FORM
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Signed, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

eCRF Audit Trail History

Casebook Signature Form		
1.	Casebook Signature	Click Here to Enable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Audit Trail

This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Mar-08-2021 09:03:22 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** INCLUSION/EXCLUSION CRITERIA - Comments

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Sep-03-2020 16:18:16 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Not applicable Not Applicable

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
6	Jan-21-2021 14:40:45 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Unknown --- Unknown

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Comments

Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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Item	Date	User	Comment
7	Mar-08-2021 08:32:28 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Dose frequency is every 3 weeks
7	Jan-21-2021 14:40:24 (UTC-08:00) Pacific Time (US & Canada)	Julie Glazier (pfe.jglazier)	Dose frequency is weekly

Header Text: c4591001

Visit: V101_VAX3 | **Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:30 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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Item	Date	User	Comment
Form	Feb-23-2021 15:06:36 (UTC-08:00) Pacific Time (US & Canada)	Elle Billman (pfe.ebillman)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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This form requires signing by a member of each of the following signature groups:

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
Helen Stacey	Approved	Mar-08-2021 09:03:22 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Julie Glazier	N/A	Mar-08-2021 08:32:28 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Feb-24-2021 08:06:55 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Elle Billman	N/A	Feb-23-2021 15:48:01 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Feb-23-2021 15:13:14 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Elle Billman	N/A	Feb-23-2021 13:25:37 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Feb-12-2021 15:49:45 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Julie Glazier	N/A	Feb-12-2021 15:20:10 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Feb-09-2021 09:49:15 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Megan Pastores	N/A	Feb-05-2021 15:29:13 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Jan-25-2021 09:18:31 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Ricell Ann Piojo	N/A	Jan-24-2021 22:24:59 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Jan-22-2021 16:14:20 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Bethany Wexler	N/A	Jan-22-2021 08:54:47 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Jan-21-2021 18:44:34 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Julie Glazier	N/A	Jan-21-2021 14:35:14 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Nov-17-2020 18:08:49 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Bethany Wexler	N/A	Nov-17-2020 14:19:09 (UTC-08:00) Pacific Time (US & Canada)		Edit - All signatures invalidated

Affidavit:
N/A

Helen Stacey	Approved	Oct-27-2020 16:57:08 (UTC-08:00) Pacific Time (US & Canada)	BOOK	Signed

Affidavit:
By my dated signature below, I, HelenStacey, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-03-2020 16:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 24 JUL 2020	Initial Entry

2. Select appropriate response - What cohort does the subject belong to?

Date	Location	User	Value	Reason
Sep-03-2020 16:16:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION	**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:02	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

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1. Consent Was:

Date	Location	User	Value	Reason
Sep-03-2020 16:17:46 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** OBTAINED Date Written Consent Obtained Sep/3/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Subject ID

Date	Location	User	Value	Reason
Sep-03-2020 16:16:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 10551182	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:16:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** (b) (6)/1958	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

5. Race: (Check X all that apply):

Header Text: c4591001

Visit: COHORT_SELECTION | **Form:** DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-03-2020 16:18:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** WHITE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-03-2020 16:18:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/3/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-03-2020 16:18:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/3/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1.a

Date	Location	User	Value	Reason
Sep-03-2020 16:22:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 1 **Medical History Term:** Seasonal allergies **Start Date:** UNK/UNK/1970 **Ongoing:** YES	Initial Entry

1.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:22:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Jan-22-2021 13:50:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Jan-22-2021 10:18:51 (UTC-08:00) Pacific Time (US &	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	Changed data per query

Canada)				
Jan-20-2021 07:06:40 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical - SAE reports subject has HTN (2019 onset) & metoprolol Rx (Oct 2020 start), but not recorded on prior Med Hx. Consider safety relevance of cardiovasc conditions for COVID & record, if appropriate
Sep-03-2020 16:22:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Seasonal allergies	Initial Entry

1.a Start Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:22:15 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** UNK/UNK/1970	Initial Entry

1.a Ongoing:

Date	Location	User	Value	Reason
Sep-03-2020 16:22:15 (UTC-08:00) Pacific	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

Time (US & Canada)				

1.b

Date	Location	User	Value	Reason
Jan-22-2021 10:17:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** **Line/MH Number:** 2 **Medical History Term:** Hypertension **Start Date:** UNK/UNK/2019 **Ongoing:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

1.b Line/MH Number:

Date	Location	User	Value	Reason
Jan-22-2021 10:17:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Jan-22-2021 10:17:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Hypertension	Initial Entry

1.b Start Date:

Date	Location	User	Value	Reason
Jan-22-2021 10:17:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** UNK/UNK/2019	Initial Entry

1.b Ongoing:

Date	Location	User	Value	Reason
Jan-22-2021 10:17:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/3/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 109.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** kg	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 180.4	Initial Entry

5. Unit:

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** cm	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 33.5	Initial Entry

7.a

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 37.1 **Temperature Unit:** C **Temperature Location::** FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 1	Initial Entry

7.a Temperature:

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 37.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** C	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-03-2020 16:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** RANDOMIZATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-03-2020 16:19:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/3/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-03-2020 16:19:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 251860	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

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1. Data Origin

Date	Location	User	Value	Reason
Sep-03-2020 16:30:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-03-2020 16:30:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-03-2020 16:31:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 16:30:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Sep-03-2020 16:30:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Date of Collection: Sep/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 16:31:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BP91XX	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:31:02 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP91XX	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-03-2020 16:31:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BP91XY	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.b Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:31:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP91XY	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-03-2020 16:31:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BPFTF1	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:31:23 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BPFTF1	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-03-2020 16:31:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BPFTF2	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.d Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:31:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BPFTF2	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-03-2020 16:31:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-03-2020 16:31:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-03-2020 16:31:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-03-2020 16:31:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Sep-03-2020 16:31:43 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Date of Collection: Sep/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-03-2020 16:31:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** **Sample ID:** BP91XV	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-03-2020 16:31:52 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** BP91XV	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-03-2020 16:19:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-03-2020 16:19:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-03-2020 16:19:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-03-2020 16:19:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Sep/3/2020 15:09	Initial Entry

5. Anatomical Location:

Header Text: c4591001
Visit: V1_DAY1_VAX1_L **Form:** VACCINATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182 **Subject Initials:** ---
Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-03-2020 16:19:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-03-2020 16:19:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-03-2020 16:19:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-03-2020 16:19:20 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Sep-03-2020 16:19:20	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L	**Form:** VACCINATION - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:04	**Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

(UTC-08:00) Pacific Time (US & Canada)				

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-03-2020 16:19:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Sep-25-2020 14:48:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/25/2020	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date:

Date	Location	User	Value	Reason
Sep-25-2020 14:48:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/25/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Sep-25-2020 14:48:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Record Identifier::** 1 **Temperature:** 36.5 **Temperature Unit:** C **Temperature Location::** FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Sep-25-2020 14:48:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason

Header Text: c4591001
Visit: V2_VAX2_L
Form: VITAL SIGNS - TEMP - eCRF Audit Trail History
Form Version: 15-Sep-2020 21:54
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1055
Site Name: (1055) Diablo Clinical Research Incorporated
Subject No: 10551182
Subject Initials: ---
Generated By: pfe.levissc
Generated Time (GMT): 29-Mar-2021 04:44

Sep-25-2020 14:48:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 36.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Sep-25-2020 14:48:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** C	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
Sep-25-2020 14:48:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** FOREHEAD	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Sep-25-2020 15:23:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-25-2020 15:23:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-25-2020 15:24:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-25-2020 15:23:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Sep-25-2020 15:23:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES Date of Collection: Sep/25/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-25-2020 15:24:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** **Sample ID:** BPV0BF	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-25-2020 15:24:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** BPV0BF	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-25-2020 14:48:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-25-2020 14:48:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-25-2020 14:48:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-25-2020 14:48:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/25/2020 13:41	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-25-2020 14:48:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-25-2020 14:48:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Sep-25-2020 14:48:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-25-2020 14:48:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** THE PROTOCOL SPECIFIED OBSERVATION PERIOD	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: V2_VAX2_L | **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Sep-25-2020 14:48:58 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L | **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Oct-26-2020 12:18:17 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Oct/26/2020	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Oct-26-2020 15:08:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-26-2020 15:08:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-26-2020 15:09:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-26-2020 15:08:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Oct-26-2020 15:08:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES Date of Collection: Oct/26/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-26-2020 15:09:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:** BR2PGK	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-26-2020 15:09:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BR2PGK	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-26-2020 15:09:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:** BS8B38	Initial Entry

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.b Sample ID

Date	Location	User	Value	Reason
Oct-26-2020 15:09:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BS8B38	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-26-2020 15:09:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:** BS8B37	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-26-2020 15:09:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BS8B37	Initial Entry

Header Text: c4591001

Visit: End of Treatment - Unscheduled | **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Oct-26-2020 12:18:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Oct/26/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-26-2020 12:18:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Oct-26-2020 12:18:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02 | **Form Status:**

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-17-2020 14:19:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Bethany Wexler (pfe.bwexler)	**Data Entry:** Melanoma	New Information
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Basal Cell Cancer	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason

Jan-22-2021 12:55:54 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Nov/16/2020 UNK:UNK	New Information
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Sep/25/2020 10:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-15-2021 02:45:35 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 3: Closed	Response satisfies query
Jan-13-2021 09:32:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Query 3: Answered	Adverse event is still ongoing.
Jan-12-2021 09:42:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 3: Opened	GPD CLINQUERY: Please confirm that adverse event is still ongoing.
Nov-20-2020 03:43:30 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 2: Closed	Response satisfies query

Nov-19-2020 10:44:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 2: Answered	confirmed, ongoing
Nov-19-2020 08:25:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 2: Opened	GPD CLINQUERY: Please confirm that adverse event is still ongoing and without change to severity.
Nov-17-2020 04:55:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 1: Closed	Closing query pending confirmation.
Nov-13-2020 06:55:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 1: Opened	GPD CLINQUERY: Please confirm that adverse event, onset date 25-SEP-20 is still ongoing and without change to severity.
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason

Jan-22-2021 08:58:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** 2	Changed Information
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-24-2021 22:24:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Jan-22-2021 09:46:39 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Closed	Response satisfies query
Jan-21-2021 14:35:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	For AE Melanoma: Response to "Is the adverse event serious?" is 'Yes' but "Serious

				Adverse Event Number" is blank.
Jan-21-2021 14:35:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Jan-21-2021 14:35:14 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES Is this serious event a ssociated with conge nital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong ho spitalization? NO Did this serious event result in persistent or significant disability/ incapacity? NO Is this serious event l ife threatening?	Changed Information

			NO Other medically imp ortant serious event YES	
Jan-19-2021 08:15:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 2: Opened	CLINICAL Serious criteria for event Melanoma are NONE; however, SAE report was submitted with serious criteria Medically Important. Please review, harmonize reporting and update where appropriate
Nov-20-2020 03:27:49 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 1: Closed	Response satisfies query
Nov-19-2020 14:11:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Bethany Wexler (pfe.bwexler)	Query 1: Answered	This event does not meet SAE criteria at this time.
Nov-19-2020 07:53:49 (UTC-08:00)	ACV0PFEINFP6000	Nandini Cossons (pfe.cossons_n)	Query 1: Opened	GPD CLINQUERY: Please confirm

Pacific Time (US & Canada)				that the adverse event does not meet protocol criteria for serious adverse event including important medical event.
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:*	Initial Entry

			Sun exposure	

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-22-2021 09:47:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Jan-21-2021 14:35:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-21-2021 14:35:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Changed Information
Jan-19-2021 08:16:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical Con Med is 'NO', however, SAE report states subject is receiving

				pembrolizumab. Please review, harmonize reporting, and update where applicable.
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-22-2021 09:47:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Closed	Response satisfies query
Jan-21-2021 14:35:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Jan-21-2021 14:35:42 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Changed Information
Jan-19-2021 08:16:55 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Kathryn Sewell (pfe.sewelk02)	Query 1: Opened	Clinical non-drug Treatment is 'NO', however, SAE report

				states subject is receiving radiation therapy. Please review, harmonize reporting, and update where applicable
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NOT RECOVERED/NOT RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Sep-25-2020 14:55:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Jan-24-2021 22:24:59 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Ricell Ann Piojo (pfe.quitor)	**Data Entry:** 2021036886	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Category:

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

3. Adverse Event:
(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** skin lesion of scalp	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Sep/25/2020 10:00	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO End Date Time: Nov/16/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** 1	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

Header Text: c4591001

Visit: Logs - Unscheduled | **Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 | **Form Status:** Data Complete, Frozen

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER *If Other, specify:* sun exposure	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

(UTC-08:00) Pacific Time (US & Canada)				

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** RECOVERED/RESOLVED WITH SEQUELAE	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Jan-22-2021 13:02:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Oct-26-2020 12:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

Date	Location	User	Value	Reason
Jan-22-2021 08:55:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Bethany Wexler (pfe.bwexler)	Form Deleted	Transcription Error
Jan-22-2021 08:54:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Bethany Wexler (pfe.bwexler)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Feb-05-2021 15:55:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. What is the medication identifier?

Date	Location	User	Value	Reason
Oct-26-2020 12:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Oct-26-2020 12:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Oct-26-2020 12:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Oct-26-2020 12:18:53 (UTC-08:00) Pacific	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Flu vaccine.	Initial Entry

Time (US & Canada)				

5. Date:

Date	Location	User	Value	Reason
Oct-26-2020 12:18:53 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Oct/14/2020	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

Back to Form

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-22-2021 08:54:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 2	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-22-2021 08:54:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-22-2021 08:54:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jan-22-2021 08:54:47 (UTC-08:00) Pacific Time (US &	ACV0PFEINFP6000	Bethany Wexler (pfe.bwexler)	**Data Entry:** Keytruda	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Deleted, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

***** THIS REPEATING FORM HAS BEEN DELETED *****

Canada)				

5. Date:

Date	Location	User	Value	Reason
Jan-22-2021 08:54:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Bethany Wexler (pfe.bwexler)	**Data Entry:** Jan/UNK/2021	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. What is the medication identifier?

Date	Location	User	Value	Reason
Feb-05-2021 15:55:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 3	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Feb-05-2021 15:55:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** VACCINATIONS	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Feb-05-2021 15:55:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Feb-12-2021 17:06:47	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle	Query 1: Clo	Discrepancy has been

(UTC-08:00) Pacific Time (US & Canada)		(pfe.PFETMS)	sed	closed.
Feb-12-2021 15:20:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-12-2021 15:20:10 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Shingles virus vaccine	New Information
Feb-05-2021 19:39:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (pfe.PFETMS)	Query 1: Opened	Clarify SHINGLES as follows...Are you reporting SHINGLES VIRUS VACCINE if so edit as such. Otherwise if reporting a non drug concept please move to appropriate panel for

				MedDRA coding. Thank you
Feb-05-2021 15:55:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Shingles	Initial Entry

5. Date:

Date	Location	User	Value	Reason
Feb-05-2021 15:55:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Jan/25/2021	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - Audit Trail

Form Version: 22-Apr-2020 21:03

Form Status:

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

Date	Location	User	Value	Reason
Jan-21-2021 14:40:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - PROHIBITED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Incomplete, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. What is the medication identifier?

Date	Location	User	Value	Reason
Jan-21-2021 14:40:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 1	Initial Entry

2. Category:

Date	Location	User	Value	Reason
Jan-21-2021 14:40:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** CONCOMITANT IMMUNOSUPPRESSIVE THERAPY	Initial Entry

3. Concomitant Medications Pre-specified:

Date	Location	User	Value	Reason
Jan-21-2021 14:40:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NO	Initial Entry

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

Date	Location	User	Value	Reason
Jan-21-2021 14:40:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Keytruda	Initial Entry

5. Dose:

Date	Location	User	Value	Reason
Jan-21-2021 14:40:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** unk	Initial Entry

6. Dose Unit:

Date	Location	User	Value	Reason
Jan-21-2021 14:40:45 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Unknown	Initial Entry

7. Dose Frequency:

Date	Location	User	Value	Reason
Mar-08-2021 22:23:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Gajanan Deshmukh (pfe.deshmg08)	Query 1: Closed	Response satisfies query
Mar-08-2021 08:33:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	Query 1: Answered	option not available in drop down menu, see in item level comment
Mar-07-2021 21:28:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Amol Shinde (pfe.shinda18)	Query 1: Opened	DM: Please complete this item. Thank you.

8. Route:

Date	Location	User	Value	Reason
Jan-21-2021 14:40:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** INTRAVENOUS	Initial Entry

9. Start Date:

Date	Location	User	Value	Reason
Jan-21-2021 14:40:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** Jan/UNK/2021	Initial Entry

10. Ongoing?

Date	Location	User	Value	Reason
Jan-21-2021 14:40:06 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Julie Glazier (pfe.jglazier)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Feb-05-2021 15:29:31 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Jan/14/2021	Initial Entry

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-05-2021 15:30:36 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2	Initial Entry

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-05-2021 15:29:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** Jan/14/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-05-2021 15:29:13 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Megan Pastores (pfe.mpastores)	**Data Entry:** ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Date of Visit

Date	Location	User	Value	Reason
Feb-23-2021 13:25:37 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Feb/23/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 | **Form:** INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Consent Was:

Date	Location	User	Value	Reason
Feb-23-2021 15:06:25 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** OBTAINED Date Written Consent Obtained Feb/23/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-23-2021 15:06:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Feb/23/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-23-2021 15:06:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-23-2021 15:06:47 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** COMPLETED	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Feb-23-2021 15:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-23-2021 15:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-23-2021 15:48:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-23-2021 15:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

Header Text: c4591001

Visit: V101_VAX3 | **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Feb-23-2021 15:48:27 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES Date of Collection: Feb/23/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-23-2021 15:48:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:** BR2P7L	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 15:48:38 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BR2P7L	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-23-2021 15:48:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:** BS3BBY	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

5.b Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 15:48:56 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BS3BBY	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-23-2021 15:49:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:** BS3BBX	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 15:49:07 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BS3BBX	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Data Origin

Date	Location	User	Value	Reason
Feb-23-2021 15:48:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-23-2021 15:48:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-23-2021 15:48:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-23-2021 15:48:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.

Header Text: c4591001

Visit: V101_VAX3 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Feb-23-2021 15:48:01 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES Date of Collection: Feb/23/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-23-2021 15:48:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** **Sample ID:** BR2P7J	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-23-2021 15:48:16 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** BR2P7J	Initial Entry

Header Text: c4591001

Visit: V101_VAX3 **Form:** VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26 **Form Status:** Data Complete, Locked, Frozen, Verified

Site No: 1055 **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 **Subject Initials:** ---

Generated By: pfe.levissc **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-23-2021 15:07:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-23-2021 15:07:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-23-2021 15:07:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-23-2021 15:07:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Feb/23/2021 12:12	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-23-2021 15:07:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-23-2021 15:07:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** LEFT	Initial Entry

7. Route:

Date	Location	User	Value	Reason
Feb-23-2021 15:07:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-23-2021 15:07:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason

Feb-23-2021 15:07:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-23-2021 15:07:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** 30 MINUTES	Initial Entry

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

Date	Location	User	Value	Reason
Feb-23-2021 15:07:09 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** YES	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled | **Form:** SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 | **Form Status:** Data Complete, Verified

Site No: 1055 | **Site Name:** (1055) Diablo Clinical Research Incorporated

Subject No: 10551182 | **Subject Initials:** ---

Generated By: pfe.levissc | **Generated Time (GMT):** 29-Mar-2021 04:44

Back to Form

1. Subject Status

Date	Location	User	Value	Reason
Oct-26-2020 12:18:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** FOLLOW-UP	Initial Entry
Sep-03-2020 16:19:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** ENROLLED/RANDOMIZED	Initial Entry
Sep-03-2020 16:18:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Oct-26-2020 12:18:32 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Oct/26/2020	Initial Entry
Oct-26-2020 12:18:28 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Sep/3/2020	Initial Entry
Sep-03-2020 16:19:04 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Sep/3/2020	Initial Entry

Header Text: c4591001

Visit: Subject Status - Unscheduled	**Form:** SUBJECT STATUS - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03	**Form Status:** Data Complete, Verified
Site No: 1055	**Site Name:** (1055) Diablo Clinical Research Incorporated
Subject No: 10551182	**Subject Initials:** ---
Generated By: pfe.levissc	**Generated Time (GMT):** 29-Mar-2021 04:44

Sep-03-2020 16:18:29 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	**Data Entry:** Sep/3/2020	Initial Entry

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1055

Site Name: (1055) Diablo Clinical Research Incorporated

Subject No: 10551182

Subject Initials: ---

Generated By: pfe.levissc

Generated Time (GMT): 29-Mar-2021 04:44

Back to Form

1. Casebook Signature

Date	Location	User	Value	Reason
Oct-27-2020 13:37:11 (UTC-08:00) Pacific Time (US & Canada)	ACV0PFEINFP6000	Elle Billman (pfe.ebillman)	**Data Entry:** Click Here to Enable	Initial Entry

ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Polack	Fernando	Pedro

Professional Mailing Address

Street Address:		Other Street Address:	
Luis María Campos 726 Piso 8		NA	
City: C.A.B.A.	State/Province: C.A.B.A	Country: Argentina	Zip/Postal Code: 1426
Email Address:	**fpolack@i-trials.com**	**fernando.p.polack@vanderbilt.edu**	

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Post-Doctoral, Infectious Diseases	1996-1999	Johns Hopkins University, Baltimore, Maryland. USA
Residency, Pediatrics	1993-1996	William Beaumont Hospital, Royal Oak, Michigan. USA
Residency, Pediatrics	1990-1992	Hospital Francés. Buenos Aires, Argentina
Medicine	1986-1990	Facultad de Medicina, Universidad de Buenos Aires (UBA). Buenos Aires, Argentina

Medical License Number	State/Province	Country
MN 83428	C.A.B.A	Argentina

Current Position at Study Site:

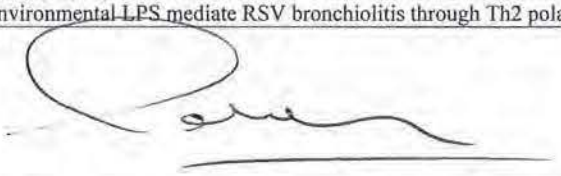
Start Date	Title	Institution or Company	State/Province & Country
2020-continue	Associate Investigator	Departamento Materno Infantil. Hospital Militar Central Cirujano Mayor Dr. Cosme Argerich	C.A.B.A., Argentina

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2016 - 2018	Board Member	International Respiratory Syncytial Virus Society	USA
2016-2017	Ad Hoc Member	Product Development for Vaccines Advisory Committee (PDVAC) at World Health Organization	Switzerland
2016-continue	Adjunct Professor	Division of Infectious Diseases, Department of Pediatrics, Vanderbilt University	USA
17-May-2017	Consultant	RBPAC, Food & Drug Administration (FDA)	USA

Brief Summary of Relevant Clinical Research Experience:

Prevention of severe covid-19 in infected elderly by early administration of convalescent plasma with high-titers of antibody against SARS- CoV2. Principal Investigator, 2020
Mortality Associated With Acute Respiratory Infections Among Children at Home. Principal Investigator, 2019 Impact of RSV Vaccine on LRTI up to 24 months of age: M-301 Follow-up. Principal Investigator, 2019-2020
Immune, clinical, demographic and viral risk factors for recurrent wheezing and poor lung function in infants with severe RSV lower respiratory tract illness. Principal Investigator, 2019-continue.
Child mortality in the community in low income regions: causes, etiologies, and risk factors in children under five years. Principal Investigator. 2017-continue
Long Term Consequences of RSV in a vulnerable population. Principal Investigator, 2017-2019.
The Impact of Respiratory Syncytial Virus Disease Prevention on Pediatric Asthma. Principal Investigator. 2016
TLR4 genotype and environmental LPS mediate RSV bronchiolitis through Th2 polarization. Principal Investigator. 2015

Signature:	**Signature Date: (dd-Mmm-yyyy)**
	06/Nov/2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.

CEPIC

CENTRO PAULISTA DE INVESTIGAÇÃO CLÍNICA

Facility address:
CEPIC – Centro Paulista de Investigação Clínica e Serviços Médicos Ltda.
Moreira e Costa, 342 – Ipiranga
04266-010 – São Paulo, SP – Brazil.
Phone Number: (55 11) 2271-3450 / Fax:(55 11) 2271-3455
E-mail: criszerb@uol.com.br

CRISTIANO AUGUSTO DE FREITAS ZERBINI

Role: Investigator
Academic Qualification: Rheumatologist

LICENCE: CRM – 19.944 / SP / Brazil

Academic Qualification

Degree/Certification :	Date: (mmm/yyyy):	Institution / City / State / Country.
Full Professor in Rheumatology	1998	Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brazil
Post Doctorate in Rheumatology	1989 - 1992	Boston University School of Medicine, Boston, MA, Estados Unidos da América
PhD in Rheumatology	1980 - 1984	Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brazil
Master ~~Maester~~'s Degree in Rheumatology	1977 - 1979	Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brazil
Rheumatology Residency	FEB/1975 – FEB/1977	Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brazil
Medicine	JAN/1968 – DEC/1973	Faculdade de Medicina da Universidade de São Paulo, São Paulo, SP, Brazil

Professional Experience

- **CEPIC – Centro Paulista de Investigação Clinica e Serviços Médicos, Ltda:**

Director / Investigator 2000 – On-going

- **Hospital Sírio – Libanês, São Paulo, SP, Brazil:**

Advanced Core Coordinator of Rheumatology 2010 – On-going

- **Serviço de Reumatologia / Hospital Heliópolis, São Paulo, SP, Brazil:**

Rheumatologist 1978 – 2014

Relevant Clinical Research Experience:

Clinical Study Phase: I, II, III and IV.

- Rheumatology — Rheumatoid Arthritis (54 studies) / Osteoarthritis (07 studies) / Psoriatic Arthritis (01 study) / Lupus (07 studies) / Osteoporosis (22 studies) / Lombalgia (01 study)
- Endocrinology — Diabetes (10 studies) / Dyslipidemia (10 studies) / Metabolic Syndrome (01 study) / Adiposidade Intra Abdominal (01 study)
- Pulmonology — Asthma (07 studies)
- Gynaecology — Menopause (01 study)
- Cardiology — Hypertension (02 studies) / Heart Failure (02 studies)
- Vaccine — Herpes Zoster (05 studies) / Flu (01 study) / Meningococcal (01 study)

17/APR/2019

Courses, Events, Certifications (related to clinical research):

- ICH/GCP Transcelarate BioPharma – Mar/2019
- Encontro de Investigadores/ Estudo de vacina para Herpes Zoster- São Paulo/ SP – Jan/2011;
- Encontro de Investigadores/ Estudo de Artrite reumatóide- Buenus Aires/ Argentina – Oct/2010
- Encontro de Investigadores/ Estudo de Artrite reumatóide- São Paulo/ SP – Apr/2010;
- Conferencista: 3rd Latin American Congress o f Clinical Research – 26 e 27 de sep/2006 - Instituto de Ensino e Pesquisa do Hospital Sirio Libanês – SP;
- Conferencista: Reunião dos CEPs do Estado de São Paulo 2005;

Languages

- Portuguese
- English

Signature: _____ Date: 17 / APR /2019.

CV_INGLÊS_VERSÃO_21MAR2016.
Rua Moreira e Costa, 342 – Ipiranga
São Paulo, SP – CEP: 04266-010
Telefone: (11) 2271-3450 Fax: (11) 2271-3455
http://www.cepic.com.br e-mail:cepic@cepic.com.br

OBRAS SOCIAIS IRMÃ DULCE

ABBREVIATED *CURRICULUM VITAE*

Full Name: Edson Duarte Moreira Junior
E-mail: edson.moreira@fiocruz.br

Current Appointment:

Name of Institution: Clinical Research Center - Organizações Sociais Irmã Dulce	
Position: Leader of the Clinical Research Center	Since: 1999

Address of Institution:

St. / Av., #, Complement – Neighbourhood – City	State	Country
Santo Antônio Hospital / Irmã Dulce Social Works Association / Avenida Dendezeiros do Bonfim, nº 161, Salvador. CEP: 40415-006	Bahia	Brazil

Graduation:

Course	Institution	Conclusion Date	Country
Medicine	federal university of Bahia	1985	Brazil

Registration Number / Medical License Number (if applicable):

Entity: CRM - Regional Council of Medicine	Register number: 9.431 – Ba / Brazil

Post-Graduation and/or Specialization:

Course	Institution	Conclusion Date	Country
Master in Public Health	Columbia University, New York	1993	EUA
PhD in Epidemiology	Columbia University, New York	1997	EUA
Post doctoral	McGill Montreal University	2012	Canada

Previous Appointments:

Institution	Position	Country	Start	Finish
Irmã Dulce Social Works Association	Leader of the Clinical Research Center.	Brazil	1999	Current
Gonçalo Moniz Research Center - FIOCRUZ.	Head of the Molecular Epidemiology and Biostatistics Laboratory.	Brazil	1998	Current

Research Experience (if applicable): Summary of experience in conducting research protocols from 1998 to the present:

Area	Role	Number of studies
Vaccine	Principal Investigator	29
Infectious diseases	Principal Investigator	9
Other	Principal Investigator	20
Total		58

Course and Training (including GCP, Language Skills etc.):

Course / Training	Conclusion Date
GCPInvestigator Site PersonnelTraining identified byTransCelerate BioPharma.	2020

Signature:	Date: 30/Jul/2020

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Addo	Marylyn	N/A

Professional Mailing Address:

Street Address: Universitätsklinikum Hamburg-Eppendorf Bernhard Nocht Centre for Clinical Trials Bernhard Nocht Institut für Tropenmedizin Bernhard-Nocht-Str.74		Other Street Address:	
City: Hamburg	State/Province: N/A	Country: Germany	Zip/Postal Code: 20246
Email Address:	**m.addo@uke.de**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Approbation (medical license)	1998	University of Bonn, Germany
Doctorate in Medicine/Microbiology	1999	University of Bonn, Germany/University of Lausanne, Switzerland
Diploma in Tropical Medicine and Hygiene	1999	London School of Hygiene and Tropical Medicine, UK
Master of science degree in Applied Molecular Biology of Infectious Diseases	1999	London School of Hygiene and Tropical Medicine, UK
Postdoctoral Research	2002	Massachusetts General Hospital, Boston, MA, USA

Medical License Number	State/Province	Country
N/A	N/A	N/A

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2018	Head, Division of Infectious Diseases	Universitaetsklinikum Hamburg-Eppendorf I. Medizinische Klinik und Poliklinik, Sektion infektiologie Martinistraße 52, Gebaeude Ost 10 20246 Hamburg	Germany

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2014-2018	Head, Division of Tropical Medicine and Infectious Diseases	Universitaetsklinikum Hamburg-Eppendorf I. Medizinische Klinik und Poliklinik	Germany
2013-present	Attending Physician Internal Medicine, Infectious Diseases	Universitaetsklinikum Hamburg-Eppendorf I. Medizinische Klinik und Poliklinik	Germany
2013-present	Honorary Professor College of Health Sciences	Nelson Mandela Medical School University of KwaZulu-Natal, Durban	South Africa
2010-2013	Consultant in Medicine	Massachusetts General Hospital, Boston, MA	USA
2010-2013	Assistant Professor in Medicine and Principal Investigator	Ragon Institute of MGH, MIT and Harvard Medical School, Boston, MA	USA
2007-2010	Instructor in Medicine	Ragon Institute of MGH, MIT and Harvard Medical School, Boston, MA	USA
2003-2006	Instructor in Medicine	AIDS Research Center / Infectious Diseases Harvard Medical School, Boston, MA	USA

Brief Summary of Relevant Clinical Research Experience:

Clinical trial experience since 1998. GCP Knowledge up to date.

Signature:	Signature Date: (dd-Mmm-yyyy)
Marylyn Addo	10 Nov 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Eich	Andreas	N/A

Professional Mailing Address:

Street Address:		Other Street Address:	
IKF Pneumologie GmbH & Co KG Institut für klinische Forschung Schaumainkai 101-103		N/A	
City: Frankfurt am Main	State/Province: N/A	Country: Germany	Zip/Postal Code: 60596
Email Address:	eich@ikf-pneumologie.de		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Specification Pulmonary Medicine	2007	Johannes-Gutenberg-University Mainz, Germany
Specification Intensive Care Medicine	2005	Johannes-Gutenberg-University Mainz, Germany
Specification Allergology	2003	Johannes-Gutenberg-University Mainz, Germany
Specification Internal Medicine	2002	Johannes-Gutenberg-University Mainz, Germany
Approbation	1995	Johannes-Gutenberg-University Mainz, Germany

Medical License Number	State/Province	Country
N/A	N/A	N/A

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2009	Medical Lead	IKF Pneumologie GmbH & Co KG, Institut für klinische Forschung	Germany

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2005-2008	Resident physician	Department of internal medicine, pulmonary diseases, University Hospital Mainz	Germany
2000-2004	Physician	Intensive care, Department of internal medicine, University Hospital Mainz	Germany
1997-2000	Physician	Klinikum Berchtesgadener Land	Germany
1994-1997	Resident physician	Hochgebirgsklinik, Davos-Wolfgang	Switzerland

Brief Summary of Relevant Clinical Research Experience:

>80 clinical studies as Investigator or Sub-Investigator phase I-IV (Asthma bronchiale, COPD, Lung cancer, Sepsis, IPF, Bronchiectasis). GCP knowledge up to date.

Signature:	Signature Date: (dd-Mmm-yyyy)
	06-Jul-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status, which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Schaefer	Axel	N/A

Professional Mailing Address:

Street Address: Medizentrum Essen Borbeck Huelsmannstrasse 6		Other Street Address: N/A	
City: Essen	State/Province: N/A	Country: Germany	Zip/Postal Code: 45355
Email Address:	**axel.schaefer@mzeb.de**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Approbation (medical license)	1996	University Giessen, Germany
Specialist of internal medicine	2000	Aerztekammer Westfalen, Germany
Specialist of sports medicine	2001	Aerztekammer Westfalen, Germany
Chirotherapy	2002	Aerztekammer Westfalen, Germany
Acupuncture	2006	Aerztekammer Nordrhein, Germany

Medical License Number	State/Province	Country
N/A	N/A	N/A

Current Position at Study Site:

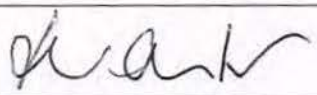
Start Date	Title	Institution or Company	State/Province & Country
2001	Specialist of internal medicine	Medizentrum Essen Borbeck Huelsmannstrasse 6, 45355 Essen	Germany

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1996-2001	Resident	Ward of internal medicine, St. Anne Hospital Herne	Germany
N/A	N/A	N/A	N/A
N/A	N/A	N/A	N/A

Brief Summary of Relevant Clinical Research Experience:

Clinical trial experience since 2003 as Investigator in about 150 phase II, III or phase IV trials. Main indications are internal medicine, sports medicine and vaccinations.
GCP knowledge up to date.

Signature:	Signature Date: (dd-Mmm-yyyy)
	18 Aug 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Luttermann	Matthias	N/A

Professional Mailing Address:

Street Address: Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher Melcherstaette 7		Other Street Address: /	
City: Stuhr	State/Province: N/A	Country: Germany	Zip/Postal Code: 28816
Email Address:	m.luttermann@gmx.de		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Approbation (medical license)	1980	University Hamburg, Germany
Doctorate	1980	University Hamburg, Germany
Expertise in emergency services	1983	Aerztkekammar Schleswig-Holstein, Germany
Specialist of internal medicine	1988	Aerztkekammar Schleswig-Holstein, Germany
Expertise in x-ray / radiology	1988	Aerztkekammar Schleswig-Holstein, Germany

Medical License Number	State/Province	Country
N/A	N/A	N/A

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2020	Consultant	Studienzentrum Brinkum Dr. Lars Pohlmeier und Torsten Drescher Melcherstaette 7, 28816 Stuhr	Germany

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2008- present	Managing director and Principal Investigator	MALU-Medizinische Studien GmbH, Anselweg 15, 26203 Wardenburg	Germany
1998-2018	Resident internal specialist	Private practice, Anselweg 15, 26203 Wardenburg	Germany
1994-1998	Deputy Chief Physician	Pius Hospital Oldenburg, Akad. Lehr-KH Uni Göttingen	Germany
1988-1994	Senior physician	Kreiskrankenhaus Kaltenkirchen	Germany
1987-1987	Ward doctor	Isreaelitisches Krankenhaus Hamburg	Germany
1981-1987	Ward doctor	Krankenhaus Pinneberg	Germany
1980-1981	Conscript surgeon major	Bundeswehr	Germany

Brief Summary of Relevant Clinical Research Experience:

Clinical trial experience since 1998 as Investigator in phase III / phase IV trials.
GCP Knowledge up to date.

Signature:	Signature Date: (dd-Mmm-yyyy)
Luttermann	05-Aug-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Schultz	Armin	N/A

Professional Mailing Address:

Street Address: CRS Clinical Research Services Mannheim GmbH Grenadierstr. 1		Other Street Address: N/A	
City: Mannheim	State/Province: N/A	Country: Germany	Zip/Postal Code: 68167
Email Address:	**armin.schultz@crs-group.de**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Approbation (medical license)	2001	University of Heidelberg, Germany
Doctorate (MD)	2007	University of Heidelberg, Germany

Medical License Number	State/Province	Country
N/A	N/A	N/A

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2015	Medical Director	CRS Clinical Research Services Mannheim GmbH	Germany

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2008 to 2015	Deputy Medical Director	CRS Clinical Research Services Mannheim GmbH	Germany
Since 2007	Physician, Department Clinical Studies	CRS Clinical Research Services Mannheim GmbH	Germany
2004-2005	Provisional Director	Institute of Clinical Pharmacology, Medical Faculty Mannheim, University of Heidelberg	Germany
2003-2007	Senior Physician	Institute of Clinical Pharmacology, Faculty for Clinical Medicine Mannheim of the University of Heidelberg	Germany

Brief Summary of Relevant Clinical Research Experience:

Clinical trial experience since 2001 as Investigator mainly in phase I and II trials.
GCP Knowledge up to date

Signature:	Signature Date: (dd-Mmm-yyyy)
A. Schultz	20 Aug 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Baumann	Sybille	N/A

Professional Mailing Address:

Street Address: CRS Clinical Research Services Berlin GmbH Sellerstr. 31		Other Street Address: N/A	
City: Berlin	State/Province: N/A	Country: Germany	Zip/Postal Code: 13353
Email Address:	**sybille.baumann@crs-group.de**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Approbation (medical license)	1987	University of Heidelberg, Germany
Doctorate	1987	Institute for Anesthesia and Resuscitation Clinic Mannheim, Germany

Medical License Number	State/Province	Country
N/A	N/A	N/A

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2016	Medical Director	CRS Clinical Research Services Berlin GmbH, Berlin; Clinical Pharmacology Unit	Germany

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2008 - 2015	Deputy Medical Director	CRS Clinical Research Services Berlin GmbH, Berlin; Clinical Pharmacology Unit	Germany
2007 - 2008	Clinical Investigator	CRS Clinical Research Services Mannheim GmbH, Mannheim	Germany
02/2007 – 03/2007	Clinical Investigator Phase I	Abott GmbH, Ludwigshafen	Germany
2004 - 2007	Head Clinical Investigator	Institute for clinical pharmacology Bobenheim	Germany

Brief Summary of Relevant Clinical Research Experience:

Clinical trial experience since 2004 as Principal Investigator mainly in phase I and II trials.
GCP knowledge up to date.

Signature: [signature]

Signature Date: (dd-Mmm-yyyy) 27 Aug 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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CLINICAL AND MEDICAL CONTROLLED DOCUMENT (CMCD) SUPPORTING DOCUMENT

Identifier	Version	Title	Effective Date
INV02-INV04-WI-GL02-SD01	2.0	ABBREVIATED CURRICULUM VITAE TEMPLATE	16-Mar-2020

Full Name:	Last Name	First Name	Middle Name
	Mitha	Essack	Aziz

Professional Mailing Address:

Street Address: Newtown Clinical Research Center,		Other Street Address: Suite 3, Newgate Centre, 104 Jeppe Street, Newtown	
City: Johannesburg	State/Province: Gauteng	Country: South Africa	Zip/Postal Code: 2113
Email Address:	emitha@newtowncrc.co.za		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Understanding Clinical Trials: Behind Statistics	2016	University of Cape Town, South Africa
MBBch	2001	University of Witwatersrand, South Africa
ACLS	2001	University of Witwatersrand, South Africa
BLS	2001	University of Witwatersrand, South Africa
Diploma Obstetrics	2000	CMSA, South Africa
MBChB	1998	University of Natal, South Africa

Medical License Number	State/Province	Country
MP0497762	Gauteng	South Africa

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2001 - Current	Principal Investigator/ Dispenser	Newtown Clinical Research Centre	Gauteng, South Africa

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2005 – 2007	Attending Doctor	Alexander Facility Clinic	South Africa
Jan 2002 - Dec 2002	Medical Officer	Non Profit Medical Center	South Africa
Jan 2000 -Dec 2002	Director	Kalafong Hospital	South Africa

Brief Summary of Relevant Clinical Research Experience:

Investigator participated in clinical trials as Principal Investigator from 2004 – Current

Therapeutic Areas:

Infectious Disease
Diabetes Musculo-skeletal Disease
Hypertension

ABBREVIATED CURRICULUM VITAE TEMPLATE

Signature:	Signature Date: (dd-Mmm-yyyy)
	28 JUL 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.

CLINICAL AND MEDICAL CONTROLLED DOCUMENT (CMCD) SUPPORTING DOCUMENT

Identifier	Version	Title	Effective Date
INV02-INV04-WI-GL02-SD01 TEMPLATE	2.0	ABBREVIATED CURRICULUM VITAE	16-Mar-2020

Instructional text is denoted in GREEN. DELETE green text upon completion of this template. This template is a sample and can be used to create the abbreviated curriculum vitae (CV). If this template is not used, please note the underlined SECTION headings represent the required components that must be included in the abbreviated CV.

Must be typed and all sections must be completed.

Full Name:	Last Name	First Name	Middle Name *if applicable*
	Fouché	Leon	Frederik

Professional Mailing Address: *Principal investigator information should be consistent with box 1 of the Statement of Investigator Form Food and Drug Administration (FDA) 1572 or Investigator International Council for Harmonisation (ICH) Good Clinical Practices (GCP) Attestation Form*

Street Address: Limpopo Clinical Research Initiative, Tamboti Medical Centre		Other Street Address: 11 Van der Bijl Street	
City: Thabazimbi	State/Province: Limpopo	Country: South Africa	Zip/Postal Code: 0380
Email Address:	leon.fouche@iafrica.com		

Academic Qualifications:

Degree and/or Certification	**Date (yyyy)**	**Institution and/or Country** *Where Obtained*
B.Med.Sc.	1986	University of the Free State, Bloemfontein, South Africa
Hons.B.Med.Sc.	1987	University of the Free State, Bloemfontein, South Africa
M.B.Ch.B.	1992	University of the Free State, Bloemfontein, South Africa

Medical License Number	**State/Province**	**Country**
All MD/DO/equivalents must provide a medical license number, and the state/province and country where the license was obtained. For countries that do not disclose or provide license numbers enter "Not applicable". Note: If the MD or DO is in Residency and not yet licensed, indicate Residency or degree on the CV		
Health Professions' Council of South Africa (HPCSA) MP0397377	N/A	Republic of South Africa
Medical Council of Ireland Registration No. 262451	N/A	Republic of Ireland

Current Position at Study Site: *current affiliation as noted in box 3 of the Form FDA 1572 or ICH GCP Attestation*

Start Date	**Title**	**Institution or Company**	**State/Province & Country**
2009	Principal Investigator	Limpopo Clinical Research Initiative	Limpopo, South Africa

ABBREVIATED CURRICULUM VITAE TEMPLATE

Previous Relevant Positions Including Academic Appointments: *provide previous 4 relevant positions if applicable*

Start and End Dates	Title	Institution or Company	Country
1999 - 2009	Independant Medical Practitioner	Dr L F Fouché	South Africa
1994 - 1999	Head Consultant	Medicross Healthcare Group	South Africa
1993 - 1994	Consultant	Medicross Healthcare Group	South Africa
1992 - 1993	Intern	Bloemfontein Academic Hospitals	South Africa

Brief Summary of Relevant Clinical Research Experience: *Enter "None" if no previous clinical research experience*

Principal Investigator during the past 20 years in more than 80 phase 2 to 4 clinical research studies of multiple therapeutic and disease areas with various consequent publications.

Signature:

Signature Date: (dd-Mmm-yyyy)
24 JUL. 2020.

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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Investigator maintains the original, signed copy of his/her abbreviated CV in the investigator site file. A copy must be forwarded with the other investigator initiation package documents.

CLINICAL AND MEDICAL CONTROLLED DOCUMENT (CMCD) SUPPORTING DOCUMENT

Identifier	Version	Title	Effective Date
INV02-INV04-WI-GL02-SD01	2.0	ABBREVIATED CURRICULUM VITAE TEMPLATE	16-Mar-2020

Full Name:	Last Name	First Name	Middle Name
	Musungaie	Dany	Badibanga

Professional Mailing Address:

Street Address: Medicross Pretoria West 1st floor, 551 WF Nkomo street,		Other Street Address:N/A	
City: Pretoria	State/Province: Gauteng	Country: South Africa	Zip/Postal Code: 0183
Email Address:	dbmusungaie@outlook.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Diploma of Bsc Biomedical	1993	University of Kinshasa, DRC, Congo
Diploma of Doctor of Medicine	1998	University of Kinshasa, DRC, Congo

Medical License Number	State/Province	Country
MP: 0563803	Gauteng	South Africa

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
Nov 2012	Principal Investigator	Jongaie Research	Gauteng, South Africa

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
Jan 1998-Dec2002	General Practitioner	Gracia Medical Clinic	Congo
Jan 2003- Jul 2010	Senior Medical Officer	George Mukhare Hospital	South Africa
Jan 2006- Nov2009	General practitioner	Emergency units Carstenhof and Mediclinic	South Africa
Dec 2009 and current	General Practitioner and travel clinic with immunization	Medicross Pretoria West	South Africa

Brief Summary of Relevant Clinical Research Experience:

Since 2009 involved in clinical trials with responsibilities of Principal Investigator, Sub-Investigator and Dispenser.

Signature:	Signature Date: (dd-Mmm-yyyy)
	24 Jul 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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CLINICAL AND MEDICAL CONTROLLED DOCUMENT (CMCD) SUPPORTING DOCUMENT

Identifier	Version	Title	Effective Date
INV02-INV04-WI-GL02-SD01	2.0	ABBREVIATED CURRICULUM VITAE TEMPLATE	16-Mar-2020

Full Name:	Last Name	First Name	Middle Name
	Nell	Haylene	N/A

Professional Mailing Address:

Street Address: Tiervlei Trial Centre, Basement Level, Karl Bremer Hospital		Other Street Address: c/o Mike Pienaar Boulevard & Frans Conradie Avenue	
City: Bellville, Cape Town	State/Province: Western Cape	Country: South Africa	Zip/Postal Code: 7530
Email Address:	haylenenell@ttctrials.co.za		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Hons. BSc (Clinical Pharmacology) Cum Laude	1997	University of Stellenbosch, South Africa
Hons. BSc (Epidemiology & Biostatistics) Cum Laude	1991	University of Stellenbosch, South Africa
MBChB	1982	University of Stellenbosch, South Africa

Medical License Number	State/Province	Country
MP0261459	N/A	South Africa

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2005	Executive Head / Investigator	Tiervlei Trial Centre	Cape Town, Western Cape, South Africa

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2013 – Current	Vice President	FUNDISA Academy	South Africa
2011 – Current	Honorary Lecturer	University of Stellenbosch	South Africa
2010 – Current	Co-Presenter (Pharmacology)	University of Stellenbosch	South Africa
2006 - 2010	Medical Advisor	Cape Town Data	South Africa

Brief Summary of Relevant Clinical Research Experience:

Dr Nell has been PI on a FIM Vaccine study as well as PI on multiple other vaccine trials.
She has >30yrs clinical trial experience as both PI & Sub-I and has been PI on multiple Biologics studies as well.

Signature:	Signature Date: (dd-Mmm-yyyy)
Nell	30 Jul 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	UNAL	Serhat	-

Professional Mailing Address:

Street Address:	Other Street Address:		
Hacettepe Universitesi Tip Fakultesi,	Enfeksiyon Hastaliklari ve Klinik Mikrobiyoloji Anabilim Dali. Sihhiye		
City: Ankara	State/Province: N/A	Country: Turkey	Zip/Postal Code: 06230
Email Address:	**sunal@hacettepe.edu.tr**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Prof. Dr.	1995	Hacettepe University Faculty of Medicine, Ankara, Turkey
Infection Diseases Spec. Dr.	1992	Harvard Medical School, New England Deaconess Hospital, Boston, USA
Assoc. Prof. Dr.	1989	Hacettepe University Faculty of Medicine, Ankara, Turkey
Internal Medicine Spec. Dr.	1985	Hacettepe University Faculty of Medicine, Ankara, Turkey
Medical Doctor	1981	Hacettepe University Faculty of Medicine, Ankara, Turkey

Medical License Number	State/Province	Country
Diploma No: 81AA076 Diploma Registration No: 31774	N/A	Turkey

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1995	Prof. Dr.	Hacettepe University Faculty of Medicine, Department of Infection Diseases and Clinical Microbiology, Ankara	Turkey

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1992 - 1995	Assoc. Prof. Dr.	Hacettepe University Faculty of Medicine, Ankara	Turkey
1989 - 1992	Fellow- (Infection Diseases Residency)	Harvard Medical School, New England Deaconess Hospital, Boston	USA
1989 - 1989	Assoc. Prof. Dr.	Hacettepe University Faculty of Medicine, Ankara	Turkey
1985 - 1989	Internal Medicine Spec. Dr.	Hacettepe University Faculty of Medicine, Ankara	Turkey
1981 - 1985	Medical Doctor (Internal Medicine Residency)	Hacettepe University Faculty of Medicine, Ankara	Turkey

Brief Summary of Relevant Clinical Research Experience:

GCP Training 2019

-Participating 20 clinical trial as PI, the ongoing studies listed below:
-2017, Pseudomonas Aeruginosa, (EVADE), Phase II
-2018, Influenza A, (CR108399), Phase III
-2018, Influenza A, (CR108400), Phase III
-2019, Severe Influenza, (CP40617) Phase III
-2019, Acinetobacter Baumannii-calcoaceticus Complex (ATTACK), Phase III
-2019, Influenza, (CP40617) Phase III

Signature:	Signature Date: (dd-Mmm-yyyy)
Serhat Unal Serhat Unal 24 Aug 2020 09:01:036+0000 REASON: I approve this document 1ead0a44-c2d3-4ca0-a599-71e41dd0e2f8	

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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Audit Trail Report

Document Name C4591001_INV02-INV04-WI-GL02-SD01 2 0 Abb CV Temp_SerhatUNAL.pdf
Document ID 34af45ae-a8bb-49c1-8c6d-145f5e68bfad

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24 Aug 2020 12:01 036+0300	Serhat Unal UUID : 1ead0a44-c2d3-4ca0-a599-71a41dd0e2f8 Email : sunal@hacettepe.edu tr	Signed	The recipient signed the document with no comments. Comments: None Reason: I approve this document
24 Aug 2020 12:02 039+0300	Didem Erten UUID : 62201ce7-9f30-4ba7-84b2-bded2517df4b Email : didem erten@iconplc com	Completed	The ePak is completed successfully.

Validation Report

1

Subject CN:	MSB
Subject DN:	EMAILADDRESS=operations@msbdocs.com,CN=MSB,OU=MSB,O=TAIGLE LLC,L=Irvine,ST=California,C=US
Email:	operations@msbdocs.com
Serial #:	103155442024134641897105422308128156249
Issuer DN:	CN=Entrust Class 3 Client CA - SHA256,OU=(c) 2015 Entrust, Inc. - for authorized use only,OU=See www.entrust.net/legal-terms,O=Entrust, Inc.,C=US
Signing Time:	24 Aug 2020 12:01:036+0300

- The Certificate chain was successfully built to a Trusted Root Certificate.
- The Signer's identity is valid.
- The Document has not been modified since the signature was applied.

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	BALIK	Ismail	-

Professional Mailing Address:

Street Address:	Other Street Address:		
Ankara Universitesi Tip Fakultesi, Ibni Sina Hastanesi,	Enfeksiyon Hastaliklari ve Klinik Mikrobiyoloji Anabilim Dali, Sihhiye		
City: Ankara	State/Province: N/A	Country: Turkey	Zip/Postal Code: 06230
Email Address:	(b) (6)		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Prof. Dr.	1996	Ankara University Faculty of Medicine, Ibni Sina Hospital, Ankara, Turkey
Assoc. Prof. Dr.	1991	Ankara University Faculty of Medicine, Ibni Sina Hospital, Ankara, Turkey
Assist. Prof. Dr.	1990	Ankara University Faculty of Medicine, Ibni Sina Hospital, Ankara, Turkey
Infection Diseases Spec. Dr.	1989	Ankara University Faculty of Medicine, Ibni Sina Hospital, Ankara, Turkey
Medical Doctor	1983	Uludag University Faculty of Medicine, Bursa, Turkey

Medical License Number	State/Province	Country
42354	N/A	Turkey

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1996	Prof. Dr.	Ankara University Faculty of Medicine, Ibni Sina Hospital, Department of Infection Diseases and Clinical Microbiology, Ankara	Turkey

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1998 - 1998	Researcher (also still Prof. Dr. at Ankara Uni. Fac. of Medicine)	Rockefeller Research Center, Newyork	USA
1991 - 1996	Assoc. Prof. Dr.	Ankara University Faculty of Medicine, Ibni Sina Hospital, Ankara	Turkey
1990 - 1991	Assist. Prof. Dr.	Ankara University Faculty of Medicine, Ibni Sina Hospital, Ankara	Turkey
1989 - 1990	Infection Diseases Spec. Dr	Ankara University Faculty of Medicine, Ibni Sina Hospital, Ankara	Turkey
1989 -1989	Researcher	Milano University Faculty of Meicine, Milano	Italy
1985 - 1989	Medical Doctor (Infection Diseases Residency)	Ankara University Faculty of Medicine, Ibni Sina Hospital, Ankara	Turkey
1983 - 1985	Medical Doctor	Afyon 3rd Health Center, Afyon	Turkey

Brief Summary of Relevant Clinical Research Experience:

GCP Training 2019

Experienced in Clinical trials with different indications as PI (Meningitis Vaccine, Hepatitis study, Infectious Disease, … etc)
examples from the studies :
-Ventilator-Associated Pneumonia – (CLASS)- prospective study
- Methicillin-Resistant Staphylococcus Aureus Hospital-Acquired Pneumonia – Phase III

Ismail Balik

Signature: Ismail Balik 15 Aug 2020 10:28:019+0000
REASON: I approve this document

Signature Date: (dd-Mmm-yyyy)

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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Validation Report

1 ✓

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Subject DN:	EMAILADDRESS=operations@msbdocs.com,CN=MSB,OU=MSB,O=TAIGLE LLC,L=Irvine,ST=California,C=US
Email:	operations@msbdocs.com
Serial #:	103155442024134641897105422308128156249
Issuer DN:	CN=Entrust Class 3 Client CA - SHA256,OU=(c) 2015 Entrust, Inc. - for authorized use only,OU=See www.entrust.net/legal-terms,O=Entrust, Inc.,C=US
Signing Time:	15 Aug 2020 13:28:019+0300

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✓ The Signer's identity is valid.
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Audit Trail Report

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Document ID: 88d082ef-04fb-4daa-889a-57378f0b49c8

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15 Aug 2020 13:28:019+0300	Ismail Balik UUID : 4425923b-dd5d-4278-b04b-2058902a065b Email : (b) (6)	Signed	The recipient signed the document with no comments. Comments: None Reason: I approve this document
15 Aug 2020 13:28:058+0300	Didem Erten UUID : 62201ce7-9f30-4ba7-84b2-bded2517df4b Email : didem.erten@iconplc.com	Completed	The ePak is completed successfully.

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	KOKSAL	Iftihar	-

Professional Mailing Address:

Street Address:	Other Street Address:		
Acibadem Atakent Hastanesi,	Enfeksiyon Hastaliklari ve Klinik Mikrobiyoloji Birimi, Kucukcekmece		
City: Istanbul	State/Province: N/A	Country: Turkey	Zip/Postal Code: 34303
Email Address:	**iftahar koksal@acibadem.com**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Prof. Dr.	1998	Karadeniz Technical University Faculty of Medicine, Trabzon, Turkey
Assoc. Prof. Dr.	1992	Karadeniz Technical University Faculty of Medicine, Trabzon, Turkey
Assist. Prof. Dr.	1989	Karadeniz Technical University Faculty of Medicine, Trabzon, Turkey
Infection Diseases Spec. Dr.	1987	Hacettepe University Faculty of Medicine, Ankara, Turkey
Medical Doctor	1981	Diyarbakir University Faculty of Medicine, Diyarbakir, Turkey

Medical License Number	State/Province	Country
25320 - 32020	N/A	Turkey

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2020	Prof. Dr.	Acibadem Atakent Hospital, Department of Infection Diseases and Clinical Microbiology, Istanbul	Turkey

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1998 - 2020	Prof. Dr.	Karadeniz Technical University Faculty of Medicine, Trabzon	Turkey
1992 - 1998	Assoc. Prof. Dr.	Karadeniz Technical University Faculty of Medicine, Trabzon	Turkey
1989 - 1992	Assist. Prof. Dr.	Karadeniz Technical University Faculty of Medicine, Trabzon	Turkey
1987 - 1988	Infection Diseases Spec. Dr.	Karadeniz Technical University Faculty of Medicine, Trabzon	Turkey
1982 - 1987	Medical Doctor (Infection Diseases Residency)	Hacettepe University Faculty of Medicine, Ankara	Turkey

Brief Summary of Relevant Clinical Research Experience:

GCP Training 2019

-Participating about 30 clinical trial as PI, the latest studies listed below:
-2018, Severe Infections Caused by Carbapenem-resistant Gram-negative Pathogens (1424R2131), Phase III
-2018, Influenza A, (CR108399), Phase III
-2018, Influenza A, (CR108400), Phase III
-2019, Respiratory Syncytial Virus Infection (53718678RSV2002), Phase II (participating as Sub-I)
-2019, Chronic Hepatitis B (REEF-1), Phase IIb
-2019, Ventilator-Associated Pneumonia (VAP) Caused by S. Aureus (AR-301-002), Phase III

Signature:	Signature Date: (dd-Mmm-yyyy)
IFTIHAR KOKSAL FT IHAR KOKSAL 19 Aug 2020 06:32:036+0000 REASON: approve this document 702bdd90-d974-4774-9b0-0a5ec7c98e36	

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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Audit Trail Report

Document Name: C4591001_INV02-INV04-WI-GL02-SD01 2.0 Abb CV Temp_IftiharKOKSAL.pdf
Document ID: bd55d2a5-c8db-46de-a091-5a022ec7bd02

Time Stamp	User	Action	Details
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14 Aug 2020 16:00:029+0300	IFTIHAR KOKSAL UUID : 702bdd90-d974-4774-9b0f-0a5ee7c98e36 Email : (b) (6)	RequestSent	Sign request sent to ePak recipient.
19 Aug 2020 09:30:052+0300	IFTIHAR KOKSAL UUID : 702bdd90-d974-4774-9b0f-0a5ee7c98e36 Email : (b) (6)	DocumentViewed	Document viewed by signer.
19 Aug 2020 09:32:036+0300	IFTIHAR KOKSAL UUID : 702bdd90-d974-4774-9b0f-0a5ee7c98e36 Email : (b) (6)	Signed	The recipient signed the document with no comments. Comments: None Reason: I approve this document
19 Aug 2020 09:35:015+0300	Didem Erten UUID : 62201ce7-9f30-4ba7-84b2-bded2517df4b Email : didem.erten@iconplc.com	Completed	The ePak is completed successfully.

Validation Report

1 ✓

Subject CN:	MSB
Subject DN:	EMAILADDRESS=operations@msbdocs.com,CN=MSB,OU=MSB,O=TAIGLE LLC,L=Irvine,ST=California,C=US
Email:	operations@msbdocs.com
Serial #:	103155442024134641897105422308128156249
Issuer DN:	CN=Entrust Class 3 Client CA - SHA256,OU=(c) 2015 Entrust, Inc. - for authorized use only,OU=See www.entrust.net/legal-terms,O=Entrust, Inc.,C=US
Signing Time:	19 Aug 2020 09:32:036+0300

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✓ The Signer's identity is valid.
✓ The Document has not been modified since the signature was applied.

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	ALTIN	Sedat	-

Professional Mailing Address:

Street Address:	Other Street Address:		
Istanbul Yedikule Gogus Hastaliklari ve Gogus Cerrahisi	Egitim Arastirma Hastanesi, Gogus Hastaliklari Birimi, Zeytinburnu		
City: Istanbul	State/Province: N/A	Country: Turkey	Zip/Postal Code: 34020
Email Address:	(b) (6)		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Prof. Dr.	2011	Erzincan University Faculty of Medicine, Erzincan, Turkey
Business Management Graduate	2006	Anadolu University Faculty of Business Administration (Distance Education), Eskisehir, Turkey
Assoc. Prof. Dr.	1996	Istanbul Yedikule Chest Diseases and Thoracic Surgery Training and Research Hospital, Istanbul, Turkey
Chest Disease Spec. Dr.	1992	Istanbul Yedikule Chest Diseases and Thoracic Surgery Training and Research Hospital, Istanbul, Turkey
Medical Doctor	1987	Istanbul University Cerrahpasa Faculty of Medicine, Istanbul, Turkey

Medical License Number	State/Province	Country
5241	N/A	Turkey

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2012	Prof. Dr.	Istanbul Yedikule Chest Diseases and Thoracic Surgery Training and Research Hospital, Chest Diseases Division, Istanbul	Turkey

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2011 - 2012	Prof. Dr.	Erzincan University Faculty of Medicine, Erzincan, Turkey	Turkey
1996 - 2011	Assoc. Prof. Dr.	Istanbul Yedikule Chest Diseases and Thoracic Surgery Training and Research Hospital, Istanbul	Turkey
1992 - 1996	Chest Disease Spec. Dr.	Istanbul Yedikule Chest Diseases and Thoracic Surgery Training and Research Hospital, Istanbul	Turkey
1991 - 1992	Medical Doctor (Chest Disease Residency)	Istanbul Yedikule Chest Diseases and Thoracic Surgery Training and Research Hospital, Istanbul	Turkey
1987 - 1991	Medical Doctor	Istanbul Yedikule Chest Diseases and Thoracic Surgery Training and Research Hospital, Istanbul	Turkey

Brief Summary of Relevant Clinical Research Experience:

GCP Training 2019

Previous experience in clinical trials in COPD (both Phase IV and III) as PI; a few example from latest studies:

2018 - Acute Exacerbation of Chronic Bronchitis (AECB) and Community-acquired Pneumonia (CAP), Phase IV
2019- Tuberculosis, retrospective study

Signature:	Signature Date: (dd-Mmm-yyyy)
Sedat Altin Sedat A tin 12 Aug 2020 16:32:027+0000 REASON: I approve this document a7dc06b0-4b23-4bec-b5e5-0c4180a2b5c9	

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.

[1] Facsimile of Original Digital Signature

Audit Trail Report

Date	User	Document	Action	Details
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12 Aug 2020 18:26:055+0300	Sedat Altin		RequestSent	Sign request sent to ePak recipient. User UUID : a7dc06b0-4b23-4bec-b5e5-0c4180a2b5c9 User Email (b) (6)
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12 Aug 2020 19:29:053+0300	Sedat Altin	C4591001 - INV02-INV04-WI-GL02-RF06 2.0 PDPForm_Non-US Sites_SedatAltin.pdf	DocumentViewed	Document viewed by signer. User UUID : a7dc06b0-4b23-4bec-b5e5-0c4180a2b5c9 User Email : (b) (6) Document UUID : 04310b01-2755-49fa-bc05-1dc58c853aeb
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12 Aug 2020 19:31:041+0300	Sedat Altin	C4591001_INV02-INV04-WI-GL02-RF08 3.0 Inv Protocol Accept F_Prot Am 5_SedatALTIN.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I approve this document User UUID : a7dc06b0-4b23-4bec-b5e5-0c4180a2b5c9 User Email : (b) (6) Document UUID : 9a1b5c2a-f848-443e-a319-2cf3bfc956a2
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12 Aug 2020 19:35:023+0300	Sedat Altin	C4591001_SQT_Financial-Disclosure_2019_Version-3.2_SedatAltin.pdf	SignerTagFilled	The signer filled Custom Checkbox. Value: true User UUID : a7dc06b0-4b23-4bec-b5e5-0c4180a2b5c9 User Email (b) (6) Document UUID : 4c42022e-df58-4562-a501-db8fb7e2207a
12 Aug 2020 19:35:023+0300	Sedat Altin	C4591001_SQT_Financial-Disclosure_2019_Version-3.2_SedatAltin.pdf	SignerTagFilled	The signer filled Custom Checkbox. Value: true User UUID : a7dc06b0-4b23-4bec-b5e5-0c4180a2b5c9 User Email : (b) (6) Document UUID : 4c42022e-df58-4562-a501-db8fb7e2207a
12 Aug 2020 19:35:023+0300	Sedat Altin	C4591001_SQT_Financial-Disclosure_2019_Version-3.2_SedatAltin.pdf	SignerTagFilled	The signer filled Custom Checkbox. Value: true User UUID : a7dc06b0-4b23-4bec-b5e5-0c4180a2b5c9 User Email : (b) (6) Document UUID : 4c42022e-df58-4562-a501-db8fb7e2207a
12 Aug 2020 19:35:023+0300	Sedat Altin	C4591001_SQT_Financial-Disclosure_2019_Version-3.2_SedatAltin.pdf	SignerTagFilled	The signer filled Custom Checkbox. Value: true User UUID : a7dc06b0-4b23-4bec-b5e5-0c4180a2b5c9 User Email : (b) (6) Document UUID : 4c42022e-df58-4562-a501-db8fb7e2207a
12 Aug 2020 19:35:023+0300	Sedat Altin	C4591001_SQT_Financial-Disclosure_2019_Version-3.2_SedatAltin.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I approve this document User UUID : a7dc06b0-4b23-4bec-b5e5-0c4180a2b5c9 User Email (b) (6) Document UUID : 4c42022e-df58-4562-a501-db8fb7e2207a
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12 Aug 2020 19:36:023+0300	Sedat Altin	C4591001_INV02-INV04-WI-GL02-RF09 5.0 Inv ICHGCP Attes Form_SedatALTIN.pdf	DocumentViewed	Document viewed by signer. User UUID : a7dc06b0-4b23-4bec-b5e5-0c4180a2b5c9 User Email : (b) (6) Document UUID : 7854bc5f-421e-4a17-97fc-a573c739b02f
12 Aug 2020 19:37:035+0300	Sedat Altin	C4591001_INV02-INV04-WI-GL02-RF09 5.0 Inv ICHGCP Attes Form_SedatALTIN.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I approve this document User UUID : a7dc06b0-4b23-4bec-b5e5-0c4180a2b5c9 User Email : (b) (6) Document UUID : 7854bc5f-421e-4a17-97fc-a573c739b02f

MSB

Validation Report as of: 21 Aug 2020 09:29:052+0300

1

Subject CN	MSB
Subject DN	EMAILADDRESS=operations@msbdocs.com,CN=MSB,OU=MSB,O=TAIGLE LLC,L=Irvine,ST=California,C=US
Email	operations@msbdocs.com
Serial #	103155442024134641897105422308128156249
Issuer DN	CN=Entrust Class 3 Client CA - SHA256,OU=(c) 2015 Entrust, Inc. - for authorized use only,OU=See www.entrust.net/legal-terms,O=Entrust, Inc.,C=US
Signing Time	12 Aug 2020 19:32:027+0300

The Certificate chain was successfully built to a Trusted Root Certificate.

The Signer's identity is valid.

The Document has not been modified since the signature was applied.

12 Aug 2020 19 37:035+0300	Didem Erten		Completed	The ePak completed the workflow successfully custodian. User UUID : 62201ce7-9f30-4ba7-84b2-bded2517df4b User Email : didem.erten@iconplc com

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	MERT	Ali	-

Professional Mailing Address:

Street Address:	Other Street Address:		
Medipol Mega Universite Hastanesi,	Ic Hastaliklari Anabilim Dali, Bagcilar		
City: Istanbul	State/Province: N/A	Country: Turkey	Zip/Postal Code: 34214
Email Address:	**alimert@medipol.edu.tr**		

Academic Qualifications:

Degree and/or Certification	**Date (yyyy)**	**Institution and/or Country**
Prof. Dr.	2003	Istanbul University Cerrahpasa Faculty of Medicine, Istanbul, Turkey
Assoc. Prof. Dr.	1997	Istanbul University Cerrahpasa Faculty of Medicine, Istanbul, Turkey
Internal Medicine Spec. Dr.	1992	Istanbul University Cerrahpasa Faculty of Medicine, Istanbul, Turkey
Medical Doctor	1982	Trakya University Faculty of Medicine, Edirne, Turkey

Medical License Number	**State/Province**	**Country**
39984	N/A	Turkey

Current Position at Study Site:

Start Date	**Title**	**Institution or Company**	**State/Province & Country**
2012	Prof. Dr.	Medipol Mega University Hospital, Department of Internal Medicine, Istanbul	Turkey

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	**Title**	**Institution or Company**	**Country**
2003 - 2012	Prof. Dr.	Istanbul University Cerrahpasa Faculty of Medicine, Istanbul	Turkey
1997 - 2003	Assoc. Prof. Dr.	Istanbul University Cerrahpasa Faculty of Medicine, Istanbul	Turkey
1992 - 1997	Internal Medicine Spec. Dr.	Istanbul University Cerrahpasa Faculty of Medicine, Istanbul	Turkey
1987 - 1992	Medical Doctor (Internal Medicine Residency)	Istanbul University Cerrahpasa Faculty of Medicine, Istanbul	Turkey
1982 - 1987	Medical Doctor	Eskipazar Health Center, Karabuk	Turkey

Brief Summary of Relevant Clinical Research Experience:

2008 - HBV infection – observational study

Signature: Ali Mert Ali Mert 13 Aug 2020 12:15:007+000 REASON: I approve this document 95fb30b7-a4e1-4dac-925e-42cd84bad3ad	**Signature Date: (dd-Mmm-yyyy)**

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.

[1] Facsimile of Original Digital Signature

MSB

Validation Report as of: 21 Aug 2020 09:19:001+0300

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Subject CN	MSB
Subject DN	EMAILADDRESS=operations@msbdocs.com,CN=MSB,OU=MSB,O=TAIGLE LLC,L=Irvine,ST=California,C=US
Email	operations@msbdocs.com
Serial #	103155442024134641897105422308128156249
Issuer DN	CN=Entrust Class 3 Client CA - SHA256,OU=(c) 2015 Entrust, Inc. - for authorized use only,OU=See www.entrust.net/legal-terms,O=Entrust, Inc.,C=US
Signing Time	13 Aug 2020 15:15:007+0300

The Certificate chain was successfully built to a Trusted Root Certificate.

The Signer's identity is valid.

The Document has not been modified since the signature was applied.

Audit Trail Report

Date	User	Document	Action	Details
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13 Aug 2020 15 00:047+0300	Ali Mert	C4591001_INV02-INV04-WI-GL02-RF08 3.0 Inv Protocol Accept F_Prot Am 5_AliMERT.pdf	DocumentViewed	Document viewed by signer. User UU D : 95fb30b7-a4e1-4dac-925e-42cd84bad3ad User Email : alimert@medipol.edu tr Document UUID : 754572c7-149d-4325-969f-ec581d944d12
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13 Aug 2020 15:14:032+0300	Ali Mert	C4591001_INV02-INV04-WI-GL02-SD01 2.0 Abb CV Temp_AliMERT.pdf	DocumentViewed	Document viewed by signer. User UU D : 95fb30b7-a4e1-4dac-925e-42cd84bad3ad User Email : alimert@medipol.edu tr Document UUID : 3b5a46bd-dcba-4ed4-a9fa-5ef239f45b50
13 Aug 2020 15:15:008+0300	Ali Mert	C4591001_INV02-INV04-WI-GL02-SD01 2.0 Abb CV Temp_AliMERT.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I approve this document User UU D : 95fb30b7-a4e1-4dac-925e-42cd84bad3ad User Email : alimert@medipol.edu tr Document UUID : 3b5a46bd-dcba-4ed4-a9fa-5ef239f45b50
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13 Aug 2020 15:17:025+0300	Ali Mert	C4591001_SQT_Financial-Disclosure_2019_Version-3 2_AliMert.pdf	SignerTagFilled	The signer filled Custom Checkbox. Value: true User UU D : 95fb30b7-a4e1-4dac-925e-42cd84bad3ad User Email : alimert@medipol.edu tr Document UU D : f0b0ace6-e3a6-4dcd-98a4-eaf9ad853611
13 Aug 2020 15:17:025+0300	Ali Mert	C4591001_SQT_Financial-Disclosure_2019_Version-3 2_AliMert.pdf	SignerTagFilled	The signer filled Custom Checkbox. Value: true User UU D : 95fb30b7-a4e1-4dac-925e-42cd84bad3ad User Email : alimert@medipol.edu tr Document UU D : f0b0ace6-e3a6-4dcd-98a4-eaf9ad853611
13 Aug 2020 15:17:025+0300	Ali Mert	C4591001_SQT_Financial-Disclosure_2019_Version-3 2_AliMert.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I approve this document User UU D : 95fb30b7-a4e1-4dac-925e-42cd84bad3ad User Email : alimert@medipol.edu tr Document UU D : f0b0ace6-e3a6-4dcd-98a4-eaf9ad853611

13 Aug 2020 15:17:025+0300	Didem Erten		Completed	The ePak completed the workflow successfully custodian. User UUID : 62201ce7-9f30-4ba7-84b2-bded2517df4b User Email : didem.erten@iconplc com

DocUUID : 3b5a46bd-dcba-4ed4-a9fa-5ef239f45b50

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	KARABAY	Oguz	-

Professional Mailing Address:

Street Address:		Other Street Address:	
Sakarya Universitesi Egitim ve Arastirma Hastanesi,		Enfeksiyon Hastaliklari ve Klinik Mikrobiyoloji Birimi, Adapazari	
City: Sakarya	State/Province: N/A	Country: Turkey	Zip/Postal Code: 54100
Email Address:	(b) (6)		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Prof. Dr.	2011	Sakarya University Training and Research Hospital, Sakarya, Turkey
Assoc. Prof. Dr.	2006	Bolu Abant Izzet Baysal University Faculty of Medicine, Bolu, Turkey
Assist. Prof.Dr.	2003	Bolu Abant Izzet Baysal University Faculty of Medicine, Bolu, Turkey
Infection Diseases Spec. Dr.	1997	Trakya University Faculty of Medicine, Edirne, Turkey
Medical Doctor	1992	Trakya University Faculty of Medicine, Edirne, Turkey

Medical License Number	State/Province	Country
43627 - 66602	N/A	Turkey

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2011	Prof. Dr.	Sakarya University Training and Research Hospital, Department of Infection Diseases and Clinical Microbiology, Sakarya	Turkey

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2008 - 2011	Assoc. Prof. Dr.	Sakarya University Training and Research Hospital, Sakarya	Turkey
2006 - 2008	Assoc. Prof. Dr.	Bolu Abant Izzet Baysal University Faculty of Medicine, Bolu	Turkey
2003 - 2006	Assist. Prof.Dr.	Bolu Abant Izzet Baysal University Faculty of Medicine, Bolu	Turkey
1998 - 2003	Infection Diseases Spec. Dr.	Duzce SSK Hospital, Duzce	Turkey
1993 - 1997	Medical Doctor (Infection Diseases Residency)	Trakya University Faculty of Medicine, Edirne	Turkey

Brief Summary of Relevant Clinical Research Experience:

GCP Training 2020

Experienced in Infection Clinical trials both as PI and Sub-I. Some of the latest studies are below listed:

2017- Chronic Hepatitis C – Prospective study
2017- Hospital-Acquired Bacterial Pneumonia – Phase III
2016- Influenza Vaccine – Phase III

Signature:	Signature Date: (dd-Mmm-yyyy)
Oguz Karabay Oguz Karabay 19 Aug 2020 14:10:013+0000 REASON: I approve this document 9db34043-bfbe-4a5e-8af5-d270a706a64e	

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.

Validation Report

1

Subject CN:	MSB
Subject DN:	EMAILADDRESS=operations@msbdocs.com,CN=MSB,OU=MSB,O=TAIGLE LLC,L=Irvine,ST=California,C=US
Email:	operations@msbdocs.com
Serial #:	103155442024134641897105422308128156249
Issuer DN:	CN=Entrust Class 3 Client CA - SHA256,OU=(c) 2015 Entrust, Inc. - for authorized use only,OU=See www.entrust.net/legal-terms,O=Entrust, Inc.,C=US
Signing Time:	19 Aug 2020 17:10:013+0300

- The Certificate chain was successfully built to a Trusted Root Certificate.
- The Signer's identity is valid.
- The Document has not been modified since the signature was applied.

Audit Trail Report

Document Name: C4591001_INV02-INV04-WI-GL02-SD01 2.0 Abb CV Temp_OmerFehmiTabak.pdf
Document ID: f11053a9-ac2d-4014-b807-6061689cbca5

Time Stamp	User	Action	Details
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19 Aug 2020 10:04:025+0300	Omer Fehmi Tabak UUID : bda09236-1b6b-4261-a13c-232f6bb4c5e8 Email : (b) (6)	RequestSent	Sign request sent to ePak recipient.
19 Aug 2020 10:21:037+0300	Omer Fehmi Tabak UUID : bda09236-1b6b-4261-a13c-232f6bb4c5e8 Email : (b) (6)	DocumentViewed	Document viewed by signer.
19 Aug 2020 10:21:056+0300	Omer Fehmi Tabak UUID : bda09236-1b6b-4261-a13c-232f6bb4c5e8 Email : (b) (6)	Signed	The recipient signed the document with no comments. Comments: None Reason: I approve this document
19 Aug 2020 10:23:021+0300	Didem Erten UUID : 62201ce7-9f30-4ba7-84b2-bded2517df4b Email : didem.erten@iconplc.com	Completed	The ePak is completed successfully.

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	TABAK	Omer	Fehmi

Professional Mailing Address:

Street Address:	Other Street Address:		
Istanbul Universitesi-Cerrahpasa, Cerrahpasa Tip Fakultesi,	Enfeksiyon Hastaliklari ve Klinik Mikrobiyoloji Anabilim Dali, Fatih		
City: Istanbul	State/Province: N/A	Country: Turkey	Zip/Postal Code: 34098
Email Address:	(b) (6)		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Prof. Dr.	2002	Istanbul University Cerrahpasa Faculty of Medicine, Istanbul, Turkey
Assoc. Prof. Dr.	1996	Istanbul University Cerrahpasa Faculty of Medicine, Istanbul, Turkey
Internal Medicine Spec. Dr.	1991	Istanbul University Cerrahpasa Faculty of Medicine, Istanbul, Turkey
Medical Doctor	1986	Istanbul University Cerrahpasa Faculty of Medicine, Istanbul, Turkey

Medical License Number	State/Province	Country
42116	N/A	Turkey

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2018	Prof. Dr.	Istanbul University-Cerrahpasa, Cerrahpasa Faculty of Medicine, Department of Infection Diseases and Clinical Microbiology, Istanbul	Turkey

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2002 - 2018	Prof. Dr.	Istanbul University Cerrahpasa Faculty of Medicine, Istanbul	Turkey
1996 - 2002	Assoc. Prof. Dr.	Istanbul University Cerrahpasa Faculty of Medicine, Istanbul	Turkey
1995 - 1995	Research Fellow	Tulane University School of Medicine, Infection Diseases section, New Orleans	USA
1991 - 1995	Internal Medicine Spec. Dr.	Istanbul University Cerrahpasa Faculty of Medicine, Istanbul	Turkey
1987 - 1991	Medical Doctor (Internal Medicine Residency)	Istanbul University Cerrahpasa Faculty of Medicine, Istanbul	Turkey

Brief Summary of Relevant Clinical Research Experience:

GCP Training 2019

-Experienced in clinical trials in infection diseases as both PI and Sub-I.
Several Chronic Hepatitis B studies (both HBeAg-Negative and HBeAg-positive) (phase III and observational).
Chronic HDV, Chronic Hepatitis C (observational)

Omer Fehmi Tabak

Signature: *Omer Fehmi Tabak* 19 Aug 2020 07:21:055+0000 **Signature Date: (dd-Mmm-yyyy)**

REASON: I approve this document

bda09236-1b6b-4261-a13c-23866bb4c5e8

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.

Validation Report

1 ✓

Subject CN:	MSB
Subject DN:	EMAILADDRESS=operations@msbdocs.com,CN=MSB,OU=MSB,O=TAIGLE LLC,L=Irvine,ST=California,C=US
Email:	operations@msbdocs.com
Serial #:	1031554420241346418971054223081281562 49
Issuer DN:	CN=Entrust Class 3 Client CA - SHA256,OU=(c) 2015 Entrust, Inc. - for authorized use only,OU=See www.entrust.net/legal-terms,O=Entrust, Inc.,C=US
Signing Time:	19 Aug 2020 10:21:056+0300

✓ The Certificate chain was successfully built to a Trusted Root Certificate.
✓ The Signer's identity is valid.
✓ The Document has not been modified since the signature was applied.

Audit Trail Report

Document Name: C4591001_INV02-INV04-WI-GL02-SD01 2.0 Abb CV Temp_OmerFehmiTabak.pdf
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Time Stamp	User	Action	Details
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19 Aug 2020 10:04:025+0300	Omer Fehmi Tabak UUID : bda09236-1b6b-4261-a13c-232f6bb4c5e8 Email : (b) (6)	RequestSent	Sign request sent to ePak recipient.
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19 Aug 2020 10:21:056+0300	Omer Fehmi Tabak UUID : bda09236-1b6b-4261-a13c-232f6bb4c5e8 Email : (b) (6)	Signed	The recipient signed the document with no comments. Comments: None Reason: I approve this document
19 Aug 2020 10:23:021+0300	Didem Erten UUID : 62201ce7-9f30-4ba7-84b2-bded2517df4b Email : didem.erten@iconplc.com	Completed	The ePak is completed successfully.

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	SIMSEK YAVUZ	Serap	-

Professional Mailing Address:

Street Address:	Other Street Address:
Istanbul Universitesi Istanbul Tip Fakultesi,	Enfeksiyon Hastaliklari ve Klinik Mikrobiyoloji Anabilim Dali, Fatih

City:	State/Province:	Country:	Zip/Postal Code:
Istanbul	N/A	Turkey	34093

Email Address: (b) (6)

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Prof. Dr.	2015	Istanbul University Istanbul Faculty of Medicine, Istanbul, Turkey
Assoc. Prof. Dr.	2006	Istanbul Dr. Siyami Ersek Thoracic and Cardiovascular Surgery Training and Research Hospital, Istanbul, Turkey
Infection Diseases Spec. Dr.	1997	Istanbul Haydarpasa Numune Training and Research Hospital, Istanbul, Turkey
Medical Doctor	1992	Istanbul University Istanbul Faculty of Medicine, Istanbul, Turkey

Medical License Number	State/Province	Country
65397	N/A	Turkey

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2015	Prof. Dr.	Istanbul University Istanbul Faculty of Medicine, Department of Infection Diseases and Clinical Microbiology, Istanbul	Turkey

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2013 - 2015	Assoc. Prof. Dr.	Istanbul University Istanbul Faculty of Medicine, Istanbul	Turkey
2006 - 2013	Assoc. Prof. Dr.	Istanbul Dr. Siyami Ersek Thoracic and Cardiovascular Surgery Training and Research Hospital, Istanbul	Turkey
1998 - 2006	Infection Diseases Spec. Dr.	Istanbul Dr. Siyami Ersek Thoracic and Cardiovascular Surgery Training and Research Hospital, Istanbul	Turkey
1993 - 1997	Medical Doctor (Infection Diseases Residency)	Istanbul Haydarpasa Numune Training and Research Hospital, Istanbul	Turkey

Brief Summary of Relevant Clinical Research Experience:

-GCP Training 2020

-Experienced in clinical research. Participating in previous infection diseases clinical trials as PI, currently ongoing studies:
- Covid-19 treatment trial
- Antifungal trial

Serap Simsek Yav z

Signature: Serap Simsek Yavuz 14 Aug 2020 10:36:005+0000
REASON: I approve this document
b891e8d4-dc41-49a4-abcc-a51551d41339

Signature Date: (dd-Mmm-yyyy)

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.

Validation Report

1 ✓

Subject CN:	MSB
Subject DN:	EMAILADDRESS=operations@msbdocs.com,CN=MSB,OU=MSB,O=TAIGLE LLC,L=Irvine,ST=California,C=US
Email:	operations@msbdocs.com
Serial #:	103155442024134641897105422308128156249
Issuer DN:	CN=Entrust Class 3 Client CA - SHA256,OU=(c) 2015 Entrust, Inc. - for authorized use only,OU=See www.entrust.net/legal-terms,O=Entrust, Inc.,C=US
Signing Time:	14 Aug 2020 13:36:005+0300

✓ The Certificate chain was successfully built to a Trusted Root Certificate.

✓ The Signer's identity is valid.

✓ The Document has not been modified since the signature was applied.

Audit Trail Report

Document Name: C4591001_INV02-INV04-WI-GL02-SD01 2.0 Abb CV Temp_SerapSIMSEKYAVUZ.pdf
Document ID: 80e78244-a6e6-4fe3-9406-4342e90188b4

Time Stamp	User	Action	Details
11 Aug 2020 16:57:004+0300	Didem Erten UUID : 62201ce7-9f30-4ba7-84b2-bded2517df4b Email : didem.erten@iconplc.com	Started	The custodian composed the ePak succesfully. Subject: IB AoR_SerapSIMSEKYAVUZ ePak UUID: afac9e0c-30be-4881-babf-89b67ccad5e5
11 Aug 2020 16:57:005+0300	Serap Simsek Yavuz UUID : b891e8d4-dc41-49a4-abcc-a51551d41339 Email : (b) (6)	RequestSent	Sign request sent to ePak recipient.
14 Aug 2020 13:35:023+0300	Serap Simsek Yavuz UUID : b891e8d4-dc41-49a4-abcc-a51551d41339 Email : (b) (6)	DocumentViewed	Document viewed by signer.
14 Aug 2020 13:36:006+0300	Serap Simsek Yavuz UUID : b891e8d4-dc41-49a4-abcc-a51551d41339 Email : (b) (6)	Signed	The recipient signed the document with no comments. Comments: None Reason: I approve this document
14 Aug 2020 13:36:007+0300	Didem Erten UUID : 62201ce7-9f30-4ba7-84b2-bded2517df4b Email : didem.erten@iconplc.com	Completed	The ePak is completed successfully.

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	AKHAN	Sila	-

Professional Mailing Address:

Street Address:	Other Street Address:
Kocaeli Universitesi Tip Fakultesi,	Enfeksiyon Hastaliklari ve Klinik Mikrobiyoloji Anabilim Dali, Umuttepe

City:	State/Province:	Country:	Zip/Postal Code:
Kocaeli	N/A	Turkey	41380

Email Address: sila.akhan@kocaeli.edu.tr

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Prof. Dr.	2009	Kocaeli University Faculty of Medicine, Kocaeli, Turkey
Assoc. Prof. Dr.	2002	Kocaeli University Faculty of Medicine, Kocaeli, Turkey
Assist. Prof. Dr.	1998	Kocaeli University Faculty of Medicine, Kocaeli, Turkey
Infection Diseases Spec. Dr.	1997	Istanbul University Istanbul Faculty of Medicine, Istanbul, Turkey
Microbiology Spec. Dr.	1992	Istanbul University Istanbul Faculty of Medicine, Istanbul, Turkey
Medical Doctor	1989	Istanbul University Istanbul Faculty of Medicine, Istanbul, Turkey

Medical License Number	State/Province	Country
19885/23353	N/A	Turkey

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2009	Prof. Dr.	Kocaeli University Faculty of Medicine, Department of Infection Diseases and Clinical Microbiology, Kocaeli	Turkey

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2002 - 2009	Assoc. Prof. Dr.	Kocaeli University Faculty of Medicine, Kocaeli	Turkey
1998 - 2002	Assist. Prof. Dr.	Kocaeli University Faculty of Medicine, Kocaeli	Turkey
1997 - 1998	Infection Diseases Spec. Dr.	Istanbul University Istanbul Faculty of Medicine, Department of Clinic Bacteriology and Infection Diseases, Istanbul	Turkey
1992 - 1997	Microbiology Spec. Dr. (Infection Diseases Residency)	Istanbul University Istanbul Faculty of Medicine, Department of Clinic Bacteriology and Infection Diseases, Istanbul	Turkey
1989 - 1992	Medical Doctor (Microbiology Residency)	Istanbul University Istanbul Faculty of Medicine, Department of Microbiology and Clinic Microbiology, Istanbul	Turkey

Brief Summary of Relevant Clinical Research Experience:

GCP Training 2018

- 2018, Influenza A, (CR108399), Phase III
- 2018, Influenza A, (CR108400), Phase III
- 2014, Chronic Hepatitis C, Observational study

Chronic Hepatitis B, non-interventional study, Chronic Hepatitis C in Turkish Patients, non-interventional study

SILA AKHAN

Signature: SILA AKHAN 13 Aug 2020 06:35:053+0000

REASON: I approve this document

d3a628c9-3cc9-47c7-aaec-8092e87956dd

Signature Date: (dd-Mmm-yyyy)

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.

[1] Facsimile of Original Digital Signature

MSB

Validation Report as of: 21 Aug 2020 09:37:056+0300

1

Subject CN	MSB
Subject DN	EMAILADDRESS=operations@msbdocs.com,CN=MSB,OU=MSB,O=TAIGLE LLC,L=Irvine,ST=California,C=US
Email	operations@msbdocs.com
Serial #	103155442024134641897105422308128156249
Issuer DN	CN=Entrust Class 3 Client CA - SHA256,OU=(c) 2015 Entrust, Inc. - for authorized use only,OU=See www.entrust.net/legal-terms,O=Entrust, Inc.,C=US
Signing Time	13 Aug 2020 09:35:053+0300

The Certificate chain was successfully built to a Trusted Root Certificate.

The Signer's identity is valid.

The Document has not been modified since the signature was applied.

Audit Trail Report

Date	User	Document	Action	Details
10 Aug 2020 15:51:019+0300	Didem Erten		Started	The custodian composed the ePak succesfully. User UUID : 62201ce7-9f30-4ba7-84b2-bded2517df4b User Email : didem.erten@iconplc.com
10 Aug 2020 15:51:020+0300	Sila Akhan		RequestSent	Sign request sent to ePak recipient. User UUID : 690bc80d-0add-42c3-b4cb-357497274b59 User Email : sila.akhan@kocaeli.edu.tr
12 Aug 2020 08:59:020+0300	Didem Erten		StarredByOwner	EPak starred by an owner change. User UUID : 62201ce7-9f30-4ba7-84b2-bded2517df4b User Email : didem.erten@iconplc.com
12 Aug 2020 08:59:020+0300	Sila Akhan		Delegated	SILA AKHAN<didem.erten@iconplc.com> delegated the ePak to another Signer SILA AKHAN(b) (6) Previous Signer: Sila Akhan<sila.akhan@kocaeli.edu.tr> Message: User UUID : 690bc80d-0add-42c3-b4cb-357497274b59 User Email : sila.akhan@kocaeli.edu.tr
12 Aug 2020 09:59:040+0300	SILA AKHAN	IB AoR_SilaAKHAN.pdf	DocumentViewed	Document viewed by signer. User UUID : d3a628c9-3cc9-47c7-aaec-8099e97956dd User Email : (b) (6) Document UUID : 960ba53b-0960-4c8d-ad56-aa0744efe209
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13 Aug 2020 09:31:011+0300	SILA AKHAN	C4591001_INV02-INV04-WI-GL02-RF09 5,0 Inv ICHGCP Attes Form_SilaAKHAN.pdf	DocumentViewed	Document viewed by signer. User UUID : d3a628c9-3cc9-47c7-aaec-8099e97956dd User Email : (b) (6) Document UUID : 5a132780-0835-4790-9965-0f4024b4f052
13 Aug 2020 09:32:028+0300	Sila Akhan		Delegated	SILA AKHAN<didem.erten@iconplc.com> delegated the ePak to another Signer SILA AKHAN(b) (6) Previous Signer: Sila Akhan<sila.akhan@kocaeli.edu.tr> Message: User UUID : 690bc80d-0add-42c3-b4cb-357497274b59 User Email : sila.akhan@kocaeli.edu.tr
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13 Aug 2020 09:36:033+0300	SILA AKHAN	C4591001_SQT_Financial-Disclosure_2019_Version-3,2_SilaAkhan.pdf	DocumentViewed	Document viewed by signer. User UUID : d3a628c9-3cc9-47c7-aaec-8099e97956dd User Email : (b) (6) Document UUID : 7833bb6b-deab-4a70-962d-6cabbeb8d57f
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13 Aug 2020 09:37:014+0300	SILA AKHAN	C4591001_SQT_Financial-Disclosure_2019_Version-3.2_SilaAkhan.pdf	SignerTagFilled	The signer filled Custom Checkbox. Value: true User UUID : d3a628c9-3cc9-47c7-aaec-8099e97956dd User Email : (b) (6) Document UUID : 7833bb6b-deab-4a70-962d-6cabbeb8d57f
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13 Aug 2020 09:37:014+0300	SILA AKHAN	C4591001_SQT_Financial-Disclosure_2019_Version-3.2_SilaAkhan.pdf	Signed	The recipient signed the document with no comments. Comments: None Reason: I approve this document User UUID : d3a628c9-3cc9-47c7-aaec-8099e97956dd User Email : (b) (6) Document UUID : 7833bb6b-deab-4a70-962d-6cabbeb8d57f
13 Aug 2020 09:37:014+0300	Didem Erten		Completed	The ePak completed the workflow successfully Signer. User UUID : 62201ce7-9f30-4ba7-84b2-bded2517df4b User Email : didem.erten@iconplc.com

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Mulligan	Mark	Joseph

Professional Mailing Address

Street Address: 430 East 29th Street		Other Street Address: 3rd Floor, Room 304	
City: New York	State/Province: NY	Country: USA	Zip/Postal Code: 10016
Email Address:	mark.mulligan@nyulangone.org		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Fellow, Infectious Disease Fellowship, Medicine	06/1990	University of Alabama at Birmingham, USA
Post-doctoral Fellow, Microbiology	06/1990	University of Alabama at Birmingham, USA
Resident, Medicine	06/1987	University of Alabama at Birmingham, USA
MD	06/1984	UT Southwestern Medical School, USA
BS (with honors)	05/1980	University of Notre Dame, USA

Medical License Number	State/Province	Country
296158	New York	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
11/2018	MD, Principal Investigator	NYU Langone Health	New York, USA
10/2018 - Present	Director	NYU Langone Vaccine Center	New York, USA
10/2018 - Present	Thomas S. Murphy, Sr. Professor of Medicine and Professor of Microbiology Departments of Medicine and Microbiology	Division of Infectious Diseases and Immunology, Department of Medicine NYU School of Medicine	New York, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2006-2018	Director, Emory University Hope Clinic Distinguished Professor of Medicine	Emory University School of Medicine	USA

Brief Summary of Relevant Clinical Research Experience:

30+ years of clinical research experience with many research papers published

Signature:	Signature Date: (dd-Mmm-yyyy)
	10/APR/2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Neuzil	Kathleen	Maletic

Professional Mailing Address

Street Address:		Other Street Address:	
685 W. Baltimore St.		HSF I, Room 480	
City:	State/Province:	Country:	Zip/Postal Code:
Baltimore	MD	USA	21201
Email Address:	kneuzil@som.umaryland.edu		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
M.P.H.	1998	Vanderbilt University School of Medicine, Nashville, TN
M.D.	1987	Johns Hopkins University School of Medicine, Baltimore, MD
B.S.	1983	Zoology, University of Maryland, College Park, MD

Medical License Number	State/Province	Country
D80514	Maryland	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2015	Director	University of Maryland, Center for Vaccine Development	MD, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2011-2015	Clinical Professor, Departments of Medicine and Global Health	University of Washington, Seattle, WA	USA
2009-2011	Clinical Associate Professor, Department of Global Health	University of Washington, Seattle, WA	USA
2005-2011	Clinical Associate Professor of Medicine, Division of Allergy and Infectious Diseases	University of Washington School of Medicine, Seattle, WA	USA
2003-2005	Associate Professor of Medicine, Division of Allergy and Infectious Diseases	University of Washington, Seattle, WA	USA

Brief Summary of Relevant Clinical Research Experience:

Dr. Neuzil is one of the world's most influential research scientists and advocates in the area of vaccine development and policy. She directs the University of Maryland School of Medicine's Center for Vaccine Development and Global Health (CVD). Throughout her career, she has conducted clinical and epidemiologic studies on vaccine-preventable diseases, yielding high profile publications that inform policy decisions and public health actions. At the global non-profit PATH, Dr. Neuzil was instrumental in the introductions of rotavirus, HPV, and Japanese encephalitis vaccines.

Signature: Kathleen Neuzil

Digitally signed by Kathleen Neuzil
DN: PostalCode: 21201, O: "University of Maryland, Baltimore", STREET: 620 W. Lexington Street, S: Maryland, L: Baltimore, C: US, CN: Kathleen Neuzil, E: kneuzil@som.umaryland.edu
Reason: I am the author of this document
Location: your signing location here
Date: 2020-04-13 17:22:05
Foxit PhantomPDF Version: 9.7.1

Signature Date: (dd-Mmm-yyyy)

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name *if applicable*
	Walsh	Edward	

Professional Mailing Address:

Street Address 1:	Street Address 2:		
Rochester General Hospital/Rochester Regional Health INFECTIOUS DISEASE DEPT DR 21 APR 2020	1425 Portland Ave. Box 246		
City: Rochester	State/Province: NY	Country: USA	Zip/Postal Code: 14621
Email Address:	**Edward.walsh@rochesterregional.org**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and Country
MD	1974	Downstate Medical Center Brooklyn NY USA
BS	1970	Manhattan College NYC NY USA

Medical License Number	State/Province	Country
127489-1	New York	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2001	Chief Infectious Disease	Rochester Regional Health/Rochester General Hospital	Rochester, NY USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1997-Present	Professor of Medicine	University of Rochester	USA
1997- Present	Attending Physician	Rochester General Hospital	USA

Brief Summary of Relevant Clinical Research Experience:

Principle Investigator for Industry sponsored, CDC, NIH and Investigator initiated research studies from 1997 to present with over 100 publications.

Signature:	Signature Date: (dd-Mmm-yyyy)
Edward Walsh	24April2018

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION CONTAINED IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. MULTI-PAGE CVS ARE NOT ACCEPTABLE. DO NOT INCLUDE ATTACHMENTS, AND TEXT ON THE REVERSE SIDE.

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Davis	Matthew	Gilruth

Professional Mailing Address

Street Address: 500 Helendale Road		Other Street Address: L20	
City: Rochester	State/Province: NY	Country: USA	Zip/Postal Code: 14609
Email Address:	mdavis@rcrclinical.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Residency	1989	Shadyside Hospital, Department of Family Medicine
Medical Doctor	1986	University of Rochester School of Medicine
BA Biology	1981	Dartmouth College

Medical License Number	State/Province	Country
189975-1	New York	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2011-Present	Medical Director	Rochester Clinical Research, Inc.	New York, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1996-2011	Associate Medical Director	Rochester Clinical Research, Inc.	USA
1996-Present	Locum tenems	Highland Hospital	USA
1998-1999	Chief	After Hours Medical Care	USA

Brief Summary of Relevant Clinical Research Experience:

Research experience on over 738 trials, 408 of which as a Principal Investigator, including:
Vaccine: 86
Migraine: 45
Diabetes: 41
Weight loss: 20
Women's Health: 39

Signature:	Signature Date: (dd-Mmm-yyyy)
Matthew Davis	07-May-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.

HELLOSIGN

Audit Trail

TITLE	Pfizer CV for COVID
FILE NAME	_Davis%20One%20Page%20CV%205.2020.pdf
DOCUMENT ID	8986d899f24dd703deb73ef98bf1a14c0bef93a0
AUDIT TRAIL DATE FORMAT	MM / DD / YYYY
STATUS	Completed

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Document History

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COMPLETED	**05 / 07 / 2020** 10:55:12 UTC-5	The document has been completed.

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Peterson	James	Todd

Professional Mailing Address:

Street Address 1: J. Lewis Research, Inc. / Foothill Family Clinic		Street Address 2: 2295 Foothill Drive	
City: Salt Lake City	State/Province: Utah	Country: USA	Zip/Postal Code: 84109
Email Address:	jpeterson@jlewisresearch.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
FAAFP	2014	American Academy of Family Physicians / USA
CCRP	2012	SOCRA / USA
Residency	2000	University of Nebraska Medical Center / USA
Doctor of Medicine	1997	University of Nebraska / USA
Bachelor of Science in Microbiology	1993	Brigham Young University / USA

Medical License Number	State/Province	Country
3086646-1205	Utah	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2008	Principal Investigator	J. Lewis Research, Inc.	Utah / USA
2000	Physician	Foothill Family Clinic	Utah / USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2000-2008	Sub-Investigator	J. Lewis Research, Inc.	USA
1999-2000	Physician	Henderson Health Care Services	USA
1999-2000	Physician	Alegent Health Express Care	USA

Brief Summary of Relevant Clinical Research Experience:

Allergic Rhinitis, Asthma, Back Pain, Celiac Disease, Conjunctivitis, Constipation, Dermatology, Diabetes, Erectile Dysfunction, GERD, Gout, Headache, Hyperlipidemia, Hypertension, IBS, Infectious Disease: (AECB, CAP, Cold, Influenza, Otitis, Pharyngitis, Sinusitis, Sinus Puncture, Skin Infection, and UTI), Migraine (Adult and Pediatric), Neuropathic Pain Relief, OA, OAB, PAR, Pediatrics, Ragweed Allergy, Vaccines (Elderly, Adult and Pediatric), Women's Studies: (Contraception, HPV, HRT, Menstrual Migraine, Uterine Fibroids, Vaginal Atrophy, Vaginal Dryness, Vaginitis, and Vaginosis), Device Studies: (PSA & Free PSA Assay)

Signature:	Signature Date: (dd-Mmm-yyyy)
	03 Jan 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.

ABBREVIATED CURRICULUM VITAE TEMPLATE

Instructional text is denoted in GREEN. DELETE green text upon completion of this template. This template is a sample and can be used to create the abbreviated curriculum vitae (CV). If this template is not used, please note the underlined SECTION headings represent the required components that must be included in the abbreviated CV.

Must be typed and all sections must be completed.

Full Legal Name:	Last Name	First Name	Middle Name *if applicable*
	Frenck, Jr., MD	Robert	W Wilson Dr 30 APR 2020

Professional Mailing Address: *Principal Investigator information should be consistent with box 1 of the Statement of Investigator Form Food and Drug Administration (FDA) 1572 or Investigator International Conference on Harmonisation (ICH) Good Clinical Practices (GCP) Attestation Form*

Street Address 1	Street Address 2		
Cincinnati Children's Hospital Medical Center Gamble Program for Clinical Studies	3333 Burnet Ave. MLC 6014		
City: Cincinnati	State/Province: OH	Country: USA	Zip/Postal Code: 45229

Email Address: Robert.frenck@cchmc.org

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country *Where Obtained*
Pediatric Infectious Disease Fellowship	1987-1990	University of Texas Medical School at Houston, USA
Pediatric Internship and Residency	1981-1984	National naval Medical Center, Bethesda, MD, USA
MD	1977-1981	University of Texas Medical School at Houston, USA
B.A. Biology	1973-1977	University of California at San Diego, USA

Medical License Number	State/Province	Country
# 88123	Ohio	USA

All MD/DO/equivalents must provide a medical license number, and the state/province and country where the license was obtained. For countries that do not disclose or provide license numbers enter "Not applicable". Note: If the MD or DO is in Residency and not yet licensed, indicate Residency or degree on the CV

Current Position at Study Site: *current affiliation as noted in box 3 of the Form FDA 1572 or ICH GCP Attestation*

Start Date	Title	Institution or Company	State/Province & Country
2006- Present	Professor of Pediatrics	Cincinnati Children's Hospital Medical Center	OH, USA

Previous Relevant Positions Including Academic Appointments: *provide previous 4 relevant positions if applicable*

Start and End Dates	Title	Institution or Company	Country
2004-2006	Professor of Pediatrics	University of California at Los Angles	USA
1997-Present	Associate Professor of Pediatrics	Uniformed Services, University of Health and Science, MD	USA
1994-1997	Associate Professor of Pediatrics	Eastern Virginia Medical School, VA	USA

Brief Summary of Relevant Clinical Research Experience: *Enter "None" if no previous clinical research experience*

Clinical Studies in the Division of Infectious Diseases at CCHMC conducts research on the prevention, diagnosis, and management of infections in subjects of all ages. PI and sub-I on numerous industry, government and PI initiated studies. PI on many studies both in military & civilian, numerous publications, academic & administrative committees, scientific review/consult & professional organizations.

Signature: *This CV is to be signed and dated by the investigator to whom the CV applies. If the investigator refuses to sign, indicate "Refusal to Sign" and date of refusal in the Signature Date box.*	**Signature Date: (dd-Mmm-yyyy)**
	19Feb2019

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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Investigator maintains the original, signed copy of his/her abbreviated CV in the investigator site file.
A copy must be forwarded with the other investigator initiation package documents.

ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Jennings	Timothy	W.

Professional Mailing Address

Street Address: Clinical Research Professionals		Other Street Address: 17998 Chesterfield Airport Rd., Suite 100	
City: Chesterfield	State/Province: Missouri	Country: USA	Zip/Postal Code: 63005
Email Address:	tjennings@clinicalresearchprofessinals.net		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
B.S. Physics	1984	Northwest Missouri State University, Kirksville, MO/USA
Doctor of Osteopathy	1989	Kirksville College of Osteopathic Medicine, Kirksville, MO/USA
Internship	1990	Normandy Hospital North, St. Louis, MO/USA
Residency	1992	Normandy Hospital North, St. Louis, MO/USA

Medical License Number	State/Province	Country
R6N64	Missouri	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2014	Investigator	Clinical Research Professionals	Missouri/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1994 to Present	Family Practice/Internist	SSM Medical Group	USA
1992 – 1994	Family Practice/Internist	Private Practice	USA

Brief Summary of Relevant Clinical Research Experience:

Experience as either a PI or Sub-I with studies involving COPD, Alzheimer's disease, Type 2 Diabetes Mellitus, Traumatic Brain Injury, Sexual Disorder, Ragweed Induced Rhinoconjunctivitis, Hypertriglyceridemic Patients with Cardiovascular Disease, C. Diff, Eosinophilic Esophagitis, NASH, Gastroparesis, Ulcerative Colitis, Gastroesophageal Reflux disease, Migraine

Signature: T. Jennings

Signature Date: (dd-Mmm-yyyy) 8 Jun 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Christensen	Shane	Glade

Professional Mailing Address:

Street Address 1: J. Lewis Research, Inc. / Foothill Family Clinic South		Street Address 2: 6360 South 3000 East, Suite 100	
City: Salt Lake City	State/Province: Utah	Country: USA	Zip/Postal Code: 84121
Email Address:	schristensen@jlewisresearch.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
FAAFP	2014	American Academy of Family Physicians / USA
CCRP	2003	SOCRA / USA
Residency	1994	University of Utah Affiliated Hospitals / USA
Doctorate of Medicine	1991	St. Louis University School of Medicine / USA
Bachelor of Science in Chemistry	1987	Utah State University / USA

Medical License Number	State/Province	Country
187690-1205	Utah	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1997	Principal Investigator	J. Lewis Research, Inc.	Utah / USA
1997	Physician	Foothill Family Clinic South	Utah / USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1994-1997	Sub-Investigator	J. Lewis Research, Inc.	USA
1994-1997	Physician	Foothill Family Clinic	USA

Brief Summary of Relevant Clinical Research Experience:

Allergic Rhinitis, Asthma, Back Pain, Celiac Disease, Conjunctivitis, Constipation, Depression, Dermatology, Diabetes, Dust Mite, Erectile Dysfunction, GERD, Gout, Headache, Heartburn, Hyperlipidemia, Hypertension, IBS, Infectious Disease: (AECB, CAP, Cold, Influenza, Otitis, Pharyngitis, Sinusitis, Sinus Puncture, Skin Infection, and UTI), Migraine (Adult and Pediatric), Neuropathic Pain Relief, OA, Obesity, OTC Indications, Pain, PAR, Pediatrics, Ragweed Allergy, Restless Leg, Sprain, Timothy Grass Allergy, Vaccines (Elderly, Adult and Pediatric), Women's Studies: (Contraception, HPV, HRT, Menstrual Migraine, Osteoporosis, Uterine Fibroids, Vaginal Atrophy, Vaginitis, and Vaginosis), Device Studies: (PSA & Free PSA Assay, RAT testing, Troponin Assays)

Signature:	Signature Date: (dd-Mmm-yyyy)
Shane Christensen	06-Jan-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Varano	Susann	

Professional Mailing Address

Street Address: 2080 Bridgeport Avenue		Other Street Address:	
City: Milford	State/Province: CT	Country: USA	Zip/Postal Code: 06460
Email Address:	svarano@clinicalrc.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Geriatric Fellowship	1999	Yale University School of Medicine, USA
Chief Residency	1998	Yale University/Norwalk Hospital, USA
Internal Medicine Residency	1997	Yale University School of Medicine, USA
M.D.	1994	Chicago Medial School, USA
B.S.	1990	Saint Joseph's College, USA

Medical License Number	State/Province	Country
136340	CT	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2007	Investigator	Clinical Research Consulting, LLC	CT/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2017-Present	Geriatric Consultant	Maplewood Assisted Living	USA
2012-2017	Geriatric Consultant	Hamden Health and Candlewood Valley Rehab	USA
2007-2009	Clinical Investigator	Danbury Clinical Research	USA
2005-2007	Clinical Investigator	Clinical Research Consultants	USA
2001-2013	Program Director and Geriatrician	Elder Horizons at Yale-New Haven Hospital	USA

Brief Summary of Relevant Clinical Research Experience:

Has been a Clinical Investigator on over 80 clinical trials while at CRC.

Signature:	Signature Date: (dd-Mmm-yyyy)
Susan Varano	20-May-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Doust	Matthew	W.

Professional Mailing Address

Street Address:		Other Street Address:	
3900 E. Camelback Road		Suite 125	
City: Phoenix	State/Province: AZ	Country: USA	Zip/Postal Code: 85018
Email Address:	**Matthew.doust@hriaz.com**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Certified, Pain Medicine	2004	American Board of Pain Medicine, USA
Certified, Anesthesiologist	2003	American Board of Anesthesiology, USA
Doctor of Medicine	1998	SUNY Health Science Center at Syracuse, USA

Medical License Number	State/Province	Country
29038	AZ	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2006	Principal Investigator	HOPE Research Institute	AZ, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2003-Present	Pain Management Physician	The Pain Center of Arizona	USA

Brief Summary of Relevant Clinical Research Experience:

Physician who has worked as a PI/ Sub-Investigator for over 14 years on Phase I-IV drug/ medical device clinical trials with an emphasis on pain management. Therapeutic areas include chronic pain conditions, device, and vaccines.

Signature:	Signature Date: (dd-Mmm-yyyy)
	14 May 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Dever	Michael	Edward

Professional Mailing Address:

Street Address 1: 618 East South Street		Street Address 2: Suite 100	
City: Orlando	State/Province: FL	Country: USA	Zip/Postal Code: 32801

Email Address: Mdever@cnshealthcare.com

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MD	1982	University of Kentucky, USA
BA	1976	University of Louisville, USA

Medical License Number	State/Province	Country
ME 0046886	FL	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
12/2013	Investigator	Clinical Neuroscience Solutions, Inc.	FL, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2012-10/2013	Investigator	Compass Research	FL, USA
2013 – Present	Physician and Medical Director	Sanford Florida First Baptist Church	FL, USA
2010 – Present	Medical Director	American General Life	TX, USA

Brief Summary of Relevant Clinical Research Experience:

Investigator on over 200 phase I-IV clinical trials in pediatric, adolescents, adults and geriatrics. Diagnoses include: Acne, Alcohol dependence, Alzheimer's disease, Asthma, Autism, Attention-deficit hyperactivity disorder (ADHD), Atopic Dermatitis, Borderline Personality Disorder, C-difficle, Chemical dependence, Chronic idiopathic constipation, Chronic pain, Cold Treatment, Constipation, Crohn's Disease, Dementias, Depressive disorders, Diabetes, Diabetic peripheral neuropathy, Diarrhea, Diverticulitis, Endometriosis, Epilepsy, Fatigue, Female sexual arousal disorder, Fibromyalgia, Flu treatment, Flu vaccine, Gambling cessation, Generalized anxiety, Gastrointestinal disorders, Gout, Hot flashes, Hyperlipidemia, Hypertension, Hyposexual arousal disorder, Infectious diseases, Influenza, Insomnia, Irritable bowel syndrome, Lower back pain, Metabolic and Endocrine disorders, Migraine, Mild cognitive impairment, Mood disorders, Musculoskeletal disorders, NASH, Obesity, Obsessive-compulsive disorder, Opioid induced constipation, Opioid withdrawal, Oppositional defiant disorder, Panic disorder, Parasitic diseases, Post-herpetic neuralgia, Post-traumatic stress disorder, Rheumatoid disorders, RSV Vaccine, Schizophrenia, Sexual dysfunction, Skin disorders, Sleep disorders, Smoking cessation, Social phobia, Stuttering, Tourette's, Tropical diseases, Uterine Fibroids, UTI, and Women's Health.

Signature:	Signature Date: (dd-Mmm-yyyy)
MEDever	02-MAR-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Barnett	Elizabeth	Day

Professional Mailing Address

Street Address: Boston Medical Center		Other Street Address: 670 Albany St., 6th Fl. (administrative offices)	
City: Boston	State/Province: Massachusetts	Country: United States	Zip/Postal Code: 02118
Email Address:	**ebarnett@bu.edu**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
ScB	1977	Brown University
MD	1985	Boston University School of Medicine
Residency in Pediatrics	1989	Boston City Hospital (now Boston Medical Center)
Fellowship in Pediatric Infectious Diseases	1992	Boston City Hospital (now Boston Medical Center)

Medical License Number	State/Province	Country
58612	Massachusetts	United States

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2018	Chief of the Section of Pediatric Infectious Diseases	Boston Medical Center	Massachusetts. United States

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2010-Present	Professor of Pediatrics	Boston University School of Medicine	United States
2008-2018	Director of Pediatric Infectious Disease Fellowship Program	Boston Medical Center	United States
1997-Present	Site Director of the GeoSentinal Surveillance Network	Boston Medical Center	United States
1995-Present	Director of International Clinic and Refugee Health Assessment Program	Boston Medical Center	United States

Brief Summary of Relevant Clinical Research Experience:

Has been the PI or Co-PI of numerous government and industry funded clinical trials involving vaccines and infectious diseases.

Signature:	Signature Date: (dd-Mmm-yyyy)
EBarnett	05-May-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Finn	Daniel	J.

Professional Mailing Address

Street Address:		Other Street Address:	
Kentucky Pediatric/Adult Research		201 South 5th Street	
City:	State/Province:	Country:	Zip/Postal Code:
Bardstown	KY	USA	40004
Email Address:	(b) (6)		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MD/FAAP	1998	University of Louisville School of Medicine, USA

Medical License Number	State/Province	Country
34862	Kentucky	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2001-Present	MD	Kentucky Pediatric/Adult Research	KY/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2001-Present	Partner	Physicians to Children & Adolescents	USA

Brief Summary of Relevant Clinical Research Experience:

Have participated in over 321 clinical trials in infant, toddler, pediatric, adult and elderly populations. Principal Investigator on approximately 29 trials, Sub investigator on remaining. Indications include anti-infective (Acute Otitis Media, Acute Sinusitis, Streptococcal Pharyngitis, Community Acquired Pneumonia, Skin and Skin Structure infections, Acute Otitis Externa, Acute Exacerbation of Chronic Bronchitis, Urinary tract infections), ADHD, Migraine, Vaccines (pneumococcal conjugate, meningococcal A, C, W, Y, meningococcal B, Hib, MMR, Varicella, Hepatitis A, Hepatitis B, influenza, Japanese Encephalitis, combination vaccines, HPV, HSV), asthma, smoking cessation, depression, functional constipation, RSV, formula, etc. Phase I-IV, including post-marketing. Began in 2001, continues to present.

Signature:	Signature Date: (dd-Mmm-yyyy)
	18-MAY-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Fragoso	Veronica	Garcia

Professional Mailing Address

Street Address: 6550 Mapleridge Street		Other Street Address: Suite 201, 206, 216, 220 01-APR-2021	
City: Houston	State/Province: Texas	Country: USA	Zip/Postal Code: 77081
Email Address:	veronica.fragoso@tcddresearch.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
FP	2006	San Jacinto Family Residency, USA
MD	2002	University of Texas Medical School, USA
BS	1995	St. Mary's University, USA
HS	1991	South Texas High School for Health Professions, Mercedes, Texas

Medical License Number	State/Province	Country
M9286	Texas	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
Dec-2013-present	Principal Investigator	Texas Center for Drug Development, Inc.	Texas- USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
Feb-2019-present	PI/Sub-I	Bellaire's Doctor Clinic	USA
Jun 2013 -present	Private Contractor	Physicians Resources, Inc.	USA
Mar-2011-Apr-2013	Visiting Physician	Visiting Physician Association	USA
Dec-2010-Mar-2011	Private Contractor	Unisource Medical Locums Company	USA
Feb-2009-Aug-2010	Assistant Professor	UT-Physicians/Baytown Community Clinic	USA
Apr-2008-Sep-2008	Physician	Medicorp Family Medicine	USA

Brief Summary of Relevant Clinical Research Experience:

Chronic Congestive Heart Failure, Chlamydia, Contraceptive vaginal Gel, Type 2 Diabetes, Migraines, COPD, Nash, Hyperlipidemia, Cardiovascular, Ebola Vaccine, Clostridium Difficile Vaccine, RSV Vaccine, Pneumococcal Disease, Major Depressive Disorder, Binge eating disorder, Schizophrenia, etc.

Signature:	Signature Date: (dd-Mmm-yyyy)
V Fragoso MD	23-Dec-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Andrews	Charles	P

Professional Mailing Address:

Street Address:		Other Street Address:	
4410 Medical Drive, Suite 360			
City: San Antonio	State/Province: Texas	Country: USA	Zip/Postal Code: 78229
Email Address:	dr.andrews@dxrg.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Subspecialty	1980	American Board of Internal Medicine (pulmonary), USA
Board Certification	1978	American Board of Internal Medicine, USA
MD	1975	University of Texas Southwestern Medical School, USA

Medical License Number	State/Province	Country
E4177	Texas	USA

Current Position at Study Site:

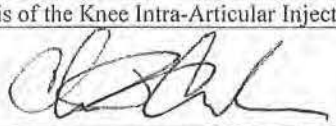
Start Date	Title	Institution or Company	State/Province & Country
2000	Principal Investigator	DIAGNOSTICS RESEARCH GROUP	TX, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1981-1982	Assistant Professor of Medicine	University of Texas Health Science	USA
1980-1981	Medical Director	Audie L. Murphy Memorial Veterans Hospital	USA
1982-2012	Staff Physician	St. Luke's Lutheran Hospital	USA

Brief Summary of Relevant Clinical Research Experience:

Dr, Andrews has been a Principal Investigator or Sub-Investigator in clinical in 200 + Clinical Trials since 2000 including Chronic Obstructive Pulmonary Disease Trials, Seasonal Allergic Rhinitis, Perennial Allergic Rhinitis, Stress Urinary Incontinence, Irritable Bowel Syndrome, Asthma, Pulmonary Arterial Hypertension, Chronic Cough, Osteoporosis, Non-Alcoholic Fatty Liver Disease (NALFD), Osteoarthritis of the Knee Intra-Articular Injection, Clostridium Difficile Vaccine, Pneumonia Vaccine.

Signature: 

Signature Date: (dd-Mmm-yyyy) 02 Jun 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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CLINICAL AND MEDICAL CONTROLLED DOCUMENT (CMCD) SUPPORTING DOCUMENT

Identifier	Version	Title	Effective Date
INV02-INV04-WI-GL02-SD01	1.0	ABBREVIATED CURRICULUM VITAE TEMPLATE	01-Apr-2019

Full Legal Name:	Last Name	First Name	Middle Name
	Rubino, MD	John	

Professional Mailing Address:

Street Address 1:		Street Address 2:	
Raleigh Medical Group, PA		3521 Haworth Drive	
City: Raleigh	State/Province: North Carolina	Country: USA	Zip/Postal Code: 27609

Email Address: jrubino@raleighmedicalgroup.com

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Resident	1986	North Carolina Memorial Hospital, USA
Doctor of Medicine	1983	University of Connecticut, USA
Master of Science	1979	University of Connecticut, USA
Bachelor of Science	1978	University of Connecticut, USA

Medical License Number	State/Province	Country
28689	North Carolina	USA

Current Position at Study Site:

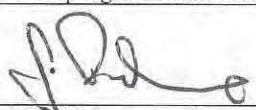
Start Date	Title	Institution or Company	State/Province & Country
2005 to Current	Network Medical Director	PMG Research of Raleigh, LLC	NC, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1990 to 2005	Director of Clinical Research	Multi-Specialty Research Associates of N.C.	USA
1986 to Current	Private Practice Physician	Raleigh Medical Group, PA	USA

Brief Summary of Relevant Clinical Research Experience:

Allergic Rhinitis, COPD, Gout, Migraine, Angina, C-Diff, Hormone Replacement, Mixed Dyslipidemia, Arthritis, Depression, Hyperlipidemia, Musculoskeletal Pain, Athlete's Foot, Diabetes, Hypertension, Myalgia, Atrial Fibrillation, Diabetes/Hypertension, Hypercholesterolemia, Nocturia, CAD, Diabetic Peripheral Neuropathy, Hypertriglyceridemia, Non-Malignant Pain, Chronic Low Back Pain, Dyslipidemia, Impotence, Osteoarthritis, Claudication, Erectile Dysfunction, Insomnia, Cardiovascular Disease, Coagulation, Flu, Low Back Pain, Rosacea, Constipation, Gastro Esophageal Reflux Disease, Interdigital Tinea pedis, Pneumonia

Signature:	Signature Date: (dd-Mmm-yyyy)
	02-Mar-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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Print Form

TransCelerate

Abbreviated Curriculum Vitae (CV)

First Name: Steven
Middle Name: Richard
Last Name: Kasler
Profession: MD, CPI
Affiliation Name: Wenatchee Valley Hospital

Address: Clinical Research Department, 820 N. Chelan Avenue

City: Wenatchee
Postal Code: 98801
State/Region/Province: WA
Country: USA
Phone: 509 436-4050
Extension: 5800
Fax: 509 664-7177
Email: rr-kaster@confluencehealth.org

Study Location Name (if different): NA

Address :

City:
Postal Code:
State/Region/Province:
Country:
Phone:
Extension:
Fax:
Email (if different):

EDUCATION

University	Degree	Year Completed
University of California, Davis, CA., USA	BS-Biological Sciences	1980
University of California, Davis, CA., USA	MS-Immunology	1982

MEDICAL EDUCATION

University	Degree	Year Completed
University of Southern California, USA	MD	1987
Department of Family and Community Medicine, University of Missouri, Columbia, MO, USA	Residency	1987-1990

TransCelerate

Abbreviated Curriculum Vitae (CV)

PROFESSIONAL EXPERIENCE/OTHER RELATED TRAINING

Institution	Medical Field	Year (Completed)
Wenatchee Valley Hospital, Medical Director, Clinical Research, Wenatchee, WA., USA	Clinical Research-Investigator	2006-Present
GroupNet, Medical Director, Clinical Research, Wenatchee, WA., USA	Clinical Research	2006-2010
Wenatchee Valley Hospital, Division of Primary Care, Wenatchee, WA., USA	Family Medicine	1992-2008

Professional License Number: MD00029645
State/Region/Province: WA
Expiration Date: 05/14/2022
Research Area(s) of Interest: Immunology, Endocrinology, Diabetes, Musculoskeletal, Cardiovascular, Adult Vaccine
Clinical Trial Phases: ☐ I ☑ II ☑ III ☑ IV

List your most Current Clinical Research below:

Therapeutic Area:	Type of Trial	Phase:	Completed	On-Going
Diabetes	Industry	II	☐	☑
Cardiovascular Disease	Industry	III	☐	☑
Hep B Vaccine	Industry	IV	☑	☐
Vascular Disease	Industry	III	☐	☑
Weight loss	Industry	IIIa	☐	☑
Type II Diabetes	Industry	IIIb	☐	☑
C-Diff Vaccine	Industry	III	☐	☑
Covid-19 Vaccine	Industry	III	☐	☑

GCP Training Documentation (Course Provider/Year Completed): ACRP-SCRS GCP / 2019

By signing this form, I confirm that the information provided on this Abbreviated CV is accurate and reflects my current employment and qualifications:

Signature: _____ Date: 5-AUG-2020

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Lucasti	Christopher	

Professional Mailing Address

Street Address: 730 Shore Road		Other Street Address:	
City: Somers Point	State/Province: NJ	Country: USA	Zip/Postal Code: 08244

Email Address: (b) (6)

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Doctor of Osteopathy	1986	Philadelphia College of Osteopathic Medicine, USA JN 03/08/20
Bachelor of Science	1982	St Josephs University, USA JN 03/08/20
Post Grad Training JN 03/08/20	~~1989~~-1991	University of Medicine and Dentistry of New Jersey, USA JN 03/08/20
Residency	~~1987~~-1989	Kennedy Memorial Hospital, USA 03/08/20

Medical License Number JN 03/08/20	State/Province	Country
25MB05201900	New Jersey	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1999-Present	Principle Investigator	South Jersey Infectious Disease	USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2000 – present	Chairman Infection Control	Shore Medical center	USA
1991-2009	Chief of Infectious Disease	Cape Regional Medical Center	USA
2004-present	Credentialing Committee	Shore Medical Center	USA

Brief Summary of Relevant Clinical Research Experience:

20+ years of research experience that includes inpatient and outpatient trials in the fields of HIV, intra-abdominal infections, skin infections, vaccines and infectious diseases.

Signature:	Signature Date: (dd-Mmm-yyyy)
	03 AUG 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Murray	Alexander	Vance

Professional Mailing Address

Street Address: 806 Green Valley Road, Suite 305		Other Street Address:	
City: Greensboro	State/Province: NC	Country: USA	Zip/Postal Code: 27408
Email Address:	amurray@pharmquest.biz		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MD	1983	University of Virginia School of Medicine, Charlottesville, VA USA

Medical License Number	State/Province	Country
29782	NC	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1998	Principal Investigator	PharmQuest	NC USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1986 – 2005	Physician	Eagle Family Medicine @ Triad	USA
1983 – 1986	Resident	Bowman Gray School of Medicine	USA

Brief Summary of Relevant Clinical Research Experience:

Principal Investigator: Cholesterol, Type II Diabetes, Urinary, Shingles Vaccination, Insomnia, Tendonitis, Hypertension, Post-Herpetic Neuralgia, Post-Menopausal with Low Bone Mass, Osteoarthritis, Alzheimer's, Asthma, Gastrointestinal, Low Back Pain, Diabetic Neuropathy, Fibromyalgia, Cardiovascular, COPD, Endometriosis and Depression studies

Signature:	Signature Date: (dd-Mmm-yyyy)
Alexander Vance Murray	04-JUN-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Lillestol	Michael	J

Professional Mailing Address: Lillestol Research LLC

Street Address 1: 4450 31st Avenue S		Other Street Address: Suite 101	
City: Fargo	State/Province: ND	Country: USA	Zip/Postal Code: 58104
Email Address:	lillestolmd@lillestolresearch.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MD	1974	University of Minnesota, MN, USA
BS Pharmacy	1970	North Dakota State University, ND, USA

Medical License Number	State/Province	Country
4830	ND	USA
22194	MN	USA
AL6707965	DEA	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2004-present	President	Lillestol Research LLC	ND, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1983-1993; 2002-present	President	Internal Medicine Associates	ND, USA
1992-2004	Consultant	Odyssey Research Services	ND, USA
1993-2002	Physician	Dakota Heartland	ND, USA

Brief Summary of Relevant Clinical Research Experience:

Dr. Lillestol has more than 29 years of clinical research experience and has now served as PI on more than 250 clinical trials. He has worked on a variety of indications related to Internal Medicine and with numerous Pharmaceutical Sponsors and CROs.

Signature:

Signature Date: (dd-Mmm-yyyy)

04 Jul 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Salata	Robert	Andrew

Professional Mailing Address

Street Address: University Hospitals Cleveland Medical Center		Other Street Address: 11100 Euclid Avenue	
City: Cleveland	State/Province: Ohio	Country: USA	Zip/Postal Code: 44106
Email Address:	**Robert.salata@uhhospitals.org**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
BA	1974	University of Notre Dame
MD	1979	Case Western Reserve University

Medical License Number	State/Province	Country
35.043998	Ohio	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2016	Chairman Department of Medicine	University Hospitals Cleveland Medical Center	Ohio/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2015-Present	Physician-in-Chief, Master Clinician in Infectious Diseases	University Hospitals Cleveland Medical Center	USA
2007-Present	PI Infectious Diseases Clinical Trials Unit	Case Western Reserve University/UHCMC	USA
1998-Present	Professor of Medicine, International Health, Biostatistics and Epidemiology	Case Western Reserve University	USA

Brief Summary of Relevant Clinical Research Experience:

I have the expertise, leadership, skills set and motivation to undertake and successfully carry out the proposed research project. I have undertaken trials on-site of several vaccines (e.g. Modified Vaccinia Ankara, influenza). I have been involved in clinical trials study design, implementation, analysis and dissemination of clinical trials studies for 30 years. I have been a site Principal Investigator for phase I trials conducted with support from the NIH and National Institute of Allergy and Infectious Diseases (NIAID) and the Division of Microbiology and Infectious Diseases (DMID) for the past 10 years. Additionally, I have been involved in AIDS Clinical Trial Group-sponsored studies (domestic and international) through NIAID and the Division of AIDS for over 15 years and have served as protocol chair and vice chair on several protocols. I am a part of the NIAID DMID Sexually Transmitted Infections Clinical Trials Group and am part of an award from the Department of Health and Human Services to undertake studies of emerging infections through the Biomedical Advanced Research Development Authority (BARDA).

Signature:	**Signature Date: (dd-Mmm-yyyy)**
Robert A. Salata, MD	17-Aug-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Lee, M.D.	Marcus	W.

Professional Mailing Address

Street Address: Trinity Clinical Research		Other Street Address: 709 NW Atlantic Street	
City: Tullahoma	State/Province: TN	Country: USA	Zip/Postal Code: 37388

Email Address: (b) (6)

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
B.S. Chemistry	1996	University of Tennessee
Doctor of Medicine	2000	University of Tennessee at Memphis
Family Practice Residency	2003	University of Tennessee Family Practice

Medical License Number	State/Province	Country
MD0000035884	TN	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2011	Principal Investigator	Trinity Clinical Research	TN/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2006 to present	CEO, MD	Universal Family Care	USA
2010-2011	PI	HCCA Clinical Research	USA

Brief Summary of Relevant Clinical Research Experience:

COPD, Diabetes, Fibromyalgia, Elevated Cholesterol, Insomnia in Alzheimer's, OIC, Migraine, Diabetic Neuropathy, Herpetic Neuralgia, C-Diff

Signature:	Signature Date: (dd-Mmm-yyyy)
MD	16-JUL-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Usdan	Lisa	S.

Professional Mailing Address:

Street Address:		Other Street Address:	
6401 Poplar Avenue Suite 420			
City: Memphis	State/Province: TN	Country: USA	Zip/Postal Code: 38119
Email Address:	lusdan@cnshealthcare.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Medical Doctor	2003	University of Tennessee
Bachelor of Science, Psychology	1999	Tulane University

Medical License Number	State/Province	Country
43169	Tennessee	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2012	Investigator	Clinical Neuroscience Solutions, Inc.	Tennessee/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2008-2009	Fellowship, Obesity	Boston University Medical Center	USA
2006-2008	Fellowship, Endocrinology	Boston Medical Center	USA
2003-2006	Residency, Internal Medicine	Thomas Jefferson	USA

Brief Summary of Relevant Clinical Research Experience:

Principal Investigator and Sub-Investigator on over 65 clinical trials in phase I – IV clinical research in children, adolescents and adults. Diagnoses include ADHD, Alzheimer's disease, ankle sprain, bipolar disorders, binge eating, constipation, chronic pain, depressive disorders, diabetes, painful diabetic neuropathy, fibromyalgia, irritable bowel syndrome, constipation, hypertension, obesity, migraines, opioid induced constipation, opioid induced constipation, osteoarthritis, osteoporosis, pain, panic disorder, post-traumatic stress disorder, schizoaffective disorder, schizophrenia, polycystic ovarian syndrome, thyroid, pituitary diseases and internal medicine.

Signature:	**Signature Date: (dd-Mmm-yyyy)**
Lisa S. Usdan	28 JUN 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Whiles	Rick	J.

Professional Mailing Address:

Street Address 1:	Street Address 2:		
Holston Medical Group 240 Medical Park Blvd. Suite 3600			
City: Bristol	State/Province: TN	Country: USA	Zip/Postal Code: 37620

Email Address: rick.whiles@myhmg.com

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Residency	2000	Akron General Medical Center & Children's Medical Center of Akron – USA
Medical Degree	1996	Medical College of Ohio- USA

Medical License Number	State/Province	Country
MD0000036471	Tennessee	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2002-Current	Internal & Pediatric Medicine Physician	Holston Medical Group	TN / USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2000-2002	Internal & Pediatric Medicine	Dorothy Lane Internal Medicine & Pediatrics	USA

Brief Summary of Relevant Clinical Research Experience:

Principal Investigator and Sub-Investigator on studies including Atrial Fibrillation , Type II Diabetes, Obesity, Osteoarthritis, Overactive Bladder, Smallpox Vaccine, Depression, Hepatitis A, Rota Virus, Hyperlipidemia, Strep, Back Pain, Hypercholesterolemia, Dyslipidemia, Cardiovascular Risk, COPD, Infant Formula, Hypertension, Otitis Externa, MMR Vaccines, and C-Diff Vaccine..

Signature:	Signature Date: (dd-Mmm-yyyy)
RWhiles MD	17 FEB 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Crook	Gretchen	

Professional Mailing Address

Street Address: 11714 Wilson Parke Ave., Suite 150		Other Street Address:	
City: Austin	State/Province: TX	Country: USA	Zip/Postal Code: 78726
Email Address:	gcrook@arcmd.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Chief Resident	2000	University of Florida College of Medicine
Residency	2000	University of Florida College of Medicine
Doctor of Medicine	1997	University of Florida College of Medicine
Bachelor of Arts	1992	Washington University

Medical License Number	State/Province	Country
L1552	TX	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2016	Investigator	ARC Clinical Research at Wilson Parke	TX, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2002 - current	Physician	Austin Regional Clinic	USA
2000 - 2001	Physician	Civilian Staffing Agency	USA

Brief Summary of Relevant Clinical Research Experience:

General Adult Trials
Osteoarthritis, COPD, Asthma, Diabetes Mellitus, Hyperlipidemia, Uterine Fibroid, Colorectal Cancer, Diagnostic Screening, Hepatocellular Carcinoma
General Pediatric Trials
Influenza
Adult Vaccine Trials
Clostridium Difficile

Signature:	Signature Date: (dd-Mmm-yyyy)
Gretchen Crook	10 Jul 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Seger	William	M

Professional Mailing Address:

Street Address: 4504 Boat Club Road Suite 400A		Other Street Address: 4504 Boat Club Road Suite 800	
City: Fort Worth	State/Province: Texas	Country: United States	Zip/Postal Code: 76135
Email Address:	williamseger@benchmarkresearch.net		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
BA in Biology	1980	Texas A&M University
MD	1985	Texas Tech University

Medical License Number	State/Province	Country
H0801	Texas	United States

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1995	Principal Investigator	Benchmark Research	TX, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1988-present	Vice President	HealthFirst Medical Group	USA
1988-present	Private Practice/Family Practice	HealthFirst Medical Group	USA
2001-present	Clinical Professor	University of North Texas Health	USA
2009-present	Director of Geriatric Vaccines	VaxNet, Premier Vaccine Network	USA

Brief Summary of Relevant Clinical Research Experience:

Clinical Trial Phases I, II, III, IV. Current Clinical Research Trials: E-Cig, phase IV; Ebola Vaccine, phase I; Gout, phase III; RSV Vaccine, phase IIb; Pediatric Flu Vaccine, phase II; Adult Flu Vaccine, phase III; Small Pox, phase III; Influenza Vaccine, phase III.

Signature:

Signature Date: (dd-Mmm-yyyy) 06 May 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE

TransCelerate BIOPHARMA INC.

Name: **Aaron N. Hartman, MD**
Professional Title: Medical Doctor
Organization: Virginia Research Center LLC
Address1: 13911 St. Francis Blvd, Suite 101
Address2: Midlothian, VA 23114
E-Mail: ahartman@virginiaresearchcenter.com

Main Daytime Phone: 804-893-2273
Pager:
Mobile Phone:
24 Hour Phone: 804-687-8250
Evening Phone:
Fax: 1-866-372-4381

AFFILIATIONS

Facility Name	Department Name	Facility/Department Address
Virginia Research Center LLC		13911 St. Francis Blvd, Suite 101, Midlothian, VA 23114

EDUCATION

University/School/Program	Degree/Certificate	Specialty	Year Completed
Virginia Commonwealth University	Bachelor of Science	Not Applicable	1995
Medical College of Virginia	Medical Doctor	Not Applicable	2000
		Not Applicable	
		Not Applicable	
		Not Applicable	

PROFESSIONAL EXPERIENCE

Job Title	Institution	Year Started	Year Completed
Medical Director	Virginia Research Center, LLC	2010	Present
Junior Partner	Family Practice Associates	2007	Present
Assistant Clinical Professor in the Department of Medicine	Virginia Commonwealth University	2011	Present
Attending Physician	Mac Dill AFB Hospital	2003	2007
Medical Director	Brandon Community Clinic	2006	2007
Part Time Attending Physician	New Tampa Urgent Care	2005	2007
Primary Care Manager	Brandon Community Clinic	2004	2006
Deployed Warrior Medical Readiness Clinic	Landstuhl Regional Medical Center	2004	2004
Staff Physician	Memorial Regional Medical Center	2002	2003
Residency	Hanover Family Practice / Medical College of Virginia	2001	2003

AN 06 Aug 2020

LICENSE DETAILS

Type of License	If Other, Type of License	License Issuer	Professional License Number	Country	State, Province or Region	Expiration Date
Medical Doctor			0101230391	United States of America	Virginia	31-Aug-2020
N/A				N/A		
N/A				N/A		
N/A				N/A		
N/A				N/A		

ABBREVIATED CURRICULUM VITAE

TransCelerate BIOPHARMA INC.

Name: **Aaron N. Hartman, MD**
Professional Title: Medical Doctor
Organization: Virginia Research Center LLC
Address1: 13911 St. Francis Blvd, Suite 101
Address2: Midlothian, VA 23114
E-Mail: ahartman@virginiaresearchcenter.com
Main Daytime Phone: 804-893-2273
Pager:
Mobile Phone:
24 Hour Phone: 804-687-8250
Evening Phone:
Fax: 1-866-372-4381

RESEARCH EXPERIENCE

Study Type (Check all that apply):

- ☐ Academic
- ☑ Industry
- ☐ Investigator-Initiated
- ☐ Government
- ☐ Other / Please specify:

Clinical Study Phases (Check all that apply): ☐ I ☑ II ☑ III ☑ IV

Therapeutic Areas of Expertise:

Therapeutic Area	Sub-Therapeutic Area
Musculoskeletal Diseases	Musculoskeletal Abnormalities
Skin and Connective Tissue Diseases	N/A
Endocrine System Diseases	Diabetes Mellitus
Respiratory Tract Diseases	Respiratory System Abnormalities
Nutritional and Metabolic Diseases	Metabolic Diseases
N/A	N/A
N/A	N/A
N/A	N/A

Total Clinical Research Experience:

Therapeutic Area	Sub-Therapeutic Area	Number of completed studies	Number of ongoing studies
Musculoskeletal Diseases	Back Injuries	7	0
Skin and Connective Tissue Diseases	Skin Diseases	2	0
Endocrine System Diseases	Diabetes Mellitus	18	3
Digestive System Diseases	Gastrointestinal Diseases	1	0
Bacterial Infections and Mycoses	Infection	0	2
Cardiovascular Diseases	Metabolic Diseases	0	2
Nutritional and Metabolic Diseases	Metabolic Diseases	3	0
Respiratory Tract Diseases	Respiratory System Abnormalities	11	0
Female Urogenital Diseases and Pregnancy Complications	Sexual Dysfunctions, Psychological	1	0
Virus Diseases	Infection	1	0
Wounds and Injuries	Tendon Injuries	1	1

Good Clinical Practice (GCP) Training Details:

Training Provider	Title of Training	Version	Date Completed	Status
Transcelerate	ICH GCP Investigator Training	3	15-Jan-2018	N/A
				N/A
				N/A
				N/A
				N/A
				N/A

By signing this form, I confirm that the information provided on this Abbreviated CV is accurate and reflects my current employment and qualifications:

Signature: _____ ***Date:*** 12/12/19

ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Hendrix	Ernest	Lee

Professional Mailing Address

Street Address: 721 West Market Street, Suite B		Other Street Address:	
City: Athens	State/Province: Alabama	Country: USA	Zip/Postal Code: 35611
Email Address:	**ehendrixmd@northalabamaresearch.com**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Residency, Family Medicine	1994	University of Alabama, USA
Medical Doctor	1991	University of South Alabama College of Medicine, USA
Bachelors of Science (Chemistry)	1986	Athens State College, USA

Medical License Number	State/Province	Country
16454	Alabama	USA

Current Position at Study Site:

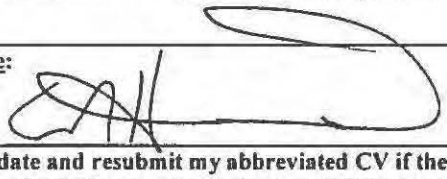
Start Date	Title	Institution or Company	State/Province & Country
2007– Present	Principal Investigator	North Alabama Research Center, LLC	Alabama, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2003-Present	Physician	Ernest Lee Hendrix, MD PC	USA
1996-2003	Physician	Athens Limestone Medical Associates of Athens	USA

Brief Summary of Relevant Clinical Research Experience:

Vaccine, Irritable Bowel Syndrome, Erosive Esophagitis, Helicobacter Pylori, Gout, COPD, Influenza, Diabetes, Asthma, IBS-C, High Risk Cardiovascular Outcome Trial, Diabetic Gastroparesis, Type-2 Diabetes, Erosive Gastroesophageal Reflux Disease, Ulcerative Colitis

Signature: 

Signature Date: (dd-Mmm-yyyy) 04-Aug-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	McMurray	James	G

Professional Mailing Address

Street Address:		Other Street Address:	
303 Williams Avenue		Suite 511	
City: Huntsville	State/Province: AL	Country: USA	Zip/Postal Code: 35801
Email Address:	jgm@marc-research.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Diplomate	1976	American Board of Urology/USA
Residency	1970-1974	University of Mississippi/USA
Internship	1967-1968	Memorial Hospital/USA
Doctor of Medicine	1963-1967	University of Mississippi/USA

Medical License Number	State/Province	Country
MD-6591	AL	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1995	Investigator	Medical Affiliated Research Center	AL/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1995-2016	Medical Director	Medical Affiliated Research Center, Inc.	USA
1974-Present	M.D.	James Gordan McMurray, Private Practice	USA

Brief Summary of Relevant Clinical Research Experience:

20-Benign Prostatic Hypertrophy, 49-Erectile Dysfunction, 7-Nocturia, 9-Premature Ejaculation, 15-Prostate Cancer, 5-Prostatitis, 14-Urinary Incontinence, 16-Testosterone, 8-Urinary Tract Infection, 3-Dyslipidemia, 7-Hypertension, 1-Acne Vulgaris, 1-Psoriasis, 1-Tinea Pedis,8- Diabetes, 3-Obesity, 2-Chronic Constipation, 1-Diabetic Gastroparesis, 2-Functional Dyspepsia, 3-Gastroesophageal Reflux Disease, 6-IBS, 2-Herpes Virus Labalis, 7- Migraine, 3- Sleep Disorders, 2-Dermatology, 4-Osteoarthritis, 1-Rheumatiod Arthritis, 1-Psoriatic Arthritis, 3-Contraceptive, 1-Endometrial Hyperplasia, 6-Endometriosis, 13-Female Sexual Dysfunction, 5-Fibroids,4-Hormone Replacement Therapy, 1-Osteoporosis, 5-Vaginal Atrophy, 3-Vulvovaginal Candidiasis , 1-Clostridium Difficile, 2-Vaccine

Signature:	Signature Date: (dd-Mmm-yyyy)
	14 Jul 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Burgher	Abram	H.

Professional Mailing Address

Street Address:		Other Street Address:	
2525 W. Greenway Road		Suite 220	
City: Phoenix	**State/Province:** AZ	**Country:** USA	**Zip/Postal Code:** 85023
Email Address:	Abram.burgher@hriaz.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Certified, Anesthesiologist	2010	American Board of Pain Medicine, USA
Doctor of Medicine	2004	University of Minnesota, Twin Cities, USA

Medical License Number	State/Province	Country
34609	AZ	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2011	Principal Investigator	HOPE Research Institute	AZ, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2011- 2020	Pain Management Physician	The Pain Center of Arizona	USA
2018- Present	Assistant Professor	Mayo Clinic Graduate School of Medicine	USA

Brief Summary of Relevant Clinical Research Experience:

Physician who has worked as a PI/ Sub-Investigator for over 9 years on Phase I-IV drug/ medical device clinical trials with an emphasis on pain management. Therapeutic areas include chronic pain conditions, device, and vaccines.

Signature:	Signature Date: (dd-Mmm-yyyy)
	24 Jul 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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AL
04Aug2020

ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Fussell	Suzanne	

Professional Mailing Address

Street Address: 2403 Atlantic Ave		Other Street Address:	
City: Long Beach	State/Province: CA	Country: USA	Zip/Postal Code: 90806
Email Address:	sfussell@lbclinicaltrials.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MD	1994	UCLA/ Charles R. Drew School Of Medicine, CA, USA

Medical License Number	State/Province	Country
A55383	CA	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1/1/2014	Principal Investigator	Long Beach Clinical Trials Services Inc.	California, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1998- Current	Medical Director	St Nazarene Medical Clinic	USA
2003- Current	Chair Of Medical Foundation	Health wise	USA
2016-2017	Medical Director	Silverado Hospice	USA

Brief Summary of Relevant Clinical Research Experience:

I have been involved in clinical research for the past 10years. I have been the principal and sub-investigator on various studies. Some areas of past research include, Gastrointestinal disorder, skin disorders, women's health, musculoskeletal disorder, infectious diseases as well as endocrinology studies. I have significant experience with GCP as well as interfacing with various EDC systems such as medidata, RAVE and trident to name a few.

Signature:	Signature Date: (dd-Mmm-yyyy)
Suzanne Fussell MD	21 / Jul / 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Leibowitz	Mark	Todd

Professional Mailing Address

Street Address: 2010 Wilshire Blvd.		Other Street Address: Suite 302 and 809	
City: Los Angeles	State/Province: CA	Country: USA	Zip/Postal Code: 90057

Email Address: Mark.Leibowitz@NRItrials.com

Academic Qualifications: M.D.

Degree and/or Certification	Date (yyyy)	Institution and/or Country
M.D.	1982	Albert Einstein College of Medicine, New York/ USA
B.A.	1978	Hofstra University, New York/ USA

Medical License Number	State/Province	Country
[illegible]	California	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
May 2019	Principal Investigator or Sub-Investigator	National Research Institute	CA/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
Feb 2013-Apr 2019	Investigator Director of Early Phase Research	Collaborative Neuroscience Network, Inc.	USA
Jan 2008-Dec2012	Investigator/ Medical Director	Cedra Clinical Research, LLC/ Worldwide Clinical Trials, Drug Development Solutions, Clinical Research Services	USA
2005-2007	Director of Early Drug Development	California Clinical Trials Medical Group	USA
2004-2005	Assistant Medical Director	California Clinical Trials Medical Group	USA

Brief Summary of Relevant Clinical Research Experience:

PHASE I-IV; Healthy Normal Subjects (Adult and Elderly) • Bioequivalence • Ethno-Bridging Studies • Studies involving CSF Sampling (Lumbar Puncture, Serial/ Continuous Collection via Lumbar Catheter)
Other Indications: Alzheimer's Disease • Anxiety Disorder • Bipolar Disorder • Depression • Diabetes • Gastrointestinal Disorders • Liver Disease • Hypertension • HIV • Insomnia • Migraine • Mild Cognitive Impairment • Multiple Sclerosis • NAFLD • NASH • Obesity • Osteoarthritis • Parkinson's Disease • Pre- and Post- Menopausal • Psoriasis • Psychotic Disorders • Schizophrenia and Schizoaffective Disorders • Uterine Fibroids

Additional: 200+ Bioequivalence & Ethno-Bridging • 70+ Healthy Normal • 40+ First in Man (FIM)

Active Contributing and Voting Member for Data Safety Monitoring Boards

Signature:	Signature Date: (dd-Mmm-yyyy)
[signature]	16-MAY-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NJ 11Aug2020

NJ 06Aug2020

Dr. Helen Lee Stacey
Diablo Clinical Research
2255 Ygnacio Valley Rd, Suite M
Walnut Creek , California ,
United States of America , 94598
Email: hstacey@diabloclinical.com

Cell/Mobile: 9259307267
Fax: 9259307392

AFFILIATIONS

Facility Name (Department Name)	Facility Address	Department Address
Diablo Clinical Research, Inc.	2255 Ygnacio Valley Road, Suite M, Walnut Creek, California, United States of America, 94598	Not Applicable

EDUCATION

University	Degree/Certificate	Specialty	Year Completed
University of Washington	MPH	Not Applicable	1996
University of Washington	Internal Medicine Residency	Not Applicable	1991
Emory University	MD	Not Applicable	1988

PROFESSIONAL EXPERIENCE

Job Title	Institution	Year Started	Year Completed
Investigator	Diablo Clinical Research	2000	Present
Internist	Muir Primary Care	1999	2001
Medical Director	Washington Corrections Center for Women	1996	1998
Medical Director	Seattle Public Schools Hepatitis B Immunization Project	1994	1995
Acting Instructor	University of Washington AIDS Vaccine Unit	1991	1994

LICENSE DETAILS

Type of License	License Issuer	Professional License Number	Country	State/Province/ Region	Expiration Date
Medical Doctor	State of California	G85228	United States of America	California	30-Nov-2020

RESEARCH EXPERIENCE

Study Type: Industry;Government;Academic
Clinical Study Phases: I,II,III,IV
Therapeutic Area of Expertise: Device;Digestive System Diseases;Endocrine System Diseases;Female Urogenital Diseases and Pregnancy Complications;Male Urogenital Diseases;Nervous System Diseases;Nutritional and Metabolic Diseases;Pain;Vaccines;Women's Health

TOTAL CLINICAL RESEARCH EXPERIENCE

Therapeutic Area	Sub Therapeutic Area	Number of Completed Studies	Number of Ongoing Studies
Endocrine System Diseases	Diabetes Mellitus	7	5
Vaccines	Vaccines	7	3
Women's Health	Women's Health	7	0
Nervous System Diseases	Neurologic Manifestations	5	1
Digestive System Diseases	Gastrointestinal Diseases	3	2
Device	Device	3	0
Male Urogenital Diseases	Genital Diseases, Male	2	1
Nutritional and Metabolic Diseases	Metabolic Diseases	2	0
Female Urogenital Diseases and Pregnancy Complications	Female Urogenital Diseases	1	0
Pain	Pain	1	0

GCP TRAINING DETAILS

Dr. Helen Lee Stacey
Diablo Clinical Research
2255 Ygnacio Valley Rd, Suite M
Walnut Creek , California ,
United States of America , 94598
Email: hstacey@diabloclinical.com

Cell/Mobile: 9259307267
Fax: 9259307392

Course Provider	Course Title	Date Completed (DD-MMM-YYYY)	Status
CITI Program	GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus) Course - 1	03-Jul-2018	Certificate Valid

By signing this form, I confirm that the information provided on this Abbreviated CV is accurate and reflects my current employment and qualifications:

Signature:	Dr. Helen Lee Stacey staceyh_8509 19-DEC-2019 18:24:27 GMT Author of CV

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Cardona	Jose	F.

Professional Mailing Address

Street Address: 3700 West 12th Ave.		Other Street Address: Suite 300	
City: Hialeah	State/Province: FL	Country: USA	Zip/Postal Code: 33012
Email Address:	jcardona@indagoresearch.org		

Academic Qualifications: MD, MBA

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MBA in Health Administration and Policy	2007	University of Miami, USA
Emergency Medicine Residence	1988	Puerto Rico Medical Center, University Hospital, Puerto Rico
Emergency Medicine Internship	1986	Puerto Rico Medical Center, University Hospital, Puerto Rico
Medical Doctor	1985	Universidad Central del Caribe School of Medicine, Puerto Rico

Medical License Number	State/Province	Country
ME 68785	Florida	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
08/2015	Principal Investigator	Indago Research & Health Center, Inc.	FL, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
07/2012 – 08/2015	Principal Investigator	Palm Springs Research Institute	USA
06/2012 – Present	Interventional osteoarthritis Pain Management Emergency Medicine Board Eligible Physician Primary Care & Urgent Car Physician	Jose F. Cardona, MD. PA	USA
01/2011 – 05/2012	Medical Director, Primary Care Physician, Pain Management Practice	Preventive and Primary Care Medical Center	USA
10/2008 – 01/2011	Medical Director, Primary Care Physician, Pain Management Practice	Arthritis and Pain Clinic	USA
03/1997-09/2008	Vice President Emergency Medicine Physician	Interned Emergency Services, PSC	Puerto Rico
09/1988 -02/1997	Emergency Medicine Department Medical Director Emergency Medicine Physician	HIMA-San Pablo Hospital	Puerto Rico

Brief Summary of Relevant Clinical Research Experience:

Alzheimer Disease, Asthma, Atherosclerosis, Back Pain, Cardiovascular Disease, Chronic Idiopathic Constipation, Chronic Kidney Disease, Clostridium Difficile, Congestive Heart Failure, Constipation, COPD, Coronary Artery Disease (CAD), Crohn Disease, Cytomegalovirus (CMV), Diabetes Type II, Diabetic Nephropathy, Diabetic Neuropathy, Diabetic Retinopathy, Diarrhea, Dyslipidemia, Endometriosis, Epilepsy, Fatty Liver Disease, Foot Ulcer, Glaucoma, Healthy, Hepatitis C, High Ocular Pressure, Hypercholesterolemia, Hyperlipidemia, Hypertriglyceridemia, Hyperuricemia, Hypogonadism, IBS-C, Influenza/Flu, Intestinal Bowel Syndrome (IBS), Migraine, Nonalcoholic Steatohepatitis (NASH), Obesity, Osteoarthritis, Overactive Bladder, Pneumococcal Disease, Postmenopausal, Prostate Cancer, Psoriasis, Rheumatoid Arthritis, Stroke, Scabies, Vaccine, Women's health.

Signature:	Signature Date: (dd-Mmm-yyyy)
	25-JUN-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

dhm 28Aug2020

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Chalhoub	Fadi	Raji

Professional Mailing Address: ***Clinical Neuroscience Solutions, Inc.***

Street Address 1: 5200 Belfort Road Suite 420		Street Address 2:	
City: Jacksonville	State/Province: Florida	Country: USA	Zip/Postal Code: 32256
Email Address:	**fchalhoub@cnshealthcare.com**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MD	1987	St. Joseph's Medical School

Medical License Number	State/Province	Country
ME82883	Florida	USA

Current Position at Study Site: ***Investigator***

Start Date	Title	Institution or Company	State/Province & Country
2012	Investigator	Clinical Neuroscience Solutions, Inc.	Florida/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2001-2012	Hospitalist	Specialty Hospital	USA
2001-2012	Hospitalist	Memorial hospital	USA
2001-2012	Medical Attending	North Florida Medical Association	USA
2010-2012	Medical Attending	Heartland Jacksonville South	USA

Brief Summary of Relevant Clinical Research Experience:

Investigator on phase II-IV clinical trials in children, adults and geriatrics. Diagnosis include-cardiac disorders. Hypertension, cholesterol, renal failure, respiratory failure, wound care, chronic pain, diabetes, asthma, peripheral vascular disease, neuropathy, stroke, anxiety disorders, attention deficit & disruptive behavior disorders, bipolar disorders, depressive disorders, eating disorders, personality disorders, psychotic disorders, sleep disorders, and substance abuse/dependence disorders.

Signature:	Signature Date: (dd-Mmm-yyyy)
F Chalhoub	14 JAN 2020

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Butuk	David	J

Professional Mailing Address

Street Address: 1525 E. Leigh Field Dr.		Other Street Address: Suite 100	
City: Meridian	State/Province: ID	Country: USA	Zip/Postal Code: 83646
Email Address:	pi@solarisclinicalresearch.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Board Certified Family Physician	1998-Present	American Board of Family Practice
Doctor of Medicine	1993	University of Toronto, School of Medicine

Medical License Number	State/Province	Country
M-8859	Idaho	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2007	Investigator	Solaris Clinical Research	Idaho / USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2006-Present	Family Physician & Owner	Meridian Family Medicine	USA
2013 – Present	Medical Director	Biolife Plasma Centers	USA
2003-2006	Family Physician & Partner	Cherry Lane Family Practice	USA
1994 – 2003	Family Physician & Partner	Visalia Family Practice	USA

Brief Summary of Relevant Clinical Research Experience:

13 years of experience as Principal Investigator and owner at current research facility. Have participated as Principal Investigator in over 90 phase 2, 3, & 4 clinical trials with indications for type 2 diabetes, hypercholesterolemia, hypertriglyceridemia, hypertension, erectile dysfunction, obesity & weight management, gout, COPD, asthma, smoking cessation, IBS, and vaccine

Signature:	Signature Date: (dd-Mmm-yyyy)
	06-AUG-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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Andrew Gentry
Bozeman Health Clinical Research
931 Highland Boulevard, Suite 3103, Gallatin County
Bozeman , Montana , United States of America , 59715
Email: investigator@bozemanhealth.org
Cell/Mobile: 1-406-414-4475

AFFILIATIONS

Facility Name (Department Name)	Facility Address	Department Address
Bozeman Health Deaconess Hospital (Bozeman Health Clinical Research)	915 Highland Boulevard, Bozeman, Montana, United States of America, 59715	931 Highland Boulevard, 3103, Bozeman, Montana, United States of America, 59715

EDUCATION

University	Degree/Certificate	Specialty	Year Completed
Walter Reed National Military Medical Center	Fellowship	Gastroenterology	2008
Naval Medical Center Portsmouth	Residency	Primary Care (General Practice, Family Practice, Internal Medicine)	2005
Naval Medical Center Portsmouth	Internship	Not Applicable	2002
Uniformed Services University of the Health Sciences	MD	Not Applicable	2001
United States Naval Academy	BS	Not Applicable	1990

PROFESSIONAL EXPERIENCE

Job Title	Institution	Year Started	Year Completed
Principle Investigator	Bozeman Health Deaconess Hospital d/b/a Bozeman Health Clinical Research	2016	Present
Gastroenterologist	Bozeman Health Deaconess Hospital	2014	Present
Gastroenterologist	Bozeman Health GI Clinic	2014	Present
Division Head Gastroenterology	Naval Medical Center Portsmouth	2010	2014
Staff Gastroenterologist	Navy Medical Center Portsmouth	2009	2010

LICENSE DETAILS

Type of License	License Issuer	Professional License Number	Country	State/Province/ Region	Expiration Date
Medical Doctor	Montana Department of Labor & Industry Board of Medical Examiners	MED-PHYS-LIC-26717	United States of America	Montana	31-Mar-2021

RESEARCH EXPERIENCE

Study Type: Academic;Industry;Investigator Initiated
Clinical Study Phases: II,III
Therapeutic Area of Expertise: Digestive System Diseases;Infectious Diseases;Vaccines

TOTAL CLINICAL RESEARCH EXPERIENCE

Therapeutic Area	Sub Therapeutic Area	Number of Completed Studies	Number of Ongoing Studies
Digestive System Diseases	Gastrointestinal Diseases	5	1
Vaccines	Vaccines	0	2
Digestive System Diseases	Inflammatory Bowel Disease	0	1

Andrew Gentry
Bozeman Health Clinical Research
931 Highland Boulevard, Suite 3103, Gallatin County
Bozeman , Montana , United States of America , 59715
Email: investigator@bozemanhealth.org
Cell/Mobile: 1-406-414-4475

GCP TRAINING DETAILS

Course Provider	Course Title	Date Completed (DD-MMM-YYYY)	Status
Pfizer	Good Clinical Practice for Investigational Site Staff - 3.0	21-Feb-2020	Certificate Valid

By signing this form, I confirm that the information provided on this Abbreviated CV is accurate and reflects my current employment and qualifications:

Signature:	Andrew Gentry gentrya_5843 16-JUL-2020 20:02:42 GMT Author of CV

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Dunn	Michael	J

Professional Mailing Address

Street Address:		Other Street Address:	
10040 Regency Cr Suite 375			
City: Omaha	State/Province: NE	Country: USA	Zip/Postal Code: 68114
Email Address:	dunn@qcromaha.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Pre-Medical degree	1960	Creighton University, Omaha NE
MD	1964	Creighton University, Omaha NE

Medical License Number	State/Province	Country
11167	NE	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2006	Investigator	Quality Clinical Research, Inc	Omaha NE, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1968-1970	Instructor	Creighton School of Medicine	USA
1968-2004	MD	Private Practice Internal Medicine	USA
1970-1975	Clinical Professor of Internal Medicine	Creighton University	USA

Brief Summary of Relevant Clinical Research Experience:

Over fourteen years of experience as a clinical research investigator including all phases and multiple therapeutic areas

Signature:	Signature Date: (dd-Mmm-yyyy)
Michael J Dunn, MD	09 JUN 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Middleton	Randle	T.

Professional Mailing Address

Street Address:		Other Street Address:	
2089 Cecil Ashburn Drive		Suite 203	
City: Huntsville	State/Province: AL	Country: USA	Zip/Postal Code: 35802
Email Address:	rmiddleton@optimalsites.net		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Doctor Of Medicine	1989	University Of Mississippi
BA, Biological Science	1982	University OF Mississippi

Medical License Number	State/Province	Country
MD18862	Alabama	USA

Current Position at Study Site:

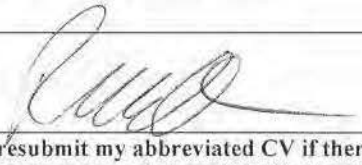
Start Date	Title	Institution or Company	State/Province & Country
June 2014	Investigator/Medical Director	Optimal Research LLC	AL_USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
02/2005-06/2014	Investigator/Medical Director	Accelovance	USA
01/1999-2/2005	Investigator	Ntouch	USA
97/1992-12-1994	Family Practice Physician	Baynes Jones Army Community Hospital	USA

Brief Summary of Relevant Clinical Research Experience:

Principal Investigator for 21 years with primary focus on vaccine studies for multiple indications. alo general health studies including but not limited to diabetes, IBS, and Hyperlipidemia

Signature:	Signature Date: (dd-Mmm-yyyy)
	01 Jun 2020

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Anderson	Corey	G

Professional Mailing Address

Street Address: 1492 S. Mill Ave. Suite 312		Other Street Address:	
City: Tempe	State/Province: AZ	Country: USA	Zip/Postal Code: 85281
Email Address:	**Corey.anderson@amrllc.com**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Medical Doctorate	1992-1996	Rosalind Franklin University of Science and Medicine
BSA- Nutrition	1987 -1992	University of Arizona

Medical License Number	State/Province	Country
25911	Arizona	USA

Current Position at Study Site: Investigator

Start Date	Title	Institution or Company	State/Province & Country
2016	Investigator	Alliance for Multispecialty Research LLC, formerly Clinical Research Consortium	Tempe , AZ

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2013-2014	Chief Executive Officer	Dedicated Clinical Research	USA
2006-2010	Investigator	Dedicated Phase 1, Inc	USA

Brief Summary of Relevant Clinical Research Experience:

PI conducting clinical research Since 2006 and has the opportunity to work with many different specialty groups, thus providing many therapeutics areas.

Signature:	Signature Date: (dd-Mmm-yyyy)

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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This page is the manifestation of the electronic signature(s).

Document Name: Corey Anderson, MD Current Sponsor-Specific CVs updated institution name "Expires:" 05 Feb 2022
Complion Document ID: 2362393

Statement of Testament: I reviewed the contents of this document
Electronic Signature for: Corey Anderson
Electronically Signed by: corey.anderson@amrllc.com
Date and Time of Signature: 08 Feb 2021 09:59 EST

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full LNaml e m N	Last Name	First Name	Middle Name
	Patel	Suchet	R

Pof sNirf gml Mmdnga AddoNir

Street Address 1: Meridian Clinical Research, LLC		Street Address 2: 415 Hooper Road	
City: Endwell	State/Province: New York	Country: USA	Zip/Postal Code: 13760
E: ml AddoNir	**iymN@: co: NdQf:**		

AcndN rc t unlsrcmrf gir

DNaoNNngd/f o CNb.nsrcmrf g	DmN()))) b	Igi.nu.rf g ngd/f o Cf ug.o)
Bachelor of Medicine	1990	BJ Medical College, India
Bachelor of Surgery	1990	BJ Medical College, India

MNdrcml LrcNgiNe u: SNb	v.mNPof prgcN	Cf ug.o)
217880-1	New York	USA

CuooNg. Pfinrf g m v.ud) vnN

v.mo. DmN	TnlN	Igi.nu.rf g f o Cf: yng)	v.mNPof prgcN& Cf ug.o)
2000	Investigator	Meridian Clinical Research, LLC.	NY, USA

PoNprf ui RNNpng. Pfinrf gi Igcludnga AcndN rc Ayyf rg.: Ng.ir

v.mo. ngd Egd DmN	TnlN	Igi.nu.rf g f o Cf: yng)	Cf ug.o)
2011 - Present	Lab Director	Endwell Family Physicians	USA
2000 -Present	Physician	Endwell Family Physicians	USA
2000 - Present	Active Staff	Wilson Medical Center	USA
2000 to July 2019	Medical Director	Regional Clinical Research, Inc	USA
1997- 2000	Family Practice Residency	Guthrie Clinic, Robert Packer Hospital	USA
1996 – 1997	Transitional Year Residency	Frankford Hospital	USA

BorNs vu: : no) f s RNNpng. Clngrcml RNNnoch ExyNonNgcN

Has conducted out-patient clinical research studies for 20 + years in collaboration with countless pharmaceutical companies. Has been an Investigator or Sub Investigator in many trials, with a wide variety of therapeutic indications, including: migraine, diabetes, stress incontinence, osteoarthritis, hypertension, hyperlipidemia, osteoporosis, GERD, COPD, erectile dysfunction, smoking cessation, episodics, weight loss, vaccines, and RSV.

vmgmuoN	vmgmuoNDmN (dd-M: : -)))) b

I wrll uydmNngd oNuS: n :) mSSoNpmNd CV rs .hNoNmoNchngaN ngd ymo.rculml) rs .hNoNri ng) chngaNng i.mui whrch wf uld mdpNoiN) nssNc. .hNmiiNi: Ng. f s:) iunmSrln) .f cf gduc./ymo.rcymNng clngrcml i.udNQ

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES

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Document Name: Suchet R. Patel, MD Sponsor Current CV 26 Jun 2020 Expires 26 Jun 2022 Archived 26 Jun 2022
Document ID: 1112650

Statement of Testament: I reviewed the contents of this document
Electronic Signature for: Suchet Patel
Electronically Signed by: spatel@rcresearchinc.com
Date and Time of Signature: 29 Jun 2020 12:27 EDT

ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Raad	George	L

Professional Mailing Address

Street Address:	Other Street Address:
1700 Abbey Place	Suite 201

City:	State/Province:	Country:	Zip/Postal Code:
Charlotte	NC	USA	28209

Email Address: graad@pmg-research.com

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Board Certification – Family Medicine	1985	American Board of Family Medicine, USA
Internship/Residency	1982 – 1985	Wake Forest University Baptist Medical Center, USA
Doctor of Medicine	1982	Medical University of South Carolina, USA
Bachelor's Degree	1978	University of South Carolina, USA

Medical License Number	State/Province	Country
27283	NC	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1982	Principal Investigator	PMG Research of Charlotte, LLC	Charlotte, NC, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1985 – Present	Medical Doctor	Park Road Medical	USA
1982 – 1985	Internship/Residency	Wake University Baptist Medical Center	USA

Brief Summary of Relevant Clinical Research Experience:

Acne, Sinusitis, Influenza, Tendonitis, Asthma, Hypercholesterolemia, Hypertension, Alcohol Dependency, Allergies, Atrial Fibrillation, Birth Control, Cardiovascular Disease Prevention, Cholesterol, Chronic Lower Back Pain, Constipation, COPD, Depression, Diabetes, Diabetic Neuropathy, Dyslipidemia , Erectile Dysfunction, Fibromyalgia, Flu Vaccine, Gout, Hypertension, Hormone Replacement Therapy, Irritable Bowel Syndrome, Low Sexual Desire in Females, Rosacea, Nocturia, Migraines, OA of Knee & Hip, Obesity, Osteoarthritis, Pneumonia Vaccine, Myocardial Infarction, Prostate Cancer Chemoprevention, Constipation, Epilepsy, GERD, Hot Flash, Hypoactive Sexual Desire Disorder, Low Testosterone, Osteoporosis, Overactive Bladder, Parkinson's Disease, Rheumatoid Arthritis, Urinary Incontinence, Vaginal Atrophy, Vaginitis, Alzheimer's Disease

Signature: Geo Raad **Signature Date: (dd-Mmm-yyyy)** 08-June-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE

TransCelerate BIOPHARMA INC.

Name: Sylvia Piqueras Shoffner, MD
Professional Title: Investigator
Organization: Raleigh Medical Group, PA
Address1: 3521 Haworth Drive
Address2: Raleigh, NC 27609 USA
E-Mail: sshoffner@carymedicalgroup.com

Main Daytime Phone: 919.342.3447
24 Hour Phone: 919.342.3447
Fax: 919.342.3422

VG 29 JUN 2020

AFFILIATIONS

Facility Name	Facility Address
Raleigh Medical Group, PA	3521 Haworth Drive Raleigh, NC 27609
PMG Research of Raleigh, LLC d/b/a PMG Research of Cary	530 New Waverly Place, Suite 200A Cary, NC 27518

Education

University/School/Program	Degree/Certificate	Specialty	Year Completed
University of North Carolina School of Medicine, NC USA	Intern/Residency	Internal Medicine	1998
University of North Carolina, NC USA	MD	N/A Canc 04 JUN 2020	1995
North Carolina State University, NC USA	BA	Zoology	1991

PROFESSIONAL EXPERIENCE

Job Title	Institution	Year Started	Year Completed
Physician	Raleigh Medical Group, PA	2001	Present
Investigator	PMG Research of Raleigh, LLC d/b/a PMG Research of Cary	2005	Present
Investigator	Multi-Specialty Research Associates of NC	2001	2005
Physician	Nashville Memorial Hospital, Skyline Medical Center	1999	2001

Type of License	License Issuer	Professional License Number	Country	State, Province or Region
Medical	NC Medical Board	9700397	USA	NC
DEA - Schedules 2, 2N, 3, 3N ,4, 5	US Department of Justice	BS6087337	USA	NC

RESEARCH EXPERIENCE

Study Type (Check all that apply):

☐	Academic	☒	Industry
☐	Investigator-Initiated	☐	Government
☐	Other / Please Specify:		

Clinical Study Phases (Check all that apply) ☒ I ☒ II ☒ III ☒ IV

Therapeutic Areas of Expertise:

Therapeutic Area	Therapeutic Area
Internal Medicine	Vaccines
Womens' Health	Cardiovascular

Total Clinical Research Experience: Total Number of completed studies: 175+

Therapeutic Area	Therapeutic Area	Therapeutic Area	Therapeutic Area
AK Lesions	Asthma	Axillary Hyperhidrosis	Bacterial Vaginosis
Birth Control	Celiac Disease	Chronic Pain	Clostridium difficile Vaccine
Constipation	Diabetes	Dyslipidemia	Ebola Vaccine
Elevated C-Reactive Protein	Erectile Dysfunction	Gout	Herpes Zoster Vaccine
H1N1 Vaccine	Hormone Replacement	Hypercholesterolemia	Hypertension
Influenza Vaccine	Migraine	Obesity	Osteoarthritis
Overactive Bladder	Pneumonia Vaccine	Psoriasis	RSV Vaccine
Smoking Cessation	Staphylococcus Aureus Vaccine	Statin-Related Myalgia	Tinnitus
Ulcerative Colitis	Menopausal Vasomotor Symptoms	Meniere's Disease	Post Hepatic Neuralgia
Prostate Cancer Prevention	Hypertriglyceridemia	GERD	Polycystic Ovary Syndrome

Good Clinical Practice (GCP) Training Details:

Training Provider	Title of Training	Date Completed
CITI Program	GCP for Clinical Trials with Investigational Drugs and Biologics	2019
Reviewed ICH Harmonized Guideline Step 4 Version 09 NOV 2016	ICH E6 R2 Addendum	2017

By signing this form, I confirm that the information provided on this Abbreviated CV is accurate and reflects my current employment and qualifications:

Signature: _____ *Date:* 16 JAN 2020

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Butcher	Michael	Bain

Professional Mailing Address

Street Address: Sterling Research Group, Ltd. 2230 Auburn Avenue, Level B		Other Street Address:	
City: Cincinnati	State/Province: OH	Country: USA	Zip/Postal Code: 45219
Email Address:	**yyu.@erQs.erlingresear@torg**		

A@demi@ ualifi@.ions:

Degree and(or Cer.ifi@.ion	Da.e)bbbbS	Ins.i.u.ion and(or Coun.rb
M.F.A.	2006	New York Academy – USA
M.D.	1995	University of Cincinnati College of Medicine – USA
B.S. in Biology	1990	Davidson College – USA

Medi@l Li@nse Numyer	v.a.e(Propin@	Coun.rb
35. 070976	OH	USA

Curren. Posi.ion a. v.udb vi.e:

v.ar. Da.e	Ti.le	Ins.i.u.ion or Com&anb	v.a.e(Propin@ h Coun.rb
2017-Present	Investigator	Sterling Research Group, Ltd.	OH – USA

Prepious Relepan. Posi.ions In@uding A@demi@A&&oin.men.s:

v.ar. and End Da.es	Ti.le	Ins.i.u.ion or Com&anb	Coun.rb
2014 – Present	Associate Professor	University of Cincinnati – College of Medicine & DAAP	USA
2012 – 2014	Adjunct Faculty – Fine Arts	Maryville College	USA
2007 - 2011	Painting & Drawing Instructor	University of Tennessee	USA
2006 – Present	Independent Painting & Drawing Instructor	Bain Butcher Studio	USA

Brief vummarb of Relepan. Clini@l Resear@ Ex&erien@:

3 years' experience in clinical research as a Principal Investigator primarily in the areas of vaccine, pain, weight loss, internal medicine

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Document Name: C4591001 Auburn Butcher, Bain Study Specific CV 28 May 2020 28 May 2022
Document ID: 1028148

Statement of Testament: I approved the contents of this document
Electronic Signature for: Bain Butcher
Electronically Signed by: bbutcher@sterlingresearch.org
Date and Time of Signature: 29 May 2020 11:31 EDT

Dr. William Smith
PI
New Orleans Center for Clinical Research
(NOCCR)/Alliance for Multispecialty Research
1928 Alcoa Highway, Suite 107
Knoxville , Tennessee , United States of America , 37920
Email: william.smith@amrllc.com

Main/Daytime: 865-305-9100 x246
Cell/Mobile (b) (6)
24 Hour: 865-305-9100
Fax: 865-305-2005

AFFILIATIONS

Facility Name (Department Name)	Facility Address	Department Address
New Orleans Center for Clinical R esearch	1928 Alcoa Highway, Suite 107, Knoxville, Tennessee, United States of America, 37920	Not Applicable

EDUCATION

University	Degree/Certificate	Specialty	Year Completed
Universidad Autonoma de Guadalajara	MD	Not Applicable	1974
University of Tennessee	BS	Not Applicable	1970

PROFESSIONAL EXPERIENCE

Job Title	Institution	Year Started	Year Completed
CEO	Alliance for Multispecialty Research, LLC, TN, USA	2017	Present
President	New Orleans Center for Clinical Research-Knoxville, TN, USA	2005	Present
President	New Orleans Center for Clinical Research-NOLA, USA	1994	Present
President	Volunteer Research Group, TN, USA	1993	Present

LICENSE DETAILS

Type of License	License Issuer	Professional License Number	Country	State/Province/ Region	Expiration Date
Medical Doctor	State of Tennessee	9963	United States of America	Tennessee	30-Jun-2021

RESEARCH EXPERIENCE

Study Type: Industry
Clinical Study Phases: I,II,III,IV
Therapeutic Area of Expertise: Cardiovascular Diseases

GCP TRAINING DETAILS

Course Provider	Course Title	Date Completed (DD-MMM-YYYY)	Status
CITI Program	GCP for Clinical Trials with Investigational Drugs - Multimodule	03-Mar-2017	Certificate Valid

By signing this form, I confirm that the information provided on this Abbreviated CV is accurate and reflects my current employment and qualifications:

Signature:	Dr. William Smith smithw_7134 07-JUL-2020 15:01:46 GMT Author of CV

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name *if applicable*
	Chu	Laurence	

Professional Mailing Address:

Street Address 1: 3100 Red River St. Suite 2		Street Address 2:	
Austin	TX	Country :USA	Zip/Postal Code:78705

Email Address: laurencechu@benchmarkresearch.net

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Certified Principal Investigator	2012	Association of Clinical Research Professionals. TX, USA
Flight Surgeon	1995	USAF School of Aerospace Medicine. TX. USA
Residency Program	1993	Emory University. GA. USA
Chief Resident	1993	Emory University. GA. USA
MD degree	1988	Boston University School of Medicine. Boston. USA

Medical License Number	State/Province	Country
L8310	TX	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2006	Principal Investigator	Benchmark Research	TX/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2004-Present	Owner, Private Practice	Laurence Chu. MD	USA
1996-2000	ENT specialist	Ear, Nose & Throat Specialist of Middletown, Inc.	USA
1993-1996	United States Air Force, Honorable Discharge Otolaryngologist-Head & Neck Surgeon	US Air Force	USA

Brief Summary of Relevant Clinical Research Experience:

Trials with indications such as Pre-Diabetes. Smoking Cessation. Influenza Vaccine (multiple trials) for pediatrics and adults. Staph Vaccine. RSV Vaccine. C. difficile Vaccine. Pneumonia Vaccine. Toenail Onychomycosis. Chronic Low Back pain. Migraines. Seasonal Allergies. Common Cold and Insomnia.

Signature:	Signature Date: (dd-Mmm-yyyy)
	28 MAY 2019

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Denham, DO, CPI	Douglas	Scott

Professional Mailing Address:

Street Address 1: Clinical Trials of Texas, Inc.		Street Address 2: 5430 Fredericksburg Rd., Suite 200	
City: San Antonio	State/Province: TX	Country: USA	Zip/Postal Code: 78229
Email Address:	**ddenham@cttexas.com**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Certified Physician Investigator	2009-Current	Academy of Pharmaceutical Physicians and Investigators, Affiliate of the Association of Clinical Research Professionals, USA
Board Certified, Family Practice	1992	American Board of Family Practice, USA
Intern/Residency, Family Practice	1989-1992	University of Texas at San Antonio Health Science Center, San Antonio, Texas USA
Doctor of Osteopathic Medicine	1985-1989	Texas College of Osteopathic Medicine, Fort Worth, Texas USA

Medical License Number	State/Province	Country
H7995	Texas	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2010 – Present	Medical Director	Clinical Trials of Texas, Inc.,	Texas/ USA

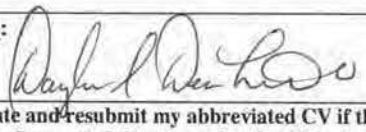
Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2008 – 2010	Director of Medical Affairs/ Primary Investigator	Cetero Research, Inc.	San Antonio, TX - USA
2006 – 2008	Director of Medical Affairs/ Sub- Investigator	Cetero Research, Inc.	San Antonio, TX - USA
2002 – Present	Medical Director (PT)	ABC Family Medicine	San Antonio, TX - USA
2001 – 2002	Staff Physician	NFR Medical PR	San Antonio, TX - USA

Brief Summary of Relevant Clinical Research Experience:

Served as Investigator on over 300 Phase I-IV clinical research studies to include:

Diabetes Type I and II	Psoriasis	Collection studies	Rosacea	Device Studies
Healthy Subject Vaccine	Vulvovaginal Candidiasis	Growth Hormone Deficiency	Overactive Bladder	Asthma
NASH	NAFDL	Hypogonadism	Crohn' s Disease	Migraine
Endometriosis	Alzheimer's	Coronary Artery Disease	Bipolar	Celiac Disease
Anxiety	Osteoarthritis	ADHD	P MDD	Epilepsy
Acne	Hypoparathyroidism			

Signature: 

Signature Date: (dd-Mmm-yyyy) 15 Apr 2019

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION CONTAINED IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. MULTI-PAGE CVS ARE NOT ACCEPTABLE. DO NOT INCLUDE ATTACHMENTS, AND TEXT ON THE REVERSE SIDE.

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Fuller	Gregory	M

Professional Mailing Address

Street Address:		Other Street Address:	
300 N. Rufe Snow Dr.			
City:	State/Province:	Country:	Zip/Postal Code:
Keller	TX	USA	76248
Email Address:	gregoryfuller. @nca@aresearQ /Qom		

AQademiQ(ualifiQacions:

Degree and)or CerQifiQacion	Dac e byyyyS	Insciucion and)or Counc ry
Residency/Chief Resident – Family Medicine	1990	Goppert Family Care Center, USA
Doctorate of Medicine	1987	University of Arkansas College of Medicine, USA
Bachelors of Arts, Chemistry	1982	Baylor University, USA

MediQal LiQense Numver	pcace)Pro@nQe	Counc ry
H8646	Texas	USA

Currenc Posicion ac pcudy pice:

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Dec 2017	Principal Investigator	Ventavia Research Group, LLC	TX, USA

Pre@ous Rele@anc Posicions InQuding AQademiQA&&oincmencs:

pcarc and End Dacs	Tide	Insciucion or Com&any	Counc ry
1991 – 1995	Principal Investigator	North Hills Family Medicine (Research)	USA
1990 – Present	Physician	North Hills Family Medicine	USA

Brief pummary of Rele@anc CliniQal ResearQ Ex&erienQe:

Growth and Tolerance of Young Infants Fed Milk-Based Infant Formula with Oligosaccharides;
A Parallel Group, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Eptinezumab Administered Intravenously in Subjects Experiencing An Acute Attack of Migraine;
A Phase 3, Multicenter, Randomized, Double-blind, Active-Comparator-controlled Study to Evaluate the Safety, Tolerability, and Immunogenicity of a 4-dose Regiment of V114 in Healthy Infants (PNEU-PED);
A Phase 3, Randomized, Open-Label Trial to Evaluate the Safety and Immunogenicity of A 20-Valent Pneumococcal Conjugate Vaccine in Adults with Prior Pneumococcal Vaccination
A Phase 3, Randomized, Double-Blind Trial to Evaluate the Safety and Immunogenicity of A 20-Valent Pneumococcal Conjugate Vaccine in Pneumococcal Vaccine-Naïve Adults 18 years of Age and Older;
A Phase 3, Randomized, Observer-Blind, Multicenter, Noninferiority Study to Evaluate Safety and Immunogenicity of a Cell-Based Quadrivalent Subunit Influenza Virus Vaccine (QIVc) and a United States Licensed Quadrivalent Influenza Virus Vaccine (QIV) in Healthy Subjects 6 Months Through 47 Months;
An Assessment of the Safety of Pediatric Ibuprofen;
A Phase IIIB FDA Study Jan 1995. XXX-XX Nasal Spray Study;
A Phase IV Study to Evaluate the Efficacy of a Second Sumatriptan Succinate Tablet (25mg or 50mg in the Acute Treatment of Migraine;
A Phase III Comparative Study of XXX vs. XXX in the Treatment of Community Acquired Pneumonia;
A Phase III Study to Compare the Safety of XXX with Ibuprofen for the Long-Term Treatment of Osteoarthritis;
A Phase III Comparison and Efficacy of XXX 400mg a day for 10 days vs. XXX 500mg BID for the Treatment of Patients with Community Acquired Pneumonia
A Phase IV Efficacy of XXX for IBS;
A Phase 2, Randomized, Open-Label Trial to Evaluate the Safety and Immunogenicity of a Multivalent Pneumococcal Conjugate Vaccine Given With, Or Separately From, 13-Valent Pneumococcal Conjugate Vaccine in Healthy Infants;

pignacure:	**pignacure Dac e: bdd-Mmm-yyyyS**

I will u&dac e and resuvmic my avvre@aced CV if ct ere are Q anges and &arciQularly if ct ere is any Q ange in scacus wt iQ would ad@rsely affeQ ct e assessmenc of my suicavilicy co QonduQ)&arciQ&ace in QiniQal scudies/

ABBREVIATED CURRICULUM VITAE TEMPLATE

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This page is the manifestation of the electronic signature(s).

Document Name: Gregory Fuller Pfizer CV Current CV 21 May 2020 Expired 20 May 2021
Document ID: 1011004

Statement of Testament: I approved the contents of this document
Electronic Signature for: Gregory Fuller
Electronically Signed by: gregoryfuller@ventaviaresearch.com
Date and Time of Signature: 22 May 2020 09:50 CDT

ABBREVIATED CURRICULUM VITAE

TransCelerate BIOPHARMA INC.

Name: Kevin Dougherty Cannon, MD
Professional Title: Investigator
Organization: Wilmington Health, PLLC
Address 1: 1202 Medical Center Drive
Address 2: Wilmington, NC 28401
E-Mail: kevin.cannon@accellacare.com

Main Daytime Phone: 910-799-5500
24 Hour Phone: 910-799-5500
Fax: 910-799-1002

AFFILIATIONS

Facility Name	Facility Address
PMG Research of Wilmington, LLC	1202 Medical Center Drive, Wilmington, NC 28401
PMG Research of Wilmington, LLC	1222 Medical Center Drive, Wilmington, NC 28401
PMG Research of Wilmington, LLC	1907 Tradd Court, Wilmington, NC 28401
PMG Research of Wilmington, LLC	1915 Tradd Court, Wilmington, NC 28401
PMG Research of Wilmington, LLC	1917 Tradd Court, Wilmington, NC 28401
PMG Research of Wilmington, LLC	2421 Silver Stream Lane, Wilmington, NC 28401
PMG Research of Wilmington, LLC	6781 Parker Farm Drive, Wilmington, NC 28405
PMG Research of Wilmington, LLC	8090 Market Street, Wilmington, NC 28411
PMG Research of Wilmington, LLC	8115 Market Street, Wilmington, NC 28411
PMG Research of Wilmington, LLC	1124 Gallery Park Blvd., Wilmington, NC 28412
Wilmington Health, PLLC	1202 Medical Center Drive, Wilmington, NC 28401
New Hanover Regional Medical Center	2131 S 17th St. Wilmington, NC 28401

Education

University/School/Program	Degree/Certificate	Specialty	Year Completed
Medical College of Virginia, Richmond, VA	Internship/Residency	Internal Medicine	2001
Medical College of Virginia, Richmond, VA	Medical	Internal Medicine	1997
University of Notre Dame, South Bend, IN	BS	Biology	1992

PROFESSIONAL EXPERIENCE

Job Title	Institution	Year Started	Year Completed
Investigator	PMG Research of Wilmington, LLC Wilmington, NC USA	2009	Present
Medical Doctor	Wilmington Health, PLLC Wilmington, NC USA	2001	Present

Type of License	License Issuer	Professional License Number	Country	State, Province or Region
Medical	NC Medical Board	200100520	USA	North Carolina
DEA Schedules 2N, 3, 3N, 4, 5 (Researcher II-V)	DEA	RC0519720	USA	North Carolina
DEA Schedules 2, 2N, 3, 3N, 4, 5 (Practitioner)	DEA	BC7296191	USA	North Carolina
DHHS Schedules 2, 2N,3, 3N, 4, 5 (Researcher)	DHHS	NC-PK 0000 5505	USA	North Carolina

RESEARCH EXPERIENCE

Study Type (Check all that apply):

- ☐ Academic
- ☒ Industry
- ☐ Investigator-Initiated
- ☐ Government
- ☐ Other / Please Specify:

Clinical Study Phases (Check all that apply) ☒ I ☒ II ☒ III ☒ IV

Therapeutic Areas of Expertise:

Therapeutic Area	Therapeutic Area
Internal Medicine	Infectious Disease
Urology	Women's Health
Cardiology	Gastroenterology
Neurology	Vaccine
Dermatology	Musculoskeletal
Endocrinology	Rheumatology
Epidemiology & Preventive Medicine	Pulmonology

Total Clinical Research Experience: 100+ **Total Number of completed studies: 65**

Therapeutic Area	Therapeutic Area	Therapeutic Area	Therapeutic Area
Diabetes Type 2	Weight Loss	Vitiligo	COPD
Influenza Vaccine	RSV Vaccine	Hidradentis Suppurativa	Rheumatoid Arthritis
Overactive Bladder (OAB)	Hypercholesterolemia	Atopic Dermatitis	COVID-19 Vaccine Trials
Chronic Back Pain	Acute Influenza	Urinary Incontinence	
C-Diff Vaccine	Hypertension	Hot Flashes	
CMV Vaccine	Pneumococcal Vaccine	Diabetic Gastrophoresis	
Osteoarthritis	Hyperlipidemia	Zoster Virus	
Sarcopenia	Erectile Dysfunction	Iron Deficiency Anaemia	
Migraine	Gout	Diarrhea-IBS (IBS-D)	
Device Trials	Smoking Cessation	Liver Cancer detection through cfDNA Methylation in Blood Samples	

Good Clinical Practice (GCP) Training Details:

Training Provider	Title of Training	Date Completed
CITI	GCP	28Feb2020

By signing this form, I confirm that the information provided on this Abbreviated CV is accurate and reflects my current employment and qualifications:

Signature: _____ *Date (DD/MMM/YYYY):* 11-MAR-2021

ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Cannon	Kevin	Dougherty

Professional Mailing Address

Street Address:		Other Street Address:	
1202 Medical Center Drive			
City: Wilmington	State/Province: North Carolina	Country: USA	Zip/Postal Code: 28401
Email Address:	**kcannon@pmg-research.com**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Board Certification – American Board of Internal Medicine	2001-continues as required	American Board of Internal Medicine
Internship/Residency: Department of Internal Medicine/Pediatrics Combined	1997-2001	Medical College of Virginia Richmond, VA USA
Medical Doctor	1993-1997	Medical College of Virginia Richmond, VA USA
Bachelor of Science, Biology	1988-1992	University of Notre Dame South Bend, Indiana USA

Medical License Number	State/Province	Country
200100520	North Carolina	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2009	Investigator	PMG Research of Wilmington, LLC	North Carolina/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2001-Present	Hospitalist	Wilmington Health, PLLC	USA

Brief Summary of Relevant Clinical Research Experience:

Conducted more than 100 trials as Principal Investigator and/or Sub Investigator from 2009 to present, including but not limited to trials in the following areas: Deep Vein Thrombosis, Type 2 Diabetes Mellitus, Obesity, Psoriasis, Hypertension, High Cholesterol, Smoking Cessation, Peripheral Artery Disease, Osteoarthritis, Migraine, Flu Vaccine, C-Diff Vaccine, RSV Vaccine, CMV Vaccine, COPD, Sarcopenia, etc

Signature:	**Signature Date: (dd-Mmm-yyyy)**
	1- MAY-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.

ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Earl	John	Keith

Professional Mailing Address:

Street Address: 221 13th Avenue Pl NW		Other Street Address: Suite 201	
City: Hickory	State/Province: NC	Country: USA	Zip/Postal Code: 28601
Email Address:	jearl@pmg-research.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Family Practice-Board Certified	2003	American Board of Family Medicine, USA
Doctor of Medicine	1972	University of Oklahoma School of Medicine, USA
Bachelor of Science-Zoology	1968	University of Oklahoma, USA
GCP	2020	CITI Good Clinical Practices Training, USA

Medical License Number	State/Province	Country
20785	NC	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1996	Principal Investigator	PMG Research of Hickory, LLC	NC, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1996-Current	Principal Investigator	PMG Research of Hickory	USA
1976-2016	Medical Director	Hickory Family Practice	USA
1974-1976	Medical Doctor	University of Virginia	USA
1972-1973	Resident Intern	University of Oklahoma School of Medicine	USA

Brief Summary of Relevant Clinical Research Experience:

Has conducted more than 375 trials as a Principal Investigator and/or Sub-Investigator from 1996-present, including but not limited to the following areas: Chronic Bronchitis, Type I Diabetes, Type II Diabetes, GERD, Heartburn Hypertension, Insomnia, IBS, Mixed Dyslipidemia, Obesity, Acne, Psoriatic Arthritis, and Pain from Herpes Zoster, Vaccine studies, Women's Health, etc.

Signature:	Signature Date: (dd-Mmm-yyyy)
John H Earl MD	20 JUL 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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VG 28 JUL 2020

ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Farrington, Jr.	Cecil	Murray

Professional Mailing Address

Street Address: : 410 Mocksville Avenue		Other Street Address:	
City: Salisbury	State/Province: NC	Country: USA	Zip/Postal Code: 28144
Email Address:	cmfarrington@pmg-research.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Bachelor of Science	1968	North Carolina State University, NC – USA
MD	1972	University of North Carolina at Chapel Hill, NC - USA

Medical License Number	State/Province	Country
17954	North Carolina	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2002	Investigator	PMG Research of Salisbury, LLC	NC, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1978-2013	Medical Doctor	Farrington Family Medical Center	USA
2013-Present	Medical Doctor	Novant Health Farrington Family Medicine	USA

Brief Summary of Relevant Clinical Research Experience:

Dr. Farrington has 18 years of experience in clinical trials in the following therapeutic areas:

Acne, COPD, Type 2 Diabetes, Hypercholesterolemia, Hyperlipidemia, Influenza A Treatment, Zoster Vaccine, Diabetes/HTN combo, Erectile Dysfunction, Erosive Esophagitis, Hypertension, GERD, Gout, NSAID associated Ulcers, Irritable Bowel Syndrome, Iron Deficiency, Osteoarthritis, Heartburn, Overactive Bladder, Rosacea, BPH, Birth Control, Celiac Disease, Chronic Insomnia, Crohn's Disease, CV Events, Post MI, Psoriatic Arthritis – Joint Accessor, Idiopathic Constipation, Pneumonia Vaccine, Nocturia BPH, Onychomycosis/Toe Nail Fungus, Rheumatoid Arthritis – Joint Accessor, Tinea Pedis, Acute Otitis Media, Ankle Sprain, Obesity, C-Diff Vaccine, Common Warts, Meningitis Vaccine, Prostate Cancer

Signature:	Signature Date: (dd-Mmm-yyyy)
	07 Jul-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Cohen	Lisa	Mauri

Professional Mailing Address:

Street Address 1: 3100 Duraleigh Road	Street Address 2: Suite 304, 303 DM 28 Jan 2021		
City: Raleigh	State/Province: NC	Country: USA	Zip/Postal Code: 27612

Email Address: LCOHEN@WAKERESEARCH.COM DM 28 Jan 2021

Academic Qualifications: DO

Degree and/or Certification	Date (yyyy)	Institution and Country
Bachelor of Arts Sociology	1985	State University of New York, USA
D.C. Chiropractic Medicine	1989	Life Chiropractic College, USA
D.O Osteopathic Medicine	1995	NY College of Osteopathic Medicine

Medical License Number	State/Province	Country
2017-02297	North Carolina	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2017	Clinical Research Investigator	M3 Wake Research, Inc.	NC, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2001-2017	CLinical Research Investigator/Medical Director	Suncoast Clinical Research, Inc.	USA
2000-2000	Physician for Osteoporosis Screening	Alliance of Home Care Physicians	USA
1998-2000	Senior Staff Physician-Family Practice	Henry Ford Hospital System	USA

Brief Summary of Relevant Clinical Research Experience:

Has conducted clinical research for 17 years as a principal and sub-investigator on study in dermatology, kidney disease, GI studies, diabetes, depression, osteoporosis, women's health, vaccines, allergies, and more

Signature:	Signature Date: (dd-Mmm-yyyy)
CVMCohen DO	23-MAY-2018

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Harper	Wayne	Lee

Professional Mailing Address:

Street Address 1:		Street Address 2:	
3100 Duraleigh Road		Suites 303, 304	
City: Raleigh	State/Province: NC	Country: USA	Zip/Postal Code: 27612
Email Address:	wharper@wakeresearch.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and Country
Internal Medicine Certificate	1981	American Board of Internal Medicine, USA
M.D.	1978	Duke University School of Medicine, USA
B.S.	1974	Duke University, USA

Medical License Number	State/Province	Country
24076	NC	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1994	Principal Investigator	M3 Wake Research, Inc.	NC/USA DH 15 Jun 2020

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1994 – Present	Physician Investigator	M3 Wake Research, Inc.	USA
1989 – 2016	Active Physician	Wake Internal Medical Consultants, Inc.	USA
1999 – 2001	Credential Committee Member	Rex Hospital	USA
1997 – 2000	Teaching Assistant	Duke University School of Medicine	USA
1994-1995	Secretary and Treasurer of Medical Executive Committee	Rex Hospital	USA
1989 -2016	Internal Medicine Staff	Rex Hospital	USA

Brief Summary of Relevant Clinical Research Experience:

Has conducted clinical research for 25 plus years as a principle investigator on 200 plus studies investigating OA, RA, osteoporosis, diabetes, gout, fibromyalgia, insomnia, smoking cessation, hypertension, obesity, weight loss, pain, men and women's health, and more.

Signature:	Signature Date: (dd-Mmm-yyyy)
Wayne Lee Harper MD	31 July 2018

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Arora	Samir	n/a

Professional Mailing Address

Street Address: 99 N. Brice Rd, Suite 260		Other Street Address:	
City: Columbus	State/Province: OH	Country: USA	Zip/Postal Code: 43213
Email Address:	Sarora@aventivresearch.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Medical Doctorate (MD)	1997	Hamot Medical Center, India
Rotating Internship	1992	Kasturba Hospital, India
MBBS Degree	1991	Kasturba Hospital, India

Medical License Number	State/Province	Country
35.080152	Ohio	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
04/2015	President, Medical Director, PI	Aventiv Research Inc	Ohio, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
04/2007 – 04/2015	President, Medical Director, PI	Columbus Clinical Research	Ohio, USA
2007-2013	Primary Care Physician	Pentagon Primary Care	Ohio, USA

Brief Summary of Relevant Clinical Research Experience:

Mild to Very Severe COPD (Phase I-IV), Hypertension (Phase II-IV), Type 2 Diabetes (Phase I-IV), Asthma (Phase II/III), Osteoarthritis (Phase II/III), Opiod Induced Constipation (Phase II), Hyperlipidemia (Phase II/III), Hypogonadism (Phase I-III), Type I Diabetes (Phase II-III); Tobacco Cessation (Phase 1)

Signature:	**Signature Date: (dd-Mmm-yyyy)**
	03-JUN 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Davit	Rajesh	Kumar

Professional Mailing Address

Street Address: Sterling Research Group, Ltd. 375 Glensprings Drive, 2nd Floor		Other Street Address: N/A	
City: Cincinnati	State/Province: OH	Country: USA	Zip/Postal Code: 45246
Email Address:	**rdayi.@s.erlingresearcQorg**		

Academic / ualifica.ions:

Degree and(or Cer.ifica.ion	Da.e)bbbbS	Ins.i.u.ion and(or Coun.rb
Doctor of Medicine	2002	St. Eustatius University, School of Medicine – UK
B.S. in Podiatry	1997	University of Wales, Institute Cardiff – UK

Medical License Numver	p.a.e(Proyince	Coun.rb
35.090620	OH	USA

Curren. Posi.ion a. p.udb pi.e:

p.ar. Da.e	Ti.le	Ins.i.u.ion or Com&anb	p.a.e(Proyince h Coun.rb
2012	Investigator	Sterling Research Group, Ltd.	OH – USA

Preyious Releyan. Posi.ions Including Academic A&&oin.men.s:

p.ar. and End Da.es	Ti.le	Ins.i.u.ion or Com&anb	Coun.rb
2008 – Present	Family Physician	Mercy Health Physicians	USA
2008 – Present	Emergency Physician	Fort Hamilton Hospital	USA
2007 – Present	Peer / Medical Reviewer	Journal of Urgent Care Medicine	USA
2005 - 2008	Family Medicine Residency	Greenville Hospital System University Medical Center	USA

Brief pummarb of Releyan. Clinical ResearcQEx&erience:

19 years' clinical research experience as a Principal and or Sub-Investigator primarily in the areas of vaccine, dermatology, arthritis, pain, anti-infective, device, heart failure & weight loss, hyperlipidemia, hypertension, diabetes.

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Document Name: C4591001 Springdale Davit, Rajesh Study Specific CV 22 Jun 2020 22 Jun 2022
Document ID: 1092649

Statement of Testament: I approved the contents of this document
Electronic Signature for: Rajesh K Davit
Electronically Signed by: rdavit@sterlingresearch.org
Date and Time of Signature: 23 Jun 2020 08:53 EDT

ABBREVIATED CURRICULUM VITAE TEMPLATE

N

Full Name:	Last Name	First Name	Middle Name
	Ensz	David	Jon

Professional Mailing Address

Street Address:		Other Street Address:	
4802 Sunnybrook Drive			
City:	State/Province:	Country:	Zip/Postal Code:
Sioux City	IA	USA	51106
Email Address:	**ensz@mcrmed.com**		

Academic Qualifications:

Degree and/or Certification	**Date (yyyy)**	**Institution and/or Country**
Family Practice	2008	University of Nebraska Medical Center / USA
Doctor of Medicine	2005	University of Nebraska Medical Center / USA
Bachelor of Science	2001	Wayne State College / USA

Medical License Number	**State/Province**	**Country**
7873	SD	USA
23832	NE	USA
MD-38811	IA	USA
FE2331685	National	USA

Current Position at Study Site:

Start Date	**Title**	**Institution or Company**	**State/Province & Country**
2010	Principal Investigator	Meridian Clinical Research, LLC	IA / USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	**Title**	**Institution or Company**	**Country**
2010 – Present	Principal Investigator	Meridian Clinical Research, LLC	USA
2006 – Present	Sub-Investigator	Meridian Clinical Research, LLC	USA

Brief Summary of Relevant Clinical Research Experience

Endocrinology- Diabetes Mellitus Type I & Type II
Dermatologic- Acne Vulgaris
Gastrointestinal- Irritable Bowel Syndrome C & D, GERD
Healthy Adult & Pediatric Vaccine Trials
Infectious- Herpes Simplex Labialis, Common Cold Syndrome
Musculoskeletal- Fibromyalgia, Chronic Lower Back Pain, Osteoarthritis
Genitourinary- Overactive Bladder, Nocturia
Respiratory- Asthma, COPD
Cardiovascular- Hypertension
Healthy Adult Trials
Neuropathic- Migraines, Restless Leg

Signature:	**Signature Date: (dd-Mmm-yyyy)**

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

OTE: HEI SCVMUBCEL: DSUSE: F ET EI : SORTPUAESTO SO EI SCE: U- DAE: RTP SOVDBCSTO SO EI : SVI 3: Y VTU- DSAOE VDSOSVADCEBF. P: - TPENALLP: MSAE: F VMCVAO L: OT UTP: EI AO Y- AG: C, FT OTE SOVDBF: AEEAVI U: OECTP E: XE TO P: M: PC: - AG: CN

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Document Name: David Jon Ensz, MD Pfizer One Page Current CV 09 Nov 2020 Expires 09 Nov 2022 Archived
Complion Document ID: 1789241

Statement of Testament: I approved the contents of this document
Electronic Signature for: David Ensz, MD
Electronically Signed by: ensz@mcrmed.com
Date and Time of Signature: 10 Nov 2020 12:00 CST

ABBREVIATED CURRICULUM VITAE TEMPLATE

N

	Last Name	First Name	Middle Name
Full Name:	Ensz	David	Jon

Professional Mailing Address

Street Address: 330 Dakota Dunes Blvd.		Other Street Address: Suite 400	
City: Dakota Dunes	State/Province: SD	Country: USA	Zip/Postal Code: 57049
Email Address:	**ensz@mcrmed.com**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Family Practice	2008	University of Nebraska Medical Center / USA
Doctor of Medicine	2005	University of Nebraska Medical Center / USA
Bachelor of Science	2001	Wayne State College / USA

Medical License Number	State/Province	Country
7873	South Dakota	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2010	Principal Investigator	Meridian Clinical Research, LLC	SD / USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2010 – Present	Principal Investigator	Meridian Clinical Research, LLC	USA
2006 – Present	Sub-Investigator	Meridian Clinical Research, LLC	USA

Brief Summary of Relevant Clinical Research Experience

Chronic Pain – Fibromyalgia, Chronic Lower Back Pain
Endocrine – Diabetes Mellitus Type I, Diabetes mellitus Type II
Gastrointestinal – Irritable Bowel Syndrome, Constipation
Infectious – Herpes Labialis, Common Cold
Healthy Adult Vaccine Trials
Pediatric Vaccine Trials
Migraine
Dermatologic - Acne

Signature:	**Signature Date: (dd-Mmm-yyyy)**

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OTE: HEI SCVMUBCEL: DSUSE: F ET EI : SORTPUAESTO SO EI SCE: U- DAE: RTP SOVDBCSTO SO EI : SVI 3: Y VTU- DSAOE VDSOSVADCEBF. P: - TPENALLP: MSAE: F VMCVAO L: OT UTP: EI AO Y- AG: C, FT OTE SOVDBF: AEEAVI U: OECTP E: XE TO P: M: PC: - AG: CN

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Document Name: David Jon Ensz, MD Pfizer One Page Current CV 15 Apr 2020 Expires 15 Apr 2022 Archived 15 Apr 2022
Document ID: 888496

Statement of Testament: I approved the contents of this document
Electronic Signature for: David Ensz, MD
Electronically Signed by: ensz@mcrmed.com
Date and Time of Signature: 21 Apr 2020 10:06 CDT

ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Mussaji	Murtaza	

Professional Mailing Address

Street Address:		Other Street Address:	
11021 Shadow Creek Parkway		Suite 102	
City: Pearland	State/Province: Texas	Country: USA	Zip/Postal Code: 77584
Email Address:	murtaza@linqresearchllc.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Medical Residency	2007	University of Texas Health Science at Houston, USA
Doctor of Osteopathic Medicine	2004	Midwestern University, USA
Bachelor of Science in Biology	1999	University of Houston, USA

Medical License Number	State/Province	Country
M3335	Texas	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2015	Principal Investigator	LinQ Research, LLC	Texas, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2008 – Present	Assistant Professor	University of Texas Health Science at Houston	USA
2010 – Present	Medical Director	Fairway and Shadow Creek Medical Clinic	USA
2018 – Present	President	Harris County Medical Society, Southeast Branch	USA

Brief Summary of Relevant Clinical Research Experience:

A PHASE 3, TREATMENT OF LIVER FIBROSIS IN ADULT SUBJECTS WITH NONALCOHOLIC STEATOHEPATITIS
A PHASE 3, CLOSTRIDIUM DIFFICILE VACCINE IN ADULTS 50 YEARS OF AGE AND OLDER
A PHASE ½, SINGLE ASCENDING DOSE-FINDING STUDY IN ELDERLY SUBJECTS WITH A PNEUMOCOCCAL VACCINE
A PHASE 3, TREATMENT OF UNCOMPLICATED URINARY TRACT INFECTIONS IN ADULT WOMEN
A PHASE 2B, PATIENTS WITH CHRONIC KIDNEY DISEASE AND HYPERURICEMIA
A PHASE 3, SYMPTOMATIC ADULTS AND CHILDREN 4 YEARS OF AGE AND OLDER WITH ASTHMA

Signature:	**Signature Date: (dd-Mmm-yyyy)**
	10-JUL-2020

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Pickrell	Paul	Keith

Professional Mailing Address:

Street Address 1:	Street Address 2:		
4534 West Gate Blvd	Suite 110		
City: Austin	State/Province: Texas	Country: USA	Zip/Postal Code: 78745

Email Address: ppickrell@tektonresearch.com

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Medical Degree	1990	University of Oklahoma Medical School/USA
Residency Interal Medicine	1993	Good Samaritan Regional Medical Center/USA
Fellow Rheumatology	1995	University of Arizona/USA

Medical License Number	State/Province	Country
K0997	Texas	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2009	Principal Investigator	Tekton Research, Inc.	Texas/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2004-2008	Investigator	Metaclin	USA
2000-2017	Rheumatologist (private practice	West Austin Rheumatology	USA
1996-2000	Associate Clinical Professor	Baylor, Scott &White/fna Scott & White	USA
1996-2000	Staff Rheumatologist	Baylor, Scott &White/fna Scott & White	USA

Brief Summary of Relevant Clinical Research Experience:

Dr. Pickrell has been involved with clinical research since 1996, becoming a Principal Investigator in 2004. He has research experience as PI in rheumatology studies, including rheumatoid arthritis, lupus, fibromyalgia , psoriatic arthritis, as well as non rheumatology studies including osteoarthritis. He has research experience as sub-I in research studies involving migraines, cholesterol, hypertension, and vaccines.

Signature:	Signature Date: (dd-Mmm-yyyy)
	19 - NOV - 2019

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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CLINICAL AND MEDICAL CONTROLLED DOCUMENT (CMCD) SUPPORTING DOCUMENT

Identifier	Version	Title	Effective Date
INV02-INV04-WI-GL02-SD01	1.0	ABBREVIATED CURRICULUM VITAE TEMPLATE	01-Apr-2019

Full Legal Name:	Last Name	First Name	Middle Name *if applicable*
	Tran	Van	Quang

Professional Mailing Address:

Street Address 1: 1919 N Loop W, Suite 218		Street Address 2:	
City: Houston	State/Province: Texas	Country: USA	Zip/Postal Code: 77008
Email Address:	vantran@ventaviaresearch.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Doctor of Medicine	2003	University of Texas at Houston/ USA

Medical License Number	State/Province	Country
L3505	Texas	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
Sep2019	Sub-Investigator	Ventavia Research Group, LLC	Houston/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2003-ongoing	Primary Care Physician	Dr. Van Tran Family Practice	USA
2010-ongoing	Primary Care Physician	Thomas Family Practice	USA
2000-2003	Internship/Residency	University of Texas Houston Family Practice Program (Memorial Hermann Hospital)	USA

Brief Summary of Relevant Clinical Research Experience:

Pediatric Pneumococcal Vaccine, Pediatric Flu Vaccine, Endometriosis, Pediatric Meningococcal Vaccine, Infant Formula Trial, Maternal Respiratory Syncytial Virus

Signature: Van Tran

Signature Date: (dd-Mmm-yyyy) 03-Feb-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Christensen	Tom	A.

Professional Mailing Address

Street Address: Main Street Physician's Care		Other Street Address: 3600 Sea Mountain Highway, Suite C	
City: Little River	State/Province: SC	Country: USA	Zip/Postal Code: 29566
Email Address:	(b) (6)		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Board Cert. Family Medicine	1986,1993,2000,2006, 2011, 2016	American Board of Family Practice, USA
Residency – Family Medicine	1985	Washington Hospital, USA
Doctor of Medicine	1982	University of Nebraska Medical School, USA
BS – Medical Technology	1975	Kearny State College, USA

Medical License Number	State/Province	Country
18363	South Carolina	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2018	Physician	Main Street Physician's Care	South Carolina, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1996 - 2018	Physician	Waterway Primary Care dba Calabash Medical Center, NC	USA
1996 – Present	Physician	Loris Healthcare System, SC	USA
1985-1996	Physician	Minden Medical Center, NE	USA

Brief Summary of Relevant Clinical Research Experience:

Feb 2015 – Apr 2019t: Principal Investigator – Post Herpetic Neuralgia
Mar 2014 – Mar 2019: Principal Investigator – Anticoagulant Medication Post-Marketing
Sep 2013 – Feb 2015: Principal Investigator – Influenza Treatment
Mar 2013 – Present: Principal Investigator – Lipid Trial
Aug 2012 – Jul 2013: Principal Investigator – IBS Trial
Aug 2012 – Apr 2018: Principal Investigator – Gout Trials
Aug 2012 – Present: Principal Investigator – Diabetes/Cardiovascular Outcomes (2 trials completed)
Dec2011 – May 2013: Principal Investigator – Diabetes/Hypertension
Aug 2012 – May 2014: Principal Investigator – Asthma Trial
Jul 2010 – Present: Principal Investigator - COPD Trials
Nov 2009 – Jan 2015 Principal Investigator – A Fib
Nov 2008 – Present: Principal Investigator - Diabetes Trials (Oral and Injectable Medication)
Oct 2008 – Feb2011: Principal Investigator – Flu Vaccine Trial
Sep 2008 – Feb 2019t: Principal Investigator – Osteoarthritis/Cardiovascular Outcomes
July 2008 – October 2009: Principal Investigator Diabetes Trial
May 2008- February 2010 Principal Investigator – Hypertension Trial – Elderly Patients
May 2008- September 2009 : Principal Investigator – Hypertension Trial
Jan 2006-Feb 2007: Sub-Investigator – Restless Legs Syndrome Trial
Nov2004- November 2009:: Sub-Investigator – Diabetes, Anemia, CKD, Cardiovascular Outcomes Trial
Nov 2004-Aug 2006: Sub-Investigator –Biphosphonate Osteoporosis Trial
Nov 2004-Present: GCP Training Modules-Various Sponsors (Multiple Modules)

Signature:	Signature Date: (dd-Mmm-yyyy)
	1-10-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Saiger	Salma	

Professional Mailing Address

Street Address: 1210 North Galloway Ave		Other Street Address:	
City: Mesquite	State/Province: Texas	Country: US	Zip/Postal Code: 75149
Email Address:	ssaiger@smsclinicalresearch.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Internal Medicine Residency	2004	Overlook Hospital (affiliate with University of Medicine & Dentistry New Jersey), US
Internal Medicine Internship	2002	Overlook Hospital (affiliate with University of Medicine & Dentistry New Jersey), US
MBBS Bachelor of Medicine & Bachelor of Surgery	1998	Dow Medical College, South Asia

Medical License Number	State/Province	Country
M8171	Texas	US

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2018	Medical Director/Principal Investigator	SMS Clinical Research, LLC	~~Mesquite~~Texas/US

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2009-Present	President and Medical Director	Salma Mazhar, MD, PA	US
2009-2009	Hospitalist	Methodist Mansfield Hospital	US
2008-2009	Staff Physician	East Texas Medical Center	US
2008-2009	Hospitalist	Flagstaff Medical Center	US

Brief Summary of Relevant Clinical Research Experience:

Amy Dunn has been under the supervision of the PI as a Sub-I. She is responsible for performing study related procedures and is responsible for making important study-related decisions pertaining to different studies.

Signature:	Signature Date: (dd-Mmm-yyyy)
Selma Saiger	17-JUL-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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MD 12 Aug 2020

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Wolf, MD	Thomas	A.

Professional Mailing Address

Street Address:		Other Street Address:	
350 W 23rd Street			
City: Fremont	State/Province: NE	Country: USA	Zip/Postal Code: 68025
Email Address:	**thomaswolf@cctresearch.com**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MD	2002	University of Nebraska Medical Center, Omaha, NE USA
BS-Biology	1997	University of Nebraska, Lincoln, NE USA

Medical License Number	State/Province	Country
23824	Nebraska	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2019-Present	Principal Investigator	Methodist Physicians Clinic/CCT Research	NE, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2011-2019	Principal and Sub-Investigator	Synexus Clinical Research US, Inc.	USA
2006-Present	MD	Methodist Physicians Clinic	USA
2008-Present	Volunteer Faculty	University of Nebraska Medical Center	USA
2007-Present	Full Endoscopy Privileges	Methodist Fremont Health Surgical Center	USA

Brief Summary of Relevant Clinical Research Experience:

Dr. Wolf has over nine years of clinical research experience. He has experience with a variety of indications, including COPD, Vaccines, Type 2 Diabetes, Migraine, and more. For a more complete list of experience, please reference their full CCT CV.

Signature:	**Signature Date: (dd-Mmm-yyyy)**

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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This page is a manifestation of an electronic record that was signed electronically.

Document Name: Pfizer CV Wolf
Document ID: 4748
No. Pages: 1

Statement of Testament: I have reviewed and approve the document
Electronic Signature for: Thomas Wolf
Electronically Signed by: TWolf
Date & Time: 15/JUL/2020 4:30 PM CDT
IP Address: 173.20.218.78

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Studdard	Harry	Earl

Professional Mailing Address:

Street Address 1:100 Memorial Hospital Dr.		Street Address 2: Annex Building, Suite 3-B	
City: Mobile	State/Province: AL	Country:US	Zip/Postal Code:36608

Email Address: harry.studdard@amrllc.com

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Residency	1986-1988	University of South Alabama Medical Center, USA
Internship	1985-1986	University of South Alabama Medical Center, USA
M.D.	1981-1985	University of South Alabama Medical Center, USA
B.S. in Biology	1978-1981	University of South Alabama Medical Center, USA

Medical License Number	State/Province	Country
MD 11620	AL	USA

Current Position at Study Site:

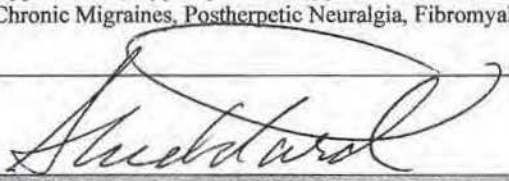
Start Date	Title	Institution or Company	State/Province & Country
2004	Principal Investigator	Coastal Clinical Research, LLC, An AMR Company	AL, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1997-Present	Physician	Mobile Adult Care Center	USA
1988-1997	Physician	Mobile Health Plan/Primehealth	USA

Brief Summary of Relevant Clinical Research Experience:

Type II Diabetes, Hypertension, Hyperlipidemia, Hypercholesterolemia, Influenza, DPN, Gout, HIV Device Testing, Smoking Cessation, Cholera Vaccine, Chronic Migraines, Postherpetic Neuralgia, Fibromyalgia, Weight Loss

Signature: 

Signature Date: (dd-Mmm-yyyy) 18 MAR 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Rankin	Bruce	G.

Professional Mailing Address:

Street Address: University Clinical Research-DeLand, LLC d/b/a Accel Research		Other Street Address:860 Peachwood Drive	
City: DeLand	State/Province: FL	Country: USA	Zip/Postal Code: 32720
Email Address:	brankin@accelclinical.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Fellowship (FACOP)	2013	American College of Osteopathic Family Physicians/USA
Certified Physician Investigator	2002	Association of Clinical Research Professionals/USA
Board Certification	1987	American College of Family Practitioners in Osteopathic Medicine and Surgery/USA
Residency	1987	Southeastern Medical Center/USA
Internship	1986	Doctors General Hospital/USA
Doctor of Osteopathic Medicine	1985	Nova Southeastern College of Osteopathic Medicine/USA
Bachelor of Science in Chemistry	1981	University of Florida/USA

Medical License Number	State/Province	Country
OS-0006029	Florida	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1998	Medical Director	Accel Research Sites-DeLand Clinical Research Unit	Florida/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1987-Present	Physician	Family Practice of West Volusia	USA

Brief Summary of Relevant Clinical Research Experience:

Has served as the Medical Director and Investigator at Accel Research Sites since 1998.

Signature:	Signature Date: (dd-Mmm-yyyy)
Signed Electronically by: Bruce Rankin - bruce.rankin@fpwv.care 28-May-2020 @ 07:46 AM EDT Reason: Approval	

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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eSignature Addendum

All eSignatures below were executed using Florence eBinders
21 CFR Part 11 compliant software for eSignatures

Current Electronic Signatures (v.2):

Signed electronically by: *Bruce Rankin (bruce.rankin@fpwv.care)*
Date: *28-May-2020 @ 07:47 AM EDT*
Reason: *Approval*

Previous Electronic Signatures:

There are no signatures for any previous versions.

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Rosen	Jeffrey	B.

Professional Mailing Address:

Street Address 1: Clinical Research of South Florida, an AMR company		Street Address 2: 370 Minorca Avenue, 2nd Floor	
City: Coral Gables	State/Province: Florida	Country: USA	Zip/Postal Code: 33134
Email Address:	Jeffrey.Rosen@amrllc.com		

Academic Qualifications: M.D.

Degree and/or Certification	Date (yyyy)	Institution and/or Country
M.D.	1979	Downstate Medical Center, State University of New York, USA
B.A.	1975	Brooklyn College, City University of New York, USA

Medical License Number	State/Province	Country
ME40205	Florida	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1985	Principal Investigator/Medical Director/President	Clinical Research of South Florida, an AMR company	Florida/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2008-Present	Chief Medical Doctor/Principal Investigator/President	Clinical Research of South Florida, an AMR company	USA
1982-Present	President/Owner/Private Practice Physician	PrimeCare of Coral Gables	USA

Brief Summary of Relevant Clinical Research Experience:

Broad spectrum of research trials in the Family Practice Arena: Hypertension, Diabetes, Osteoarthritis, Hypogonadism, Hyperlipidemia, Vaccines, ect.

Signature:	Signature Date: (dd-Mmm-yyyy)
	02/JUN/2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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CLINICAL AND MEDICAL CONTROLLED DOCUMENT (CMCD) SUPPORTING DOCUMENT

Identifier	Version	Title	Effective Date
INV02-INV04-WI-GL02-SD01	2.0	ABBREVIATED CURRICULUM VITAE TEMPLATE	16-Mar-2020

Full Name:	Last Name	First Name	Middle Name *if applicable*
	Stephens	Michael	A.

Professional Mailing Address:

Street Address: 1679 Eagle Harbor Parkway, Suite D		Other Street Address:	
City: Fleming Island	State/Province: FL	Country: USA	Zip/Postal Code: 32003

Email Address: mstephens@encoredocs.com

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MD	1992	University of Miami School of Medicine

Medical License Number	State/Province	Country
ME64230	Florida	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2010	Clinical Investigator	Fleming Island Center for Clinical Research	USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2001-Present	Family Physician	Michael Stephens Family Practice, PA	USA
1995-2010	Medical Director	HCR Heartland Skilled Nursing Facility	
1994-2001	Family Physician	Stephens Family Practice	USA
1994-Present	Medical Director	Moosehaven Retirement Community	USA
1992-1994	Residency	St. Vincent's Medical Center	USA

Brief Summary of Relevant Clinical Research Experience:

Dr. Stephens has been a Principal/Sub- Investigator for Fleming Island Center for Clinical Research since 2010. Study experience includes diabetes, hyponatremia, vaccines, women's studies, gastrointestinal studies, cardiovascular diseases, gout, flu, Overactive Bladder, RA, ACS, and arthritis. All trials have been Phases 2-4

Signature:	Signature Date: (dd-Mmm-yyyy)
	03JUN2020

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Investigator maintains the original, signed copy of his/her abbreviated CV in the investigator site file.

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Segall	Nathan	

Professional Mailing Address:

Street Address 1: 175 Country Club Drive		Street Address 2: Building 100, Suite A	
City: Stockbridge	State/Province: GA	Country: USA	Zip/Postal Code: 30281

Email Address: nsegall@clinicalresearchatlanta.com

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Doctor of Medicine Degree	1973	University of Alabama/USA
Internship Internal Medicine	1973-1974	Charity Hospital, LSU Division/ USA
Resident, Internal Medicine	1975-1977	University of South Alabama/ USA
Fellowship, Internal Medicine	1977-1979	National Jewish Hospital/ USA

Medical License Number	State/Province	Country
020602	GA	USA

Current Position at Study Site:

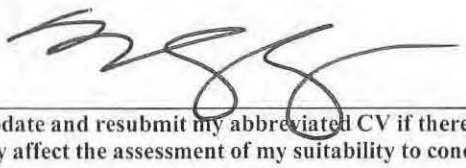
Start Date	Title	Institution or Company	State/Province & Country
1992	PI/ Sub Investigator	Clinical Research Atlanta	GA/ USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1994-2016	Allergist/Internist	Nathan Segall, MD, PC	USA
1992-1994	Internist	Del Mazo Medical Services	USA
1979-1992	Internist	Atlanta Medical Associates	USA

Brief Summary of Relevant Clinical Research Experience:

Over 27 years in multi-therapeutic areas, allergy/immunology, cardiovascular, Endocrinology, gastroenterology, pulmonary/respiratory, Vaccine, orthopedics, normal healthy, neurological, dermatology, women's health, and urology.

Signature:	Signature Date: (dd-Mmm-yyyy)
	24 APR 2020

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ABBREVIATED CURRICULUM VITAE

Full Legal Name:	Last Name	First Name	Middle Name
	Glover	Richard	M.

Professional Mailing Address:

Street Address 1: Alliance for Multispecialty Research, LLC		Street Address 2: 700 Medical Center Drive, Suite 110	
City: Newton	State/Province: KS	Country: USA	Zip/Postal Code: 67114
Email Address:	**richard.glover@amrllc.com**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Medical Doctorate	1988	University of Kansas School of Medicine
Bachelor of Science	1980	University of Kansas School of Medicine

Medical License Number	State/Province	Country
04-22805	KS	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
02/2017	Sub-I	Alliance for Multispecialty Research, LLC	KS/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2003- 02/2017	Sub-I	Heartland Research Associates, LLC	USA
2005- Present	Physician	Axtell Clinic, PA	USA
1991- 2005	Physician	Axtell Clinic- Broadway	USA

Brief Summary of Relevant Clinical Research Experience:

Sub-I conducting clinical research Phase II- V in areas including Gastroenterology, Anti-Infective, Auditory, Cardiovascular, Dermatology, Device, Endocrine/Metabolism, Female Health, Hyperlipidemia, Hypertension, Male Health, Musculoskeletal, Neurological, Ophthalmology, Psychiatric, Respiratory, Smoking Cessation, Urogenital, Weight Control, Vaccines.

Signature:	**Signature Date: (dd-Mmm-yyyy)**

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Document Name: Richard M. Glover, II, MD Current Sponsor-Specific CVs "Expires:" 28 May 2022
Document ID: 1030432

Statement of Testament: I reviewed the contents of this document
Electronic Signature for: Richard M. Glover, II, MD
Electronically Signed by: richard.glover@amrllc.com
Date and Time of Signature: 28 May 2020 18:24 EDT

ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Matherne	Paul	

Professional Mailing Address

Street Address:	Other Street Address:		
15190 Community Rd.	Suite 300		
City:	**State/Province:**	**Country:**	**Zip/Postal Code:**
Gulfport	MS	USA	39503
Email Address:	paulmatherne@medpharmics.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
BS	1974	LSU
MD	1978	LSU School of Medicine
Residency, Family Practice	1981	Earl K. Long Hospital

Medical License Number	State/Province	Country
09445	MS	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2016	PI	MedPharmics, LLC	MS, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2016 – Present	PI	MedPharmics, LLC	USA
1991 – 2006	Hyperbaric Medicine & Wound Care	Gulf Coast Medical Center, Director – Chief of Staff (2004)	USA
1984 - Present	Clinical Professor	University of MS Medical School, Jackson, MS	USA

Brief Summary of Relevant Clinical Research Experience:

Post-Surgical Pain, Phase III; Influenza, Pediatric, Phase III; Influenza, Adult, Phase III; C-Difficile Vaccine, Phase III; RSV Maternal Vaccine, Phase III; Chlamydia Trachomatis, Phase II; Pediatric Meningitis, Phase III; Migraine, Phase II; Migraine, Phase II/III; ; Pediatric Influenza, III; Hot Flash, Phase III;

Signature:	Signature Date: (dd-Mmm-yyyy)
Paul Matherne MD	13 JUL 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Wadsworth III	Larkin	Tyler

Professional Mailing Address:

Street Address 1:		Street Address 2:	
711 Old Ballas Road		Suite 105	
City: St. Louis	State/Province: Missouri	Country: USA	Zip/Postal Code: 63141
Email Address:	ty.wadsworth@sbcglobal.net		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Bachelor of Science, Zoology, Magna Cum Laude	1982	North Carolina State University, Raleigh, NC, USA
Doctor of Medicine	1986	University of North Carolina School of Medicine, Chapel Hill, NC, USA
Family Medicine Residency	1986-89	Hennepin County Medical Center, Minneapolis, MN, USA
Fellowship, Primary Care Sports Medicine	1989-90	Hennepin County Medical Center, Minneapolis, MN, USA

Medical License Number	State/Province	Country
103386	Missouri	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2005	Medical Director	Sundance Clinical Research, LLC	Missouri, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2016-present	Attending Physician	St. Louis Medical Clinic	USA
2012-present	Adjunct Associate Professor	Dept of Family Medicine, St. Louis Univ School of Medicine	USA
2005-present	Medical Director	Sundance Clinical Research	USA
1997-present	Attending Physician	Sports Medicine Consultants	USA

Brief Summary of Relevant Clinical Research Experience:

42 vaccine trials, Phase I-IV, 2005-present
45 Osteoarthritis trials, Phase II-IV, 2005-present
15 Chronic Low Back Pain trails, Phase II-III, 2005-present
3 cardiovascular trials, Phase III, 2007, 2009, 2010
5 acute injury trials, Phase III, 2006 - present
5 OIC, Phase II and III, 2013 - present
3 Acne, Phase III, 2015 and 2016
2 Non Cancerous Pain, Phase III, 2012 and 2015

Signature: [signature]

Signature Date: (dd-Mmm-yyyy) 21 MAY 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full LNaml e m Nr	Last Name	First Name	Middle Name
	Eder	Frank	Steven

Pof sNirf gml Mmdrga AddoNir

Street Address 1:	Street Address 2:
Meridian Clinical Research, LLC	1290 Upper Front Street

City:	State/Province:	Country:	Zip/Postal Code:
Binghamton	NY	USA	13901

E: ml AddoNir sNdNoy : . o: Nd@f:

A. mdN n c unlrsn mQf gir

DNaoNNngdtf o CNoQsn mQf g	DmQN/(((()	IgiQQuQf g ngdtf o CfugQ(
Doctor of Medicine	1993	State University of New York – Health and Science Center at Brooklyn, USA
Bachelor of Science	1989	Long Island University, USA

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197948-1	*New York*	*USA*

CuooNgQPf inQf g mQSQd(SnQr

SQmoQDmQN	TnQN	IgiQQuQf g f o Cf: pmg(	SQmQNPof vrg. N& CfugQ(
7/2019	Investigator	Meridian Clinical Research, LLC	NY, USA

PoNvrf ui RNNvng QPf inQf gi Ig. ludrga A. mdN n AppfrgQ NgQr

SQmoQ ng d Egd DmQNi	TnQN	IgiQQuQf g f o Cf: pmg(	CfugQ(
1996 to Present	Attending Physician	UHS Primary Care	USA
9/2002 – 7/2019	Investigator	Regional Clinical Research, Inc.	USA
1995 to 1996	Chief Resident	Wilson Memorial Hospital	USA
1993 to 1995	Resident	Wilson Memorial Hospital	USA

BorNs Su: : mo(f s RNNvng QClrgn ml RNNmo. h ExpNonNg. Nr

Conducting Pharmaceutical Clinical Research in the area of out-patient studies for 18 + years with numerous pharmaceutical companies. Has been an Investigator for numerous clinical studies in the areas of migraine, diabetes, stress incontinence, osteoarthritis, hypertension, hyperlipidemia, osteoporosis, GERD, COPD, Flu Vaccines, RSV, meningitis, depression and erectile dysfunction

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NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.

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Document Name: Frank Steven Eder, MD Sponsor CV 19 May 2020 C4591001 United Medical Associates
Document ID: 1000083

Statement of Testament: I reviewed the contents of this document
Electronic Signature for: Frank Steven Eder, MD
Electronically Signed by: frank.eder@nyuhs.org
Date and Time of Signature: 20 May 2020 08:50 EDT

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Bradley	Paul	Simon

Professional Mailing Address:

Street Address 1:	Street Address 2:		
340 Eisenhower Drive	Suite 1200		
City: Savannah	**State/Province:** GA	**Country:** USA	**Zip/Postal Code:** 31406
Email Address:	pbradley@mcrmed.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Bachelor's Degree	1982	Tulane University (USA)
Doctorate of Medicine	1986	Emory University (USA)
Internal Medicine	1989	Memorial Medical Center (USA)

Medical License Number	State/Province	Country
30016	Georgia	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2012	Principal Investigator	Meridian Clinical Research, LLC	Georgia (USA)

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
NA	NA	NA	NA

Brief Summary of Relevant Clinical Research Experience:

75+ Clinical trials including but not limited to RSV Vaccine, Osteoarthritis, Overactive bladder, Influenza Vaccine, Meningococcal Vaccine, Migraine Treatment, Hypertriglyceridemia, C-Diff Vaccinations

Signature:	Signature Date: (dd-Mmm-yyyy)

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION CONTAINED IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. MULTI-PAGE CVS ARE NOT ACCEPTABLE. DO NOT INCLUDE ATTACHMENTS, AND TEXT ON THE REVERSE SIDE.

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Document Name: Paul Simon Bradley, Md Pfizer One Page Current CV 31 Jan 2019 Expires 01 Jan 2021 Archived
Document ID: 201638

Statement of Testament: I approved the contents of this document
Electronic Signature for: Paul Bradley, MD
Electronically Signed by: pbradley@mcrmed.com
Date and Time of Signature: 01 Feb 2019 09:19 CST

ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Brune	Daniel	H

Professional Mailing Address

Street Address: 4911 N Executive Drive 2nd Floor			
City: Peoria	State/Province: IL	Country: USA	Zip/Postal Code: 61614
Email Address:	dbrunemd@optimalsites.net		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Doctor of Medicine	1985	University of Illinois
Bachelor of Science	1980	MacMurray College

Medical License Number	State/Province	Country
036.073081	Illinois	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2014	Principle Investigator	Optimal Research	Illinois USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2005-2014	Principle Investigator	Accelovance	USA
2000-2005	Principle Investigator	NTouch Research	USA
1992-2000	Principle Investigator	Health Advance Institute	USA
1988-Present	MD	Creve Couer Family Practice	USA

Brief Summary of Relevant Clinical Research Experience:

Numerous Influenza Vaccines; Zika Vaccine; RSV Vaccines; Transdermal Contraceptive' Pediatric Influenza Vaccine; C. difficile vaccine; COPD; Chronic Constipation; ADPKD; Hypercholesterolemia; Diabetes screening device; Chronic Low back pain; Rosacea; Overactive Bladder; Type 2 Diabetes; Asthma; Meningococcal Diphtheria; Obesity; CMV Vaccine; E. Coli Vaccine, Anthrax Vaccine

Signature:	**Signature Date: (dd-Mmm-yyyy)**
Daniel H Brune	18 MAY 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.

ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Donskey	Curtis	N/A

Professional Mailing Address

Street Address: 10701 East Blvd		Other Street Address:	
City: Cleveland	State/Province: Ohio	Country: United States	Zip/Postal Code: 44106

Email Address: Curtis.donskey@va.gov

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MD	1990	Medical College of Wisconsin, USA

Medical License Number	State/Province	Country
35.068561	OH	United States

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1998	Staff Physician	VA Northeast Ohio Healthcare System	OH, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
N/A	N/A	N/A	N/A

Brief Summary of Relevant Clinical Research Experience:

Previous experience as PI on several clinical research studies

Signature: Curtis J Donskey 402815 Digitally signed by Curtis J Donskey 402815 Date: 2020.07.09 13:28:26 -07'00' **Signature Date: (dd-Mmm-yyyy)**

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Essink	Brandon	James

Professional Mailing Address:

Street Address 1:	Street Address 2:		
3319 North 107th Street			
City: Omaha	State/Province: Nebraska	Country: USA	Zip/Postal Code: 68134
Email Address:	**bessink@mcrmed.com**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Family Practice Procedural Fellowship	2004	University of Nebraska Medical Center, USA
Family Practice Residency	2003	University of Nebraska Medical Center, USA
Doctor of Medicine	2001	University of Nebraska Medical Center, USA
Bachelor of Science	1997	University of Nebraska – Lincoln, USA

Medical License Number	State/Province	Country
22302	Nebraska	USA
74013	Georgia	USA
7971	South Dakota	USA
04-41270	Kansas	USA

Current Position at Study Site: Principal Investigator

Start Date	Title	Institution or Company	State/Province & Country
2003-Present	Principal Investigator	Meridian Clinical Research, LLC	NE/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2002-Present	Sub-Investigator	Meridian Clinical Research, LLC	USA
2015-Present	Physician	Bryan Telemedicine	USA

Brief Summary of Relevant Clinical Research Experience:

Cardiovascular (HTN) Hyperlipidemia – 15
Respiratory (COPD) – 12
Gastrointestinal (GERD, Constipation, Heartburn) – 15
Vaccine (Adult and Pediatric) – 86
Musculoskeletal (OA, chronic pain, fibromyalgia, IBS) – 17
Dermatologic (herpes labials, psoriasis) – 15
Migraine - 8
OTC - 10
Restless Legs - 4
Osteoporosis - 4
Contraception - 3
Genitourinary (OAB, BPH, sexual dysfunction, UTI) - 12
Endocrinology (diabetes, thyroid) - 8

Signature:	**Signature Date: (dd-Mmm-yyyy)**

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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Document Name: Brandon James Essink, MD Version 2.0 16 MAR 2020 Pfizer One Page Current CV 24 Apr 2020 Expires 24 Apr 2022 Archived
Document ID: 908335

Statement of Testament: I reviewed the contents of this document
Electronic Signature for: Brandon Essink
Electronically Signed by: bessink@mcrmed.com
Date and Time of Signature: 24 Apr 2020 15:55 CDT

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Fried	David	L.

Professional Mailing Address:

Street Address 1: Omega Medical Research		Street Address 2: 400 Bald Hill Road	
City: Warwick	State/Province: RI	Country: USA	Zip/Postal Code: 02886
Email Address:	dr.fried@omegamedicalresearch.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MD	1989	Emory University, USA
BS	1985	Dickinson College, USA

Medical License Number	State/Province	Country
MD07840	RI	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1996	Medical Director/Principal Investigator	Omega Medical Research	RI, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1997-Present	Clinical Asst. Professor	Brown University	USA
1992-Present	MD-Private Practice	Coastal Medical	USA

Brief Summary of Relevant Clinical Research Experience:

Principal Investigator of over 340 Clinical Trials for multiple indications since 1996. Became Medical Director of Omega Medical Research in 1999 and oversees all clinical trials at this site. Lead Sub-Investigator for Pediatric, Gastroenterology and Urology trials conducted at Omega Medical Research with other Principal Investigators.

Signature: David Fried

Signature Date: (dd-Mmm-yyyy) 19 MAY 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Harper	Charles	Harold

Professional Mailing Address

Street Address 1:		Street Address 2:	
1410 N. 13th Street		Suite #5	
City: Norfolk	State/Province: NE	Country: USA	Zip/Postal Code: 68701
Email Address:	charper@mcrmed.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Internal Med Residency	2008	University of Nebraska Medical Center / USA
Doctor of Medicine	2005	University of Nebraska Medical Center / USA

Medical License Number	State/Province	Country
24405	Nebraska	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2015	Investigator	Meridian Clinical Research, LLC	NE / USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2015 - Present	Sub-Investigator	Meridian Clinical Research, LLC	USA
2016 - Present	MD	Norfolk Medical Group	USA
2009-2016	MD	Faith Regional Internal Medicine	USA

Brief Summary of Relevant Clinical Research Experience:

Healthy Adult Vaccines (Adult and Pediatric)
Women's Health (OAB)
Dermatologic

Signature:	Signature Date: (dd-Mmm-yyyy)

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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Document Name: Charles Harold Harper, MD Pfizer One Page Current CV 22 Jan 2019 Expires 01 Jan 2021 Archived 01 Jan 2021
Document ID: 196341

Statement of Testament: I approved the contents of this document
Electronic Signature for: Charles Harper
Electronically Signed by: charper@mcrmed.com
Date and Time of Signature: 23 Jan 2019 10:27 CST

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Klein	Nicola	

Professional Mailing Address:

Street Address 1: Kaiser Permanente Vaccine Study Center One Kaiser Plaza 16th Floor		Street Address 2:	
City: Oakland	State/Province: California	Country: United States	Zip/Postal Code: 94612

Email Address: Nicola.klein@kp.org

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MD	1991-1998	New York University School of Medicine, USA
PhD	1989-1991	New York University School of Medicine, USA

Medical License Number A69589 **State/Province** California **Country** *USA*

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2006	Co-Director Vaccine Study Center	Kaiser Permanente	California, United States
2006	Research Scientist II	Kaiser Permanente	California, United States
2006	Senior Physician	Kaiser Permanente	California, United States

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
n/a			

Brief Summary of Relevant Clinical Research Experience:

Nicola P. Klein, MD, PhD, is the Director of the Kaiser Permanente Vaccine Study Center, a research group in Oakland, California, since 2006. As a pediatrician vaccine researcher and clinical trial investigator, her research interests include vaccine safety and efficacy, genetic influences on vaccine responses, and vaccine responses among at-risk populations. She is the principal investigator for many ongoing studies of vaccines, biologics, and the epidemiology of infectious diseases, and has published extensively on vaccine safety and effectiveness. In addition, she serves as the Chair of the California Immunization Committee and is the Principal Investigator of the CDC-sponsored Vaccine Safety Datalink (VSD) Project and Clinical Immunization Safety Assessment (CISA) Network. She received her medical degree and doctorate in biochemistry at New York University School of Medicine and completed a residency in pediatric medicine at Lucile Salter Packard Children's Hospital at Stanford University School of Medicine, Palo Alto, CA. She also serves as an adjunct clinical instructor at the Department of Pediatrics at Stanford.

Signature: [signature]

Signature Date: (dd-Mmm-yyyy) 13 FEB 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Klein	Tracy	R.

Professional Mailing Address:

Street Address 1: Alliance for Multispecialty Research, LLC		Street Address 2: 1709 S. Rock Rd.	
City: Wichita	State/Province: KS	Country: USA	Zip/Postal Code: 67207
Email Address:	_brak@ leinQ amrllkdom		

Akademik t ualifikations:

Degree and/or Cerbifikation	Dabe (@@@@	Institution and/or Counbr@
Residency	2002	Wichita State University
Medical Doctorate	1999	University of Kansas School of Medicine
BA / Chemistry	1995	Tabor College

Medikal Likense Num) er	State/Provinke	Counbr@
04-28967/ MD	KS	USA

CurrenbPosibion abStud@Sibe:

StarbDabe	Tibe	Institution or Compan@	State/Provinke & Counbr@
2017	PI	Alliance for Multispecialty Research, LLC (east)	KS/ USA

Previous RelevanbPosibions Inkluding Akademik Appoinbments:

Starband End Dabes	Tibe	Institution or Compan@	Counbr@
2002- 2017	PI/ Sub- I	Heartland Research Associates, LLC (East)	USA
2003- 2005	Medical Director	Heartland Diabetes Associates, LLC	USA
2001- Present	Family Practice	Family Medicine East, Chartered	USA

Brief Summar@of RelevanbClinikal Researkh Experienke:

PI conducting clinical research Phase II –V in areas including Gastroenterology, Anti- Infective, Auditory, Cardiovascular, Dermatology, Device, Endocrine/ Metabolism, Female Health, Hyperlipidemia, Hypertension, Male Health, Musculoskeletal, Neurological, Ophthalmology, Psychiatric, Respiratory, Smoking Cessation, Urogenital, Weight Control, Vaccines.

Signabure:	Signabure Dabe: (dd-Mmm-@@@@

I will updabe and resu) mibm@a)) reviabed CV if bhere are khanges and parbikularl@if bhere is an@khange in sbabus whikh would adversel@affekbbhe assessmenbof m@suiba) ilib@bo kondukb/parbikipabe in klinikal sbudiesc

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION CONTAINED IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. MULTI-PAGE CVS ARE NOT ACCEPTABLE. DO NOT INCLUDE ATTACHMENTS, AND TEXT ON THE REVERSE SIDE.

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Document Name: Tracy R. Klein, MD Current Sponsor-Specific CVs removed additional USA "Expires:" 30 Jun 2022
Document ID: 1111433

Statement of Testament: I reviewed the contents of this document
Electronic Signature for: Tracy R. Klein, MD
Electronically Signed by: tracy.klein@amrllc.com
Date and Time of Signature: 30 Jun 2020 14:18 EDT

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full e ga Nm	Last Name	First Name	Middle Name
	Koch	Mark	

P: roNffsri gl Mgslsi n Add: Nff

Street Address:		Other Street Address:	
1307 8th Avenue		Suite 202	
City:	State/Province:	Country:	Zip/Postal Code:
Fort Worth	TX	USA	76104

Ea gsl Add: Nfm a g: bbrk@c . N Q. sg: NNg: k@kra

AkgdNa sk/ uglsoskgQri fm

DNn: NNgi d(r: CNQoskgQri	DgQNy)))) S	Ii fQuQri gi d(r: Crui Q)
Doctor of Medicine	1992	University of Texas Health Science Center at San Antonio
Bachelor of Science in Biochemistry	1988	University of Dallas

MNdskgl LskN fNe ua vN	pQgQNP: r. si kN	Crui Q)
J4274	Texas	USA

Cu: : N QPrfsQri gQpQud) psQNm

pQg: QDgQN	TsQN	Ii fQuQri r: Cra &gi)	pQgQNP: r. si kNh Crui Q)
May 2016	Principal Investigator	Ventavia Research Group, LLC	TX, USA

P: N sruf RNN gi QPrfsQri f Ii kudsi n AkgdNa sk A&&rsi Q N Qm

pQg: Qgi d Ei d DgQNf	TsQN	Ii fQuQri r: Cra &gi)	Crui Q)
Oct 2015 – Present	Sub-Investigator	Ventavia Research Group, LLC	USA
Oct 2000 – Present	Physician	JPS Residency Program	USA
Sep 2005 – Present	Physician/Member	JPS Physicians Group	USA
2000 – 2005	Physician	North Texas Affiliated Medical	USA

B: sNopua a g:) roRNN gi QClsi skgl RNfNg: k@Ex&Ns N kNm

Trial for Efficacy, Immunogenicity, And Safety Study of Clostridium Difficile Vaccine in Subjects at Risk of C. Difficile Infection;
RSV Vaccine with Aluminum in Healthy Third-Trimester Pregnant Women and Safety and Efficacy of Maternally Transferred Antibodies in Preventing RSV Disease in Their Infants;
Study to Describe the Safety, Tolerability, And Immunogenicity of a Respiratory Syncytial Virus (RSV) Vaccine in Healthy Adults;
Study to Assess the Efficacy, Safety, And Immunogenicity of a Plant-Derived Quadrivalent VLP Influenza Vaccine in Adults 65 Years of Age and Older;
A Phase 3, Randomized, Double-Blind Trial to Evaluate the Safety and Immunogenicity of A 20-Valent Pneumococcal Conjugate Vaccine in Pneumococcal Vaccine-Naïve Adults 18 Years of Age and Older;
A Phase 3, Randomized, Observer-Blind, Multicenter Study to Evaluate the Efficacy, Immunogenicity and Safety of Seqirus' Cell-Based Quadrivalent Subunit Influenza Virus Vaccine (Qivc) Compared to A Non-Influenza Vaccine When Administrated in Healthy Subjects Aged 6 Months Through 47 Months;
A Phase 2b, Placebo-Controlled, Randomized, Observer-Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of A Respiratory Syncytial Virus (Rsv) Vaccine When Administered Concomitantly with Tetanus, Diphtheria, and Acellular Pertussis Vaccine (Tdap) in Healthy Nonpregnant Women 18 to 40 Years of Age;

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I wsll u&dgQNgi d : Nuva sQa) gvv: N sgQNd CV soQ@N Ng: Nk@gi nN gi d &g: Qkulg: l) soQ@N Nsf gi) k@gi nNsi fQgQuf w@k@wruld gd. NfN) goNkQQ@NgffNfa N Qroa) fusQgvslsQ Q kri dukQ&g: Qks&gQNsi kdsi skgl fQudsNt

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Document Name: Mark Koch Pfizer CV Current CV 20 May 2020 Expired 19 May 2021
Document ID: 1006732

Statement of Testament: I approved the contents of this document
Electronic Signature for: Mark Koch
Electronically Signed by: markkoch@ventaviaresearch.com
Date and Time of Signature: 22 May 2020 15:04 CDT

CLINICAL AND MEDICAL CONTROLLED DOCUMENT (CMCD) SUPPORTING DOCUMENT

Identifier	Version	Title	Effective Date
INV02-INV04-WI-GL02-SD01	2.0	ABBREVIATED CURRICULUM VITAE TEMPLATE	16-Mar-2020

Full Name:	Last Name	First Name	Middle Name *if applicable*
	Koren	Michael	J.

Professional Mailing Address:

Street Address: 4085 University Boulevard South, Suite 1		Other Street Address:	
City: Jacksonville	State/Province: FL	Country: USA	Zip/Postal Code: 32216

Email Address: mkoren@encoredocs.com

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Internal Medicine/Cardiovascular Disease	2017	National Board of Physicians and Surgeons, USA
Internal Medicine	2002	American Board of Internal Medicine, USA
MD	1985	Harvard University Medical School/Massachusetts Institute of Technology
BA	1981	Brandeis University, USA

Medical License Number	State/Province	Country
ME60337	Florida	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1997	CEO/Medical Director	Jacksonville Center for Clinical Research and affiliated sites	FL, USA 32216

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2018-Present	Cardiologist	First Coast Heart & Vascular Center	USA
2000-2018	Cardiologist	Apex Cardiovascular Group	USA
1991-2000	Cardiologist	Jacksonville Cardiovascular Clinic	USA
1988-1991	Cardiologist	New York Hospital Coverage Group	USA
1988-1988	Chief Resident	New York Hospital	USA
1985-1988	Intern/Resident	New York Hospital/Sloan-Kettering Cancer Center/Cornell Medical Center	USA

Brief Summary of Relevant Clinical Research Experience:

Dr. Koren has been a Principal Investigator and Sub-Investigator of research studies since 1997. Indications include cardiovascular diseases, hypertension, hypercholesterolemia, hyperlipidaemia, gastrointestinal disease, diabetes, vaccines, hyponatremia, arthritis, autoimmune diseases, panic disorders, women's heath, men's health, sleep disorders, and obesity, among others. In recent years, he has served as the international lead principal investigator for several large multiple centered trials including ALLIANCE (a pivotal statin study), ROLE

ABBREVIATED CURRICULUM VITAE TEMPLATE

(ranolazine safety study). MENDEL (evolocumab) and OSLER (evolocumab). Dr. Koren has experience working with all age ranges, and has worked on placebo-controlled studies including open label and double-blind trials. He has been actively involved as a principal/sub-investigator of over 800 trials ranging from phases I-IV.

Signature:	Signature Date: (dd-Mmm-yyyy)
[signature]	28-APR-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.

Investigator maintains the original, signed copy of his/her abbreviated CV in the investigator site file.

Print Form

TransCelerate BIOPHARMA INC

Abbreviated Curriculum Vitae (CV)

First Name: Stephen
Middle Name: Paul
Last Name: Fortmann
Profession: MD
Affiliation Name: Kaiser Permanente Center for Health Research
Address: 3800 North Interstate Avenue
City: Portland
Postal Code: 97227-1098
State/Region/Province: Oregon
Country: USA
Phone: 503-249-3315
Extension:
Fax: 503-331-3096
Email: Stephen.P.Fortmann@kpchr.org

Study Location Name (if different):
Address :
City:
Postal Code:
State/Region/Province:
Country:
Phone:
Extension:
Fax:
Email (if different):

EDUCATION

University	Degree	Year Completed
Stanford University	A.B. (Biology)	1970

MEDICAL EDUCATION

University	Degree	Year Completed
University of California, San Francisco	M.D.	1974
Santa Clara Valley Medical Center, San Jose California Intership in Medicine and Pediatrics, Residency in Medicine	Intern/Resident	1977
Stanford University School of Medicine, Stanford, California Research Fellow in Cardiovascular Disease Epidemiology and Prevention	Fellow	1979

TransCelerate BIOPHARMA INC

Abbreviated Curriculum Vitae (CV)

PROFESSIONAL EXPERIENCE/OTHER RELATED TRAINING

Institution	Medical Field	Year (Completed)
Kaiser Permanente Center for Health Research Senior Director, Science Programs, Distinguished Investigator and Medical Director		current
Oregon Health and Science University - Portland State University School of Public Health Affiliate Professor		current
Stanford University School of Medicine C.F. Rehnborg Professor in Disease Prevention (Emeritus)		current

Professional License Number: MD157289
State/Region/Province: Oregon Medical Board
Expiration Date: 12/31/2021
Research Area(s) of Interest: Cardiovascular Disease Epidemiology and Prevention; Primary Care
Clinical Trial Phases: ☐ I ☐ II ☑ III ☑ IV

List your most Current Clinical Research below:

Therapeutic Area:	Type of Trial	Phase:	Completed	On-Going
Impact of Retail Tobacco Advertising on Youth Smoking, National Cancer Institute.	None		☐	☑
Hawaii Asian and Pacific Islander Diabetes Study (HAPI-D), National Institute of Diabetes and Digestive and Kidney Diseases.	None		☐	☑
Health and Economic Effects of Light Rail Lines: A Natural Experiment, National Institute of Diabetes and Digestive and Kidney Diseases.	None		☐	☑
Glycemia Reduction Approaches in Diabetes: A Comparative Effectiveness Study (GRADE), National Institute of Diabetes and Digestive and Kidney Diseases.	None		☐	☑
Cardiovascular Disease Among Asians and Pacific Islanders (CASPER), National Heart, Lung, and Blood Institute.	None		☐	☑
Evaluating the Implementation of Diabetes Prevention Program in an Integrated Health System, National Institute of Diabetes and Digestive and Kidney Diseases.	None		☐	☑
Advancing Geriatrics Infrastructure & Network Growth, National Institute on Aging.	None		☐	☑
Treatment of Hypertension In Adults with ThiaZIDES: Pragmatic Trial Pilot Study, National Heart, Lung, and Blood Institute.	None		☑	☐

GCP Training Documentation (Course Provider/Year Completed): 12/27/2017
CITI GCP

By signing this form, I confirm that the information provided on this Abbreviated CV is accurate and reflects my current employment and qualifications:

Signature: Stephen P. Fortmann **Date:** 21 July 2020

ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Randall	William	

Professional Mailing Address

Street Address:		Other Street Address:	
948 Patterson Road			
City: Dayton	State/Province: Ohio	Country: USA	Zip/Postal Code: 45419
Email Address:	(b) (6)		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Specialty Certification, Family Medicine	1991	American Board of Family Medicine, USA
Doctor of Medicine	1988	University of Cincinnati, USA
Premedical Studies	1984	University of Dayton, USA

Medical License Number	State/Province	Country
35.059106	Ohio	USA

Current Position at Study Site:

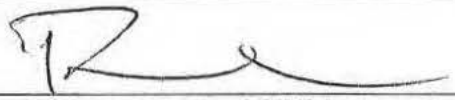
Start Date	Title	Institution or Company	State/Province & Country
SEP 2010	Principal Investigator	PriMed Clinical Research	OH/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
7/1991- Present	Practicing Family Physician	PriMed Family Practice	USA
7/1988-6/1991	Family Practice Resident	St. Elizabeth Medical Center	USA

Brief Summary of Relevant Clinical Research Experience:

I have approximately 11 years of clinical research experience in a variety of indications and developmental phases.

Signature:	Signature Date: (dd-Mmm-yyyy)
	09 JUN 2020

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Schwartz	Howard	I

Professional Mailing Address:

Street Address 1:7261 Sheridan Street		Street Address 2: Suite 210	
City: Hollywood	State/Province: Florida	Country: USA	Zip/Postal Code: 33024

Email Address: Howard.schwartz@rcatrials.com

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Doctor of Medicine	1984	University of Miami School of medicine, Miami, USA
American Board of Internal Medicine	1985	USA
American Board of Internal Medicine, Gastroenterology	1989	USA

Medical License Number	State/Province	Country
ME47067	Florida	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
12/2017	Chief Medical Officer	Research Centers of America, LLC	Florida, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
06/2018 - Present	President and CEO	Dream Life Recovery	Pennsylvania, USA
06/2017 - Present	President and CEO	Ventre Medical	Oakland Park, USA
01/2016 – 01/2019	Managing Director	Monarch Specialty Group	Miami, USA
07/2015 – 08/2016	Clinical Trial Lead	Miami Cancer Center	Miami, USA
10/1996 – 06/2015	President	Miami Research Associates	Miami, USA

Brief Summary of Relevant Clinical Research Experience:

Clinical Trial Expert who has worked in the Pharmaceutical industry for the past 20 years conducting over 1000 clinical trials and participating in the commercializing of over 40 products. Participated in the design and execution of Phase 1-3 Trials across multiple areas including Biologics, Vaccines, Oncology, Gastroenterology, Neurology, Rheumatology, Sleep Medicine, Diabetes and Psychiatry.

Signature:	Signature Date: (dd-Mmm-yyyy)
	13/MAR/2020

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ABBREVIATED CURRICULUM VITAE

TransCelerate BIOPHARMA INC.

Name: Jonathan Paul Wilson, DO
Professional Title: Investigator
Organization: PMG Research of Winston-Salem, LLC
Address1: 1901 S. Hawthorne Road, Suite 306
Address2: Winston-Salem, NC 27103 USA
E-Mail: jonathan.wilson@pmg-research.com

Main Daytime Phone: 336.768.8062
24 Hour Phone: 336.768.8062
Fax: 336.760.2957

VG 14 JUN 2020

AFFILIATIONS

Facility Name	Facility Address
PMG Research of Winston-Salem, LLC	1901 S. Hawthorne Road, Suite 306, Winston-Salem, NC 27103

Education

University/School/Program	Degree/Certificate	Specialty	Year Completed
NorthEast Medical Center, NC USA	Intern/Residency	Family Medicine	2004
Nova Southeastern University College of Osteopathic Medicine, FL – USA	DO	Family Medicine	2001
Nova Southeastern University College of Osteopathic Medicine, FL – USA	Masters	BioMedical Science	1997
University of North Carolina Chapel Hill, NC - USA	BA	NA	1991

PROFESSIONAL EXPERIENCE

Job Title	Institution	Year Started	Year Completed
Investigator	PMG Research of Winston-Salem	2006	Current
Private Practice	FairBrook Medical Clinic	2006	2008
Private Practice	Central Carolina Family Physicians	2005	2006

Type of License	License Issuer	Professional License Number	Country	State, Province or Region
Medical	NC State Board	200500132	USA	NC
DEA Schedule 2,2N, 3, 3N, 4, 5	DEA	BW9087619	USA	NC

RESEARCH EXPERIENCE

Study Type (Check all that apply):

- ☐ Academic
- ☒ Industry
- ☐ Investigator-Initiated
- ☐ Government
- ☐ Other / Please Specify:

Clinical Study Phases (Check all that apply) ☐ I ☒ II ☒ III ☒ IV

Therapeutic Areas of Expertise:

Therapeutic Area	Therapeutic Area
Family Medicine – All areas	Vaccine
Diabetes	Hypertension
Cholesterol	Osteoarthritis
Obesity	Device

Total Clinical Research Experience: Total Number of completed studies: 225 +

Therapeutic Area	Therapeutic Area	Therapeutic Area	Therapeutic Area
Acne	Acute Flu Device	Acute Respiratory	Allergy
Bone Metabolism	C-Diff	COPD	Diabetes/HTN Combo
CV Events Post MI	Cholesterol	Erectile Dysfunction	Erosive Esophagitis
NSAID Associated Ulcers	Flu Vaccine (All types)	Diabetes Mellitus & Type II Diabetes	OA of Hips and Knees
Fatty Liver (NASH)	Heartburn	Herpes Zoster Vaccine	GERD
IBS	Idiopathic Constipation	Crohn's Disease	Ulcerative Colitis
Celiac Disease	Gastroparesis	Pneumonia Vaccine	C-Diff Vaccine
RSV vaccine	dTAP vaccine	Psoriasis	Rosacea
BPH	Birth Control	Nocturia	Prostate Cancer
Overactive Bladder	Hypertension	Rheumatoid Arthritis	Fibromyalgia
Obesity	Weight Loss	Asthma	

Good Clinical Practice (GCP) Training Details:

Training Provider	Title of Training	Date Completed
CITI	GCP	2019

By signing this form, I confirm that the information provided on this Abbreviated CV is accurate and reflects my current employment and qualifications:

Signature: JPWilsonDO *Date (DD/MMM/YYYY):* 07/JAN/2020

SHARED INVESTIGATOR PLATFORM

Dr. Peter John Winkle
Investigator
Anaheim Clinical Trials, LLC
2441 W. La Palma Avenue, Suite 140
Anaheim , California , United States of America , 92801
Email: pwinkle@act-trials.com

Main/Daytime: (714) 774-7777
Cell/Mobile: (b) (6)
24 Hour: (714) 778-1300
Evening: (949) 295-7809
Fax: (714) 778-0667

AFFILIATIONS

Facility Name (Department Name)	Facility Address	Department Address
Anaheim Clinical Trials, LLC	2441 West La Palma Avenue, Suite 140, Anaheim, California, United States of America, 92801	Not Applicable

EDUCATION

University	Degree/Certificate	Specialty	Year Completed
American Board of Internal Medicine	American Board of Internal Medicine (FACG)	Primary Care (General Practice, Family Practice, Internal Medicine) - Gastroenterology	1995
University of California, Los Angeles	Fellowship	Gastroenterology	1994
American Board of Internal Medicine	American Board of Internal Medicine (FACP)	Primary Care (General Practice, Family Practice, Internal Medicine)	1994
University of Southern California	Medical Degree	Primary Care (General Practice, Family Practice, Internal Medicine)	1989
University of California, Davis	Bachelor of Science	Not Applicable	1984

PROFESSIONAL EXPERIENCE

Job Title	Institution	Year Started	Year Completed
Medical Director	Anaheim Clinical Trials, LLC	2011	Present
Investigator	Advanced Clinical Research Institute	2007	2011
Investigator	Associated Gastroenterology Medical Group	2007	2018
Investigator	AGMG Endoscopy Center	2001	Present
Investigator	Orange County Clinical Research	1994	2007

LICENSE DETAILS

Type of License	License Issuer	Professional License Number	Country	State/Province/ Region	Expiration Date
Medical Doctor	The Medical Board of California	G70077	United States of America	California	31-Mar-2022
Other	Association of Clinical Research Professionals	None	United States of America	Virginia	30-Nov-2021
Other	United States Department of Justice	BW2564993 / XW2564993	United States of America	California	31-May-2023
Other	United States Department of Justice	RW0442537	United States of America	California	31-May-2023

RESEARCH EXPERIENCE

Study Type: Government;Industry;Academic
Clinical Study Phases: I,II,III,IV
Therapeutic Area of Expertise:

Dr. Peter John Winkle
Investigator
Anaheim Clinical Trials, LLC
2441 W. La Palma Avenue, Suite 140
Anaheim , California , United States of America , 92801
Email: pwinkle@act-trials.com

Main/Daytime: (714) 774-7777
Cell/Mobile: (b) (6)
24 Hour: (714) 778-1300
Evening: (949) 295-7809
Fax: (714) 778-0667

Cardiovascular Diseases;Digestive System Diseases;Endocrine System Diseases;Female Urogenital Diseases and Pregnancy Complications;Immune System Diseases;Musculoskeletal Diseases;Respiratory Tract Diseases;Skin and Connective Tissue Diseases;Vaccines;Virus Diseases

TOTAL CLINICAL RESEARCH EXPERIENCE

Therapeutic Area	Sub Therapeutic Area	Number of Completed Studies	Number of Ongoing Studies
Endocrine System Diseases	Diabetes Mellitus	38	2
Digestive System Diseases	Gastrointestinal Diseases	32	2
Skin and Connective Tissue Diseases	Skin Diseases	18	5
Vaccines	Vaccines	17	3
Immune System Diseases	Autoimmune Diseases	14	0
Respiratory Tract Diseases	Lung Diseases	7	0
Female Urogenital Diseases and Pregnancy Complications	Female Urogenital Diseases	6	0
Female Urogenital Diseases and Pregnancy Complications	Pregnancy Complications	6	0
Virus Diseases	Hepatitis, Viral, Human	1	1

GCP TRAINING DETAILS

Course Provider	Course Title	Date Completed (DD-MMM-YYYY)	Status
Pfizer	Good Clinical Practice for Investigational Site Staff - 3.0	24-Jan-2019	Certificate Valid

By signing this form, I confirm that the information provided on this Abbreviated CV is accurate and reflects my current employment and qualifications:

Signature:	Dr. Peter John Winkle winklep_5031 03-JUN-2020 20:16:13 GMT Author of CV

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Levin	Michael	L.

Professional Mailing Address

Street Address: 1022 East Sahara Avenue		Other Street Address:	
City: Las Vegas	State/Province: Nevada	Country: USA	Zip/Postal Code:89104
Email Address:	mlevin@crcnnv.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Clinical and Molecular Genetics Fellowship	1991-1995	Baylor College of Medicine, USA
Pediatrics Residency	1988-1991	Tulane University School of Medicine, USA
M.D.	1984-1988	Tulane University School of Medicine, USA

Medical License Number	State/Province	Country
7954	Nevada	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
6/2019	Principal Investigator / Sub-Investigator	Wake Research - Clinical Research Center of Nevada, LLC (WR-CRCN, LLC)	Nevada USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2002-Present	Pediatrician	Henderson Pediatrics	USA
2002-2019	Principal Investigator / Sub-Investigator	Clinical Research Center of Nevada	USA
2001-2002	Pediatrician	Foothills Pediatrics	USA
1996-2001	Assistant Professor	University of Nevada School of Medicine	USA

Brief Summary of Relevant Clinical Research Experience:

Pediatrics: MMR/MMRV, RSV, Men ACWY, Pneumococcal, Havrix, Influenza, Epilepsy, ADHD, Weight Loss, Insomnia, Otitis Media, Otitis Externa, Nasal Swabs, Pharyngitis, Strep, Dermatitis, ABC in New Born, Brain Networking Activation

Adults: Influenza Vaccines, Shingles Vaccines, Pneumococcal Vaccines, C-Difficile Vaccine, Insomnia, E. Coli Vaccine, Dengue Vaccine, Rabies Vaccine, Anthrax Vaccine, Weight Loss, Post-Op Surgical Pain, Brain Networking Activation, Hepatitis B Vaccine

Signature:	Signature Date: (dd-Mmm-yyyy)
	26-JUN-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Walter, Jr.	Emmanuel	Benjamin

Professional Mailing Address

Street Address: 2608 Erwin Road, Suite 210		Other Street Address: 3024 Pickett Road	
City: Durham	State/Province: NC	Country: USA	Zip/Postal Code: 27705
Email Address:	Chip.walter@duke.edu		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
B.S.	1979	University of Notre Dame
M.D.	1983	University of Maryland at Baltimore
M.P.H./Epidemiology	1992	University of North Carolina at Chapel Hill

Medical License Number	State/Province	Country
31677	North Carolina	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2016	Director	Duke University Medical Center/Duke Human Vaccine Institute; Duke Vaccine and Trials Unit Study Site Address: Clinical Research Pickett Road 3024 Pickett Road Durham, NC 27705 Accessioning Unit and Repository 2 Genome Court Durham, NC 27710	North Carolina, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2009-current	Professor of Pediatrics with Tenure	Duke University Medical Center	USA
2002-2009	Associate Professor of Pediatrics with Tenure	Duke University Medical Center	USA
1998-2002	Associate Professor of Pediatrics	Duke University Medical Center	USA

Brief Summary of Relevant Clinical Research Experience:

Dr. Walter is trained in the fields of pediatrics, infectious diseases, and epidemiology and his primary research interest is related to disease prevention through vaccination. He is the Chief Medical Officer at the Duke Human Vaccine Institute and directs the Duke Vaccine and Trials Unit (DVTU). He has been the principal investigator or co-investigator for a large number of federally and industry funded vaccine studies. He has extensive experience conducting trials with both investigational and FDA approved vaccines for viral and bacterial pathogens. He is currently the co-principal investigator for the NIAID funded Vaccine and Treatment Evaluation Unit (VTEU) and the CDC Clinical Immunization Safety Assessment (CISA) project and principal investigator for the NIAID funded Collaborative Influenza Vaccine Innovation Center - Clinical Core. He is a recent past member of the CDC Advisory Committee on Immunization Practices. He has also served as a member of data safety monitoring boards for a number of vaccine and therapeutic studies.

Signature:	Signature Date: (dd-Mmm-yyyy)
Emmanuel Benjamin Walter Jr	05 MAR 2021

TO 8-MAR-2021

ABBREVIATED CURRICULUM VITAE TEMPLATE

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Walter, Jr.	Emmanuel	Benjamin

Professional Mailing Address

Street Address: 2608 Erwin Road, Suite 210		Other Street Address:	
City: Durham	State/Province: NC	Country: USA	Zip/Postal Code: 27705
Email Address:	Chip.walter@duke.edu		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
B.S.	1979	University of Notre Dame
M.D.	1983	University of Maryland at Baltimore
M.P.H./Epidemiology	1992	University of North Carolina at Chapel Hill

Medical License Number	State/Province	Country
31677	North Carolina	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2016	Director	Duke University Medical Center/Duke Human Vaccine Institute; Duke Vaccine and Trials Unit	North Carolina, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2009-current	Professor of Pediatrics with Tenure	Duke University Medical Center	USA
2002-2009	Associate Professor of Pediatrics with Tenure	Duke University Medical Center	USA
1998-2002	Associate Professor of Pediatrics	Duke University Medical Center	USA

Brief Summary of Relevant Clinical Research Experience:

Dr. Walter is trained in the fields of pediatrics, infectious diseases, and epidemiology and his primary research interest is related to disease prevention through vaccination. He is the Chief Medical Officer at the Duke Human Vaccine Institute and directs the Duke Vaccine and Trials Unit (DVTU). He has been the principal investigator or co-investigator for a large number of federally and industry funded vaccine studies. He has extensive experience conducting trials with both investigational and FDA approved vaccines for viral and bacterial pathogens. He is currently the co-principal investigator for the NIAID funded Vaccine and Treatment Evaluation Unit (VTEU) and the CDC Clinical Immunization Safety Assessment (CISA) project and principal investigator for the NIAID funded Collaborative Influenza Vaccine Innovation Center - Clinical Core. He is a recent past member of the CDC Advisory Committee on Immunization Practices. He has also served as a member of data safety monitoring boards for a number of vaccine and therapeutic studies.

Signature:	**Signature Date: (dd-Mmm-yyyy)**
Emmanuel Benjamin Walter Jr	01 MAY 2020

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Thomas	Stephen	J

Professional Mailing Address

Street Address: 725 Irving Avenue		Other Street Address: Suite 311	
City: Syracuse	State/Province: NY	Country: USA	Zip/Postal Code: 13210

Email Address: thomstep@upstate.edu

Academic Qualifications: MD

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MD	1996	Albany Medical College, Albany, NY
BA in Biomedical Ethics	1992	Brown University, Providence, RI

Medical License Number	State/Province	Country
286005-1	NY	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
11/2016	Director, Infectious Disease Assoc., Director, Institute for Global Health and Translational Science	State University of NY, Upstate Medical University	NY, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
4/2014-3/2016	Infectious Diseases Consultant to the US Army Surgeon General	U.S. Army Medical Command	USA
10/2014-3/2016	Team Leader, USAMRMC Ebola Response Management Team	U.S. Army Medical Research and Material Command	USA
7/2013-7/2016	Director, WRAIR-GEIS Operational Clinical Infectious Diseases Course	Walter Reed Army Institute of Research	USA
6/2011-5/2014	Director, Viral Diseases Branch	Walter Reed Army Institute of Research	USA
12/2007-5/2011	Director, Dengue Vaccine Development	U.S. Army-Armed Forces Research Institute of Medical Sciences	USA
9/2004-11/2007	Project Leader, Dengue Vaccine Development	Walter Reed Army Institute of Research	USA
9/2002-9/2004	Virology Department	U.S. Army Medical Component Armed Forces Research Institute	Thailand
7/2014-present	Associate Professor, Dept. of Medicine	Uniformed Services University of the Health Sciences	USA

Brief Summary of Relevant Clinical Research Experience:

Significant experience and knowledge base in Virology and Vaccine development. Successful completion of numerous viral disease research studies as well as extensive background as a project leader and as director in both the military and public health field.

Signature:	Signature Date: (dd-Mmm-yyyy)
S Q Thom	04/MAY/2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Winokur	Patricia	Lee

Professional Mailing Address

Street Address: 200 Hawkins Drive		Other Street Address: Department of Internal Medicine, University of Iowa Hospitals & Clinics	
City: Iowa City	State/Province: Iowa	Country: USA	Zip/Postal Code: 52242
Email Address:	**Patricia-winokur@uiowa.edu**		

Academic Qualifications: MD

Degree and/or Certification	Date (yyyy)	Institution and/or Country
BA	June 1, 1981	Brown University
MD	June 1, 1985	Washington University
Residency, Internal Medicine	June 30, 1988	University of Iowa Hospitals and Clinics
Fellowship, Infectious Diseases	June 30, 1991	University of Iowa Hospitals and Clinics

Medical License Number	State/Province	Country
26690	Iowa	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
July 1, 1993	Assistant Prof-Full Professor	University of Iowa	Iowa USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
July 1, 1991-June 30, 1993	Postdoctoral Fellow	National Institutes of Health	USA

Brief Summary of Relevant Clinical Research Experience:

Dr. Winokur is a trained Infectious Disease Specialist with 18 years of experience performing clinical trials in infectious diseases. The studies have ranged from evaluation of novel diagnostics, drug therapies and vaccines. She has been the Principal Investigator for the University of Iowa NIH funded Vaccine and Treatment Evaluation Unit since 2007.

Signature: Patricia Winokur

Signature Date: (dd-Mmm-yyyy) 01 May 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Rupp	Richard	E.

Professional Mailing Address

Street Address: University of Texas Medical Branch		Other Street Address: 301 University Boulevard	
City: Galveston	State/Province: TX	Country: USA	Zip/Postal Code: 77555-1115
Email Address:	rrupp@utmb.edu		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Adolescent Medicine Fellowship	1993	William Beaumont Army Medical Center, Texas, USA
Pediatrics Residency	1989	Wilford Hall Medical Center, Texas, USA
Medical Doctorate	1986	St. Louis University School of Medicine, Missouri, USA
Zoology Bachelor of Science	1982	Arizona State University, Arizona, USA

Medical License Number	State/Province	Country
J9316	Texas	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
05/2008	Director for Clinical Trials and Clinical Research	University of Texas Medical Branch, Sealy Institute for Vaccine Sciences	Texas, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2016-Present	Medical Director, Island Pediatrics	Department of Pediatrics, UTMB	USA
2010-2012	Director, Institutional Review Board	University of Texas Medical Branch (UTMB)	USA
2009-Present	Chief Division Adolescent and Behavioral Health	Department of Pediatrics, UTMB	USA
2008-Present	Director for Clinical Trials and Clinical Research	Sealy Center for Vaccine Development, UTMB	USA

Brief Summary of Relevant Clinical Research Experience:

Richard Rupp, MD has over a decade of experience as a collaborator or principal investigator on phase I-III clinical trials. The trials include both NIH and industry sponsors. Trials span the age range from infants through the elderly and have included vaccine for meningococcus (ACWY&B), pneumococcus, influenza (seasonal, novel H1N1, avian), smallpox, cytomegalovirus, herpes simplex virus, human papillomavirus, and Ebola. He also heads the Office of Clinical Trials for the Sealy Center for Vaccine Development ensuring the success of the trials meeting regulatory demands, sponsor requirements and the needs of the subject.

Signature:	Signature Date: (dd-Mmm-yyyy)
Richard E Rupp	19 May 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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DC 26 MAY 2020

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Talaat	Kawsar	R.

Professional Mailing Address

Street Address: 624 N Broadway		Other Street Address: Hampton House Rm 249	
City: Baltimore	State/Province: MD	Country: USA	Zip/Postal Code: ~~20912~~ 21205
Email Address:	**ktalaat@jhu.edu**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MD	1997	University of Washington, Seattle, WA
BS	1993	University of Washington, Seattle, WA

Medical License Number	State/Province	Country
D0066043	Maryland	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2017	Assistant Professor	Johns Hopkins Bloomberg School of Public Health	Maryland, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2016-2017	Associate Scientist	JHSPH	USA
2007-2016	Assistant Scientist	JHSPH	USA
2006-2007	Assistant Clinical Investigator	NIH	USA

Brief Summary of Relevant Clinical Research Experience:

I am a Board-Certified physician in Internal Medicine, Pediatrics and Infectious Diseases. I have served as the Principal Investigator for Phase 1 or 2 trials for a variety of vaccines, including influenza, malaria, Ebola, and enteric bacteria such as Enterotoxigenic *E. coli* (ETEC) and Shigella. I have also conducted several human challenge studies to look at the efficacy of novel therapies and vaccines for ETEC and Shigella.

Signature:	Signature Date: (dd-Mmm-yyyy)
Kawsar R. Talaat, MD Digitally signed by Kawsar R. Talaat, MD Date: 2020.05.06 19:37:03 -04'00'	06-May-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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MJ 07 Aug 2020

MJ 07 Aug 2020

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Falcone	Robert	S

Professional Mailing Address:

Street Address 1:	Street Address 2:		
34 E. Somerset St.			
City: Raritan	State/Province: New Jersey	Country: USA	Zip/Postal Code: 08869

Email Address: robert.falcone@amicicr.com

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MD	1984	Boston University School of Medicine

Medical License Number	State/Province	Country
25MA04684000	New Jersey	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
10-FEB-2016	Principal Investigator	Amici Clinical Research	New Jersey/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
21-FEB-2015 – 01-NOV-2016	Sub-Investigator	Amici Clinical Research	USA
May 2011 – February 2015	Site Occupational Health & Wellness Physician	Pfizer, Inc	USA
July 1996 – September 2008	Corporate Medical Director	Merck & Co., Inc	USA
December 1990 – July 1996	Site Medical Director	Merck & Co., Inc	USA

Brief Summary of Relevant Clinical Research Experience:

Sub-Investigator & Study Coordinator for PCSK9 Inhibitor study (Pfizer)
Principal Investigator for preventive migraine medication (Teva)
Principal Investigator for preventive migraine medication (Allergan)
Principal Investigator for Alzheimer Disease registry study (Avid/Lilly)
Principal Investigator for NASH study (Intercept)
Principal Investigator for NASH study (Allergan)
Principal Investigator for NASH study (Galmed)
Principal Investigator for 3 C. Difficile vaccine studies (Pfizer)
Principal Investigator for 2 PCSK9 Inhibitor studies (The Medicines Company)
Principal Investigator for Osteoarthritis Knee/Hip pain (Regeneron)
Principal Investigator for hypogonadism in men with increased CV disease risk (AbbVie)
Principal Investigator for Effect of Efpeglenatide on Cardiovascular Outcomes in Type 2 Diabetes Patients at High Cardiovascular Risk (Sanofi)
Principal Investigator for chronic cough (Merck)
Principal Investigator for 24 hour BP monitoring study in hypogonadal men with receiving testosterone replacement therapy (AbbVie)

Signature:	Signature Date: (dd-Mmm-yyyy)
Robert A. Falcone	29-May-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Garcia-Diaz	Julia	

Professional Mailing Address

Street Address:	Other Street Address:		
1514 Jefferson Highway			
City: New Orleans	State/Province: LA	Country: USA	Zip/Postal Code: 70121
Email Address:	jgarcia-diaz@ochsner.org		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Medical Doctor	1993	Louisiana State University School of Medicine/USA
Master of Science	1989	University of New Orleans/USA
Bachelor of Science	1983	Nicholls State University/USA

Medical License Number	State/Province	Country
10817R	LA	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1/2020	Director, Medical Subspecialties Research	Ochsner Health	LA, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
9/2016-present	Director, Medical Student Research	University of Queensland, Ochsner Clinical School	Australia
7/2015-present	Director Clinical Infectious Diseases Research	Ochsner Medical Center	USA
8/2014-present	Associate Professor	University of Queensland, Ochsner Clinical School	Australia / USA
3/2004-6/2015	Program Director	Infectious Diseases Fellowship	USA
2004-present	Certified Principle Investigator	Ochsner Clinic Foundation	USA

Brief Summary of Relevant Clinical Research Experience:

Certified Principal Investigator with over 20 years of experience. Over 50+ research studies completed

Signature:	Signature Date: (dd-Mmm-yyyy)
	20 MAY - 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Reynolds	Steven	H.

Professional Mailing Address

Street Address: 2600 Redondo Avenue		Other Street Address: Suite 415	
City: Long Beach	State/Province: CA	Country: USA	Zip/Postal Code: 90806
Email Address:	**stevenreynolds@cnstrial.com**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
DO	1992	Midwestern University, Chicago College of Osteopathic Medicine, USA
American Board of Family Practice	1999	USA

Medical License Number	State/Province	Country
6475	California	USA

Current Position at Study Site:

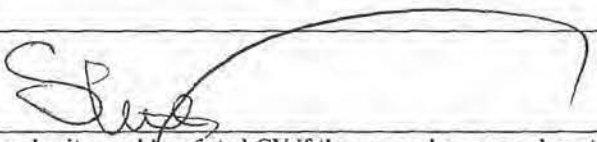
Start Date	Title	Institution or Company	State/Province & Country
2010 – Present	Investigator	Collaborative Neuroscience Research, LLC	USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2018 – Present	Private Practice	Naples Medical Group Long Beach, CA	USA
2010 – Present	Staff Physician	Ocean View Psychiatric Health Facility, Long Beach, CA	USA
2009 – Present	Medical Review Officers	ACOEM Certified at Central Drug Systems	USA
2005 – 2018	Private Practice	Family Health Care of Long Beach, CA	USA

Brief Summary of Relevant Clinical Research Experience:

N/A

Signature:	Signature Date: (dd-Mmm-yyyy)
	29-Jul-2020

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Senders	Shelly	D

Professional Mailing Address:

Street Address 1: 2054 South Green Road			
City: South Euclid	State/Province: Ohio	Country: USA	Zip/Postal Code: 44121
Email Address:	ssenders@senderspediatrics.com		

Academic Qualifications: MD

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Resident in Pediatrics, Chief Resident in Pediatrics	1986	The Brookdale Hospital Medical Center
Doctorate in Medicine	1983	Albert Einstein College of Medicine
Bachelor of Arts in Chemistry, Summa Cum Laude	1978	Yeshiva University

Medical License Number	State/Province	Country
35.053726	Ohio	USA

Current Position at Study Site: Principal Investigator

Start Date	Title	Institution or Company	State/Province & Country
1987	President and Chief Physician	Senders Pediatrics	Ohio, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
N/A	N/A	N/A	N/A

Brief Summary of Relevant Clinical Research Experience:

Phase III, modified double blind, randomized, parallel group, active- controlled, multi- centered study to describe the safety of MenACWY conjugate vaccine when administered concomitantly with routine pediatric vaccines given to healthy infants and toddlers 2019

Phase IIIB, observer blind, randomized, placebo controlled, multi center study to assess the safety and immunogenicity of GSK Men B and PCV 13 when administered with routine vaccines in healthy infants 2019

Double-blind, Randomized, Placebo-controlled Phase 2b, Multi-center study to evaluate the Safety, Tolerability, Efficacy and Immunogenicity of a 2-dose and a 3-dose regimen of V160 (Cytomegalovirus [CMV] Vaccine) in healthy seronegative women, 16-35 years of age. 2018

Signature:	Signature Date: (dd-Mmm-yyyy)
	29 Jun 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Brandon	Donald	M.

Professional Mailing Address:

Street Address 1:		Street Address 2:	
California Research Foundation		4180 Ruffin Road, Suite 255	
City: San Diego	State/Province: CA	Country: USA	Zip/Postal Code: 92123 - 1881
Email Address:	dbrandon@crftrials.com		

DM 03 Aug 2020

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Board Certified, Internal Medicine	1993	ABIM, USA
Residency, Internal Medicine	1992	Mercy Hospital & Medical Center, San Diego, USA
Internship, Internal Medicine	1990	Mercy Hospital & Medical Center, San Diego, USA
M.D.	1989	USC Keck School of Medicine, USA
B.A.	1984	University of San Diego, USA

Medical License Number	State/Province	Country
G 71000	CA	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1992	Medical Director/Investigator	California Research Foundation	CA/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1992-present	Physician	Olive Park Family Health	USA

Brief Summary of Relevant Clinical Research Experience:

Investigator has more than 30 years of clinical research experience having participated in over 400 industry sponsored Phase I-IV clinical trials over the past 25 years that focus on use of medications for health maintenance and disease treatments for diverse patient populations.

Signature:	Signature Date: (dd-Mmm-yyyy)
	22 JUN 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Rodriguez	Hector	Antonio

Professional Mailing Address:

Street Address 1:	Street Address 2:		
2400 NW 54th Street			
City: Miami	State/Province: FL	Country: USA	Zip/Postal Code: 33142
Email Address:	hrodriguez.md@acevedoclinicalresearch.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Transitional-FM Residency	1990	Chestnut Hill Hospital, Philadelphia, PA
MD	1985	Universidad Cenral de Este, Dominican Republic

Medical License Number	State/Province	Country
ME 57069	FL	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2017	Investigator	Acevedo Clinical Research Associates	FL/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2006 - 2015	Investigator	South Miami Clinical Research	USA
2005 - Present	Medical Director	Acevedo Medical Care Group	USA
2000-2017	Family Physician	Wellmax Medical Center	USA

Brief Summary of Relevant Clinical Research Experience:

Experienced in Pulmonology (Asthma/COPD), Vaccine (Ped & Adult), Dermatology (AD, Acne,) Neurology (Migraine, HA), Psychiatric (MDD, ADHD), Endocrinological (T2DM, Hyperlipidemia), Gastroenterological (Constipation, IBS)

Signature:	Signature Date: (dd-Mmm-yyyy)

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This page is a manifestation of an electronic record that was signed electronically.

Document Name: Rodriguez, Hector A - Pfizer Abbreviated CV
Document ID: 852
No. Pages: 1

Statement of Testament: I approve the document
Electronic Signature for: Hector Rodriguez, MD
Electronically Signed by: hrodriguez
Date & Time: 13/APR/2020 1:47 PM EDT
IP Address: 96.84.26.6

ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Saleh	Jamshid	N/A

Professional Mailing Address

Street Address: 3652 Eureka Way		Other Street Address: N/A	
City: Redding	State/Province: CA	Country: USA	Zip/Postal Code: 96001
Email Address:	jsaleh@paradigm-research.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Doctorate of Medicine	1980	University of Birmingham Medical School, England
Fellow of American College of Surgeons (F.A.C.S)	2002	United States
American Board of Neurological Surgery Board Certified	2001	United States

Medical License Number	State/Province	Country
A061022	California	United States

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
Jan-2009	Principal Investigator	Paradigm Clinical Research Center	Ca, United States

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1997-Present	Owner/Physician	Northern California Neurological Surgery	United States
2011-Present	Privileges	Northern California Rehabilitation Hospital	United States
1997-Present	Privileges	Shasta Regional Medical Center	United States
1997-Present	Privileges	Mercy Medical Center	United States

Brief Summary of Relevant Clinical Research Experience:

Eleven years of experience working in clinical research. Experience includes conducting trials as a PI for vaccine and medical trials, Phase I-IV. Vaccine trial experience includes studies for Influenza, RSV, Ebola, Rabies, Small Pox, and C. difficile. Experience includes conducting informed consent procedures, study visit procedures, lab and ECG result review and sign off, and participating in Investigator meetings, Site Selection Visits, SIVs, COVs, and regulatory submissions.

Signature:	Signature Date: (dd-Mmm-yyyy)
J. Saleh	29 JUNE 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Herrington	Darrell	T.

Professional Mailing Address

Street Address: 3605 Executive Dr		Other Street Address: N/A	
City: San Angelo	State/Province: TX	Country: USA	Zip/Postal Code: 76904
Email Address:	darrellherrington@benchmarkresearch.net		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
DO	1987-1988	General Rotating Internship- Chief Intern
Residency	1983-1987	Texas College of Osteopathic Medicine
Diplomate, American Board of Hospice and Palliative Medicine	2006	United States

Medical License Number	State/Province	Country
H4402	TX	United States

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1998 to present	Principal Investigator	Benchmark Research	San Angelo, TX, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1995- Present	DO of Family Practice	West Texas Medical Associates	United States
2016- Present	Medical Director	Solaris Hospice	United States
2002-2010	Medical Director	Hospice	United States

Brief Summary of Relevant Clinical Research Experience:

Principal Investigator for over 250 trials to include Vaccine, Pediatric, Indication, and device trials over 21years experience.

ABBREVIATED CURRICULUM VITAE TEMPLATE

Signature:	**Signature Date: (dd-Mmm-yyyy)**
	17 JUL 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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Abbreviated Curriculum Vitae (CV)

ACMR ATLANTA CENTER FOR MEDICAL RESEARCH

Full Name, Credentials	*Current Position at Study Site*
Robert A. Riesenberg, MD	**PI/Sub-I** 23-Jul-2020

Study Site / Professional Mailing Address

Atlanta Center for Medical Research 501 Fairburn Road SW Atlanta, GA 30331	*Phone* (404) 881-5800
	Fax (404) 532-6849
	Email RRiesenberg@acmr.org

Academic Qualifications

Dates (Years)	*Degree / Certification*	*Institution*
1972	BS	Memphis State University, USA
1975	MD	University of Tennessee, USA
1978	Psychiatry Residency	Washington University in St Louis, USA

Professional Experience (Previous 4 Relevant Positions)

Dates (Years)	*Title / Position*	*Institution*
1984 - Pres	Medical Director/PI/Sub-Investigator	Atlanta Center for Medical Research, USA
1979 - 2008	Private Practice - Psychiatry	BioBehavioral Associates, USA
1979 - 2000	Staff Psychiatrist	Dept of Psychiatry, Dekalb Medical Center, USA
1978 - 1979	VA Hospital Staff, Psychiatrist	Emory University, USA

Summary of Experience

Dr. Riesenberg has a wide range of experience in the research field. His primary focus is on CNS, PK, Healthy Normal and Child/ Adolescent disorders. His experience also includes treating psychiatric disorders (Schizophrenia, Anxiety, Bipolar, Major Depression Disorder, Substance Abuse, etc) and Neurological disorders (Parkinson's Disease, Alzheimer's Disease, Dementia, Epilepsy, etc). He has also worked on several General Medicine trials including Migraines, Diabetes, Shingles, Interstitial Cystitis, Cardiovascular, Pain, Asthma and COPD. Dr. Riesenberg has been the Principal Investigator in over 500 studies, including trials with pediatric and elderly subjects. His years of experience allow him to personally train staff on Good Clinical Practices, Human Subject Protection and conducting a clinical trial. He also has several years of experience is assessing rating scales. Some of the scales that Dr. Riesenberg has used on a daily basis are.

Adult

HAM-A	HAM-D	Calgary Depression	WRAT3	PEC
PANSS	YMRS	CVLT	RAVLT	ACES
BPRS	MADRS	SADS-C	BACS	CAARS
MMSE	STROOP	WAIS-III Subtest	SIB	CAADID
CELF3	ADAS	SAS, AIMS, BARS	SCoRS	IDS
CGI	GAF	Y-BOCS	NIMH-GOCS	Tanner Staging
NPI	ACDS	Vitiello Agression Scale	K-BIT	CSSRS
Wisconsin Card Sorting Task		Buschke Selective Reminding Test		ESRS
Finger Tapping Task		Rivermead Behavioral Memory Test		TETRAS
Benton Visual Retention Task		Vineland Adaptive Behavior Scales	FAQ	GDS
Newcastle Scale for Depression			WMS-R	MOAA/S

Child/Adolescent

Kiddie-SADS	CDRS-R	CGI	YQOL-R	NY ACCENT	PAERS	Vitiello Agression Scale
K-SADS-PL	CGAS	ADHD-RS-IV	P-QLES-Q	R-MOAS	K-BIT	Tanner Staging

Diagnostic:

MINI SCID

Professional License

Type	*License #*	*Issuing Authority*	*Expiration Date*
MD	019589	GA	08/31/21

Good Clinical Practices (GCP) Training

Course Provider	*Date of Completion*
CITI Program	12/07/18

By signing this form, I confirm that the information provided is accurate and reflects my current qualifications

Signature	*Date (mm/dd/yyyy)*
	06/15/2020

Version 06/2018

ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Bauer	George	H

Professional Mailing Address:

Street Address:	Other Street Address:		
4517 Veterans Memorial Blvd			
City: Metairie	State/Province: LA	Country: USA	Zip/Postal Code: 70006
Email Address:	~~jeffsegner@benchmarkresearch.net~~ georgebauer@BenchmarkResearch.net 17 July 2020		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Bachelor of Science	1963	University of New Orleans
MD	1967	Louisiana State University

Medical License Number	State/Province	Country
MD.0107039	*LA*	*USA*

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2008	Principal Investigator	Benchmark Research	LA / USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1973-2007	Partner, Pediatrician	Lakeside Children's Clinic	USA
1970-1972	Major, Pediatrician	U.S. Air Force	Iran

Brief Summary of Relevant Clinical Research Experience:

Sub-Investigator/Site Director/Project Manager on 100+ Phase I - IV studies with indications ranging from Diabetic Foot Ulcer, OA of the Knee, Hypertension, Smoking Cessation and Multiple Vaccine Studies

Signature:	Signature Date: (dd-Mmm-yyyy)
GB	16 JUL 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Manning	Mary Beth	

Professional Mailing Address:

Street Address: Rapid Medical Research, Inc. 3619 Park East Drive Suite 300		Other Street Address:	
City: Cleveland	State/Province: Ohio	Country: USA	Zip/Postal Code:44122
Email Address:	mbmanning@velocityclinical.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MD	1987	Case Western Reserve University / USA
Residency – Internal Medicine	1990	CWR University - Metro Health Medical Center / USA
Internship	1988	Cleveland Clinic Foundation / USA

Medical License Number	State/Province	Country
35.058161	Ohio	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
Aug 2013	Investigator	Rapid Medical Research, Inc.	Ohio, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
Aug 2013-present	Investigator	Rapid Medical Research, Inc.	USA
Apr 2010-Mar 2013	Staff Physician	St. Vincent Charity Medical Ct.	USA
Jul 2007-Dec 2012	Staff Physician	University ER	USA
2000-2010	Senior Clinical Instructor	CWR University	USA

Brief Summary of Relevant Clinical Research Experience:

1992 – Present – Investigator on various trials (see completed CV)
Phases: II, III & IV

Signature:	Signature Date: (dd-Mmm-yyyy)
MBManning	15 JUL 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Morawski	Emily	J.

Professional Mailing Address:

Street Address 1:	Street Address 2:		
Holston Medical Group 105 West Stone Drive 3rd Floor Suite 3A			
City: Kingsport	State/Province: TN	Country: USA	Zip/Postal Code: 37660
Email Address:	emily.morawski@myhmg.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Residency	2001	Carilion Health Systems- Roanoke, VA- USA
Medical Degree	1999	Eastern Virginia Medical School- Norfolk, VA- USA
Undergraduate B.S. Biology	1994	College of William and Mary, Williamsburg, VA- USA

Medical License Number	State/Province	Country
MD0000036817	Tennessee	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2002- Current	Family Practice Physician / Principal Investigator	Holston Medical Group	TN - USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
N/A			

Brief Summary of Relevant Clinical Research Experience:

Experience in Clinical Research : Principal Investigator and Sub-Investigator since 2002 on studies including Type I Diabetes, Type II Diabetes, Chronic Kidney Disease, Obesity, Cardiovascular Outcomes, Lipid Studies, Rheumatoid Arthritis, Alzheimer's Disease, Pneumonia Vaccines, and Low Testosterone Studies.

Signature:	Signature Date: (dd-Mmm-yyyy)
EM	10 Aug 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Cox	Steven	E.

Professional Mailing Address

Street Address: 630 24th Avenue SW		Other Street Address:	
City: Norman	State/Province: OK	Country: USA	Zip/Postal Code: 73069
Email Address:	scox@lhsi.net		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
D.O.	1983	Oklahoma State University College of Osteopathic Medicine & Surgery – USA
B.S.	1980	University of Oklahoma - USA

Medical License Number	State/Province	Country
2360	Oklahoma	USA

Current Position at Study Site:

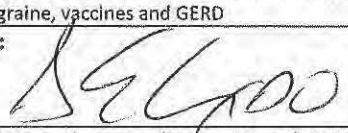
Start Date	Title	Institution or Company	State/Province & Country
2016	Principal Investigator	Lynn Institute of Norman	Oklahoma/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2008 – 2012	Principal Investigator	Legacy Clinical Research	USA
1996 – 1998	Physician	Family Practice	USA
1998 – present	Physician	Family Practice	USA

Brief Summary of Relevant Clinical Research Experience:

Investigator has more than 12 years of diverse clinical research experience as a specialist in Family Medicine. He has participated as both PI and sub-Investigator in numerous industry sponsored Phase II-IV clinical trials over the past 12 years that focus on optimizing the use of medications for health maintenance and disease treatments related to hypertension, hypercholesterolemia, stress urinary incontinence, Type 2 diabetes, fibromyalgia, overactive bladder, migraine, vaccines and GERD

Signature: 

Signature Date: (dd-Mmm-yyyy) 21/JUL/2020

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Yozviak	Joseph	Leo

Professional Mailing Address

Street Address:		Other Street Address:	
Lehigh Valley Health Network -NORI		1255 S. Cedar Crest, Suite 3200	
City: Allentown	State/Province: PA	Country: USA	Zip/Postal Code: 18103
Email Address:	joseph.yozviak@lvhn.org		

Academic Qualifications: DO

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Internal Medicine Residency	2003-2006	Lehigh Valley Hospital /LVHN/USA
Osteopathic Internship	2003-2004	Lehigh Valley Hospital/LVHN/USA
Doctor of Osteopathic Medicine	1999-2003	Philadelphia College of Osteopathic Medicine/USA
Bachelor of Science, Chemistry/Biology	1995-1999	West Chester University/USA

Medical License Number	State/Province	Country
OS013090	Commonwealth of Pennsylvania	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2016	Medical Director	Lehigh Valley Health Network	PA/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2006 – PRESENT	Medical Director (2016-present) Acting medical Director (2015-2016)	Lehigh Valley Health Network Comprehensive Health Services (formerly AIDS Activities Office)	USA
2006 – PRESENT	Medical Director (2016-Present) Acting Medical Director (201-2016) Lead Physician (2008-2015)	Lehigh Valley Health Network Hepatitis Care Center	USA
2019-PRESENT	Academic/Clinical Subgroup member	Pennsylvania Viral Hepatitis Elimination Planning Committee	USA
2018-PRESENT	CDC Medical Leadership Committee At-large Member	Lehigh Valley Hospital	USA

Brief Summary of Relevant Clinical Research Experience:

Working in research since 2006, primarily working on industry sponsored studies. Most of the studies were focused on Infectious Diseases.

Signature:	Signature Date: (dd-Mmm-yyyy)
Signed Electronically by: Joseph Yozviak - Joseph.Yozviak@lvhn.org 27-Aug-2020 @ 10:34 AM EST Reason: Approval	27-Aug-2020 @ 11:33 AM EDT

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eSignature Addendum

All eSignatures below were executed using Florence eBinders
21 CFR Part 11 compliant software for eSignatures

Current Electronic Signatures (v.3):

Signed electronically by: Joseph Yozviak (Joseph.Yozviak@lvhn.org)
Date: *27-Aug-2020 @ 10:34 AM EST*
Reason: *Approval*

Previous Electronic Signatures:

There are no signatures for any previous versions.

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Berhe	Mezgebe	

Professional Mailing Address

Street Address: 3409 Worth Street		Other Street Address: Suite 710	
City: Dallas	State/Province: Texas	Country: USA	Zip/Postal Code: 75246
Email Address:	**Mezgebe.berhe@ntidc.org**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MD	1993	Addis Ababa University Medical School
Internal Medicines Residency	2003	Virginia Commonwealth University School of Public Health
Infectious Diseases Fellowship	2005	St. Barnabas Hospital/ Cornell Montefiore
MPH	2005	Virginia Commonwealth University School of Public Health

Medical License Number	State/Province	Country
M1510	Texas	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2005	PI	North Texas Infectious Diseases Consultants, P.A.	Texas, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2005 – Present	Instructor in Medicine	Baylor University Medical Center	USA
2013 – Present	Assistant Professor of Medicine	Texas A&M School of Medicine	USA
2005 – Present	Infectious Diseases Consultant	Baylor University Medical Center	USA

Brief Summary of Relevant Clinical Research Experience:

2006 to 2015: Sub-Investigator for multiple clinical trials
2015 to date: Principal Investigator for multiple clinical trials
Total 75 clinical trials

Signature:	Signature Date: (dd-Mmm-yyyy)
	10 Jul 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name *if applicable*
	Martin	Earl	Francis

Professional Mailing Address:

Street Address 1: 710 Lawrence St		Street Address 2:	
City: Tomball	State/Province: TX	Country: USA	Zip/Postal Code: 77375
Email Address:	drearlfmartin@dmclinicalresearch.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
M.D.	1964	University of Nuevo Leon, Mexico

Medical License Number	State/Province	Country
E0259	TX	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1976	Owner/Director/Physician	Martin Diagnostic Clinic	TX, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1971-1974	Residency	Patterson Air Force Base	USA

Brief Summary of Relevant Clinical Research Experience:

Experience in clinical trials for 10+ years in but not limited to the following indications:

Diabetes, Rheumatoid Arthritis, Cardiovascular Disease, Chronic Nonmalignant Nonneuropathic pain, Kidney Disease, Influenza. Over 25+ studies conducted.

Signature:	Signature Date: (dd-Mmm-yyyy)
	21 July 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Poretz	Donald	Martin

Professional Mailing Address

Street Address:	Other Street Address:		
Clinical Alliance for Research and Education – Infectious Diseases, LLC (CARE-ID) 3289 Woodburn Road Suite 250			
City: Annandale	State/Province: VA	Country: USA	Zip/Postal Code: 22003
Email Address:	dporetz@careidresearch.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Fellowship	1972	Medical College of Virginia
Residency	1971 1968	Medical College of Virginia
M.D.	1966	Medical College of Virginia, School of Medicine
B.A.	1962	University of Virginia

Medical License Number	State/Province	Country
0101018020	Commonwealth of Virginia	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2005 - Present	Investigator	CARE-ID	Virginia, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2007-present	Director	Infectious Diseases Fellows Rotation, NIAID (NIH)	USA
2007-2008	President	Infectious Diseases Society of America	USA
2004-2006	President	National Foundation for Infectious Diseases	USA
1973-present	Infectious Diseases Physician	Infectious Diseases Physicians, LLC	USA
1972-2001	Chief, Infectious Diseases	INOVA Fairfax Hospital	USA

Brief Summary of Relevant Clinical Research Experience:

Dr. Poretz began Infectious Diseases research in 1971. Since that time he has been a Principal Investigator and Sub-investigator for prevention and treatment clinical trials involving antivirals, antibiotics, antiretrovirals, and vaccines. Dr. Poretz has participated in over 100 trials during the course of his career. These research studies have been both industry and NIH sponsored.

Signature:	**Signature Date: (dd-Mmm-yyyy)**
	13-JUL-2020

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Fitz-Patrick	David	

Professional Mailing Address

Street Address: 1585 Kapiolani Blvd.		Other Street Address: Suite 1500	
City: Honolulu	State/Province: HI	Country: USA	Zip/Postal Code: 96814
Email Address:	dfitz@eastwestresearch.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Clinical and Research Fellowships in Diabetes and Endocrinology	1981	McGill University, Montreal, Canada
MB, BS Medicine and Surgery (U.K. equivelant of MD in U.S.)	1974	University of Newcastle Upon Tyne, United Kingdom

Medical License Number	State/Province	Country
4149	HI	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1998	President	East-West Medical Research Institute	Hawaii / U.S.A.

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1994 - Present	Associate Clinical Professor	John A. Burns School of Medicine	U.S.A.
1991 - Present	Attending Physician	Queens Medical Center	U.S.A.
1990 - Present	Medical Director	Diabetes & Hormone Center of the Pacific	U.S.A.
1984 - 1991	Medical Director	The Diabetes Center of the Pacific, Straub Clinic and Hospital	U.S.A.
1986 - 1991	Chief	Department of Endocrinology and Metabolism, Straub Clinic and Hospital	U.S.A.
1981 - 1991	Attending Physician	Straub Clinic and Hospital	U.S.A.
1982 - 1994	Assistant Clinical Professor	John A. Burns School of Medicine	U.S.A.
1981 - 1997	Consulting Physician	Kapiolani Medical Center	U.S.A.

Brief Summary of Relevant Clinical Research Experience:

Principal Investigator of more than 250 clinical trials

Signature:	Signature Date: (dd-Mmm-yyyy)
	24 JUN 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Sharp	Stephan	C.

Professional Mailing Address:

Street Address: 1500 Church Street		Other Street Address: Suite 100	
City: Nashville	State/Province: Tennessee	Country: USA	Zip/Postal Code: 37203
Email Address:	Ssharp@CRAnashville.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
B.S., Biology	1983	Southwestern at Memphis (Rhodes College)
M.D.	1987	University of Tennessee
Internship & Residency	1990	University of Tennessee/Department of Internal Medicine
Fellowship	1993	Vanderbilt University School of Medicine/Division of Endocrinology

Medical License Number	State/Province	Country
MD0000019021	Tennessee	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1996	Principal Investigator	Clinical Research Associates, Inc.	TN/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1996 – Present	Medical Director and Principal Investigator	Clinical Research Associates, Inc.	USA
1996 – 2014	Private Practice of Endocrinology	Stephan Sharp, MD (Private Practice)	USA
1996 – 1997	Assistant Professor, Dept. of Medicine	Meharry Medical College	USA

Brief Summary of Relevant Clinical Research Experience:

I have conducted clinical research since 1982 in a variety of areas, including basic physiology, fertility/contraception, hypertension, diabetes, lipids, vascular disease, arthritis, headaches, menopause, osteoporosis, DUB, PMS, PTSD, heartburn, herpes, etc., as well as vaccine and device studies.

Signature:	Signature Date: (dd-Mmm-yyyy)
Stephan C Sharp MD	15 JUL 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Katzman	Steven	

Professional Mailing Address

Street Address: Michigan Center of Medical Research		Other Street Address: 30160 Orchard Lake Road	
City: Farmington Hills	State/Province: Michigan	Country: USA	Zip/Postal Code: 48334
Email Address:	drkatzman@michmer.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
D.O.	1990	University of Osteopathic Medicine and Health Sciences, Des Moines, Iowa
B.A. Biology	1986	Wayne State University, Detroit, Michigan

Medical License Number	State/Province	Country
5101010946	Michigan	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2012	Principal Investigator	Michigan Center of Medical Research	Michigan, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2002-Present	Internal Medicine, Director of Research	Beaumont Health System	USA
2017-Present	Chapter Board Member	American Diabetes Association/Michigan	USA
2001-Present	Director of Board Review Internal Medicine Residency Program	Beaumont Hospital Farmington Hills Botsford Campus	USA

Brief Summary of Relevant Clinical Research Experience:

1. Involvemnet in Evaluation of Immune Response in Patients Recently Infected with HIV-1, Identified by Serological Technical Enzyme-Linked Immunosorbent Assay with Double Testing Strategy (Detuned).
2. MERS-CoV Infection tReated With A Combination of Lopinavir /Ritonavir and Interferon Beta-1b (MIRACLE)
3. A Phase III, Multicenter, Randomized, Double-Blind, Controlled Study to Evaluate the Efficacy and Safety of Peramivir Administered Intravenously in Addition to Standard of Care Compared to Standard of Care Alone in Adults and Adolescents who are Hospitalized Due to Serious Influenza
4. A Study to Evaluate the Safety and Immunogenicity of a Candidate Ebola Vaccine in Adults

Signature:	Signature Date: (dd-Mmm-yyyy)
Steven Katzman, DO Steven Katzman, DO (Jul 10, 2020 09:12 EDT)	Jul 10, 2020

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Aberg	Judith	A

Professional Mailing Address

Street Address:	Other Street Address:		
One Gustave L. Levy Place, Box 1090			
City:	**State/Province:**	**Country:**	**Zip/Postal Code:**
New York	NY	USA	10029
Email Address:	judith.aberg@mssm.edu		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
American Board of Internal Medicine/ Infectious Disease Subspecialty #155629	1996	USA
American Board of Internal Medicine #155629	1994	USA
National Board of Medical Examiners #388218	1991	USA
MD, Doctor of Medicine	1990	The Pennsylvania State University College of Medicine Hershey, PA
A S C P - National Boards MLT022970	1981	USA
A S C P -National Boards CLA014648	1976	USA

Medical License Number	State/Province	Country
230579-1	New York	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1/1/2014	Chief of Infectious Disease	Icahn School of Medicine at Mount Sinai (ISMMS) and Mount Sinai Health System	New York, NY USA
2014	The George Baehr Professor of Medicine with Tenure	ISMMS and Mount Sinai Health System,	New York, NY USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2011-2013	Jeffrey Bergstein Professor of Medicine and Director, Division of Infectious Diseases and Immunology	New York University School of Medicine, New York, NY	USA
2010-2013	Professor of Medicine with Tenure	New York University School of Medicine New York, NY	USA
2004-2013	Director of Virology	Bellevue Hospital Center and the South Manhattan Healthcare Network	USA
2004-2010	Associate Professor of Medicine with Tenure	New York University School of Medicine, New York, NY	USA
2000-2003	Associate Professor of Medicine, Director of HIV Services,	Washington University, St Louis, MO	USA
1996-1999	Assistant Professor of Medicine	University of California, San Francisco AIDS Program, San Francisco General Hosp , San Francisco, CA	USA
1994-1996	Emergency Medicine Consultant	The Cleveland Clinic Hospital, Cleveland, OH	USA
1993-1994	Clinical Associate, HIV Clinic, Department of Rheumatic & Immunologic Disease	The Cleveland Clinic Foundation, Cleveland, OH	USA

Brief Summary of Relevant Clinical Research Experience:

I transitioned to clinical and translational research during my 4th year in medical school after involvement in immune modulating therapy for patients with multiple sclerosis I began designing and conducting clinical trials in HIV infected patients in 1992 and focused my ID fellowship learning the necessary skills to become an independent clinical researcher I developed my career using the infrastructure of the DAIDS supported AIDS Clinical Trials Group (ACTG) and to date, I have served as a PI for over a 100 randomized controlled trials of which I have serve(d) as chair or vice-chair of 17 ACTG studies In 2004, I was recruited to NYU to be Director of Virology at Bellevue Hospital/ NYU I competitively obtained funding for the NIH-funded AIDS Clinical Trials Unit (ACTU) and later became Director of the Division of ID and Immunology I was recruited to Sinai January 2014 in order to develop a comprehensive basic, translational and clinical research program in infectious diseases/HIV I readily accepted this offer given the merger and creation of a large health system with access to over 10,000 patients with HIV infection Subsequently I created the Clinical and Translational Research Center (CTRC) and have successfully recruited over 20 faculty including basic and translational scientists and have established five clinical research sites located throughout Manhattan The mission of the CTRC is to conduct NIH sponsored studies, to provide support to junior faculty and form collaborations with translational and basic scientists given our rich population base My main area of interest is complications of HIV disease, specifically pathogenesis of inflammation contributing to the co-morbidities associated with HIV infection I currently serve as chair or vice-chair of 5 NIAID ACTG Studies I also received an Empire Clinical Research Program award December 2016 to develop an ID-Genomics training program of which I oversaw 4 research fellows in collaboration with the ISMMS Genomics Institute who now hold faculty positions at ISMMS During the COVID Pandemic March-present 2020, my team has enrolled over 800 patients into clinical trials The COVID pandemic brought many challenges especially where there is insufficient knowledge and data to initially guide the use of PPE, protect health care workers and those exposed and manage patients especially those who developed rapid respiratory failure with systemic inflammatory responses I was among the teams providing treatment guidance as well as best exposure prevention strategies on the COVID units With Sinai being among the first to develop an antibody test, we were able to screen individuals who recovered from COVID and those with high titers of antibody were asked if they would be willing to donate plasma to be transfused to hospitalized patients with COVID We were the first center in the US to offer convalescent plasma To date, we have transfused over 500 unique patients I will serve as site PI for this trial

Signature:	Signature Date: (dd-Mmm-yyyy)
DocuSigned by: Judith Aberg Signer Name: Judith Aberg Signing Reason: I approve this document Signing Time: 2020-Jul-30 | 2:16:36 PM EDT	2020-Jul-30

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Hammitt	Laura	

Professional Mailing Address

Street Address: 415 N. Washington St, 4th floor		Other Street Address:	
City: Baltimore	State/Province: MD	Country: USA	Zip/Postal Code: 21231
Email Address:	Lhammitt@jhu.edu		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
BSc	1995	University of Utah, USA
MD	1999	University of Utah, USA

Medical License Number	State/Province	Country
D72855	Maryland	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2011-present	Associate Professor	Johns Hopkins Center for American Indian Health	~~Maryland~~, USA AZ, NM 10 Sept 2020

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2008-2011	Clinical Epidemiologist	University of Oxford/KEMRI	Kenya
2005-2008	Pediatric Infectious Disease Fellow	University of Colorado	USA
2003-2005	Epidemic Intelligence Service Officer	CDC	USA

Brief Summary of Relevant Clinical Research Experience:

Currently Lead Infectious Disease Prevention team of masters and doctoral level epidemiologists, as well as a site-based research staff of 30-50 people conducting observational and interventional studies including phase 3 clinical trials

Signature:	Signature Date: (dd-Mmm-yyyy)
	10 SEP 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Hammitt	Laura	

Professional Mailing Address

Street Address: 415 N. Washington St, 4th floor		Other Street Address:	
City: Baltimore	State/Province: MD	Country: USA	Zip/Postal Code: 21231
Email Address:	Lhammitt@jhu.edu		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
BSc	1995	University of Utah, USA
MD	1999	University of Utah, USA

Medical License Number	State/Province	Country
D72855	Maryland	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2011-present	Associate Professor	Johns Hopkins Center for American Indian Health	~~Maryland~~, USA AZ, NM

10 Sept 2020

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2008-2011	Clinical Epidemiologist	University of Oxford/KEMRI	Kenya
2005-2008	Pediatric Infectious Disease Fellow	University of Colorado	USA
2003-2005	Epidemic Intelligence Service Officer	CDC	USA

Brief Summary of Relevant Clinical Research Experience:

Currently Lead Infectious Disease Prevention team of masters and doctoral level epidemiologists, as well as a site-based research staff of 30-50 people conducting observational and interventional studies including phase 3 clinical trials

Signature:	Signature Date: (dd-Mmm-yyyy)
	10 SEP 2020

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Hammitt	Laura	

Professional Mailing Address

Street Address: 415 N. Washington St, 4th floor		Other Street Address:	
City: Baltimore	State/Province: MD	Country: USA	Zip/Postal Code: 21231
Email Address:	Lhammitt@jhu.edu		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
BSc	1995	University of Utah, USA
MD	1999	University of Utah, USA

Medical License Number	State/Province	Country
D72855	Maryland	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2011-present	Associate Professor	Johns Hopkins Center for American Indian Health	~~Maryland~~, USA New Mexico 11 Sept 2020

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2008-2011	Clinical Epidemiologist	University of Oxford/KEMRI	Kenya
2005-2008	Pediatric Infectious Disease Fellow	University of Colorado	USA
2003-2005	Epidemic Intelligence Service Officer	CDC	USA

Brief Summary of Relevant Clinical Research Experience:

Currently Lead Infectious Disease Prevention team of masters and doctoral level epidemiologists, as well as a site-based research staff of 30-50 people conducting observational and interventional studies including phase 3 clinical trials

Signature:	Signature Date: (dd-Mmm-yyyy)
	10 SEP 2020

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Hammitt	Laura	

Professional Mailing Address

Street Address: 415 N. Washington St, 4th floor		Other Street Address:	
City: Baltimore	State/Province: MD	Country: USA	Zip/Postal Code: 21231
Email Address:	Lhammitt@jhu.edu		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
BSc	1995	University of Utah, USA
MD	1999	University of Utah, USA

Medical License Number	State/Province	Country
D72855	Maryland	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2011-present	Associate Professor	Johns Hopkins Center for American Indian Health	~~Maryland~~, USA New Mexico RJK 11 Sept 2020

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2008-2011	Clinical Epidemiologist	University of Oxford/KEMRI	Kenya
2005-2008	Pediatric Infectious Disease Fellow	University of Colorado	USA
2003-2005	Epidemic Intelligence Service Officer	CDC	USA

Brief Summary of Relevant Clinical Research Experience:

Currently Lead Infectious Disease Prevention team of masters and doctoral level epidemiologists, as well as a site-based research staff of 30-50 people conducting observational and interventional studies including phase 3 clinical trials

Signature:	Signature Date: (dd-Mmm-yyyy)
	10 SEP 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Ogbuagu	Onyema	

Professional Mailing Address

Street Address: 135 College Street; Suite 323		Other Street Address:	
City: New Haven	State/Province: CT	Country: USA	Zip/Postal Code: 06510
Email Address:	Onyema.ogbuagu@yale.edu		

Academic Qualifications: Associate Professor

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MD	2003	University of Calabar, Cross River State, Nigeria

Medical License Number	State/Province	Country
49514	Connecticut	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2018	Associate Professor	Yale University	CT, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2012-2018	Assistant Professor	Yale University	USA
2017-present	Director, Clinical Trials Program	Yale University	USA
2013-present	Visiting Faculty (ID/Inf.Dis)	Nat'l University of Rwanda	Rwanda

Brief Summary of Relevant Clinical Research Experience:

Principal Investigator (PI) of 7 active COVID-19 treatment studies, 5 HIV-1 treatment studies; one HIV PrEP study; and 4 International research grants

Investigator on 8 prior HIV-1 treatment studies, 5 HCV treatment studies, 3 HCV assay studies, 1 intensive PK study; and 2 HIV PrEP studies

Signature:	Signature Date: (dd-Mmm-yyyy)
Onyi E Ogbuagu	20-JUL-2020

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Full Name:	Last Name	First Name	Middle Name
	Odekirk	Larry	L

Professional Mailing Address

Street Address: 1411 S. Potomac Street, Suite 420	Other Street Address:

City: Aurora	State/Province: CO	Country: USA	Zip/Postal Code: 80012

Email Address:	lodekirk@lhsi.net TLO 12-MAR-21

Academic Qualifications:

Degree and/or Certification	**Date (yyyy)**	**Institution and/or Country**
D.O.	1963	University of Medicine & Bioscience, USA

Medical License Number	**State/Province**	**Country**
DR. 0014859	Colorado	USA

Current Position at Study Site:

Start Date	**Title**	**Institution or Company**	**State/Province&Country**
2014	Investigator	Lynn Institute of Denver	Colorado / USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	**Title**	**Institution or Company**	**Country**
2003 – present	Physician	Plum Creek Medical	USA
2003– present	Physician	Holland American Cruise Line	USA

Brief Summary of RelevantClinical Research Experience:

Investigator has more than 17 years of diverse clinical research experience as a Family Practitioner. He has participated as both PI and Sub-Investigator in numerous industry sponsored Phase II-IV clinical trials over the past 17 years that focus on optimizing the use of medications for health maintenance and disease treatments related to osteoporosis, hypercholesterolemia, hypogonadism, OA, OAB, hypertension, diabetes, Flu vaccine, IBS-C, and Women's health.

Signature:	**Signature Date: (dd-Mmm-yyyy)**
[signature]	20-Jul-2020

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Kingsley	Jeffrey	Kenneth

Professional Mailing Address

Street Address: 800 Talbotton Rd		Other Street Address:	
City: Columbus	State/Province: GA	Country: United States	Zip/Postal Code: 31904
Email Address:	jkingsley@iacthealth.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Master of Business Education	2011	Emory University, Atlanta, GA
Family Medicine Residency	2004	Columbus Regional Medical Center, Columbus, GA
Family Medicine Internship	2002	Columbus Regional Medical Center, Columbus, GA
Doctor of Osteopathic Medicine	2001	Philadelphia College of Osteopathic Medicine, Philadelphia, PA
Master of Science, Biochemistry	1997	University of Scranton, Scranton, PA
Bachelor of Science, Biology, Chemistry, History, Cultural Anthropology	1996	University of Scranton, Scranton, PA

Medical License Number	State/Province	Country
52973	Georgia	United States

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
Jun 2020	Clinical Investigator	IACT Health	Georgia, United States

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2013 – Present	Clinical Investigator	Columbus Regional Research Institute	United States
2005 – 2013	Clinical Investigator	Southeast Regional Research Group	United States

Brief Summary of Relevant Clinical Research Experience:

Dr. Kingsley has 15 years of experience as a Clinical Investigator, and has participated in 100+ clinical trials across multiple areas, including but not limited to, Cardiology, Dermatology, Endocrinology, Infectious Disease, Nephrology, Pain, and Women's Health.

Signature:	Signature Date: (dd-Mmm-yyyy)
See appended page for signature and date	See appended page for signature and date

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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Signature Page for VV-13400 v1.0

Reason for signing: Approve	Name: Jeff Kingsley Role: Self Date of signature: 29-Jul-2020 11:17:16 GMT+0000

Signature Page for VV-13400 v1.0

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Vanchiere	John	Anthony

Professional Mailing Address:

Street Address 1: LSUHSC-Shreveport/Department of Pediatrics		Street Address 2: 1501 Kings Highway	
Shreveport	State/Province: LA	Country: USA	Zip/Postal Code: 71103
Email Address:	jvanch@lsuhsc.edu		

Academic Qualifications: M.D., Ph.D.

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Ph.D. Neuroscience	1996	Emory University; Atlanta, Georgia
M.D.	1996	Emory University School of Medicine

Medical License Number	State/Province	Country
MD023912	LA	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
June 2015	Director of Children's Clinical Research Center	LSUHSC-Shreveport	LA/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
June 2015 – Present	Professor of Pediatrics	LSUHSC-Shreveport	USA
July 2009 – June 2015	Associate Professor - Peds	LSUHSC-Shreveport	USA
June 2007 – June 2009	Assistant Professor – Peds	LSUHSC-Shreveport	USA
January 2003 – May 2007	Assistant Professor – Peds	Baylor College of Medicine	USA

Brief Summary of Relevant Clinical Research Experience:

20 years of basic, translational and clinical research experience in infectious diseases; 30 NIH- and Pharma-sponsored clinical trials (Phases 1-4), including diagnostics, antibiotics, antivirals and EUAs.

Signature:	Signature Date: (dd-Mmm-yyyy)
	29-MAY-2020

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Al-Ibrahim	Mohamed	Salman

Professional Mailing Address

Street Address:		Other Street Address:	
800 West Baltimore Street		5th floor	
City: Baltimore	State/Province: Maryland	Country: USA	Zip/Postal Code: 21201
Email Address:	**Mohamed.al-ibrahim@pharmaron-us.com**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Bachelor of Medicine, Master of Surgery	1967	Baghdad College of Medicine
American Board of Internal Medicine	1972	USA
American Board of Infectious Disease	1974	USA

Medical License Number	State/Province	Country
D0015450	Maryland	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2017	Principal Investigator	Pharmaron	Maryland, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
May 2017-Present	Infectious Disease Specialist	Northwest Hospital	USA
1976-2018	Infectious Disease Specialist	University of Maryland Medical Center	USA
Mar 2016- 15 May 2017	Sr. Advisor	SNBL Clinical Pharmacology Center, Inc	USA
Oct 2006-March 2016	Chief Operating Officer and President	SNBL Clinical Pharmacology Center, Inc	USA

Brief Summary of Relevant Clinical Research Experience:

Very experienced clinical research and medical professional. Currently serving as Principal Investigator or Sub-Investigator at Pharmaron CPC.

Signature:	Signature Date: (dd-Mmm-yyyy)
Mohamed-Ibrahim	24 Jul 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Williams	Hayes	T.

Professional Mailing Address

Street Address: Achieve Clinical Research LLC, d/b/a Accel Research Sites		Other Street Address: 860 Peachwood Drive	
City: DeLand	State/Province: FL	Country: USA	Zip/Postal Code: 32720
Email Address:	**hwilliams@accelclinical.com**		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Residency: Ears, Nose, Throat	1980	University of Alabama/USA
Surgical Internship	1977	Baptists Hospital/USA
Doctor of Medicine	1976	Louisiana State University School of Medicine/USA
Doctor of Philosophy	1970	University of Alabama/USA
Master of Science, Genetics	1967	University of Alabama/USA
Bachelor of Science	1963	University of Alabama/USA

Medical License Number	State/Province	Country
Alabama MD.8063	Alabama	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2008	Medical Director/Investigator	Birmingham Clinical Research Unit	AL/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2005-2008	Medical Director/Investigator	West Alabama Research, LLC	USA
2001-2005	Investigator	Capstone Clinical Trials, Inc	USA
2001-2001	Physician	Private Practice	USA
1982-2000	Physician	Ear, Nose Throat Private Practice	USA
1980-1982	Physician	Dennis Pappas Sr., MD & Robert Baldwin, MD	USA

Brief Summary of Relevant Clinical Research Experience:

Served as a Medical Director for Birmingham Clinical Research Unit since 2008.

Signature: Signed Electronically by:
Hayes T. Williams, MD, PhD - hwilliams@accelclinical.com
20-Jul-2020 @ 01:32 PM CDT Reason: Approval

Signature Date: (dd-Mmm-yyyy)

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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eSignature Addendum

All eSignatures below were executed using Florence eBinders
21 CFR Part 11 compliant software for eSignatures

Current Electronic Signatures (v.2):

Signed electronically by: Hayes T. Williams, MD, PhD (hwilliams@accelclinical.com)
Date: *20-Jul-2020 @ 01:32 PM CDT*
Reason: *Approval*

Previous Electronic Signatures:

There are no signatures for any previous versions.

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Grubb	Stephen	D

Professional Mailing Address

Street Address: Main Street Physician's Care		Other Street Address: 3612 Mitchell Street	
City: Loris	State/Province: SC	Country: USA	Zip/Postal Code: 29569
Email Address:	(b) (6)		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Board Cert. Family Medicine	1979, 1986, 1993, 2000, 2008, 2016	American Board of Family Practice, USA
Board Cert. Geriatrics	1979, 1986, 1993, 2000, 2008, 2016	American Board of Family Practice, USA
Family Medicine Residency	1978	Medical University of South Carolina USA
MD	1975	Washington University USA

Medical License Number	State/Province	Country
7841	South Carolina	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2018	Physician	Main Street Physician's Care	South Carolina, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1978 – 2018	Physician	Waterway Primary Care LLC dba Tabor City Family Medicine	USA
1992 – 2018	Physician	Waterway Primary Care LLC dba Calabash Medical Center	USA

Brief Summary of Relevant Clinical Research Experience:

Feb 2015 – Apr2019: Sub Investigator – Post Herpetic Neuralgia
Mar 2014 – Mar2019t: Sub Investigator – Anticoagulant Medication Post-Marketing
Sep 2013 – Feb 2015: Sub Investigator – Influenza Treatment
Mar 2013 – Present: Sub Investigator – Lipid Trial
Aug 2012 – Jul 2013: Sub Investigator – IBS Trial
Aug 2012 – Apr2018: Sub Investigator – Gout Trials
Aug 2012 – Present Sub Investigator – Diabetes/Cardiovascular Outcomes (1 trial completed, 2 ongoing)
Dec2011 – May 2013: Sub Investigator – Diabetes/Hypertension
Aug 2012 – May 2014: Sub Investigator – Asthma Trial
Jul 2010 – Present: Sub Investigator - COPD Trials
Nov 2009 – Jan 2015 Sub Investigator – A Fib
Nov 2008 – Present: Sub Investigator - Diabetes Trials (Oral and Injectable Medication)
Oct 2008 – Feb2011: Sub Investigator – Flu Vaccine Trial
Sep 2008 – Feb2019: Sub Investigator – Osteoarthritis/Cardiovascular Outcomes
July 2008 – October 2009: Sub Investigator Diabetes Trial
May 2008- February 2010 Sub Investigator – Hypertension Trial – Elderly Patients
May 2008- September 2009 : Sub Investigator – Hypertension Trial
Jan 2006-Feb 2007: Sub-Investigator – Restless Legs Syndrome Trial
Nov2004- November 2009:: Investigator – Diabetes, Anemia, CKD, Cardiovascular Outcomes Trial
Nov 2004-Aug 2006: Investigator –Biphosphonate Osteoporosis Trial
Nov 2004-Present: GCP Training Modules-Various Sponsors (Multiple Modules)

Signature:	Signature Date: (dd-Mmm-yyyy)
	23 July 2020

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Heller	Robert	Joel

Professional Mailing Address

Street Address:		Other Street Address:	
12626 Riverside Drive, Suite 404			
City: Valley Village	State/Province: CA	Country: U.S.A.	Zip/Postal Code: 91607
Email Address:	rheller@bayviewresearch.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
B.S. in Psychology	1957	University of Illinois, Illinois, USA
M.D.	1961	Chicago Medical School, Illinois, USA
Internship	1962	Cook County Hospital Illinois, USA
Residency in Internal Medicine and Endocrinology	1965	Veterans Administration/UCLA, California, USA
Chief Resident Internal Medicine	1966	Cedars Sinai Medical Center, California, USA
Diplomat, American Board Internal Medicine	1969	American Board of Internal Medicine®

Medical License Number	State/Province	Country
G8042	CA	U.S.A.

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
Jul 2016 - Present	Principal Investigator	Bayview Research Group	CA, U.S.A.

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1966 – Present	Assistant Clinical Professor of Medicine	UCLA Medical Center	USA
1999 – Present	Attending Physician in Internal Medicine, Emeritus	Cedars Sinai Medical Center	USA
2014 -- 2016	CEO	Edge-3D, LLC (3D Microscope Company)	USA
2009 -- 2013	CEO	K Space LLC (Function MRI for Alzheimer's)	USA
2008 --2010	Medical Director	Alpha Health Care, Los Angeles	USA
1980 – 1999	Principal Investigator & Sub-Investigator	Medical Group of Culver City	USA
1966 – 1999	M.D., Owner, and Managing Partner	Medical Group of Culver City	USA

Brief Summary of Relevant Clinical Research Experience:

Investigator conducting Phase II – IV clinical trials in the following indications:

- Pneumococcal vaccine in adult patients
- Women's health: Birth Control, Heavy menstrual period, Uterine Fibroid
- Hypocholesteremia in adult patients with CVD
- Urge Incontinence Overactive Bladder in adult and geriatric population
- Osteoarthritic pain in adult population
- Low back pain in adult population
- Cytomegalovirus vaccine in adult women
- Testosterone Replacement Therapy with CV risks adult men
- Vasomotor symptoms in postmenopausal women

Signature:	Signature Date: (dd-Mmm-yyyy)
Robert Heller	23-Jul-2020

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Schear	Martin	

Professional Mailing Address

Street Address: 1100 Salem Ave		Other Street Address:	
City: Dayton	State/Province: Ohio	Country: USA	Zip/Postal Code: 45406

Email Address: (b) (6)

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Medical Doctor	1977	University of Chicago, USA

Medical License Number	State/Province	Country
35.041256	Ohio	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
1994	PI	Dayton Clinical Research	Ohio/USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
N/A			

Brief Summary of Relevant Clinical Research Experience:

25 years as a PI

Signature:	Signature Date: (dd-Mmm-yyyy)
MS	20/JUL/2020

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Finberg	Robert	William

Professional Mailing Address

Street Address: UMass Medical School 55 Lake Ave North		Other Street Address:	
City: Worcester	State/Province: MA	Country: USA	Zip/Postal Code: 01655

Email Address: Robert.Finberg@UMASSMED.EDU

Academic Qualifications: MD

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MD	1974	Albert Einstein College of Medicine
AB	1971	University of Chicago
MA	1996	Harvard University (Hon.)

Medical License Number	State/Province	Country
40199	MA	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2000	Professor of Medicine	UMass Medical School	Worcester, MA USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
1996-1999	Professor of Medicine	Harvard Medical School	USA
1985-1995	Associate Professor of Medicine	Harvard Medical School	USA
1980-1984	Assistant Professor of Medicine	Harvard Medical School	USA

Brief Summary of Relevant Clinical Research Experience:

Dr. Finberg's clinical expertise is in the treatment and prevention of infections. His current projects include heading a multi-center study to predict the evolution of influenza viruses and the study of new drugs to treat influenza. Recently he has participated in several COVID-19 trials and continues to work on the pathogenesis and treatment of SARS-CoV-2. He is actively involved in all phases of patient care, from primary care and prevention of disease in healthy people, to treatment of severely immunocompromised hosts. He has a particular focus on the development of ways to ensure health as opposed to treating illness.

Signature:	Signature Date: (dd-Mmm-yyyy)
	13-AUG-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

	Last Name	First Name	Middle Name
Full Name:	Greenbaum	Carla	Joy

Professional Mailing Address

Street Address: 1201 9th Ave		Other Street Address:	
City: Seattle	State/Province: WA	Country: USA	Zip/Postal Code: 98101
Email Address:	cjgreen@benaroyaresearch.org		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
ScB	1978	Brown University USA
MD	1981	Brown University USA

Medical License Number	State/Province	Country
MD090019995	Washington	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2000	Director, Diabetes Program and Center for Interventional Immunology	Benaroya Research Institute	WA, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2007-present	Affiliate Faculty	UW Medicine Diabetes & Obesity Center for Excellence, University of Washington	USA
2000-2003	Associate Member	Virginia Mason Research Center	USA
2003-present	Clinical Associate Professor	Div. of Metabolism, Endocrinology and Nutrition, Dept. of Medicine, University of Washington	USA
2000-2003	Research Associate	DVA Puget Sound Health Care System	USA

Brief Summary of Relevant Clinical Research Experience:

More than 30 years of clinical research including clinical trials of industry, investigator initiated studies, and academic funded projects.

Signature:	**Signature Date: (dd-Mmm-yyyy)**
	30JUL2020

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Albertson	Timothy	Eugene

Professional Mailing Address

Street Address:		Other Street Address:	
4150 V Street		Suite 3400	
City:	**State/Province:**	**Country:**	**Zip/Postal Code:**
Sacramento	CA	USA	95817
Email Address:	tealbertson@ucdavis.edu		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
BA Biology and Psychology	1973	University of California, San Diego, USA
M.S Pharmacology and Toxicology	1976	University of California, Davis, USA
M.D Medicine	1977	University of California, Davis, USA
PhD Pharmacology and Toxicology	1980	University of California, Davis, USA

Medical License Number	State/Province	Country
G37112	CA	USA

Current Position at Study Site:

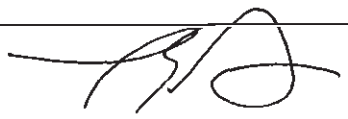
Start Date	Title	Institution or Company	State/Province & Country
1993	Professor	University of California Davis Medical Center	CA/ USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2012 – Present	Chair, Department of Internal Medicine	University of California, Davis, School of Medicine,	USA
2011 Present	Health Sciences Clinical Professor, Department of Clinical Pharmacy	University of California, San Francisco	USA
2009 2012	Interim Chair, Department of Internal Medicine	University of California, Davis, School of Medicine	USA
2006 2007	Medical Director for Clinical Care	University of California, Davis Health System	USA

Brief Summary of Relevant Clinical Research Experience:

Over 20 years of experience with clinical research.

Signature: 

Signature Date: (dd-Mmm-yyyy) 18-05-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Towner	William	James

Professional Mailing Address

Street Address: SCPMG/Kaiser Permanente Medical Center, Infectious Disease		Other Street Address: 1505 North Edgemont Street, 2nd Floor	
City: Los Angeles	State/Province: CA	Country: USA	Zip/Postal Code: 90027
Email Address:	William.J.Towner@kp.org		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
Doctor of Medicine	1993	University of Southern California School of Medicine, USA
Master of Science	1989	University of California, Los Angeles, USA
Bachelor of Science	1987	University of California, Los Angeles, USA

Medical License Number	State/Province	Country
80011	California	USA

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2004	Principal Investigator, Infectious Disease Clinical Research Program	Kaiser Permanente Los Angeles Medical Center	CA, USA

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2013 Present	Regional Physician Director, Division of Clinical Trials	Southern California Permanente Medical Group	USA
2006-Present	Regional Representative, HIV Initiative	Kaiser Permanente and Garfield Memorial Fund of the Permanente Federation	USA
2000-Present	Physician Partner	Southern California Permanente Medical Group (SCPMG)	USA
1997-Present	Assistant Clinical Professor of Medicine	UCLA School of Medicine	USA

Brief Summary of Relevant Clinical Research Experience:

I have been extensively involved in HIV research for the last 17 years and have served as a PI for over 100 HIV related clinical trials at Kaiser Permanente. These clinical trials have provided HIV positive patients with effective lifesaving medications prior to commercial availability which has saved hundreds of lives and significantly preserved and improved their quality of life. In addition, this work has directly informed the scientific community about the effectiveness and safety of emerging antiretroviral medicines.

Signature:	Signature Date: (dd Mmm-yyyy)
William Towner, MD William Towner, MD (Jul 20, 2020 16:23 PDT)	20-Jul-2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

NOTE: THIS CV MUST BE LIMITED TO THE INFORMATION IN THIS TEMPLATE FOR INCLUSION IN THE ICH-E3 COMPLIANT CLINICAL STUDY REPORT. ABBREVIATED CV'S CAN BE NO MORE THAN 3 PAGES, DO NOT INCLUDE ATTACHMENTS OR TEXT ON REVERSE PAGES.

ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Name:	Last Name	First Name	Middle Name
	Sligh	Teresa	Sheahan

Professional Mailing Address

Street Address: 6400 Laurel Canyon Blvd.		Other Street Address: Suite 300A	
City: North Hollywood	State/Province: CA	Country: USA	Zip/Postal Code: 91606
Email Address:	tsligh@providenceclinical.com		

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MD	6/1996	Texas A&M College of Medicine
BS	6/1987	University of New Mexico

Medical License Number	State/Province	Country
A72660	California	United States

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
10/2003	Medical Director	Providence Clinical Research	California, United States

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
2019 - present	Advisory Board Member	CTIS, Inc.	United States
2001–2003 and 2018-2019	Chief Medical Officer	CTIS, Inc.	United States
2001-2003	Clinical Research Fellow	Univ of Southern CA – Division of Colon & Rectal Surgery	United States
1998-2001	Principal Investigator	Sciman Biomedical Research	United States

Brief Summary of Relevant Clinical Research Experience:

A total of 30 years in translational research. Twenty of these have been in clinical research as a principal investigator on more than 400 clinical trials. Served as sub-I, monitor/auditor, or coordinator on an additional 27 trials. This spans biological, pharmaceuticals, radio-pharmaceuticals, in vitro diagnostics, serologicals, devices, supplements and botanicals across most therapeutic areas. Have conducted Phase 1, 2, 3, 4, PK/PD, PG, device, health outcomes, real world, MACE, Rx-to-OTC and observational studies. Have served as an IRB reviewing member. Have served as clinical research subject matter expert to NIH software development teams for the development of clinical research applications and databases. Have contributed to clinical development plans, clinical study reports, abstracts & publications.

Signature:	Signature Date: (dd-Mmm-yyyy)
	31JUL2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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ABBREVIATED CURRICULUM VITAE TEMPLATE

Full Legal Name:	Last Name	First Name	Middle Name
	Klein	Nicola	

Professional Mailing Address:

Street Address 1:		Street Address 2:	
~~Kaiser Permanente Vaccine Study Center~~ One Kaiser Plaza 16th Floor			
City: Oakland	State/Province: California	Country: United States	Zip/Postal Code: 94612

Email Address: Nicola.klein@kp.org

Academic Qualifications:

Degree and/or Certification	Date (yyyy)	Institution and/or Country
MD	1991-1998	New York University School of Medicine, USA
PhD	1989-1991	New York University School of Medicine, USA

Medical License Number A69589 **State/Province** California **Country** *USA*

Current Position at Study Site:

Start Date	Title	Institution or Company	State/Province & Country
2006	Co-Director Vaccine Study Center	Kaiser Permanente	California, United States
2006	Research Scientist II	Kaiser Permanente	California, United States
2006	Senior Physician	Kaiser Permanente	California, United States

Previous Relevant Positions Including Academic Appointments:

Start and End Dates	Title	Institution or Company	Country
n/a			

Brief Summary of Relevant Clinical Research Experience:

Nicola P. Klein, MD, PhD, is the Director of the Kaiser Permanente Vaccine Study Center, a research group in Oakland, California, since 2006. As a pediatrician vaccine researcher and clinical trial investigator, her research interests include vaccine safety and efficacy, genetic influences on vaccine responses, and vaccine responses among at-risk populations. She is the principal investigator for many ongoing studies of vaccines, biologics, and the epidemiology of infectious diseases, and has published extensively on vaccine safety and effectiveness. In addition, she serves as the Chair of the California Immunization Committee and is the Principal Investigator of the CDC-sponsored Vaccine Safety Datalink (VSD) Project and Clinical Immunization Safety Assessment (CISA) Network. She received her medical degree and doctorate in biochemistry at New York University School of Medicine and completed a residency in pediatric medicine at Lucile Salter Packard Children's Hospital at Stanford University School of Medicine, Palo Alto, CA. She also serves as an adjunct clinical instructor at the Department of Pediatrics at Stanford.

Signature: [signature]

Signature Date: (dd-Mmm-yyyy) 13 FEB 2020

I will update and resubmit my abbreviated CV if there are changes and particularly if there is any change in status which would adversely affect the assessment of my suitability to conduct/participate in clinical studies.

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NL 18 Aug 2020

Site Identifier	Investigator Name	Site Address at Time of Clinical Study	Site Contact Information at Time of Clinical Study
276-01	Armin Schultz	CRS Clinical Research Services Mannheim GmbH Grenadierstraße 1 68167 Mannheim GERMANY	Phone: +49 62115045110 Email: Armin.Schultz@crs-group.de
276-02	Sybille Baumann	CRS Clinical Research Services Berlin GmbH Sellerstraße 31 13353 Berlin GERMANY	Phone: +49 30859949101 Email: Sybille.Baumann@crs-group.de
276-03	Atef Halabi	CRS Clinical Research Services Kiel GmbH Lornsenstraße 7 24105 Kiel GERMANY	Phone: +49 4318999801 Email: Atef.Halabi@crs-group.de
276-04	Antje Blank	Medizinische Universitätsklinik Heidelberg Klinisch-Pharmakologisches Studienzentrum Im Neuhenheimer Feld 410 69120 Heidelberg GERMANY	Phone: +49 62215639537 Email: Antje.Blank@med.uni-heidelberg.de
276-05	Maria Vehreschild	Universitätsklinikum Frankfurt Infektiologie Theodor-Stern-Kai 7 60590 Frankfurt GERMANY	Phone: +49 1705376001 Email: Maria.Vehreschild@kgu.de

CRS Clinical Research Services

CURRICULUM VITAE

Personal Data

Name:	Dr Dr Armin Schultz, MD
Date and Place of Birth:	(b) (6)
Nationality:	German

School Education

(b) (6)	Graduation: General Qualification for University Entrance

Career

1977 - 1984	Studies of Biology Ruprecht Karls University of Heidelberg
1985 –1986	Diploma Thesis Institute for Immunology and Genetics German Center for Cancer Research Heidelberg
1987 – 1991	Scientific Assistant (PhD Thesis) Institute for Immunology and Genetics German Center for Cancer Research Heidelberg
1991 – 1992	Scientific Employee Laboratory for Oncologic Surgery University Clinic for Surgery Heidelberg
06/1992	Doctorate in Biology (PhD) Ruprecht Karls University of Heidelberg
1992 – 1998	Studying Human Medicine Ruprecht Karls University Heidelberg
04/1998 – 05/1999	Practical Year General Hospital Schwetzingen
08/1999 – 01/2001	Resident Institute for Clinical Pharmacology, Faculty for Clinical Medicine Mannheim of the University of Heidelberg

CRS Clinical Research Services

02/2001	License to practice Medicine
as of 08/2001	Qualification as Principal Investigator of Clinical Trials acc. to § 40 German Drug Law
02/2001 – 01/2003	Assistant Physician Institute for Clinical Pharmacology, Faculty for Clinical Medicine Mannheim of the University of Heidelberg
02/2003 – 03/2007	Senior Physician Institute for Clinical Pharmacology, Faculty for Clinical Medicine Mannheim of the University of Heidelberg
06/2007	Doctorate in Medicine (MD) Medical Faculty Mannheim of the University of Heidelberg
2004 – 10/2005	Provisional Director of the Institute for Clinical Pharmacology, Medical Faculty Mannheim, University of Heidelberg
since 04/2007	Physician Department Clinical Studies Phase I-II CRS Clinical Research Services Mannheim GmbH Mannheim
04/2008 – 12/2015	Deputy Medical Director Clinical Pharmacology Unit CRS Clinical Research Services Mannheim GmbH Mannheim
as of 01/2016	Medical Director Clinical Pharmacology Unit CRS Clinical Research Services Mannheim GmbH Mannheim
Language Skills	German, native speaker English fluent in speaking and writing

4 JAN 2020

Dr Dr Armin Schultz, MD
Mannheim

Date

CRS Clinical Research Services

CURRICULUM VITAE

Personal Data

Name:	Dr Sybille Katharina Baumann, MD
Date and Place of Birth:	(b) (6)
Nationality:	German

School Education

(b) (6)	Graduation: General Qualification for University Entrance

Career

1979 - 1981	Nursing School Municipal Hospital Frankenthal
1981 - 1987	Studying Human Medicine University of Heidelberg
12.05.1987	Physician Exam
05.06.1987	License to practice Medicine Regional Administrative Authority Stuttgart
12.05.1987	Doctorate Institute for Anaesthesia and Resuscitation Clinic Mannheim
10/1987 - 01/1988	Assistant Physician Anaesthesia Department Protestant Hospital "Hochstift" Worms
02/1988 - 03/1991	Assistant Physician Anaesthesia Department District Hospital "Bergstrasse" Heppenheim
04/1991 - 01/1997	Assistant Physician at the Clinic for Anaesthesia and Intensive Care Medicine University Clinics "Saarland" Homburg/Saar
28.01.1993	Recognition as Doctor for Anaesthesia

08/1993	Appointment as Functional Head Physician of the University Clinics "Saarland" Homburg/Saar
1995 - 1997	Practice Substitute for Dr. M. Penninger Neustadt/Weinstraße
	Practice Substitute for Dr. A. Penninger Ludwigshafen
07/1997 - 07/1999	Group Practice together with Physicians Dr. Penninger and Dr. Kohler Ludwigshafen
08/1999 – 12/2003	Physician Department Clinical Studies Phase I-II Institut für Klinische Pharmakologie Bobenheim Prof. Dr. Lücker GmbH, (IKP GmbH) Grünstadt
since 01/2004	Qualification as Principal Investigator of Clinical Trials acc. to § 40 German Drug Law
01/2004 – 01/2007	Head Clinical Investigator Department Clinical Studies Phase I-II Institut für Klinische Pharmakologie Bobenheim Prof. Dr. Lücker GmbH As of January 01, 2007 operating as: CRS Clinical Research Services Mannheim GmbH Mannheim
02/2007 – 03/2007	Clinical Investigator Phase I Abbott GmbH Ludwigshafen
04/2007 – 04/2008	Clinical Investigator Department Clinical Studies Phase I-II CRS Clinical Research Services Mannheim GmbH Mannheim
04/2008 – 12/2015	Deputy Medical Director Clinical Pharmacology Unit CRS Clinical Research Services Mannheim GmbH Mannheim
02/2015	Recognition as Specialist in Clinical Pharmacology District Medical Association, Karlsruhe

CRS Clinical Research Services

as of 01/2016

Medical Director
Clinical Pharmacology Unit
CRS Clinical Research Services Berlin GmbH
Berlin

Language Skills

German, native speaker
English, fluent in writing and speaking

Dr Sybille Baumann, MD
Berlin

13 MAY 2019
Date

CRS Clinical Research Services

CURRICULUM VITAE

Personal Data

Name:	Dr Atef Halabi, MD
Date and Place of Birth:	(b) (6)
Nationality:	German

School Education

(b) (6)	General Qualification for University Entrance
1978 – 1980	German Language Course

Career

1976 – 1978	Studies of Construction Engineering Damascus, Syria
1981 – 1986	Studies of Human Medicine Christian Albrechts University Kiel
1987	License to practice Medicine Christian Albrechts University Kiel
06/1988	Promotion thesis: "Influence of Famotidin on the pharmacokinetic of Nifedipin and on non-invasive hemodynamic parameters."
1992	Certificate as Emergency Physician
1994	Board certified internal medicine specialist
1986 - 1988	Assistant Doctor, Clinical Pharmacology Head Prof. Dr. Kirch Internal Medicine/ University Hospital Kiel
since 1986	Experience in conducting all types of clinical phase I/IIa studies (as Co-Investigator and Principal Investigator) in young and elderly healthy subjects and in patients with cardiovascular diseases, impaired renal function, liver diseases, diabetes etc. with different drugs

1988 – 1994	Resident Physician Internal Medicine/University Hospital Head: Prof. Ohnhaus, Prof. Fölsch Kiel
1993 – 1994	Private Assistant of Prof. Dr. Kirch, Clinical Pharmacology Internal Medicine/ University Hospital Kiel
1994 – 07/1998	Head of Clinical Pharmacology Unit Clin-Pharma Research AG Kiel
08/1998 – 08/1999	Executive Medical Director VanTx Research Ltd. Kiel
09/1999 – 09/2000	Managing Partner and Managing Director AVOXOVA GmbH Kiel
10/2000 – 12/2006	Managing Partner and Managing Director Institute for Clinical Pharmacology /Prof. Dr. Lücker – Zentrum Kiel GmbH Kiel
since 1986	Experience as clinical investigator
since 1988	Qualification as Principal Investigator of Clinical Trials acc. to § 40 German Drug Law
since 07/2006	Managing Partner CRS Clinical Research Services GmbH Andernach
since 01/2007	Managing Partner and Managing Director Clinical Pharmacology Unit CRS Clinical Research Services Kiel GmbH Kiel
Language Skills	Arabic, native speaker English, business fluent in writing and speaking German, business fluent in writing and speaking

02 Mar 2020

Dr Atef Halabi, MD
Kiel

Date

CURRICULUM VITAE

PERSONAL INFORMATION

Title, Name: Dr. med. Antje Barbara Blank

Nationality: German

Business Address: Clinical Pharmacology and Pharmacoepidemiology
Internal Medicine Department (Krehl-Klinik)
Heidelberg University Hospital
Im Neuenheimer Feld 410
69120 Heidelberg
Germany
Phone +49 (0)6221 56 39537,
Fax +49 (0)6221 56 8523
antje.blank@med.uni-heidelberg.de

Current Position: Head of Clinical Trial Unit

EDUCATION

School:

(b) (6) *"Abitur"* (German university entrance qualification), Kolleg St. Sebastian, Freiburg, Germany

University:

10/1987 – 05/1995	Medical School at the Albert-Ludwigs-University in Freiburg, Germany
04/1991 – 04/1993	Doctoral thesis: Point mutations in the Interferon induced protein Mx1: The antiviral activity is dependent on a functional GTPase-binding motif, Medical School at the University of Freiburg, Department of Virology and Immunology

PROFESSIONAL QUALIFICATIONS

Date	Qualification	University / Institution
05/1995	Final Medical Examination (3. Staatsexamen)	Medical School at the University of Freiburg
07/1995	Doctoral Examination for doctoral thesis and conferment of doctorate	Medical School at the University of Freiburg
07/1995	Temporary license to practice medicine (*"Ärztin im Praktikum"*)	
01/1997	German License to practice medicine (*"Approbation"*)	
05/2012	German Board Certification Clinical Pharmacology (*"Facharzt"*)	Landesärztekammer Baden-Württemberg
12/2013	State certification for academic teaching "Baden Württemberger Hochschullehre Zertifikat"	University of Heidelberg

02/2009	Project Management Seminar	Akademie für Gesundheitsberufe, Heidelberg
02/2019	Most current certification to conduct clinical trials acc. to GCP as principal investigator	KKS Heidelberg and AGAH e.V:

PREVIOUS APPOINTMENTS

Date	Position	University / Institution
07/1995 – 09 1996	Intern/ resident (*"Ärztin in Praktikum"*)	University Hospital of Heidelberg, Cardiology Department
10/1996 – 02/1997	Resident (*"Assistenzärztin"*)	Transfusion Medicine and Immunology department of the "Blutspendezentrale Nordbaden" / University of Mannheim
04/1997 – 09/ 2001	Research Physician; Clinical Scientist Phase I trials and international multicenter phase III mortality trials	Hoffman – La Roche, Cardiovascular Clinical Development, Roche GmbH, Mannheim, Germany
10/2001 – 06/ 2003	Clinical research consultant (consultancy for Hoffmann La Roche)	*Clinical Research Consulting Ltd.*, Personal registered clinical research consultancy business, Singapore
07/2003 – 09/2007	Family management	
Since 09/2007	Resident and research physician at the current department. Since 07/2018 deputy head of Clinical Trial Unit. Since 01/2020 Head of Clinical Trial Unit Since 06/2020 Oberärztin • Trial experience see attachment	

SUMMARY OF TEACHING AND RESEARCH EXPERIENCE

Teaching

1996/1997:	Teaching at the "Schule für Medizinisch technische Assistenten" at the Mannheim University Hospital.
Since 2007:	Regular academic teaching in clinical pharmacology at the medical school of the university of Heidelberg.

Research

1989-1991:	PHD research in the department of virology research laboratory of the University of Freiburg.

	Methods of DNA/ RNA and protein molecular biology and cell culture.
1995-1996	Heidelberg University Hospital, internal medicine III. Research in atherosclerosis, smooth muscle cell differentiation. Junior Grant of the medical faculty of the Heidelberg University.
1997-2001:	Research at the clinical development department; cardiovascular group, of Roche Pharmaceuticals. Mainly clinical phase III studies, regulatory procedures, phase I trials; all cardiovascular indications
2001-2003:	Consultant for Clinical Research; cardiovascular compounds. Expert reports, investigator brochures.
Since 2007:	Heidelberg University Hospital, clinical pharmacology and pharmacoepidemiology. Clinical phase I and II studies, First in man administration. Clinical expert systems, electronic clinical decision support.

MEMBERSHIPS IN ACADEMIC SOCIETIES AND COMMITTEES:

Since 02/2012	Arbeitsgemeinschaft für Angewandte Humanpharmakologie e.V. (AGAH)
Since 07/2019	Member of the Ethics Committee of the Medical Faculty of the Heidelberg University

EXPERIENCE IN CONDUCTION OF CLINICAL TRIALS:

☒ **Yes, since 1997, *see attachment*** ☐ **No**

23 Nov 2020
Date

Signature

Clinical Trial Experience

Studies undertaken as research physician at the University Hospital of Heidelberg, Department for Clinical Pharmacology and Pharmacoepidemiology, since September 2007

No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
1	DNA Biobank for Genotype Screening of Volunteers for the Participation in Clinical Studies	N/A	Non-AMG	healthy volunteers	N/A	Principle Investigator
2	Prospective, open, uncontrolled Phase I Study to evaluate the pharmacokinetics of Artesunate more specifically of its active Metabolite Dihydroartemisinin in Patients with metastatic or locally advanced breast Cancer	I	2007-004432-23	patients with metastatic or locally advanced breast cancer	27	Investigator
3	Monocenter, randomized phase I study to assess the potential induction of CYP3A4 after exposition to honey using midazolam pharmacokinetics as a marker	I	2007-007125-52	healthy volunteers	12	Monitor
4	A monocenter prospective open-label single rising dose study with a new monoclonal antibody, FIM	I; FIM	2006-003777-27	healthy volunteers	57	Investigator
5	Monocenter, single dose, open phase I study to investgate the formation and elimination of 11-nor-9-carboxy-Δ9-tetrahydrocannabinol (CTHC) after inhaled administration of 14 mg Δ9-tetrahydrocannabinol (THC) in healthy human subjects	I	2007-001284-30	healthy volunteers	10	Monitor
6	Multicenter, open trial to investigate the impact of Efavirenz therapy in HIV patients on the results of drug screening tests	N/A	Non-AMG	HIV patients	18	Coordinating investigator

No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
7	A randomiesed, placebo-controlled, double-blind dose escalation study to evaluate the efficacy, safety ans pharmacokinetic properties of the humanised CD4 monoclonal antibody BT061	I/IIa	2007-003530-42	patients with chronic plaque psoriasis	56	Investigator
8	Multicenter, open-label, clinical firtst-in-human, single dose escalation i.v. infusion study to evaluate the safety and tolerability of claudiximab (iMAB-362)	I	2008-004719-37	patients with advanced gastroesophageal cancer	5	Investigator
9	An open-label, two-period, single-sequence phase I study to evaluate the pharmacokinetics of AFQ056 when given alone and in combiantion with ketoconazole	I	2008-004107-66	healthy volunteers	17	Investigator
10	Multicenter, two-part, open-label, dose escalation, FIM, Phase I/II study of the tumor-targeting human L19IL2 monoclonal antibodycytokine fusion protein in combination with gemcitabine in patients with advanced pancreatic cancer	I / II; FIM	2007-001609-81	patients with advanced pancreatic cancer	6	Investigator
11	First-in-human, monocenter, double-blind, placebo-controlled, phase I dose escalation study to examine safety, tolerability, and immune response to the investigational VEGFR-2 DNA vaccine VXM01	I, FIM	2011-000222-29	patients with pancreas carcinoma	72	Investigator
12	Randomized, open mono-centre, phase I- trial to investigate the time course of CYP3A4 inhibition using a new limited sampling strategy of midazolam as a marker for CYP3A4 activity	I	2009-013060-39	healthy volunteers	16	Monitor
13	An open-label, single center Phase Ia clinical trial to evaluate the safety, tolerability, and pharmacokinetics of Myrcludex B	Ia	2010-022776-31	Healthy volunteers	36	Investigator

No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
14	A proof-of-concept Phase II study to evaluate efficacy, safety and pharmacokinetics of 4SC-201 and the treatment combination of Sorafenib plus 4SC-201 in patients with hepatocellular carcinoma exhibiting progressive disease under Sorafenib treatment	II	2009-010760-42	patients with hepatocellular carcinoma	12	Investigator
15	Multicenter Phase I, open-label, non-placebo controlled study to determine the safety, pharmacokinetics, and pharmacodynamics of BAY 73-4506 in combination with FOLFOX or FOLFIRI as first or second line therapy	I	2008-007151-27	patients with metastatic colorectal cancer	5	Investigator
16	Two-part, randomized, double-blind, placebo-controlled, singel dose, dose escalalting phase I study to evaluate the safety, tolerability, pharmacokinetics, immunogenicity and to explore the pharmacodynamics of CDP7657	I	2009-013617-10	Patients with systemic Lupus erythematosus	1	Investigator
17	Open-label, cross-over, monocenter, randomised phase I study to investigate the effect of ketoconazole and fluconazole as an inhibitor of CYP3A4 on PXR-mediated induction of CYP3A4 activity	I	2010-018962-22	healthy volunteers	14	Monitor
18	Multicenter, randomised, replicate administration, four-way change-over, single dose bioequivalence study Xeloda - Capecitabine	I	2009-015067-14	patients receiving Xeloda as cancer treatment	1	Investigator
19	Phase I/II, randomized, open-label, multi-centre dose-escalation study to investigate safety and tolerability of BIBF1120 in conjunction with radiotherapy	I / II	2011-000921-61	Patients with first or second progression of glioblastoma	12	Investigator
20	A phase I trial to assess the safety and immunogenicity of the HD-MSP1-Vac1 malaria vaccine	I	2016-002463-33	Healthy volunteers	32	Deputy Investigator

No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
21	Open-label, monocentre, two period, one sequence clinical phase I trial to evaluate influence of OATP1B1 and CYP2C9 genotypes on the pharmacokinetics of steady state bosentan before and during CYP3A4-inhibition by clarithromycin	I	2010-021392-93	healthy volunteers	12	Investigator
22	A phase I/II study to evaluate the safety, tolerability pharmacokinetics and efficacy of resminostat (4SC-201) in combination with a second line treatment	I / II	2010-020171-23	patients with k-ras mutated advanced colorectal carcinoma	11	Investigator
23	Open-label, monocenter, one sequence pase I trial to investigate the influence of CP3A4-induction by SJW on the steady state pharmacokinetics of bosentan	I	2010-022328-64	healthy volunteers	14	Responsible investigator
24	Open-label, monocentre, one sequence clinical phase I trial to investigate the influence of CYP3A4-induction by St. John's wort (SJW) on the steady state pharmacokinetics of ambrisentan	I	2010-022868-13	healthy volunteers	14	Investigator
25	International, multicenter, open label, phase II study to investigate the efficacy and safety of multiple doses of IMAB362	II	2009-017365-36	patients with advanced gastroesophageal cancer	5	Investigator
26	Pase I, open-label, single oral dose study to investigate the pharmacokinetics safety and tolerability of ACT-179811	I	2009-017945-71	Patients with Clostridium difficile infection	0	Investigator
27	Open-label, multicentre, dose-escalation study to characterize the safety and preliminary efficacy of the human anti-CD38 antibody MOR03087 in adult subjects with relapsed/refractory multiple myeloma as monotherapy and in combination with standard therapy	I, FIM	2009-015942-50	patients with multiple myeloma	43	Investigator

No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
28	Randomised, placebo-controlled, cross over phase I study to evaluate the pharmacokinetic interactions between the weak opioid tilidine with grapefruit juice and efavirenz	I	2010-024658-12	healthy volunteers	12	Monitor
29	Open label, two arm, one-sequence, two phase, randomised, mono-centre, dose escalation phase I study to evaluate pharmacokinetic linearity of parent drug and metabolites before and during CYP3A inhibition after microdosing of Midazolam	I	2011-000540-21	healthy volunteers	14	Investigator
30	Open-label, prospective, dose escalation, PK- and safety study,non-randomized, multi-center with single agent CetuGEX™	I	2010-019552-50	patients with advanced and/or metastatic cancer	6	Investigator
31	Open-label, randomized, three-sequence, two-period, single-centre phase I study with oral administration of midazolam, simvastatin and ritonavir	I	2011-004297-29	healthy volunteers	18	Investigator
32	Pharmacokinetic Enhancement of Crizotinib plasma concentrations with Cobicistat or Itraconazole in Anaplastic Lymphoma Kinase positive advanced Non-Small Cell Lung Cancer Patients (PrECIsioN)	I	2016-002187-14	Non-Small Cell Lung Cancer Patients	0	Medical Member of the Study Group
33	Prospective, open-label, randomized, monocenter, phase I study to investigate pharmacokinetic and pharmacodynamic properties of single SC doses of the humanized monoclonal antibody BT061	I	2011-004956-20	healthy volunteers	36	Investigator
34	A multi-center, open-label, dose escalation, Phase 1 study of oral LGH447 (FIM)	I; FIM	2011-003820-10	patients with multiple myeloma	38	Medical Member of the Study Group

No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
35	Phase I, multi-center, non-randomized, open label, dose escalation design study to investigate safety, PK, QT/QTc and anti-tumor activity of sorafenib-eribulin combination	I	2011-005849-12	patients with advanced, metastatic or refractory solid tumors	16	Investigator
36	An autoinhibition study with voriconazole under measurement of the hepatic and total CYP3A4 activity measured with midazolam microdosing	I	2012-000970-52	healthy volunteers	28	Investigator
37	An open-label, Phase I, FIM dose-escalation study to characterize the safety, tolerability, pharmacokinetics, and maximum tolerated dose of BAY 1000394 given in 3 days on/4 days off schedule	I; FIM	2010-019191-79	Patients with CLL, NHL and Hodgkin Lymphoma	2	Investigator
38	Evaluating a drug interaction of topical erythromycin on CYP3A4 using midazolam as a marker substance	I	2012-004272-19	healthy volunteers	16	Investigator
39	A double-blind, randomized, placebo-controlled, single ascending dose study to assess the safety, tolerability, pharmacokinetics, immunogenicity and pharmacodynamics of the plasmacytoid dendritic cell specific humanized monoclonal antibody MB101	I; FIM	2013-001923-38	patients with Psoriasis	9	Medical Member of the Study Group
40	Randomized open-labelled two-arm phase I microdose study of the CYP2E1 marker substrate chlorzoxazone evaluating pharmacokinetic linearity of parent drug and metabolite and effect of midazolam clearance	I	2014-003348-11	healthy volunteers	14	Medical Member of the Study Group
41	Open-labelled, sequential one phase explorative drug interaction study to analyse the time dependence of the drug-drug interaction between the novel antiretroviral drug rilpivirine and the phospho-diesterase-5-inhibitor tadalafil	I	2013-002212-28	healthy volunteers	18	Medical Member of the Study Group

No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
42	A Phase I, multi-center, non-randomized, open-label, dose escalation design study to characterize safety, tolerability, pharmacokinetics and maximum tolerated dose of BAY 1125976	I	2012-004671-39	patients with advanced tumors	30	Deputy investigator
43	Open labelled drug-interaction phase I study to investigate the effect of increasing doses of St. John's Wort and Rifampicin co-administration on CYP3A-activity and Oral Glucose Tolerance Test	I	2013-004374-10	healthy volunteers	12	Deputy investigator
44	Open labelled drug-interaction phase I study to investigate the live assessment of CYP3A Activity during administration of Modulators of CYP3A or Placebo (Midazolam CLAMP) under midazolam continuous infusion	I	2013-004869-14	healthy volunteers	32	Deputy Investigator
45	Assessment of a potential drug-drug interaction between the novel antiviral drug candidate Myrcludex B and the nucleotide analogue reverse transcriptase inhibitor tenofovir	I	2014-003289-26	healthy volunteers	12	Deputy investigator
46	A phase Ib/II, multi-center, open-label study of oral LGH447 in combination with oral BYL719	Ib/II	2013-004959-21	patients with relapsed and refractory multiple myeloma	2	Medical Member of the Study Group
47	Phase 3, randomized, open-label, active-controlled, parallel-group, multicenter study comparing Daratumumab, Lenalidomide, and Dexamethasone vs Lenalidomide and Dexamethasone	IIIb	2013-005525-23	subjects with relapsed or refractory multiple myeloma	3	Medical Member of the Study Group
48	First-in-human Clinical Study with RNA-Immunotherapy Combination of IVAC_W_bre1_uID and IVAC_M_uID for Individualized Tumor Therapy in Triple Negative Breast Cancer Patients	I, FIM	2014-002274-37	Patients with triple negative breast cancer	1	Medical Member of the Study Group

No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
49	Open-label, multicenter phase I study in patients with metastatic colorectal cancer with liver metastasis under second or third line therapy to examine safety, efficacy, and immune biomarkers after treatment with VXM01	I	2015-003068-34	Patients with metastatic colorectal cancer with liver metastasis	24	Medical Member of the Study Group
50	A Multicenter, Open-label, Randomized Clinical Study to Assess Efficacy and Safety of 3 Doses of Myrcludex B for 24 Weeks in Combination with Tenofovir Compared to Tenofovir Alone to Suppress HBV Replication in Patients with Chronic Hepatitis D	II	2016-000395-13	Patients with chronic hepatitis D	6	Deputy Investigator
51	Pilot Study on the effect of Myrcludex B on lipid metabolism, metabolic parameters, myocardial function, myocardial tissue and vascular function in volunteer patients with dyslipidemia	I	2017-003137-28	patients with dyslipidemia	59	Deputy investigator
52	Multi-center, randomized, placebo-controlled, double-blind parallel group, Phase Ib study to evaluate the effect of 0.4 mg nitroglycerin spray after pretreatment with multiple oral doses of 2.5 mg, 5 mg and 10 mg vericiguat (BAY 1021189) each given over 14 ± 3 days on safety, tolerability and blood pressure in a multi-center, randomized, placebo-controlled, double-blind group comparison study in - VEricIguat NItroglycerin Clinical IntEraction (VENICE) study	Ib	2015-001444-11	Patients with stable coronary artery disease (CAD)	14	Medical Member of the Study Group
53	Non-randomized 3-phase sequential clinical trial to evaluate the pharmacokinetics of single regular dose and microdose chlorzoxazone after chronic alcohol consumption and after oral disulfiram administration (Premier cru)	I	2015-005227-34	Healthy volunteers	8	Medical Member of the Study Group

No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
54	A Phase 1a/1b Multicenter, Single-Arm, Open-Label, Dose-Escalation Study to Determine the Maximum Tolerated Dose, Safety, and Preliminary Activity of Oral ACY-241 Alone and in Combination With Pomalidomide and Low-Dose Dexamethasone	Ia/Ib	2015-002922-38	Patients With Relapsed or Relapsed-and-Refractory Multiple Myeloma	7	Medical Member of the Study Group
55	Assessment of the effect of drug formulation on the extent of the pharmacokinetic interaction between voriconazole and tacrolimus	I	2016-004137-24	Healthy volunteers	18	Medical Member of the Study Group
56	Open-label, single-centre, fixed-sequence, randomised, two-arm, cross-over trial to investigate the effect of food on the pharmacokinetics of once-daily prolonged-release tacrolimus	I	2017-000410-32	Healthy volunteers	36	Medical Member of the Study Group
57	Pharmacokinetic interaction of macitentan with rivaroxaban and effect of CYP3A4 induction by St. John´s wort (SJW) on the steady-state pharmacokinetics of macitentan and its active metabolite in healthy volunteers - ϕmax (Phimax)	I	2016-002300-61	Healthy volunteers	12	Medical Member of the Study Group
58	A Multicenter, Phase 1/1b, Open-Label, Dose-Escalation Study of ABBV-838, an Antibody Drug Conjugate	I/Ib	2014-002609-39	Subjects with Relapsed and Refractory Multiple Myeloma	6	Medical Member of the Study Group
59	characterisation of Yohimbine after oral administration in relation to different CYP2D6 genotypes	I	2017-001801-34	healthy volunteers	18	Deputy Investigator
60	Open-label, monocenter trial to evaluate the pharmacokinetic linearity of microdosed factor Xa antagonists in healthy volunteers	I	2017-000293-11	Healthy Volunteers	20	Medical Member of the Study Group
61	Pharmacokinetics of microdose rivaroxaban, apixaban and edoxaban co-administrated with ketoconazole, voriconazole, rifampicin and a fixed combination of elvitegravir, cobicistat, emtricitabine and tenofovir alafenamide fumarate	I	2016-003024-23	Healthy volunteers	18	Medical Member of the Study Group

No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
62	Effects of ciclosporin and its combination with fluconazole on the pharmacokinetics of rivaroxaban in healthy volunteers	I	2016-003120-23	Healthy volunteers	12	Medical Member of the Study Group
63	A Phase 1B multicenter, open-label study to determine the Recommended Dose and Regimen of durvalumab (MEDI4736) either as monotherapy OR in combination with pomalidomide (POM) with or without low-dose dexamethasone (dex)	Ib	2015-003066-93	subjects with Relapsed and Refractory Multiple Myeloma (RRMM)	6	Medical Member of the Study Group
64	Pharmacokinetics of microdose rivaroxaban, apixaban and edoxaban in geriatric patients	I	2017-000785-29	geriatric patients	0	Deputy investigator
65	A Phase 2, Multicenter, Open-label, Study to Determine the Safety and Efficacy for the Combination of Durvalumab (DURVA) and Daratumumab (DARA) (D2)	II	2016-001209-17	Subjects with Relapsed and Refractory Multiple Myeloma	2	Medical Member of the Study Group
66	A Phase Ib/II Open-label, Multi-center Study of the Safety and Efficacy of IMCgp100 in Combination with Durvalumab (MEDI4736) or Tremelimumab or the Combination of Durvalumab and Tremelimumab Compared to IMCgp100 Alone (IMCgp100-201)	Ib/II	2015-002971-12	Patients with Advanced Melanoma	13	Medical Member of the Study Group
67	Phase I open label, multi-center study to characterize the safety, tolerability and pharmacokinetics of intravenously administered MIK665, a Mcl-1 inhibitor, in patients with refractory or relapsed lymphoma or multiple myeloma	I	2016-003624-22	Multiple Myeloma	3	Medical Member of the Study Group
68	A Phase 1, Open-label, Drug Interaction Study to Evaluate the Effect of Ustekinumab on Cytochrome P450 Enzyme Activities Following Induction and Maintenance Dosing in Participants with Moderate to Severe Crohn's Disease.	I	2017-000831-16	Crohn's Disease	4	Medical Member of the Study Group

No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
69	Vericiguat ISOsoRbite mononitrate interaction (VISOR) study, multi-center, randomized, placebo-controlled, double-blind group comparison study to investigate safety, tolerability and blood pressure of 2.5 mg, 5.0 mg and 10 mg vericiguat each given over 14 ± 3 days together with isosorbite mononitrate (ISMN) 60 mg extended release formulation after a pretreatment phase (ISMN-starting dose: 30 mg)	Ib	2016-005178-36	stable coronary artery disease (CAD) patients with or without heart failure	6	Medical Member of the Study Group
70	A phase 1 first-in-human, randomized, double–blind, placebo-controlled dose escalation trial of a single intravenous dose of the anti-herpes simplex virus monoclonal antibody HDIT101 in healthy volunteers	I,FIM	2017-004452-37	healthy volunteers	24	Deputy Investigator
71	Dose-dependent inhibition of CYP2C19 and CYP3A metabolism by meropenem	I	2017-003136-37	Healthy volunteers	18	Sub-Investigator
72	Phase II open-label, single-arm, multicenter trial of MP0250 plus bortezomib+dexamethasone	II	2016-002771-10	Subjects with Relapsed and Refractory Multiple Myeloma	2	Medical Member of the Study Group
73	Study to clinically evaluate the QT/QTc interval prolongation potential of vericiguat in patients with stable coronary artery disease in a 2-arm, placebo-controlled, randomized, double-blind, double-dummy design including a vericiguat multiple-dose part with fixed up-titration periods and moxifloxacin as positive control (for assay sensitivity testing, nested into the placebo treatment)	Ib	2017-003094-33	stable coronary artery disease (CAD) patients with or without heart failure	5	Medical Member of the Study Group
74	Phase I/Ib, multi-center, open-label, study of single agent CJM112, and PDR001 in combination with LCL161 or CJM112	I/Ib	2016-005130-30	Multiple Myeloma	10	Medical Member of the Study Group

No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
75	A Phase IB/II Study of Cobimetinib Administered as Single Agent and in Combination with Venetoclax, with or without Atezolizumab	Ib/II	2017-000830-68	Multiple Myeloma	4	Medical Member of the Study Group
76	Assessment of pharmacokinetic interactions between azole fungistatics drugs and three factor Xa inhibitors administered simultaneously	I	2017-004453-16	healthy volunteers	14	Deputy Investigator
77	Use of Doxapram as a new antiarrhythmic drug for a specific therapy of atrial fibrillation Doctos Trial (Doxapram conversion to sinus rhythm study)	Ib/IIa	2018-002979-17	patients with atrial fibrillation	9	Deputy
78	Assessment of a potential drug-drug interaction between the antiviral drug candidate myrcludex B and the OATP-substrate pravastatin	I	2018-000012-21	Healthy volunteers	20	Principle Investigator
79	An open-label Phase Ib/ II, multi-center study of 4SC-202 in Combination with Pembrolizumab	Ib/II	2017-001050-33	Participants with Advanced or Metastatic Solid Tumors	8	Medical Member of the Study Group
80	A Clinical Phase II, multicenter, Open-label study evaluating iNduction, consolidation and maintenance treatment with Isatuximab (SAR650984), Carfilzomib, Lenalidomide and Dexamethasone (I-KRd) in Primary diagnosed high-risk multiple myeloma paTients GMMG-CONCEPT	II	2016-000432-17	Multiple Myeloma	6	Medical Member of the Study Group
81	A Phase 1, Open-Label, Multicentre, Non-Randomized Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Antitumor Activity of AZD4573, a Potent and Selective CDK9 Inhibitor, in Subjects with Relapsed or Refractory Haematological Malignancies	I	2017-000817-22	hematological malignancies	0	Medical Member of the Study Group

No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
82	An open labelled first human dose phase 1/2a study to evaluate safety, feasibility and efficacy of multiple dosing with individualised VB10.NEO immunotherapy in patients with locally advanced or metastatic melanoma, NSCLC, clear renal cell carcinoma, urothelial cancer or squamous cell carcinoma of head and neck, who did not reach complete responses with current standard of care immune checkpoint blockade	I/IIa	2017-002474-39	patients with skin cancers	11	Medical Member of the Study Group
83	Assessment of the effect of the potential perpetrator effects of clarithromycin, carbamazepine, gabapentin, and pregabalin on the pharmacokinetics of edoxaban and a microdosed cocktail of three simultaneously administered factor Xa inhibitors	I	2018-002490-22	healthy volunteers	49	Deputy Investigator
84	A Phase II Randomized, Open-label, Multi-center Study of the Safety and Efficacy of IMCgp100 Compared with Investigator's Choice in HLA-A*0201 Positive Patients with Previously Untreated Advanced Uveal Melanoma (IMCgp100-202)	II	2015-003153-18	Patients with Uveal Melanoma	9	Medical Member of the Study Group
85	A phase 1B/2A multicenter, open-label, doseescalation study to determine the maximum tolerated dose, assess the safety and tolerability, pharmacokinetics and preliminary effecacy of CC-220 Monotherapy, in combination with Dexamethasone, and in combination with Dexamethasone and Daratumumab or Bortezomib in subjects with relapsed and refractory multiple myeloma.	Ib/IIa	2016-000860-40	Multiple Myeloma	2	Medical Member of the Study Group
86	A Phase I/II, Open-label, Multi-center Study of the Safety and Efficacy of IMCgp100 using the Intra-patient Escalation Dosing Regimen in Patients with Advanced Uveal Melanoma (IMCgp 100-102)	I/II	2015-004222-34	Patients with Uveal Melanoma	9	Medical Member of the Study Group

No	Description/phase of the study	Phase	EudraCT-No	Indication	No. of patients/ volunteers	Function
87	A Phase 1 open-lable study, evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of AMG701 in subjects with multiple myeloma.	I	2017-001997-41	patients with multiple myeloma	3	Medical Member of the Study Group
88	A Multicenter, Open-label, Randomized Phase 3 Clinical Sudy to Assess Efficacy and Safety of bulevirtide in Patients with Chronic Hepatitis Delta	III	2019-001213-17	patients with HBV/HDV	4	Principle Investigator
89	A Randomized Open-Label Phase ½ Study of INCB001158 Combined With Subcutaneous (SC) Daratumumab, Compared to Daratumumab SC, in Participants with Relapsed or Refractory Multipe Myeloma	I / II	2018-004076-35	patients with multiple myeloma	0	Medical Member of the Study Group
90	A Phase I, First in Human, Double-Blind, Placebo-Controlled, Multicenter, Single and Multiple Ascending Dose Study of NI006 in Patients with Amyloid Transthyretin Cardiomyopathy followed by an Open-Label-Extension	I/FIM	2019-001932-80	patients with ATTR cardiomyopathy	12	Medical Member of the Study Group

23 Nov 2020
Date

Signature

CURRICULUM VITAE

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Aktuelle Position

Leitung des Instituts, Universitätsklinikum Frankfurt, Goethe Universität, ZIM II, Infektiologie, Haus 68, Theodor-Stern-Kai 7, 60590 Frankfurt, None

Medizinische Qualifikationen

	Art	Erläuterung	Datum	Institution	Stadt
1	Sonstige med. Qualifikationen	Bachelor of Sciences Program Psychology, Dauer: 5 months	08.1999	New York University	New York/USA
2	Studium	Medizin, Dauer: 6 years 7 months	04.200	Charité Universitätsmedizin	Berlin
3	Promotion/Doktor-Arbeit	Reserach Neuroradiology, Dauer: 5 years	01.2003	Technical University Munich	Munich
4	Arzt/Ärztin im Praktikum	Dauer: 7 months	10.2004	University of Nice Antipolis	Nice/France
5	Arzt/Ärztin im Praktikum	Dauer: 4 months	10.2005	Federal University of Minas Gerais	Belo Horizonte/Brazil
6	Arzt/Ärztin im Praktikum	Dauer: 8 months	02.2006	University of São Paulo	São Paulo/Brazil
7	Approbation		11.2006	Landesamt für Gesundheit und Soziales	Berlin
8	Assistenzarzt/-ärztin	Hematology/Oncology, Dauer: 10 months	08.2007	University Hospital Cologne	Cologne
9	Assistenzarzt/-ärztin	Emergencies, Dauer: 5 months	07.2008	University Hospital Cologne	Cologne
10	Assistenzarzt/-ärztin	Intensive Care, Dauer: 12 months	01.2009	University Hospital Cologne	Cologne

11	Assistenzarzt/-ärztin	Infectious diseases unit (consultancy Service), Dauer: 6 months	01.2010	University Hospital Cologne	Cologne
12	Assistenzarzt/-ärztin	cardiology, Dauer: 5 months	07.2010	University Hospital Cologne	Cologne
13	Assistenzarzt/-ärztin	Hematology/Oncology, Dauer: 13 months	01.2011	University Hospital Cologne	Cologne
14	Assistenzarzt/-ärztin	Gastroenterology, Dauer: 5 months	03.2012	University Hospital Cologne	Cologne
15	Facharzt/-ärztin	Internal medicin	09.2012		
16	Arzt/Ärztin	Infectious diseases/Hematology/Oncology, Dauer: 5 years	03.2013	University Hospital Cologne	Cologne
17	Habilitation	Internal medicine, Dauer: 5 years	09.2013	University Hospital Cologne	Cologne
18	Facharzt/-ärztin	Infectious diseases	12.2014	Board Examination of the German Society of Infectious diseases (DGI)	Cologne
19	Facharzt/-ärztin	Hematology and Oncology	11.2016		
20	Institutsleitung	Infectious diseases, Dauer: ongoing	08.2018	University Hospital Frankfurt	Frankfurt/Main

Preise

k.A.

Fachgesell.-Mitgliedsch.

1. German Society of Hematology and Oncology (DGHO)
2. German Speaking Mycological Society (DMykG)

Studienschwerpunkte

k.A.

Fortbildungen und Schulungen bez. Durchfuehrung klinischer Studien

	Art	Erläuterung	Datum	Institution	Stadt
1	Prüfarztkurs	Dauer: 4 days	26.11.2007	KKS Cologne-Düsseldorf	
2	GCP-Training	e-Learning Training	03.2009		

3	GCP-Training	online Training GCP/ICH Obligations of Sponsors, Monitors and Investigators	07.2011		
4	GCP-Update	Web Training: Änderungen des Arzneimittelgesetzes	01.2013		
5	GCP-Training	online Training: GCP Combacte	01.2016		
6	GCP-Training	MPG Ergänzungskurs	03.2018	ZKS Köln	Cologne
7	GCP-Update		03.2019	University Hospital Frankfurt	Frankfurt/Main
8	GCP-Update	Dauer: 2h	25.11.2020	Uniklinik Frankfurt	Frankfurt/Main

Teilnahme an klinischen Studien (QualiPRO)

	Rolle	Studiencode	Eudra CT Nr.	Titel	Phase	Studien-Start	Studien-Ende
1	LKP national	IBIS		Prospektive und retrospektive Studie zu Chlostridium diff. Infektionen	k.A.	01.01.2019	
2	Prüfer (engl.: PI)	CALVID-1	2020-001264-28	A Prospective, Multi-Center, Randomized, Placebo-Controlled, Double-Blinded Study to Evaluate the Efficacy, Safety and Tolerability of IMU-838 as Addition to Investigator's Choice of Standard of Care Therapy, in Patients with Coronavirus Disease 19	2	04.05.2020	
3	Prüfer	FURI	2017-000381-29	Open-Label Study to Evaluate the Efficacy and Safety of Ibrexafungerp in Patients with Fungal Diseases that are Refractory to or Intolerant of Standard Antifungal Treatment	3	05.07.2017	
4	Prüfer (Stellv.)	CALAVI	2020-001644-25	A Phase 2, Open Label, Randomized Study of the Efficacy and Safety of Acalabrutinib with Best Supportive Care Versus Best Supportive Care in Subjects Hospitalized with COVID-19	2	06.05.2020	
5	Prüfer (Stellv.)	XPORT-CoV-1001	2020-001411-25	A Phase 2 Randomized Single-Blind Study to Evaluate the Activity and Safety of Low Dose Oral Selinexor (KPT-330) in Patients with Severe Covid-19 Infection (XPORT-CoV-1001)	2	14.04.2020	
6	Prüfer (Stellv.)	Adaptive COVID-19 Treatment Trial (ACTT)	2020-001052-18	A Multicenter, Adaptive, Randomized Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19	k.A.	25.03.2020	

7	Prüfer (Stellv.)	Adaptive COVID-19 Treatment Trial (ACTT)	2020-001052-18	A Multicenter, Adaptive, Randomized Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for the Treatment of COVID-19	k.A.	25.03.2020	

Andere klinische Studien und Projekte (nicht QualiPRO):

1. 2693 ABSSSI
2. 1134 ACT-179811 eudra-ct: 2010-020941-29
3. 1159 Ambiguard eudra-ct: 2010-019562-91 Phase 3
4. 2530 ANEMONE
5. 599 Anidulafungin/Voriconazole eudra-ct: 2007-002445-20
6. 3080 ANIMA Role: LKP,PI
7. 2801 ANTICIPATE
8. 3104 APX001-103 eudra-ct: 2017-000524-10
9. 3229 APX001-201 eudra-ct: 2017-003571-56
10. 2111 ASARI Role: PI
11. 3078 ASARI II
12. 2979 ASN100-201 eudra-ct: 2016-002146-23 Phase 2
13. 268 Aspergillus terreus-Epidemiologie
14. 986 AspIRS n.a.
15. 882 BCX1812-301 eudra-ct: 2009-012367-34 Phase 3
16. 3005 BLOOMY Role: PI
17. 2019 Cadazolid/ ACT-179811 eudra-ct: 2013-002528-17
18. 184 CASLAMB
19. 172 Caspofungin High Dose eudra-ct: 2005-004504-36
20. 175 Caspofungin MTD eudra-ct: 2006-001936-30 Phase 2
21. 1969 CDAD und intestinale Mikrobiota
22. 2789 CDIFF
23. 1915 C-DIFF H-030-014 eudra-ct: 2013-000775-32
24. 2777 CLARITY
25. 1962 CLEAR eudra-ct: 2013-003048-21 Role: LKP,PI,PM
26. 3008 CLOVER eudra-ct: 2016-003866-14
27. 1528 COAT
28. 1278 CoCoNut entfällt
29. 3030 COLLECT Role: PI
30. 1968 CONTAIN Role: LKP,PI
31. 2623 CONTROL Role: LKP, PI
32. 985 CytoFab - AZD9773
33. 3103 DAENARYS
34. 2733 DIVA
35. 815 EpiDi Role: LKP,PI
36. 2374 Eradicate eudra-ct: 2014-000180-41
37. 1498 ESBL-E
38. 2664 EVADE eudra-ct: 2015-001706-34 Phase 2

39. 2358 EXTEND eudra-ct: 2013-004619-31 Phase 3b/4
40. 3492 F2G eudra-ct: 2017-001290-17 Phase 2b
41. 1675 FREEDOM eudra-ct: 2012-000531-88 Phase 3b/4
42. 498 Fungiscope
43. 2986 FURI (SCY-078-301) eudra-ct: 2017-000381-29 Role: SI Phase 3
44. 2232 GMALL 08/2013 eudra-ct: 2013-003466-13 Phase 4
45. 541 HD17 für intermediäre Stadien eudra-ct: 2007-005920-34
46. 3305 HERACLES eudra-ct: 2017-002697-39
47. 3015 IBIS Role: LKP, PI
48. 564 IC43-201
49. 171 IDEA (Voriconazol) nicht vorhanden
50. 2823 IMBICO
51. 952 INTENSE 2008-006409-18
52. 392 Isavuconazole WSA-CS-003 eudra-ct: 2006-005003-33 Phase 3
53. 246 Isavuconazole WSA-CS-004 eudra-ct: 2006-003868-59 Phase 3
54. 247 Isavuconazole WSA-CS-008 eudra-ct: 2006-003951-18
55. 1782 KPUK-14-GenPOPPK
56. 1660 LCD-CDAD-10-07 (CUBIST) eudra-ct: 2012-000252-34
57. 1674 LFF571 eudra-ct: 2011-000947-26
58. 115 Maribavir eudra-ct: 2006-005692-18
59. 2375 MicroTrans
60. 2905 Minocin® 702 eudra-ct: 2016-002247-41
61. 2649 ML-3341-306 (Delafloxacin) eudra-ct: 2015-003026-14 Phase 3
62. 1547 MODIFY I eudra-ct: 2011-004590-90 Role: SI Phase 3
63. 1535 MODIFY II dra-ct: 2011-004590-90 Phase 3
64. 176 Moxifloxacinprophylaxe bei autologer SZT eudra-ct: 2005-003271-21
65. 2822 MSG-11
66. 1865 NanoMR
67. 3262 NIDIFF eudra-ct: 2017-004531-36
68. 3107 Online Registry for Chronic Pulmonary Aspergillosis (CPA) Infections: A CPAnet Initiative
69. 2564 ORCHID
70. 269 P05115 eudra-ct: 2007-003148-31 Phase 4
71. 826 P05520 eudra-ct: 2008-000235-18 Role: SI
72. 861 P05615 eudra-ct: 2008-006684-36 Role: SI
73. 1786 P06200 udra-ct: 2011-003938-14 Phase 3
74. 113 PAR-101 bei C.diff.-assoziierter Diarrhö eudra-ct: 2006-004291-12
75. 3523 PILGRIM
76. 1504 PIMDA
77. 999 PROGRESS-CAP
78. 2663 REJUVENATE eudra-ct: 2015-002726-39 Phase 2a
79. 3522 Ri-CoDIFy eudra-ct: 2017-001642-10 Phase 3
80. 2935 R-Net Prävalenz
81. 2415 SAATELLITE eudra-ct: 2014-001097-34 Phase 2
82. 2787 SAFEGUARD eudra-ct: 2016-000919-33
83. 2971 SAFEGUARD FP eudra-ct: 2016-002271-97 Phase 2a
84. 2595 SCY-078-202

85. 2056 SEPIA Role: LKP,SI
86. 3364 SHIELD
87. 2803 STRIVE eudra-ct: 2015-005599-51 Phase 2
88. 2587 Urinstudie
89. 1107 V-212-001 eudra-ct: 2010-020150-34 Phase 3
90. 1266 V-212-011 eudra-ct: 2010-023156-89 Phase 3
91. 173 Vosifi eudra-ct: 2004-000365-35
92. 1160 VP 20621-200 eudra-ct: 2010-020484-20 Phase 2
93. 1163 VP 26021-901

Publikationen

k.A.

Frankfurt 21.12.2020

Ort, Datum/City, date *Unterschrift/Signature*

Anhang: Erläuterungen

1. **Aktuelle Position seit**: CV Pflichtfeld: Angabe zum Beginn der aktuellen Funktion in der Organisation (dd.mm.yyyy).
2. **Publikationen**: CV Pflichtfeld: Liste der wichtigsten und aktuellsten Publikationen aufsteigend in chronologischer Reihenfolge; Empfehlung: max. 5 Angaben.
3. **Andere klinische Studien und Projekte**: Liste der wichtigsten und aktuellsten Studien und Projekte, die nicht in QualiPRO („Studien", „Anträge") eingegeben sind. Eingabe als Freitext bitte aufsteigend in chronologischer Reihenfolge unter Angabe von
    - Studientitel (dieser muß nicht vollständig sein, sollte aber die Indikation und Phase beinhalten, oder diese müssen ergänzt werden)
    - Indikation (falls nicht im Studientitel enthalten)
    - Phase (falls nicht im Studientitel enthalten)
    - EudraCT-Nr. (ggf.)
    - Beginn (mind. Jahresangabe) und
    - Ende der Studie (mind. Jahresangabe) und
    - Funktion in der Studie.
4. **Teilnahme an klinischen Studien (QualiPRO)**: CV Pflichtfeld: Eintrag erfolgte über das Menü "Anträge" in QualiPRO: "Automatische" und tabellarische Auflistung der Teilnahme an klinischen Studien, die in die Datenbank QualiPRO eingegeben sind, mit Detailangaben. Die Auflistung erfolgt nicht chronologisch, sondern gruppiert bzw. priorisiert nach Funktion des Mitarbeiters in der Studie. Das Datum entspricht in der Regel dem Datum des Beginns und/oder des Endes einer Studie gemäß Prüfplan/Sponsor. In Ausnahmen kann es sich bei dem Beginn um den ungefähren Beginn (Jahresangabe) handeln - falls das Datum nicht bekannt ist. Bei genauem Datum handelt es sich um den Beginn laut Prüfplan (oder in absteigender Reihenfolge: Genehmigung in Deutschland oder Initiierung in einem Prüfzentrum oder erster Patienteneinschluss in einem Prüfzentrum). Als Endzeitpunkt der Studie soll nicht das geplante Studienende eingetragen werden, sondern das Studienende, welches der Sponsor festlegt, i.d. Regel "letzter Patient, letzter Visit, letztes Prüfzentrum". In Ausnahmen kann es sich auch um das Rekrutierungsende in Zentren (o.ä.) handeln. Diese tab. Angaben müssen im Menü "Anträge" sorgfältig eingegeben und im Word-Dokument (CV) geprüft und ggf. geändert werden, bevor dieser unterzeichnet wird.

DEPARTMENT OF HEALTH & HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Rockville, MD 20857

December 13, 2021

Mr. Aaron Siri
Siri & Glimstad LLP
200 Park Avenue
Seventeenth Floor
New York, NY 10166

Sent via email: aaron@sirillp.com

Re: FDA FOIA Request 2021-5683; *Public Health and Medical Professionals for Transparency v. FDA*, 21-cv-01058-P

Dear Mr. Siri,

This is a partial response to the Freedom of Information Act (FOIA) request number **2021-5683** that is the subject of the Complaint filed in *Public Health and Medical Professionals for Transparency v. FDA*, 21-cv-01058, now pending in the U.S. District Court for the Northern District of Texas.

Enclosed are 2,890 pages of records, some of which contain redaction to prevent the disclosure of material exempt from the FOIA.

In addition to those 2,890 pages, please find enclosed three txt files from page 10 and one txt file from page 11 of the provided Index as you requested in prioritized item number 5.[1] We have also enclosed one xpt (SAS) file from page 13 and four xpt (SAS) files from page 14 of the Index.[2] Because we have assessed that there is no exempt material in these txt and xpt files, there have been no deletions to the txt or xpt files. Per your request, we have provided data files in their native format.

We have withheld portions of pages under FOIA Exemption (b)(4), 5 U.S.C. § 552(b)(4). That exemption permits the withholding of trade secrets and commercial or financial information that was obtained from a person outside the government and that is privileged or confidential.

[1] Plaintiff provided its priority list of records via two emails from you to Courtney Enlow at the Department of Justice on November 4, 2021.

[2] In your request for records listed on page 10 of the Index, you indicated that you were interested in obtaining "sample" SAS files. Although the files listed on page 10 and 11 all may appear to be SAS files, we have determined that none of the files listed on page 10 and 11 are SAS files. As indicated above, we processed three files from page 10 and one file from page 11 for this production because you requested a record from page 10. To accommodate your request for sample SAS files, we also processed one xpt (SAS) file that was listed on page 13 and four xpt (SAS) files that were listed on page 14 of the Index, even though you did not prioritize files from pages 13 and 14 of the Index.

We have withheld portions of pages under FOIA Exemption (b)(6), 5 U.S.C. § 552(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

Please direct any questions regarding this response to Courtney Enlow of the Department of Justice, at (202) 616-8467 or Courtney.D.Enlow@usdoj.gov.

Sincerely,

Beth Brockner Ryan
Chief, Access Litigation and Freedom of Information Branch
Division of Disclosure and Oversight Management
Office of Communication Outreach and Development
Center for Biologics Evaluation and Research

Enclosure(s)

2.5 CLINICAL OVERVIEW

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ABBREVIATIONS

Abbreviation	Definition
ACE-2	angiotensin-converting enzyme 2
ADR	adverse reaction
AE	adverse event
AESI	adverse event of special interest
BMI	body mass index
C4591001 Efficacy Final Analysis Interim CSR	Study C4591001 interim clinical study report including prespecified final analysis of efficacy and available immunogenicity and safety data up to data cutoff date of 14 November 2020
C4591001 6-Month Update Interim CSR	Study C4591001 interim clinical study report including updated efficacy, immunogenicity, and safety up to 6 months after Dose 2 up to data cutoff date of 13 March 2021
CBER	(US FDA) Center for Biologics Evaluation and Research
CDC	(US) Centers for Disease Control and Prevention
CDS	Core Data Sheet
CFR	case fatality rate
CHMP	Committee for Human Products for Medicinal Use
CMC	chemistry, manufacturing, and controls
CoV	Coronavirus
COVID-19	Coronavirus Disease 2019
CTA	Clinical Trial Application
DART	developmental and reproductive toxicity
DMC	(US Study C4591001) Data Monitoring Committee
ELISPOT	enzyme-linked immuno-spot
EMA	European Medicines Agency
EU	European Union
EUA	Emergency Use Application
FACS	fluorescence-activated cell sorting
FDA	(US) Food and Drug Administration
FIH	first-in-human
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GMFR	geometric mean-fold rise
GMT/GMC	geometric mean titer/concentration
HIV	human immunodeficiency virus
ICH	International Council on Harmonisation
ICU	intensive care unit
ID	intradermal(ly)
IFNγ	interferon-gamma
IL-2	interleukin-2
IL-4	interleukin-4
IM	intramuscular(ly)
IND	Investigational New Drug application
iPSP	initial Pediatric Study Plan
IRC	(US Study C4591001) Internal Review Committee

Abbreviation	Definition
IRR	illness rate ratio
LLN	lower limit of normal
LNP	lipid nanoparticle
LPX	lipoplex
MedDRA	Medical Dictionary for Regulatory Activities
MERS	Middle East respiratory syndrome
modRNA	nucleoside-modified messenger RNA
mRNA	messenger RNA
NAAT	nucleic acid amplification testing
NHP	non-human primate
NI	Non-inferiority
P2 S	SARS-CoV-2 full-length, P2 mutant, “heads up,” prefusion spike glycoprotein
PDCO	Paediatric Committee
PCR	polymerase chain reaction
PIP	Paediatric Investigational Plan
PSP	Pediatric Study Plan
PT	Preferred Term
RBD	receptor binding domain
RNA-LNP	RNA lipid nanoparticle
saRNA	self-amplifying messenger RNA
SRC	(German Study BNT162-01) Safety Review Committee
ssRNA	single-stranded RNA
SAE	serious adverse event
SARS	severe acute respiratory syndrome
SARS-CoV-2	SARS Coronavirus-2; virus causing the disease COVID-19
S glycoprotein, S	spike glycoprotein
SmPC	Summary of Product Characteristics
SMQ	Standard MedDRA query
SOC	System Organ Class
Th1/Th2	helper T cell type 1/type 2
UK	United Kingdom
uRNA	non-modified uridine containing mRNA
US	United States
USP	United States Pharmacopeia
VAE(R)D	vaccine-associated enhanced (respiratory) disease
VE	vaccine efficacy
WHO	World Health Organization

2.5. CLINICAL OVERVIEW

This Clinical Overview (CO) describes the clinical data for a prophylactic, RNA-based SARS-CoV-2 vaccine developed by BioNTech and Pfizer. Evidence is presented in this CO for the efficacy, immunogenicity, and safety and tolerability of the vaccine compared with placebo administered to healthy participants ≥12 years of age.

The pivotal data are derived from a single registrational study, Phase 1/2/3 Study C4591001, conducted under a United States (US) Investigational New Drug (IND) Application. Supporting data are presented from the first-in-human (FIH) dose-finding study, Phase 1/2 Study BNT162-01, conducted in Germany under a Clinical Trial Application (CTA). The clinical experience reflected in this CO represents approximately 44,000 study participants ≥16 years of age, including individuals with stable infections and common comorbidities that represent real-world population characteristics.

The proposed indication and dosing administration for BNT162b2 (30 μg) are:

- **Proposed indication**: Active immunization to prevent COVID-19 disease caused by SARS-CoV-2 virus, in individuals ≥16 years of age

- **Dosing administration**: single 0.3-mL intramuscular (IM) dose followed by a second 0.3-mL dose 3 weeks later

Efficacy analyses are event-driven in Study C4591001 Phase 2/3 participants ≥12 years of age. Prespecified analyses were conducted on 94 confirmed COVID-19 cases (interim analysis data cutoff date: 04 November 2020) and 170 confirmed cases (final analysis data cutoff date: 14 November 2020) reported in participants without evidence of past SARS-CoV-2 infection before or during the vaccination regimen. Updated analyses of 1165 confirmed cases in blinded placebo-controlled follow-up from Dose 1 to a data cutoff date of 13 March 2021 evaluated duration of protection.

Immunogenicity analyses of adults (18 to 85 years of age) in Study C4591001 include data up to 1 month after Dose 2 in Phase 2, and up to 6 months after Dose 2 in Phase 1.

Safety data are collected cumulatively in Study C4591001. Some participants ≥16 years of age have been unblinded to treatment assignment, therefore safety data are presented separately for blinded placebo-controlled and open-label periods. Key safety data in the CO include:

- **Blinded placebo-controlled period**: Dose 1 to 1 month after Dose 2 and to unblinding date:
  - Phase 1 participants randomized to BNT162b2 30 μg (to ~6 months after Dose 2)
  - Phase 2/3 participants ≥16 years of age including HIV+ subset (to ~5 months after Dose 2)

- **Open-label observational period**: from unblinding data to data cutoff date:
  - Phase 2/3 participants ≥16 years of age originally randomized to BNT162b2
  - Phase 2/3 participants ≥16 years of age originally randomized to placebo who then received BNT162b2 after being unblinded

- **Cumulative follow-up from Dose 1 to 6 months after Dose 2**: Phase 2/3 participants originally randomized to BNT162b2 (inclusive of blinded data and open-label data), comprised of at least 3000 in each adult age group (16 to 55 years of age, >55 years of age)

Supportive analyses from Study BNT162-01 are presented for immunogenicity data including T cell responses, and safety data including reactogenicity and adverse events (AEs), for adult participants in the Phase 1 portion of the study.

2.5.1. Product Development Rationale

2.5.1.1. Therapeutic Context

2.5.1.1.1. Disease or Condition

COVID-19 is caused by SARS-CoV-2, a zoonotic virus that first emerged as a human pathogen in China and has rapidly spread around the world by human to human transmission.

In December 2019, a pneumonia outbreak of unknown cause occurred in Wuhan, China. In January 2020, it became clear that a novel Coronavirus (2019-nCoV) was the underlying cause. In early January 2020, the genetic sequence of the 2019-nCoV became available to the World Health Organization (WHO) and public (MN908947.3), and the virus was categorized in the Betacoronavirus subfamily. By sequence analysis, the phylogenetic tree revealed a closer relationship to severe acute respiratory syndrome (SARS) virus isolates than to other coronaviruses that infect humans, including the Middle East respiratory syndrome (MERS) coronavirus.[1,2]

SARS-CoV-2 infections and the resulting disease COVID-19 have spread globally, and on 11 March 2020 the WHO characterized the COVID-19 outbreak as a pandemic. As of April 2021, there have been >145 million globally confirmed COVID-19 cases and >3 million deaths, with 192 countries/regions affected; among these, the US leads with the highest number of reported cases at >31 million confirmed cases and >570,000 deaths.[3]

At the time of this submission, the ongoing pandemic remains a significant challenge to public health and economic stability worldwide, for which for a licensed prophylactic vaccine is a necessary and critical mitigation.

2.5.1.1.2. Clinical Features and Epidemiology of COVID-19

COVID-19 presentation is generally with cough and fever, with chest radiography showing ground-glass opacities or patchy shadowing.[4] However, many patients present without fever or radiographic changes, and infections may be asymptomatic which is relevant to controlling transmission. For symptomatic patients, disease progression may lead to acute respiratory distress syndrome requiring ventilation, subsequent multi-organ failure, and death.[4]

Common symptoms in hospitalized patients (in order of highest to lowest frequency) include fever, dry cough, shortness of breath, fatigue, myalgias, nausea/vomiting or diarrhea, headache, weakness, and rhinorrhea.[4] Anosmia (loss of smell) or ageusia (loss of taste) may be the sole presenting symptom in approximately 3% of individuals who have COVID-19.[4]

The US Centers for Disease Control and Prevention (CDC) defined COVID-19 symptoms as including 1 or more of the following:[5]

- Fever
- New or increased cough
- New or increased shortness of breath
- Chills
- New or increased muscle pain
- New loss of taste or smell
- Sore throat
- Diarrhea
- Vomiting
- Fatigue
- Headache
- Nasal congestion or runny nose
- Nausea

All ages may present with the disease, but notably, case fatality rates (CFR) are elevated in persons >60 years of age.[6] Comorbidities are also associated with increased CFR, including cardiovascular disease, diabetes, hypertension, and chronic respiratory disease.[7] Healthcare workers are over-represented among COVID-19 patients due to occupational exposure to infected patients.[7]

2.5.1.2. Vaccine Clinical Development Program

2.5.1.2.1. Rationale for Development

2.5.1.2.1.1. Current Therapies

Clinical management of COVID-19 includes a variety of therapies, which are primarily recommended for use in a hospitalized or clinical trial setting, such as:[8]

- Severe disease or critical care hospital setting
  - dexamethasone (corticosteroid)
  - tocilizumab (targeted immunotherapy agent)
  - remdesivir (antiviral agent)
  - baricitinib (JAK inhibitor) in combination with remdesivir
- Ambulatory care setting
  - casirivimab and imdevimab (monoclonal antibodies)
  - bamlanivimab (monoclonal antibody)
- Clinical trial setting
  - convalescent plasma
  - famatodine (H2 blocker)
  - ivermectin (anti-parasitic).

Currently available therapies have different benefit-risk considerations depending on the stage of illness and disease manifestations.[4,8] While care for individuals who have COVID-19 has improved with clinical experience, there remains an urgent and unmet need for a licensed prophylactic vaccine during the ongoing pandemic.

2.5.1.2.1.2. BNT162b2 Development

Pfizer and BioNTech developed an investigational vaccine that targets SARS-CoV-2, intended to prevent COVID-19, for which BioNTech initiated a FIH study in April 2020 in Germany (BNT162-01) and Pfizer initiated a Phase 1/2/3 study (C4591001) shortly afterwards in the US which expanded to include global sites upon initiation of the Phase 2/3 part of the study. Additional information on Study BNT162-01 is provided in Section 2.5.1.2.3.2.1, and on Study C4591001 is provided in Section 2.5.1.2.3.2.2.

The vaccine is based on SARS-CoV-2 spike glycoprotein (S) antigens encoded in RNA formulated in lipid nanoparticles (LNPs) and is referred to as BNT162b2 (BioNTech code number BNT162, Pfizer code number PF-07302048). The structural elements of the vector backbones of BNT162 vaccines are optimized for prolonged and strong translation of the antigen-encoding RNA. The potency of RNA vaccines is further optimized by encapsulation of the RNA into LNPs, which protect the RNA from degradation by RNAses and enable transfection of host cells after IM delivery.

Development of RNA-based vaccines encoding viral antigens provides significant advantages over more traditional vaccine approaches:

- RNA-based vaccines do not carry risks associated with infection.
- RNA-based vaccines can mimic antigen expression during natural infection by directing expression of a pathogen antigen with high precision and flexibility of antigen design.
- RNA occurs naturally in the body, is metabolized and eliminated by the body's natural mechanisms, does not integrate into the genome, and is transiently expressed.
- RNA-based vaccines are manufactured by a cell-free in vitro transcription process, which allows easy and rapid production and the prospect of producing high numbers of vaccine doses within a shorter time period than could be traditionally achieved with conventional vaccine approaches. This capability is pivotal to enable the most effective response in outbreak scenarios and makes RNA-based vaccines an attractive platform to achieve a timely and effective response to emerging infectious disease threats.

BioNTech is a pioneer in the field of RNA technology. The core innovation is based on in vivo delivery of a pharmacologically optimized, antigen-encoding RNA to induce robust neutralizing antibodies and a concomitant T cell response to achieve protective immunization with minimal vaccine doses.[9,10,11]

2.5.1.2.2. Vaccine Product Information

BioNTech has developed multiple RNA-LNP platforms, including nucleoside-modified RNA (modRNA) which has blunted innate immune sensor activating capacity and thus augmented antigen expression. Each modRNA candidate encodes either a P2 mutant S (P2 S) or the trimerized receptor binding domain (RBD) of S. Each candidate is given a V number to indicate the specific version of the optimized insert genomic sequence. BNT162 vaccine candidates tested in German Study BNT162-01 and pivotal Study C4591001 are:

- **BNT162b1** (RBP020.3) modRNA encoding RBD (V5)
- **BNT162b2** (RBP020.2) modRNA encoding P2 S (V9)

Vaccine candidates based on other RNA platforms that were tested in Study BNT162-01 but were not tested in pivotal Study C4591001 are not discussed further herein.

2.5.1.2.2.1. Characterization of the Vaccine Product

Coronavirus Spike Glycoprotein as Vaccine Target

Coronaviruses are a family of (+) ssRNA enveloped viruses that encode four structural proteins. Among these four structural proteins, S is the key target antigen for vaccine development. The vaccine candidates used for clinical testing featured the following vaccine antigens:

- Secreted, trimerized variant RBD of SARS-CoV-2 S (V5)[12]

- Membrane-anchored, full-length S with 2 point mutations within central helix domain (V9). Mutation of these 2 amino acids to proline locks S in an antigenically preferred prefusion conformation.[13,14]

Lipid Nanoparticle Formulation

Vaccine candidates are encapsulated into LNPs, which enable transfection of the RNA into host cells after IM injection. The same LNP formulation is used for all vaccine candidates.

The LNPs are composed of four different lipids in a defined ratio. During mixing of the RNA and the dissolved lipids, the lipids form the nanoparticles encapsulating the RNA. After injection, the LNPs are taken up by the cells, and the RNA is released into the cytosol. In the cytosol, the RNA is translated into the encoded viral protein. The encoded antigen induces an adaptive immune response. The antigen may be incorporated into cellular membranes (P2 S) or secreted into the extracellular environment (RBD) and induces an adaptive immune response. As S is the antigen that recognizes the host cell receptor and enables infection of the host cells, it is a key target of virus neutralizing antibodies. Further, as RNA-expressed S is being degraded intracellularly, the resulting peptides can be presented at the cell surface, triggering a specific T cell-mediated immune response with activity against the virus.

Additional details on the product formulation are provided in Section 2.5.2.1.

2.5.1.2.3. Vaccine Development Program

2.5.1.2.3.1. Nonclinical Studies

Key nonclinical evaluations of BNT162b2 included pharmacology (mouse immunogenicity studies, non-human primate [NHP] immunogenicity and challenge studies) and toxicity (two Good Laboratory Practice [GLP] rat repeat-dose toxicity studies) in vitro and in vivo. A developmental and reproductive toxicity (DART) study was completed in rats.

Nonclinical studies in mice and NHP demonstrate that BNT162b2 elicits a rapid antibody response with measurable SARS-CoV-2 neutralizing titers after a single dose and substantial increases in titers after a second dose that exceed titers in sera from SARS-CoV- 2/ COVID-19-recovered individuals. A Th1-dominant T cell response was evident in both mice and NHPs. S-specific CD8+ T cell responses were also detectable in BNT162b2-immunized animals. The strongly Th1-biased CD4+ T cell response and interferon-γ (IFNγ)+ CD8+ T cell response after immunization with BNT162b2 is a pattern favored for vaccine safety and efficacy and provided added reassurance for clinical safety.[15] In A SARS-CoV-2 rhesus challenge model, BNT162b2 provided complete protection from the presence of detectable viral RNA in the lungs compared to the saline control with no clinical, radiological, or histopathological evidence of vaccine-elicited disease enhancement.[16]

Administration of BNT162b2 by IM injection to male and female Wistar Han rats once every week, for a total of 3 weekly cycles of dosing, was tolerated without evidence of systemic toxicity in GLP-compliant repeat-dose toxicity studies.

In a DART study, 0.06 mL of a vaccine formulation containing the same quantity of nucleoside-modified mRNA (30 µg) and other ingredients included in a single human dose of BNT162b2 was administered to female rats by the IM route on four occasions: 21 and 14 days prior to mating, and on gestation days 9 and 20. No vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported in the study.

In summary, the nonclinical package summarized above supports BNT162b2 administered twice by IM injection at a dose of 30 µg RNA. Additional details of nonclinical studies are provided in Module 2.4.

2.5.1.2.3.2. Clinical Studies

2.5.1.2.3.2.1. Phase 1/2 Study BNT162-01

Study BNT162-01 is the ongoing, FIH, Phase 1 dose level-finding study, in which healthy younger adults (18 to 55 years of age) and older adults (56 to 85 years of age) all receive active vaccine. This study is evaluating the safety and immunogenicity of several different candidate vaccines at various dose levels. The available Phase 1 safety and immunogenicity data for younger and older adults are reported in this submission.

Multiple vaccine candidates are being evaluated in this study. For each vaccine candidate, participants received escalating dose levels (N=12 per dose level) with progression to subsequent dose levels based on recommendation from a Sponsor Safety Review Committee (SRC).

The study design is detailed in the Module 5.3.5.1 BNT162-01 Protocol.

Study Eligibility Criteria

The BNT162-01 study population includes male and female adult participants deemed healthy and without COVID-19 symptoms or evidence of SARS-CoV-2 infection within 30 days prior to entering the study. Inclusion criteria allowed for preexisting stable disease defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks prior to enrollment. Individuals with medical conditions considered to possibly confound evaluation of vaccine safety or immunogenicity were excluded.

Phase 1

In Study BNT162-01, vaccine candidates from the modRNA platform, administered IM in the upper arm in a two-dose regimen separated by approximately 21 days, were:

- **BNT162b1** (dose levels: 1, 3, 10, 20, 30, 50, 60 µg)
- **BNT162b2** (dose levels: 1, 3, 10, 20, 30, 50, 60 µg)

For each vaccine candidate, participants received escalating dose levels (N=12 per dose level) with progression to subsequent dose levels based on recommendation from a Sponsor Safety Review Committee (SRC). Note: the SRC recommended that a second dose of BNT162b1 at 60 µg not be administered due to reactogenicity after the first dose. Note that at the time of BNT162-01 Interim CSR preparation, data for BNT162b2 dose levels of 50 µg and 60 µg were not available.

Dosing with other candidates on different platforms, BNT162a1 (uRNA) and BNT162c2 (saRNA), is not discussed as it is not relevant to progression with modRNA candidates.

Safety and immunogenicity data (including T cell immune response data) from the Phase 1 part of Study BNT162-01 are summarized in this submission in support of the larger dataset from the Phase 1/2/3 registration Study C4591001.

2.5.1.2.3.2.2. Phase 1/2/3 Study C4591001

Study C4591001 is the ongoing, randomized, placebo-controlled, Phase 1/2/3 registration study. It was started as a Phase 1/2 study in adults in the US, was then amended to expand the study to a global Phase 2/3 study planning to enroll enough participants to accrue sufficient COVID-19 cases to conduct a timely efficacy assessment; amended to include older adolescents 16 to 17 years of age, then later amended to include younger adolescents 12 to 15 years of age.

The study design is detailed in Module 5.3.5.1 C4591001 Protocol.

Study Eligibility Criteria

In Phase 1, two age groups were studied separately, younger participants (18 to 55 years of age) and older participants (65 to 85 years of age). The study population includes male and

female participants deemed healthy as determined by medical history, physical examination (if required), and clinical judgment of the investigator to be eligible for inclusion in the study. Exclusions included screened individuals with high risk of exposure to SARS-CoV-2 infection due to exposure in the workplace and/or medical conditions that represent risk factors, clinically important prior illness or laboratory abnormalities, serological evidence of prior SARS-CoV-2 infection or current SARS-CoV-2 infection as measured by polymerase chain reaction (PCR).

In Phase 2/3, participants were enrolled with stratification of younger adults (18 to 55 years of age) and older adults (>55 years of age) to achieve approximately 40% enrollment in the older adult group. Additional adolescents were added later by a protocol amendment: older adolescents 16 to 17 years of age are included in the younger adult stratum (ie, 16 to 55 years of age), and younger adolescents 12 to 15 years of age were analyzed as a separate age stratum. Eligibility in Phase 2/3 included higher risk for acquiring COVID-19 in the investigator's judgment, due to medical conditions or exposure, such as:

- Chronic condition (eg, hypertension; diabetes; asthma; pulmonary, liver, or kidney disease)
- Autoimmune disease requiring therapeutic intervention (or history of)
- Chronic HIV, HCV, or HBV infection that is stable and controlled
- Vaping or smoking (or history of smoking within the prior year)
- Resident in a long-term facility
- Occupation with high risk of SARS-CoV-2 exposure (eg, healthcare, emergency response)

Phase 1

The Phase 1 part of the study, randomized participants 4:1 to receive active vaccine or placebo. The vaccines candidates, administered IM in the upper arm in a two-dose regimen separated by approximately 21 days, were:

- **BNT162b1** (dose levels: 10, 20, 30, 100 µg)
- **BNT162b2** (dose levels: 10, 20, 30 µg)

Phase 1 of Study C4591001 was conducted in the US. For each of the two vaccine candidates evaluated, younger participants received escalating dose levels (N=15 per dose level, 4:1 randomization ratio between vaccine and placebo) with progression to subsequent dose levels and the older age group (N=15 per dose level, 4:1 randomization ratio between vaccine and placebo) based on recommendation from an Internal Review Committee (IRC). Note: the IRC recommended that a second dose of BNT162b1 at 100 µg not be administered and discontinued due to reactogenicity after the first dose in the younger age group. Participants in this group of younger adults instead received a second dose of BNT162b1 at the 10 µg dose level approximately 3 months after Dose 1, and the 100 µg dose level was discontinued (ie, not administered to older adults receiving BNT162b1).

The Sponsor/agent study team was not blinded in this part of the study. Participants who enrolled in Phase 1 are followed for cases of COVID-19 but do not contribute to the efficacy assessment. Safety follow-up will continue for at least 2 years and/or end of study. Based upon review of safety and immunogenicity from the Phase 1 part of the study, the final

candidate and dose level was selected as BNT162b2 at 30 µg given twice 21 days apart. Details are provided in Section 2.5.1.2.5.

Booster Evaluation

Phase 1 participants who were randomized to either BNT162b1 or BNT162b2 at dose levels of 10, 20, or 30 µg are being offered booster vaccination with BNT162b2 at 30 µg, approximately 6 to 12 months after their second dose of BNT162b1 or BNT162b2. This provides an early assessment of the safety and immunogenicity associated with a third vaccine dose. Data from Phase 1 participants who receive a booster are not included in this submission and will be reported at a later time.

Phase 2

Phase 2/3 of Study C4591001 commenced with the selected vaccine candidate and dose level administered to participants who were randomized 1:1 to receive vaccine or placebo.

Phase 2 was conducted in the US. The Phase 2 portion of the study evaluated reactogenicity and immunogenicity for 360 participants 18 to 85 years of age enrolled into the study when the Phase 2/3 part commenced, balancing younger (≤55 years of age) and older (>55 years of age) strata within each group. Phase 2 participants in this blinded part of the study also contribute to the overall efficacy and safety assessments in the Phase 3 portion of the study.

Phase 3

Phase 3 (which is ongoing) included planned interim analyses of the first primary efficacy endpoint, ongoing efficacy and safety evaluations including reactogenicity assessment in a subset of participants, and exploratory vaccine immunogenicity evaluation in a subset of participants. Phase 3 is being conducted at sites in the US, Brazil, Argentina, Turkey, South Africa, and Germany. Participants were stratified by age group as previously described. The final efficacy analysis was conducted when at least the prespecified total number of 164 efficacy events accrued. Safety and long-term persistence of efficacy follow-up will continue for at least 2 years and/or end of study. Safety and efficacy analyses included the 360 participants who were analyzed for Phase 2.

Booster and Variant Strain Evaluation

For further evaluation of booster effects and protection against emerging SARS-CoV-2 variants of concern, a subset of existing Phase 3 participants 18 to 55 years of age will be randomized 1:1 to receive either receive a third dose of BNT162b2 or a third dose of prototype based upon the South African variant, BNT162b2$_{SA}$, approximately 5 to 7 months after their second dose of BNT162b2. An additional subset of existing Phase 3 participants 18 to 55 years of age will be enrolled to receive a third and fourth dose of BNT162b2$_{SA}$. A new cohort will be recruited who are COVID-19 vaccine-naïve (ie, have not received BNT162b2) and have not experienced COVID-19 to receive BNT162b2$_{SA}$ as a two-dose series 21 days apart. Data from Phase 3 participants who receive a booster and/or BNT162b2$_{SA}$ are not included in this submission and will be reported at a later time.

Unblinding Considerations

Unblinding to randomized treatment assignment has begun for participants ≥16 years of age in the study, with respect to the participants, Sponsor, and site personnel. This is subsequent to authorizations/approvals granted in the US and other regions starting in December 2020 (refer to Section 2.5.1.3).

Individuals 16 years of age or older have been unblinded at such time that they become locally eligible and wish to know their treatment assignment to confirm prior vaccination with BNT162b2 (if randomized to this group), or to receive BNT162b2 (if randomized to placebo). Unblinded recipients originally randomized to BNT162b2 continue to be followed in an open-label (ie, observational) manner. Unblinded recipients originally randomized to placebo are offered BNT162b2 vaccination and thereafter followed in an open-label manner.

Participants randomized to placebo who became eligible for vaccination with BNT162b2 (or another COVID-19 vaccine) had the opportunity to receive BNT162b2 in a phased manner as part of the study (no later than at the approximate time participants in Phase 2/3 reach Visit 4). The investigator ensured the participant met at least one of the recommendation criteria. Any participant who originally received placebo and subsequently received BNT162b2 was moved to a new visit schedule to receive both doses of BNT162b2 at each of two additional vaccination visits (Visits 101 and 102).

Sponsor and site personnel who are responsible for the ongoing conduct of the study remain blinded to the data from participants whose treatment assignment has not been disclosed in the ongoing study (ie, not unblinded), with regard to individual participants' randomization. Safety evaluation for these participants by the study team remains blinded until a decision is made to unblind the entire study. A separate (from study conduct) unblinded submissions team is responsible for regulatory submissions.

All participants continue to be expected to remain in study follow-up for a maximum of approximately 2 years after Dose 2 of randomized study intervention.

2.5.1.2.3.2.3. Planned Studies

The following studies (or additional analyses from ongoing studies) are planned in 2021:

- Pediatric studies in children <12 years of age: C4591007
- Maternal immunization during pregnancy: C4591015
- Immunocompromised adults, children <18 years of age: BNT162-01, C4591024
- Lot consistency: C4591017
- Lyophilized product bridging: C4591020
- Process 1 and Process 2 comparison: C4591001
- Booster vaccination(s) with BNT162b2: C4591001
- SARS-CoV-2 variant strain change ($BNT162b2_{SA}$): C4591001

2.5.1.2.4. Proposed Indication

The proposed indication for BNT162b2 (30 µg) is:

- Active immunization to prevent COVID-19 disease caused by SARS-CoV-2 virus, in individuals ≥16 years of age.

Supplemental applications are planned for (b) (4) (b) (4), pending conclusion of the appropriate studies/analyses and Agency feedback.

2.5.1.2.5. Rationale for Candidate and Dose Selection

BioNTech has evaluated multiple RNA-LNP platforms, including nucleoside-modified RNA (modRNA) which has blunted innate immune sensor activating capacity and thus augmented antigen expression. Two modRNA candidates were evaluated in the Phase 1 portions of Studies BNT162-01 and C4591001. The final candidate and dose level (BNT162b2 at 30 µg) was selected following review of immunogenicity and safety data from the Phase 1 part of Study C4591001 and available nonclinical data.

The final vaccine candidate selection for clinical development in Phase 2/3 was based on:

- NHP challenge data; BNT162b2 led to earlier virus clearance, no evidence of virus in lung
- Favorable reactogenicity for BNT162b2 in both younger and older Phase 1 participants
- Robust immunogenicity in both younger and older Phase 1 participants at 30 µg dose level.

BNT162b2 at 30 µg proceeded into the Phase 2/3 portion of Study C4591001 because this dose and construct provided the optimum combination of a favorable reactogenicity profile and a robust immune response, likely to afford protection against COVID-19 in younger and older age groups.

2.5.1.3. Regulatory Status

BNT162b2 has received temporary authorizations for emergency supply in 28 countries and conditional marketing authorizations in 39 countries globally. The name of the product supplied under emergency/temporary use authorization for all applicable regions is Pfizer-BioNTech COVID-19 Vaccine. The name of the product supplied under conditional marketing authorization for all applicable regions is COMIRNATY [COVID-19 mRNA Vaccine (nucleoside modified)].

United States

In the US, the vaccine is in clinical development under an Investigative New Drug (IND) application, BB-IND 19,736. Fast Track Designation was granted on 07 July 2020 for individuals ≥18 years of age. An EUA application was filed to the US Food and Drug Administration (FDA) on 20 November 2020 and the product was authorized for emergency use in the US on 11 December 2020 for individuals ≥16 years of age (EUA 27034). An amendment to the EUA was submitted 09 April 2021 to support emergency use in participants 12 to 15 years of age.

The agreed Pediatric Study Plan (PSP) was submitted to the FDA on 02 April 2021 and was agreed by the FDA on 23 April 2021.

European Union

A rolling Marketing Authorization Application (MAA) was initiated on 05 October 2020 with nonclinical data, followed by Module 3 documents submitted on 05 November 2020, and completed with submission of clinical modules on 07 December 2020. Conditional marketing approval was granted by the European Medicines Agency (EMA) on 21 December 2020 for individuals ≥16 years of age. A Type II Variation to support use individuals ≥12 years of age is planned to be submitted to EMA in second quarter 2021.

A Paediatric Investigational Plan (PIP) was submitted to the Paediatric Committee (PDCO) on 21 September 2020. An agreed PIP decision was received 27 November 2020. A PIP modification request was submitted to PDCO on 24 March 2021 and was agreed by PDCO on 21 April 2021.

Rest of World

Marketing Authorization Applications were initiated beginning in October 2020 and have been approved in many countries globally including Switzerland, Japan, Australia, New Zealand and Brazil. Requests for temporary authorization for emergency supply have been filed and approved in many countries globally under emergency or temporary use authorization procedures or special import procedures beginning in November 2020 (including the UK and Canada). The World Health Organization (WHO) issued a positive opinion on the Emergency Use Listing of COMIRNATY on 31 December 2021.

2.5.1.4. Ethical Considerations

All studies in the clinical development program were conducted in compliance with the ethical principles originating in or derived from the Declaration of Helsinki and in compliance with all International Council on Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines. They were designed, performed, and analyzed in accordance with all applicable regulations, laws, and guidelines in effect at the time they were conducted from the US FDA, EU Directive 2001/20/EC, and local regulatory agencies in countries where the study was conducted. The study design reflects recommendations from local review boards/committees, and other local regulatory authorities.

The pivotal Phase 1/2/3 Study C4591001 was conducted at sites in the US, Brazil, Argentina, Turkey, South Africa, and Germany; the majority of participants were enrolled at sites in the US (refer to Section 2.5.5.5.1). The supporting Phase 1/2 Study BNT162-01 was conducted at sites in Germany.

2.5.2. Overview of Biopharmaceutics

2.5.2.1. Formulation Development

The BNT162b2 vaccine is provided in a multi-dose vial that contains a frozen concentrated solution that is preservative-free and must be thawed and diluted prior to administration. The

BNT162b2 concentrate must be diluted in its original vial using 0.9% Sodium Chloride Injection, USP, resulting in an off-white suspension. The 0.9% Sodium Chloride Injection, USP is not packaged with the vaccine and must be sourced separately.

The vaccine is administered IM as a series of two 30-µg doses of the diluted vaccine solution (0.3 mL each) according to the following schedule: a single 0.3-mL dose followed by a second 0.3-mL dose 21 days later.

Details of formulation development and storage conditions are provided in Module 3.

Manufacturing Process

The scale of BNT162b2 manufacturing has been increased to support future supply. The safety and immunogenicity of prophylactic BNT162b2 in Study C4591001 participants vaccinated with material generated using the existing manufacturing process (Process 1) and with material from lots generated using the manufacturing process supporting increased supply (Process 2) is planned to be evaluated (as noted in in Section 2.5.1.2.3.2.3).

2.5.2.2. Biopharmaceutical Studies

Bioavailability and bioequivalence assessments are not relevant to vaccine antigenicity and have not been measured.

The major pharmacodynamic effect of a vaccine, unlike a drug, is to elicit an immune response to the antigens included in the vaccine. Vaccine induced activation of antigen-presenting cells takes place at the site of injection (ie, muscle) which is rapidly followed by antigen-presenting cell migration via lymphatic vessels towards the draining lymph node where vaccine antigens activate specific B and T cells. There is no specific vaccine antigen blood level required to elicit the immune response.

2.5.2.3. Bioanalytical and Analytical Methods Used in Human Studies

Information on assays used to assess SARS-CoV-2 infection and immune response is in Module 2.7.1. Only validated (PCR and neutralization immunoassay) or qualified (Luminex immunoassay) methods were used.

2.5.3. Overview of Clinical Pharmacology

Pharmacokinetic studies are not usually required for vaccines. Measurement of the plasma concentration of the vaccine over time is not feasible.

2.5.4. Overview of Efficacy (Including Immunogenicity)

Efficacy was evaluated in Phase 2/3 of pivotal study C4591001; the methods for evaluation of efficacy are provided in Section 2.5.4.1 and results are in Section 2.5.4.3.

Immunogenicity was evaluated in Phase 1 of Study BNT162-01 and in all phases of Study C4591001. The methods for evaluation of immunogenicity are provided in Section 2.5.4.2, and results are provided in Section 2.5.4.4. Phase 3 immunogenicity analyses are planned to be completed at a later time and are not included in this submission.

Details of efficacy and immunogenicity analysis methods in Study C4591001 are provided in the Module 5.3.5.1 C4591001 Protocol and SAP, and for Study BNT162-01 are provided in the Module 5.3.5.1 BNT162-01 Protocol and SAP.

2.5.4.1. Efficacy Endpoints and Analysis Methods

Methods and validation of the PCR test for efficacy analyses are provided in Module 2.7.1. Details of efficacy evaluations are provided in Module 2.7.3 and summarized below. Statistical analysis methods are summarized in Section 2.5.4.1.2.

2.5.4.1.1. Efficacy Endpoints in Study C4591001

Efficacy was assessed based on confirmed cases of COVID-19, where the case onset date was the date that symptoms were first experienced by the participant and the cases met evaluable criteria as summarized below.

2.5.4.1.1.1. Primary Efficacy Endpoints

Study C4591001 is the pivotal (and only) efficacy study. The primary efficacy endpoints in the Phase 3 part of the study were:

- **First primary endpoint**: COVID-19 incidence per 1000 person-years of follow-up in participants without serological or virological evidence of past SARS-CoV-2 infection before and during the vaccination regimen – cases confirmed ≥7 days after Dose 2

- **Second primary endpoint**: COVID-19 incidence per 1000 person-years of follow-up in participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen – cases confirmed ≥7 days after Dose 2.

2.5.4.1.1.2. Secondary Efficacy Endpoints

Study C4591001 has secondary endpoints based on different approaches to COVID-19 case evaluation criteria as follows:

- **COVID-19 confirmed at least 14 days after Dose 2**: COVID-19 incidence per 1000 person-years of follow-up in participants either (1) without or (2) with or without serological or virological evidence of past SARS-CoV-2 infection before and during the vaccination regimen – cases confirmed ≥14 days after Dose 2

- **Severe COVID-19**: incidence per 1000 person-years of follow-up in participants either (1) without or (2) with or without evidence of past SARS-CoV-2 infection before and during the vaccination regimen – cases confirmed either (1) ≥7 days after Dose 2 or (2) ≥14 days after Dose 2

- **CDC-defined COVID-19**: incidence per 1000 person-years of follow-up in participants either (1) without or (2) with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen – cases confirmed either (1) ≥7 days after Dose 2 or (2) ≥14 days after Dose 2.

2.5.4.1.1.3. COVID-19 Case Determination

Participants who developed any potential COVID-19 symptoms listed in the protocol were to contact the site immediately and if confirmed to participate in an in-person or telehealth visit as soon as possible (optimally within 3 days of symptom onset, and at the latest 4 days after symptom resolution). At the visit (or prior to the visit, if a participant utilized a self-swab as permitted per protocol), investigators were to collect clinical information and results from local standard-of-care tests sufficient to confirm a COVID-19 diagnosis.

Investigators were to obtain a nasal swab (mid-turbinate) for testing at a central laboratory using a validated reverse transcription–polymerase chain reaction (RT-PCR) test (Cepheid; EUA200047/A001) to detect SARS-CoV-2. If the evaluation was conducted by telehealth, the participant was to self-collect a nasal swab and ship for assessment at the central laboratory. A local nucleic acid amplification test (NAAT) result was only acceptable if it met protocol-specified criteria and if a central laboratory result was not available, in which case a local NAAT result could be used if obtained using one of the following assays:

- Cepheid Xpert Xpress SARS-CoV-2
- Roche cobas SARS-CoV-2 real-time RT-PCR test (EUA200009/A001)
- Abbott Molecular/RealTime SARS-CoV-2 assay (EUA200023/A001).

Evidence of prior SARS-CoV-2 infection were determined by virological testing via NAAT on mid-turbinate swab and serological testing for SARS-CoV-2 N-binding antibodies.

Case Definitions

COVID-19 cases (defined per FDA guidance)[17] were based on SARS-CoV-2 positive test result per central laboratory or local testing facility (using an acceptable test per protocol and if no central laboratory result was available) and presence of <u>at least 1 of the following</u>:

- Fever
- New or increased cough
- New or increased shortness of breath
- Chills
- New or increased muscle pain
- New loss of taste or smell
- Sore throat
- Diarrhea
- Vomiting

CDC criteria-defined COVID-19 cases could include the following <u>additional</u> symptoms:

- Fatigue
- Headache
- Nasal congestion or runny nose
- Nausea

Severe COVID-19 cases (defined per FDA guidance)[17] included presence of at least 1 of the following:

- Clinical signs at rest indicative of severe systemic illness:
  - Respiratory rate ≥30 breaths per minute
  - Heart rate ≥125 beats per minute
  - SpO_2 ≤93% on room air at sea level or PaO_2/FiO_2 <300 mm Hg
- Respiratory failure:
  - needing high-flow oxygen
  - noninvasive ventilation
  - mechanical ventilation
  - ECMO
- Evidence of shock:
  - Systolic blood pressure <90 mm Hg
  - Diastolic blood pressure <60 mm Hg
  - Requiring vasopressors
- Significant acute renal, hepatic, or neurologic dysfunction
- Admission to an intensive care unit (ICU)
- Death

Efficacy analysis for severe COVID-19 cases was also conducted using the CDC definition of severe COVID-19 (hospitalization, admission to the ICU, intubation or mechanical ventilation, or death).[18]

2.5.4.1.2. Efficacy Analysis Methods in Study C4591001

The statistical analyses of efficacy data presented in this CO are from Study C4591001 and were based on the evaluable efficacy and all-available populations.

2.5.4.1.2.1. Sample Size Determination

For Phase 1: the study sample size was not based on any statistical hypothesis testing. Efficacy was not evaluated in Phase 1.

For Phase 2/3: the sample size assumed a true VE of 60% after the second dose of study intervention, for which a total of approximately 164 first confirmed COVID-19 illness cases would provide approximately 90% power. This would be achieved with 17,600 evaluable participants per group (or 21,999 vaccine recipients randomized in a 1:1 ratio with placebo) for a total sample size of 43,998. This assumed a 1.3% illness rate per year in the placebo group, accrual of 164 primary endpoint cases within 6 months, and 20% of the participants being non-evaluable or having serological evidence of prior infection with SARS-CoV-2 (potentially making them immune to further infection).

2.5.4.1.2.2. Efficacy Analysis Methods

The statistical analyses of efficacy data from Study C4591001 were based on the evaluable efficacy populations and all-available efficacy populations (described in Module 2.7.3).

Interim Analysis

During Phase 2/3, interim analyses were pre-specified in the protocol to be conducted after accrual of at least 62, 92, and 120 evaluable COVID-19 cases, where overwhelming efficacy could be declared if the primary endpoint was met with a posterior probability that the true VE is >30% (ie, Pr[VE >30%|data] >99.5% at an interim analysis or >98.6% at the final analysis). The success threshold for each interim analysis was calibrated to protect overall type I error at 2.5%. Futility was also assessed, and the study could be stopped for lack of benefit if the predicted probability of demonstrating vaccine efficacy at the final analysis was <5% at any of the first 2 planned interim analyses. Efficacy and futility boundaries were applied in a nonbinding way. The calculation of posterior probability and the credible interval were adjusted for surveillance time. For subgroup analyses of the primary efficacy endpoint, a 2-sided 95% confidence interval (CI) was calculated.

VE is defined as 100% × (1 – IRR), where illness rate ratio (IRR) is calculated as the ratio of first confirmed COVID-19 illness rate in the vaccine group to the corresponding illness rate in the placebo group. VE is demonstrated if there is convincing evidence (ie, posterior probability greater than 99.5% at an interim analysis or greater than 98.6% at the final analysis) that the true VE of BNT162b2 is >30% using a beta-binomial model, where VE represents efficacy for prophylactic BNT162b2 against confirmed COVID-19 in participants without evidence of past SARS-CoV-2 infection before and during the vaccination regimen. Participants with positive or unknown NAAT results at any illness visit prior to 7 days after Dose 2 were not included in the evaluation for VE. Cases were counted from 7 days after Dose 2.

Interim analysis was performed for the first primary efficacy endpoint only. Other efficacy data analyzed for the interim analysis were summarized with descriptive summary statistics, including COVID-19 case counts in the BNT162b2 and placebo groups on the basis of:

- evidence of prior SARS-CoV-2 infection at baseline per NAAT or N-antigen binding assay
- demographic subgroup (ie, age, sex, race, ethnicity, country)
- COVID-19 cases meeting protocol criteria as severe after the first and second doses.

Overwhelming efficacy success criteria on the first primary efficacy endpoint were met at the first planned interim analysis of 94 accrued COVID-19 cases as of 04 November 2020, after which additional formal interim analyses were not conducted.

Final Analysis

The final analysis of primary and secondary efficacy endpoints was pre-specified in the protocol to be conducted after accrual of the final number of COVID-19 cases (at least 164 cases). Subgroup analyses of VE based on baseline SARS-CoV-2 status and demographics were performed for the primary endpoints and secondary endpoint of severe COVID-19 cases. Additional post hoc analyses of subgroups defined by comorbidity risk assessment were

performed. Secondary efficacy was analyzed in the same manner as primary efficacy (Section 2.5.4.1.2.2), using the case definitions for severe COVID-19 and CDC criteria for COVID-19 (Section 2.5.4.1.1.2).

Final analysis of efficacy was based on 170 COVID-19 cases accrued in the evaluable efficacy population of participants without evidence of past SARS-CoV-2 infection before and during the vaccination regimen as of 14 November 2020. The prespecified final analyses of efficacy included primary and secondary endpoints in the evaluable and all-available efficacy populations. No additional formal hypothesis testing for analyses of clinically confirmed COVID-19 cases is planned.

Updated Analysis

Following the protocol specified interim analysis of efficacy and final analysis of efficacy, updated descriptive efficacy analyses were conducted for the two primary efficacy endpoints, including subgroup analyses, and for the secondary efficacy endpoint of severe disease, using statistical methods described in the study statistical analysis plan.

The point estimate of VE and associated 2-sided 95% CI derived using the Clopper-Pearson method adjusted for surveillance time were provided as descriptive summary. Updated analyses in the EUA amendment include COVID-19 cases accrued in blinded follow-up to the data cutoff date (13 March 2021).

2.5.4.2. Immunogenicity Endpoints and Analysis Methods

Assay methods and qualification/validation reports for immunoassays are provided in Module 2.7.1. Details of immunogenicity analyses are provided in Module 2.7.3 and summarized below. Statistical analysis methods are provided in Section 2.5.4.2.3.

2.5.4.2.1. Immunogenicity Endpoints in Study BNT162-01

In Study BNT162-01, immunogenicity was evaluated in Phase 1 using a SARS-CoV-2 serum neutralization assay to determine neutralizing titers and the fold rise in SARS-CoV-2 serum neutralizing titers. Only validated neutralization assays were used. Immunogenicity was assessed at Day 1 (before Dose 1) and at 7 days after Dose 1 (Day 8); and at Day 22 (before Dose 2) and at 7 days after Dose 2 (Day 29), 21 days after Dose 2 (Day 43), 28 days (approximately 1 month) after Dose 2 (Day 50), and 63 days (9 weeks or approximately 2 months) after Dose 2 (Day 85).

T cells isolated from peripheral blood mononuclear cells (PBMCs) obtained from whole blood samples of vaccinated Phase 1 participants were evaluated by enzyme-linked immuno-spot (ELISPOT) and intracellular cytokine staining visualized with fluorescence-activated cell sorting (FACS). Blood samples were collected prior to Dose 1 and on Day 29 (7 days after Dose 2). In a subset of study participants who received 10, 20, and 30 µg BNT162b2, blood samples were also collected on Day 85 (63 days, or approximately 2 months, after Dose 2) and Day 184 (162 days, or approximately 6 months, after Dose 2) and analyzed. Assessments included cytokines associated with Th1 responses such as IFNγ and IL-2 and those associated with Th2 responses such as IL-4, to analyze the induction of balanced versus Th1-dominant or Th2-dominant immune responses.

2.5.4.2.2. Immunogenicity Endpoints in Study C4591001

In Study C4591001, immunogenicity was evaluated in Phase 1 and Phase 2 using a SARS-CoV-2 serum neutralization assay to determine titers and a SARS-CoV-2 RBD- or S1-binding IgG direct Luminex immunoassay to determine antibody binding levels. Only validated neutralization and qualified Luminex assays were used.

In Phase 1, immunogenicity was assessed at Day 1 (before Dose 1) and 7 days after Dose 1; and at Day 21 (before Dose 2) and 7 days, 14 days, 1 month, and 6 months after Dose 2. Data were summarized for each dose level and age group.

In Phase 2, immunogenicity was assessed at Day 1 (before Dose 1) and 1 month after Dose 2. Data were summarized by age group and by evidence of prior SARS-CoV-2 infection at baseline per NAAT (PCR) or N-binding IgG assay. Data from the 6-month post Dose 2 time point were not available at the time of the submission data cutoff date (13 March 2021).

In Phase 2/3, exploratory immunogenicity assessments are planned at time points up to 24 months, to be reported at a later time.

2.5.4.2.3. Immunogenicity Analysis Methods

2.5.4.2.3.1. Immunogenicity Analysis Methods in Study BNT162-01

The statistical analyses of immunogenicity data from Study BNT162-01 were based on the immunogenicity set (described in Module 2.7.3).

Immunogenicity data from the SARS-CoV-2 neutralization assay were analyzed for Study BNT162-01 participants similarly to data in Study C4591001 (refer to Section 2.5.4.2.3.2).

T cells were isolated from CD4- and CD8- depleted PBMCs obtained from whole blood samples of vaccinated Phase 1 participants. PBMCs were tested for antigen induced cytokine production, evaluated by ELISPOT and intracellular cytokine staining with FACS analysis.

ELISPOT

Sample controls included anti-CD3 antibody-mediated stimulation (positive), medium (negative), and an optional mix of viral antigens for T cell response benchmarking:

- **CEF:** HLA class I restricted peptides originating from cytomegalovirus (CMV), Epstein-Barr Virus (EBV), and influenza virus, which are expected to stimulate IFNγ production from CD8+ T cells in the majority of donors.

- **CEFT:** HLA class II restricted peptides originating from CMV, EBV, influenza virus, and tetanus toxin, which are expected to stimulate IFNγ production from CD4+ T cells in the majority of donors.

The ELISPOT assay was used to measure the frequency of cytokine-secreting cells in samples of peripheral blood mononuclear cells (PBMCs) obtained from whole blood samples of vaccinated participants. Briefly, PBMCs enriched for CD4+ or CD8+ effector cells were

placed in ELISPOT plates pre-coated with antibodies specific for IFNγ and incubated overnight (≥18 hours) with peptides originating from the vaccine antigens (ie, from RBD or full-length S protein). IFNγ secreted by CD4+ or CD8+ cells in response to stimulation by the peptides was bound to the plate by the coating antibody. After incubation, the plates were developed by addition of alkaline phosphatase conjugated secondary anti-IFNγ antibody followed by enzyme substrate; each spot corresponds to the IFNγ secreted by a single cell. Developed plates were read by an AID ELISPOT Reader.

Intracellular Cytokine Staining with FACS Analysis

Intracellular cytokine staining is a flow cytometry-based assay to detect production and accumulation of cytokines intracellularly upon cell stimulation. Antigen stimulation was performed using synthetic peptides covering the encoded antigens (eg, 15-mer overlapping peptides covering the whole length of the vaccine antigen with 11 amino acid overlap). These peptide pools represent the vaccine-encoded SARS-CoV-2 RBD, and SARS-CoV-2 S1 subpool 1 and subpool 2 pepmixes as well as a combination of subpool 1 and subpool 2.

Briefly, vaccine antigen-stimulated PBMCs were treated with protein transport inhibitors to retain intracellular cytokines and labelled on the extracellular surface with fluor-conjugated antibodies for CD4, CD8, and CD3. PBMCs were fixed and permeabilized for intracellular cytokine staining of cytokines with fluor-conjugated antibodies, and samples were analyzed using FACS on a flow cytometer to visualize the proportions of vaccine antigen-specific Th1 and Th2 CD4+ T cells and cytotoxic CD8+ T cells producing each cytokine.

Comparisons between pre- and post-vaccination samples for each subject were used as a surrogate for induction or expansion of cellular immune responses, and to characterize the balance of generated Th1 and Th2 responses upon vaccination. For benchmarking, PBMCs from recovered COVID-19 patients were used.

2.5.4.2.3.2. Immunogenicity Analysis Methods in Study C4591001

The statistical analyses of immunogenicity data from Study C4591001 were based on the evaluable immunogenicity populations and all-available immunogenicity populations (described in Module 2.7.3).

Data were reported for SARS-CoV-2 serum neutralizing titers and SARS-CoV-2 S1-binding and RBD-binding IgG concentrations, including:

- geometric mean titers/concentrations (GMTs/GMCs)
- geometric mean-fold rise (GMFR)

For immunogenicity results of SARS-CoV-2 serum neutralizing titers and S1- or RBD-binding IgG concentrations, GMTs or GMCs were computed with associated 95% CIs. The GMTs and GMCs were calculated as the mean of assay results after logarithm transformation and then exponentiating the mean to express results on the original scale. Two-sided 95% CIs were obtained by taking log-transforms of titers, calculating the 95% CI with reference to Student's t-distribution, and then exponentiating the confidence limits.

GMFRs were limited to participants with non-missing values prior to first dose and the post-dose time point. The GMFR was calculated by exponentiating the mean of the difference of logarithm transformed assay results: (later time point) – (earlier time point). Two-sided CIs were obtained by calculating CIs using Student's t-distribution for the mean difference of the logarithm transformed assay results and exponentiating the confidence limits.

Exact 95% CIs for binary endpoints were computed using F distribution (Clopper-Pearson).

2.5.4.2.3.3. Human Convalescent Sera Panel for Serology Comparisons

To facilitate interpretation of immunogenicity data generated in Studies BNT162-01 and C4591001, a human convalescent serum (HCS) panel was obtained from Sanguine Biosciences (Sherman Oaks, CA), MT Group (Van Nuys, CA), and Pfizer Occupational Health and Wellness (Pearl River, NY).[19,20] The 38 sera in the panel were collected from SARS-CoV-2 infected or COVID-19 diagnosed individuals 18 to 83 years of age ≥14 days after PCR-confirmed diagnosis at a time when they were asymptomatic. The serum donors had predominantly had symptomatic infections (35/38) including 1 who had been hospitalized.

2.5.4.3. Efficacy Results

Details of efficacy analysis results from the first planned (and successful) interim analysis and the planned final analysis of efficacy are provided in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 10 and Section 11. Updated efficacy results are provided in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 10 and Section 11.

All efficacy data are also presented in Module 2.7.3 and summarized below.

2.5.4.3.1. Interim Analysis of Efficacy in Study C4591001

A prespecified interim analysis of efficacy was conducted after accrual of 94 COVID-19 cases. Efficacy data for the Phase 3 portion of Study C4591001 were analyzed for all enrolled participants who met the protocol-specified criteria for efficacy evaluation, with an interim analysis cutoff date of 04 November 2020. Data are summarized for the efficacy populations. Additional analyses were conducted by subgroups (age, sex, race, ethnicity, country, and baseline SARS-CoV-2 status).

COVID-19 case evaluation is discussed in Section 2.5.4.1. For the first primary efficacy endpoint, VE for BNT162b2 against confirmed COVID-19 was evaluated in participants without evidence of past SARS-CoV-2 infection before and during the vaccination regimen. Participants with positive or unknown NAAT results at any illness visit prior to 7 days after Dose 2 were not included in VE evaluation. Cases were counted from 7 days after Dose 2.

Efficacy population characteristics in the interim analysis are presented in Section 2.5.4.3.1.1, and results of the interim analysis are presented in Section 2.5.4.3.1.2 (first primary endpoint) and Section 2.5.4.3.1.3 (additional descriptive results).

2.5.4.3.1.1. Efficacy Populations – Interim Analysis

The proportions of participants included in the interim analysis efficacy populations was similar in the BNT162b2 and placebo groups (Table 1). Most participants who were excluded from the evaluable efficacy population had not received all vaccinations as randomized or did not receive Dose 2 within the predefined window (ie, 19 to 42 days after Dose 1). There were 302 participants (1.4%) in the BNT162b2 group and 52 participants (0.2%) in the placebo group excluded for having important protocol deviations on or prior to 7 days after Dose 2.

Table 1. Efficacy Populations – Interim Analysis 1

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	**Placebo n[a] (%)**	**Total n[a] (%)**
Randomized[b]	21653 (100.0)	21672 (100.0)	43325 (100.0)
Dose 1 all-available efficacy population	21617 (99.8)	21633 (99.8)	43250 (99.8)
Subjects without evidence of infection before Dose 1	17237 (79.6)	17221 (79.5)	34458 (79.5)
Subjects excluded from Dose 1 all-available efficacy population	36 (0.2)	39 (0.2)	75 (0.2)
Reason for exclusion[c]			
Did not receive at least 1 vaccination	35 (0.2)	39 (0.2)	74 (0.2)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Dose 2 all-available efficacy population	18868 (87.1)	18877 (87.1)	37745 (87.1)
Subjects without evidence of infection prior to 7 days after Dose 2	16463 (76.0)	16426 (75.8)	32889 (75.9)
Subjects excluded from Dose 2 all-available efficacy population	2785 (12.9)	2795 (12.9)	5580 (12.9)
Reason for exclusion[c]			
Did not complete 2 vaccination doses	2784 (12.9)	2795 (12.9)	5579 (12.9)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Evaluable efficacy population (7 Days)	18380 (84.9)	18618 (85.9)	36998 (85.4)
Subjects without evidence of infection prior to 7 days after Dose 2	16061 (74.2)	16218 (74.8)	32279 (74.5)
Subjects excluded from evaluable efficacy population (7 Days)	3273 (15.1)	3054 (14.1)	6327 (14.6)
Reason for exclusion[c]			
Randomized but did not meet all eligibility criteria	15 (0.1)	16 (0.1)	31 (0.1)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)	3038 (14.0)	3035 (14.0)	6073 (14.0)
Had other important protocol deviations on or prior to 7 days after Dose 2	302 (1.4)	52 (0.2)	354 (0.8)

Table 1. Efficacy Populations – Interim Analysis 1

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)

Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.
a. n = Number of subjects with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. Subjects may have been excluded for more than 1 reason.
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Demographics of participants in the interim analysis evaluable efficacy population for participants without evidence of infection before and during the vaccination regimen were similar in the BNT162b2 and placebo groups (Table 2). This analysis population had generally similar demographics compared to the safety population (refer to Section 2.5.5.5.1).

Demographic characteristics for the interim analysis Dose 2 all-available efficacy population were similar to the evaluable efficacy population.

Table 2. Demographic Characteristics – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (7 Days) – Interim Analysis 1

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=16061) n[b] (%)	Placebo (N[a]=16218) n[b] (%)	Total (N[a]=32279) n[b] (%)
Sex			
Male	8197 (51.0)	8144 (50.2)	16341 (50.6)
Female	7864 (49.0)	8074 (49.8)	15938 (49.4)
Race			
White	13502 (84.1)	13692 (84.4)	27194 (84.2)
Black or African American	1298 (8.1)	1303 (8.0)	2601 (8.1)
American Indian or Alaska native	88 (0.5)	82 (0.5)	170 (0.5)
Asian	712 (4.4)	716 (4.4)	1428 (4.4)
Native Hawaiian or other Pacific Islander	40 (0.2)	26 (0.2)	66 (0.2)
Multiracial	341 (2.1)	297 (1.8)	638 (2.0)

Table 2. Demographic Characteristics – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (7 Days) – Interim Analysis 1

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=16061) n[b] (%)	Placebo (N[a]=16218) n[b] (%)	Total (N[a]=32279) n[b] (%)
Not reported	80 (0.5)	102 (0.6)	182 (0.6)
Ethnicity			
Hispanic/Latino	4415 (27.5)	4383 (27.0)	8798 (27.3)
Non-Hispanic/non-Latino	11553 (71.9)	11736 (72.4)	23289 (72.1)
Not reported	93 (0.6)	99 (0.6)	192 (0.6)
Country			
Argentina	2445 (15.2)	2415 (14.9)	4860 (15.1)
Brazil	889 (5.5)	889 (5.5)	1778 (5.5)
South Africa	215 (1.3)	218 (1.3)	433 (1.3)
USA	12512 (77.9)	12696 (78.3)	25208 (78.1)
Age group			
16-55 Years	9093 (56.6)	9172 (56.6)	18265 (56.6)
>55 Years	6968 (43.4)	7046 (43.4)	14014 (43.4)
Age at vaccination (years)			
Mean (SD)	50.9 (15.58)	50.7 (15.68)	50.8 (15.63)
Median	52.0	52.0	52.0
Min, max	(16, 89)	(16, 91)	(16, 91)

Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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(Cutoff Date: 04Nov2020, Snapshot Date: 04Nov2020) Output File: ./nda2_unblinded_ia/C4591001_IA_62/adsl_demo_7d_eval_eff

2.5.4.3.1.2. Primary Efficacy – Interim Analysis

Among participants included in the evaluable efficacy population, 32,279 participants overall (16,061 in the BNT162b2 group and 16,218 in the placebo groups) did not have evidence of prior infection with SARS-CoV-2 through 7 days after Dose 2 (Table 2).

As of the time of the interim analysis, there were 4 confirmed COVID-19 cases in the BNT162b2 group and 90 confirmed COVID-19 cases in the placebo group (Table 3). All evaluable cases were confirmed by tests conducted at the central laboratory.

VE for BNT162b2 against confirmed COVID-19 cases was evaluated in participants without evidence of past SARS-CoV-2 infection before and during the vaccination regimen with cases counted from 7 days after Dose 2.

VE of BNT162b2 was 95.5% with a >99.99% posterior probability for the true VE being >30% conditioning on available data, to overwhelmingly meet the prespecified interim analysis success criterion (>99.5%).

The 95% credible interval for the vaccine efficacy was 88.8% to 98.4%, indicating that given these observed data there was a 95% probability that the true VE lies in this interval. Also, note that the posterior probability that true VE >86.0% is 99.5% and VE >88.8% is 97.5%.

VE of BNT162b2 for the same primary efficacy endpoint based on the all-available efficacy population was 95.7%, with 4 cases in the BNT162b2 group and 93 cases in the placebo group.

Table 3. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (7 Days) – Interim Analysis 1

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=16061)		Placebo (N[a]=16218)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	4	1.722 (15899)	90	1.732 (16010)	95.5	(88.8, 98.4)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details. This probability must be at least 99.5% at the interim analysis in order to conclude that the vaccine is efficacious.
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(Cutoff Date: 04Nov2020, Snapshot Date: 04Nov2020) Output File:
./nda2 unblinded ia/C4591001 IA 62/adc19ef ve cov 7pd2 wo eval

Efficacy in Subgroups – Interim Analysis

VE in participants without prior evidence of SARS-CoV-2 infection was further evaluated by subgroups based on age, sex, race, ethnicity, and country. VE was >90% in all subgroups (Table 4).

Results for the Dose 2 all-available population were similar, with no clinically meaningful differences in VE on the basis of subgroup.

Table 4. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (7 Days) – Interim Analysis 1

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=16061)		Placebo (N[a]=16218)			
Efficacy Endpoint Subgroup	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**
First COVID-19 occurrence from 7 days after Dose 2						
Overall	4	1.722 (15899)	90	1.732 (16010)	95.5	(88.1, 98.8)
Age group (years)						
16 to 55	2	0.954 (8994)	67	0.959 (9040)	97.0	(88.7, 99.6)
>55	2	0.767 (6905)	23	0.773 (6970)	91.2	(64.6, 99.0)
Sex						
Male	2	0.874 (8115)	38	0.865 (8029)	94.8	(79.8, 99.4)
Female	2	0.848 (7784)	52	0.867 (7981)	96.1	(85.1, 99.5)
Race						
White	4	1.477 (13399)	85	1.491 (13530)	95.3	(87.4, 98.7)
Black or African American	0	0.124 (1263)	4	0.124 (1277)	100.0	(-51.8, 100.0)
All others[f]	0	0.121 (1237)	1	0.118 (1203)	100.0	(-3690.1, 100.0)
Ethnicity						
Hispanic/Latino	1	0.464 (4389)	34	0.459 (4342)	97.1	(82.7, 99.9)
Non-Hispanic/non-Latino	3	1.247 (11418)	56	1.262 (11570)	94.6	(83.3, 98.9)
Country						
Argentina	0	0.271 (2436)	28	0.266 (2402)	100.0	(86.2, 100.0)
Brazil	0	0.087 (878)	2	0.087 (879)	100.0	(-432.5, 100.0)
USA	4	1.360 (12384)	60	1.376 (12530)	93.3	(81.8, 98.2)

Table 4. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (7 Days) – Interim Analysis 1

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=16061)		Placebo (N[a]=16218)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.
f. American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, not reported race categories are presented as "All others".
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2.5.4.3.1.3. Additional Descriptive Efficacy Results – Interim Analysis

2.5.4.3.1.3.1. Vaccine Efficacy by Baseline SARS-CoV-2 Status – Interim Analysis

COVID-19 cases evaluable for efficacy after Dose 2 were further evaluated by participant SARS-CoV-2 status at baseline (ie, evidence of prior infection with SARS-CoV-2).

At the time of the interim analysis, there were 2 participants in the evaluable efficacy population who had evaluable COVID-19 and were baseline positive for prior SARS-CoV-2 infection: 1 participant in the BNT162b2 group and 1 participant in the placebo group.

Results were similar for the Dose 2 all-available population (ie, 1 participant with COVID-19 in each group was baseline SARS-CoV-2 positive.

2.5.4.3.1.3.2. Efficacy for Severe COVID-19 Cases – Interim Analysis

Severe cases of COVID-19 were evaluated from after Dose 1 onwards, reported for the Dose 1 all-available efficacy population (see efficacy analysis populations in Section 2.5.4.3.1.1).

As of the time of the interim analysis of efficacy, a total of 7 severe cases of COVID-19 were reported as occurring from Dose 1 onwards (Table 5). All of these severe cases were reported in the placebo group. Of these, 5 of 7 severe cases were reported as occurring after Dose 1 and prior to Dose 2; the remaining 2 cases were reported ≥7 days after Dose 2.

Of these 7 severe cases reported in the placebo group, all were confirmed as being SARS-CoV-2 negative at baseline.

Severe COVID-19 cases are also discussed in Section 2.5.5.7.1 with regard to safety and the hypothetical risk of vaccine-associated enhanced disease (VAED) including vaccine-associated enhanced respiratory disease (VAERD).

Table 5. Severe COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population – Interim Analysis 1

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=21617)	Placebo (N[a]=21633)
Efficacy Endpoint	**n[b]**	**n[b]**
Severe COVID-19 occurrence after Dose 1	0	7

Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.
a. N = number of subjects in the specified group.
b. n = Number of subjects meeting the endpoint definition.
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(Cutoff Date: 04Nov2020, Snapshot Date: 04Nov2020) Output File: ./nda2_unblinded_ia/C4591001_IA_62/adc19ef_sev_cov_d1_aai

2.5.4.3.1.4. Efficacy Conclusions – Interim Analysis

Interim Analysis of Efficacy Against Confirmed COVID-19

The first primary efficacy objective met success criteria at the first interim analysis performed on an accrued 94 cases of COVID-19. BNT162b2 achieved VE of 95.5% with a 95% credible interval of 88.8% to 98.4% among participants without evidence of infection before and during the vaccination regimen, and a >99.99% posterior probability for the true VE being >30%, conditioning on available data.

Interim Analysis of Efficacy in Subgroups

There was no clinically meaningful difference in VE for the first primary efficacy endpoint by participant subgroup, as VE was >90% across age groups, for both male and female participants, across race and ethnic groups, and on the basis of geographic location across study countries.

Evaluation of efficacy among participants who had COVID-19 based on prior SARS-CoV-2 infection status showed 2 participants with COVID-19 cases were SARS-CoV-2 positive at baseline, 1 in each group.

Interim Analysis of Efficacy Against Severe Disease

A total of 7 severe cases of COVID-19 were reported in the interim analysis of efficacy, with 5 cases reported after Dose 1 and prior to Dose 2 and the remaining 2 cases reported ≥7 days after Dose 2. All severe cases were reported in placebo recipients and none were reported in BNT162b2 recipients. None were baseline positive for SARS-CoV-2.

Overall Conclusions from Interim Analysis of Efficacy

The interim analysis efficacy results suggest BNT162b2 at 30 µg provided protection against COVID-19 overall and across subgroups of participants who had no evidence of prior infection with SARS-CoV-2, with severe cases observed exclusively in the placebo group.

2.5.4.3.2. Final Analysis of Efficacy in Study C4591001

Efficacy data for the Phase 3 portion of Study C4591001 were analyzed for all enrolled participants who met the protocol-specified criteria for efficacy evaluation, in the prespecified final analysis of primary and secondary endpoints after accrual of 170 confirmed COVID-18 cases, with a final analysis cutoff date of 14 November 2020. Data were analyzed for the efficacy populations.

COVID-19 case evaluation for primary and secondary efficacy endpoints is discussed in Section 2.5.4.1. Efficacy endpoints evaluated confirmed COVID-19 cases in participants either without or with or without evidence of prior SARS-CoV-2 infection before and during the vaccination regimen. Participants with positive or unknown NAAT results at any illness visit prior to either 7 days after Dose 2 or 14 days after Dose 2 (depending on the primary or secondary endpoint definition) were not included in the evaluation for VE. Cases were counted from either 7 days or 14 days (depending on the endpoint definition) after Dose 2.

Efficacy population characteristics in the final analysis are presented in Section 2.5.4.3.2.1.1, and results of the final analysis are presented in Section 2.5.4.3.2.1.2 (primary endpoints) and Section 2.5.4.3.2.1.3 (secondary endpoints).

2.5.4.3.2.1.1. Efficacy Populations – Final Analysis

The proportions of participants included in the final analysis efficacy populations was similar in the BNT162b2 and placebo groups (Table 6). Most participants who were excluded from the evaluable efficacy population had not received all vaccinations as randomized or did not receive Dose 2 within the predefined window (ie, 19 to 42 days after Dose 1).

There were 311 participants (1.4%) in the BNT162b2 group and 60 participants (0.3%) in the placebo group excluded for having important protocol deviations on or prior to 7 days after Dose 2. A post hoc evaluation was performed to assess the imbalance of these important protocol deviations in the BNT162b2 and placebo groups for the final analysis of efficacy. This showed that the majority of exclusions from the evaluable efficacy (7 days) population in the BNT162b2 group were due to dosing/administration errors or administration of study intervention that was deemed not suitable for use. This is detailed in the C4591001 Final Analysis Interim CSR and in Module 2.7.3.

Table 6. Efficacy Populations

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Randomized[b]	21823 (100.0)	21828 (100.0)	43651 (100.0)
Dose 1 all-available efficacy population	21768 (99.7)	21783 (99.8)	43551 (99.8)
Subjects without evidence of infection before Dose 1	20314 (93.1)	20296 (93.0)	40610 (93.0)
Subjects excluded from Dose 1 all-available efficacy population	55 (0.3)	45 (0.2)	100 (0.2)
Reason for exclusion[c]			
Did not receive at least 1 vaccination	54 (0.2)	45 (0.2)	99 (0.2)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Dose 2 all-available efficacy population	20566 (94.2)	20536 (94.1)	41102 (94.2)
Subjects without evidence of infection prior to 7 days after Dose 2	18701 (85.7)	18627 (85.3)	37328 (85.5)
Subjects without evidence of infection prior to 14 days after Dose 2	18678 (85.6)	18563 (85.0)	37241 (85.3)
Subjects excluded from Dose 2 all-available efficacy population	1257 (5.8)	1292 (5.9)	2549 (5.8)
Reason for exclusion[c]			
Did not receive 2 vaccinations	1256 (5.8)	1292 (5.9)	2548 (5.8)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Evaluable efficacy (7 days) population	20033 (91.8)	20244 (92.7)	40277 (92.3)
Subjects without evidence of infection prior to 7 days after Dose 2	18242 (83.6)	18379 (84.2)	36621 (83.9)
Evaluable efficacy (14 days) population	20033 (91.8)	20243 (92.7)	40276 (92.3)
Subjects without evidence of infection prior to 14 days after Dose 2	18219 (83.5)	18315 (83.9)	36534 (83.7)

Table 6. Efficacy Populations

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Subjects excluded from evaluable efficacy (7 days) population	1790 (8.2)	1584 (7.3)	3374 (7.7)
Subjects excluded from evaluable efficacy (14 days) population	1790 (8.2)	1585 (7.3)	3375 (7.7)
Reason for exclusion[c]			
Randomized but did not meet all eligibility criteria	36 (0.2)	26 (0.1)	62 (0.1)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)	1550 (7.1)	1561 (7.2)	3111 (7.1)
Had other important protocol deviations on or prior to 7 days after Dose 2	311 (1.4)	60 (0.3)	371 (0.8)
Had other important protocol deviations on or prior to 14 days after Dose 2	311 (1.4)	61 (0.3)	372 (0.9)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. n = Number of subjects with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. Subjects may have been excluded for more than 1 reason.
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(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsl_eff_pop

Demographics of participants in the final analysis evaluable efficacy population for participants without evidence of infection prior to 7 days after Dose 2 were similar in the BNT162b2 and placebo groups (Table 7). This analysis population had generally similar demographics compared to the safety population (refer to Section 2.5.5.5.1).

Demographic characteristics for the final analysis Dose 2 all-available efficacy population and the evaluable population without evidence of infection prior to 14 days after Dose 2 were similar to the Dose 2 evaluable efficacy (7 days) population.

Table 7. Demographic Characteristics – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=18242) n[b] (%)	Placebo (N[a]=18379) n[b] (%)	Total (N[a]=36621) n[b] (%)
Sex			
Male	9318 (51.1)	9225 (50.2)	18543 (50.6)
Female	8924 (48.9)	9154 (49.8)	18078 (49.4)
Race			
White	15110 (82.8)	15301 (83.3)	30411 (83.0)
Black or African American	1617 (8.9)	1617 (8.8)	3234 (8.8)
American Indian or Alaska native	118 (0.6)	106 (0.6)	224 (0.6)
Asian	815 (4.5)	810 (4.4)	1625 (4.4)
Native Hawaiian or other Pacific Islander	48 (0.3)	29 (0.2)	77 (0.2)
Multiracial	448 (2.5)	402 (2.2)	850 (2.3)
Not reported	86 (0.5)	114 (0.6)	200 (0.5)
Ethnicity			
Hispanic/Latino	4886 (26.8)	4857 (26.4)	9743 (26.6)
Non-Hispanic/non-Latino	13253 (72.7)	13412 (73.0)	26665 (72.8)
Not reported	103 (0.6)	110 (0.6)	213 (0.6)
Country			
Argentina	2561 (14.0)	2539 (13.8)	5100 (13.9)
Brazil	1232 (6.8)	1223 (6.7)	2455 (6.7)
Germany	121 (0.7)	126 (0.7)	247 (0.7)
South Africa	287 (1.6)	279 (1.5)	566 (1.5)
USA	14041 (77.0)	14212 (77.3)	28253 (77.1)
Age group			
12-15 Years	46 (0.3)	42 (0.2)	88 (0.2)
16-55 Years	10428 (57.2)	10507 (57.2)	20935 (57.2)
>55 Years	7768 (42.6)	7830 (42.6)	15598 (42.6)
≥65 Years	3980 (21.8)	4038 (22.0)	8018 (21.9)
Age at vaccination (years)			
Mean (SD)	50.6 (15.70)	50.4 (15.81)	50.5 (15.76)
Median	52.0	52.0	52.0
Min, max	(12, 89)	(12, 91)	(12, 91)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsl_demo_7d_eval_eff

2.5.4.3.2.1.2. Primary Efficacy – Final Analysis

For the first primary efficacy endpoint, VE for BNT162b2 against confirmed COVID-19 was evaluated in participants without evidence of past SARS-CoV-2 infection before and during the vaccination regimen. Cases were counted from 7 days after Dose 2. For the second primary efficacy endpoint, VE for BNT162b2 against confirmed COVID-19 was evaluated in participants with or without evidence of past SARS-CoV-2 infection before and during the vaccination regimen. Cases were counted from 7 days after Dose 2.

Signs and symptoms of COVID-19 cases contributing to efficacy analyses are presented in the C4591001 Final Analysis Interim CSR.

2.5.4.3.2.1.2.1. Vaccine Efficacy Without Prior Evidence of SARS-CoV-2 Infection – 7 Days After Dose 2 – Final Analysis

As noted above, overwhelming efficacy was declared at the first (and only) interim analysis for the first primary efficacy endpoint. A descriptive update based on 170 evaluable cases accrued at the time of the final analysis (of the other efficacy endpoints) is summarized below.

Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 95.0%, with 8 COVID-19 cases in the BNT162b2 group compared to 162 COVID-19 cases in the placebo group (Table 8). The 95% credible interval for the vaccine efficacy was 90.3% to 97.6%, indicating that the true VE is at least 90.3% with a 97.5% probability given the observed data.

The vaccine efficacy of BNT162b2 for the same primary efficacy endpoint based on the Dose 2 all-available efficacy population was 95.2%, with 8 and 165 cases in the BNT162b2 and placebo group (Table 9).

Table 8. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	8	2.214 (17411)	162	2.222 (17511)	95.0	(90.3, 97.6)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:46)
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Table 9. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=18650)		Placebo (N[a]=18570)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	8	2.266 (17852)	165	2.244 (17746)	95.2	(90.6, 97.7)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102,1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
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(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 7pd2 wo aai

2.5.4.3.2.1.2.2. Vaccine Efficacy With or Without Prior Evidence of SARS-CoV-2 Infection – 7 Days After Dose 2 – Final Analysis

For the second primary efficacy endpoint, VE for BNT162b2 against confirmed COVID-19 was evaluated in participants with or without evidence of prior SARS-CoV-2 infection through 7 days after Dose 2. Cases were counted from 7 days after Dose 2.

Among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen, VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 94.6%, with 9 and 169 cases in the BNT162b2 and placebo groups respectively. The posterior probability of >99.99% for the true VE greater than 30% met the prespecified success criterion of >98.6% for this endpoint. The 95% credible interval for the vaccine efficacy was 89.9% to 97.3%, indicating that the true VE is at least 89.9% with a 97.5% probability given the available data (Table 10). Note that with a posterior probability of 98.6%, the true vaccine efficacy is at least 89.2% given the available data.

The vaccine efficacy of BNT162b2 for the same primary efficacy endpoint based on the Dose 2 all-available efficacy population was 94.8%, with 9 and 172 cases in the BNT162b2 and placebo group respectively (Table 11).

Table 10. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20172)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	9	2.332 (18559)	169	2.345 (18708)	94.6	(89.9, 97.3)	>0.9999

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
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(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 7pd2 eval

Table 11. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=20488)		Placebo (N[a]=20459)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	9	2.389 (19049)	172	2.370 (18971)	94.8	(90.2, 97.4)	>0.9999

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
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All Confirmed Cases of COVID-19 After Dose 1 – All-Available Efficacy Population

A number of confirmed cases of COVID-19 are not captured in the analyses of the first primary endpoint for the evaluable efficacy population because they occurred less than 7 days after Dose 2, or because they occurred in participants who were excluded from the evaluable efficacy population or who had evidence of infection before or during the vaccination regimen.

All reports of COVID-19 with onset at any time after Dose 1 are accounted for in Table 12, which provides a summary of cases for all participants in the Dose 1 all-available efficacy (modified intention-to-treat) population, regardless of evidence of infection before or during the vaccination regimen. Among these participants, 50 cases of COVID-19 occurred after Dose 1 in the BNT162b2 group compared to 275 cases in the placebo group (Table 12). Notably, in the BNT162b2 group, most cases occurred before Dose 2. The estimated VE against confirmed COVID-19 occurring after Dose 1 was 82% (2-sided 95% CI: 75.6 %, 86.9%), with an estimated VE of 52.4% (2-sided 95% CI: 29.5%, 68.4%) against confirmed COVID-19 occurring after Dose 1 but before Dose 2.

Table 12. Vaccine Efficacy – First COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=21669)		Placebo (N[a]=21686)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence after Dose 1	50	4.015 (21314)	275	3.982 (21258)	82.0	(75.6, 86.9)
After Dose 1 to before Dose 2	39		82		52.4	(29.5, 68.4)
Dose 2 to 7 days after Dose 2	2		21		90.5	(61.0, 98.9)
≥7 Days after Dose 2	9		172		94.8	(89.8, 97.6)

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method (adjusted for surveillance time for overall row).
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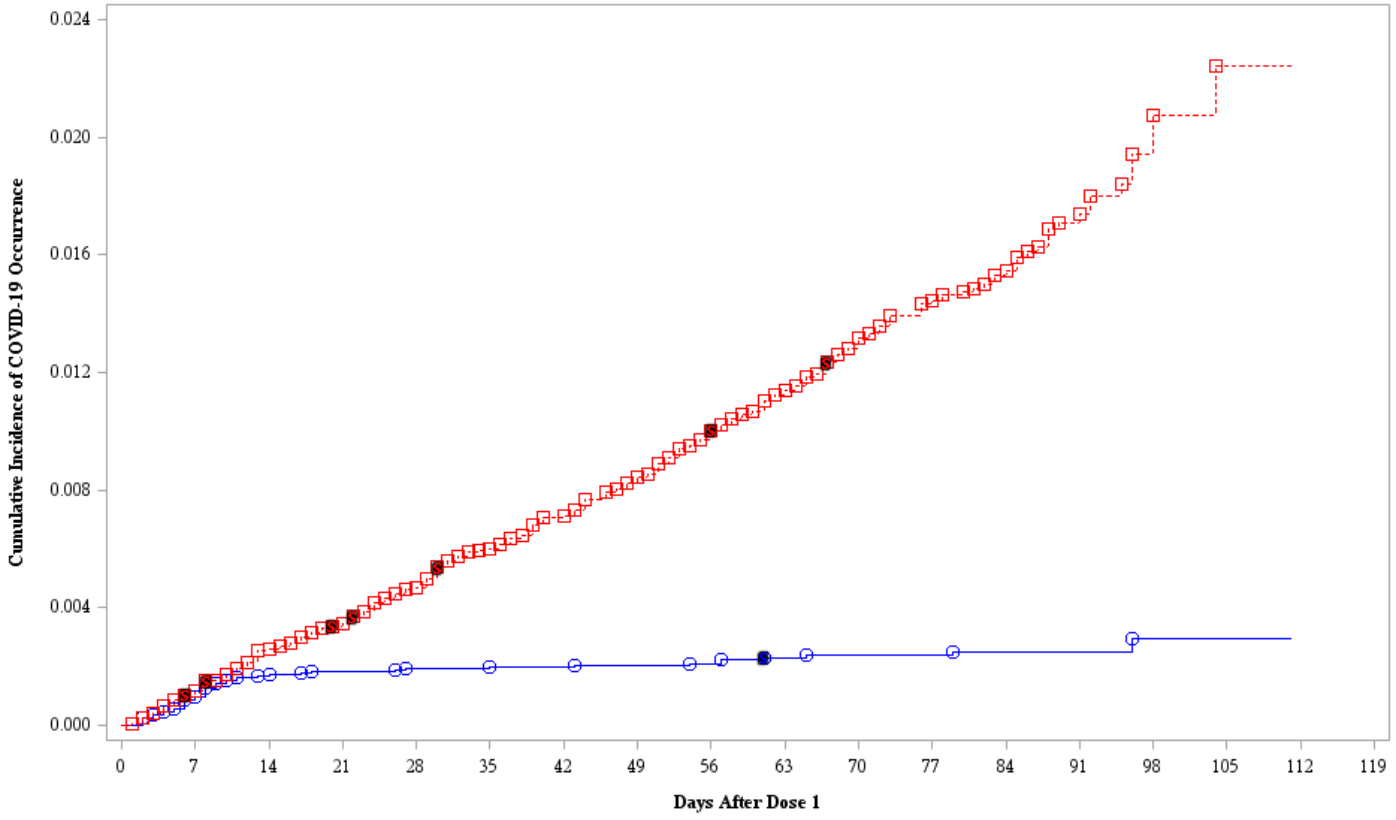
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_cov_pd1_aai

The early onset of protection is readily apparent in Figure 1, which displays cumulative incidence for the first COVID-19 occurrence after Dose 1 among all vaccinated participants based on Dose 1 all-available efficacy (modified intention-to-treat) population. Disease onset appears to track together for BNT162b2 and placebo until approximately 14 days after Dose 1, at which point the curves diverge, with cases steadily accumulating in the placebo group, while remaining virtually flat in the BNT162b2 group. The darker-appearing symbols for both BNT162b2 (blue circles) and placebo (red squares) curves in Figure 1 have an "S" written inside the open symbol, which denotes severe cases; note that there are instances in which 2 cases in the placebo group are "overlapping" relative to the placebo curve. Severe COVID-19 cases reported in the final analysis are discussed further in Section 2.5.4.3.2.1.3.2.

Figure 1. Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population – Final Analysis



Note: "S" indicates subjects with severe COVID-19 or COVID-19 leading to hospitalization.
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(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_f001_km_d1_aai

2.5.4.3.2.1.2.3. Vaccine Efficacy by Subgroup – Final Analysis

Subgroup Analyses by Age, Sex, Race, Ethnicity, and Country

For both primary endpoints, VE was also evaluated for subgroups of participants by age, sex race, ethnicity, and country (Table 13) (without evidence of prior infection) and Table 14 (with or without evidence of prior infection).

Among participants without prior evidence of SARS-CoV-2 infection, VE was >93% in all subgroups, with the exception of "all others" race group (89.3% VE) and Brazil (87.7% VE) (Table 13). Notably, VE was 94.7% (2-sided 95% CI: 66.7%, 99.9%) in participants ≥65 years of age (1 case in BNT162b2 group vs 19 cases in placebo group).

An additional analysis of age subgroups showed observed VE in participants ≥75 years of age was 100% (0 cases in BNT162b2 group vs 5 cases in placebo group; 2-sided 95% CI: -13.1%, 100.0%) (Table 15).

Among participants with or without prior evidence of SARS-CoV-2 infection, VE was >93% in all subgroups, with the exception of "all others" race group (78.2% VE), Brazil (75.4% VE), and positive prior SARS-CoV-2 infection at baseline (-7.1% VE, 1 case in each vaccine group) (Table 14).

Results for the all-available population were similar; no clinically meaningful differences were observed in VE on the basis of subgroup.

Post Hoc Subgroup Analyses by Risk Status

Post hoc analyses of efficacy based on risk status were performed. Risk assessment included select comorbidities. At-risk participants were those meeting at least one Charlson Comorbidity Index condition (see Section 2.5.5.5.1 for Charlson comorbidities) or who were obese (defined as body mass index ≥30 kg/m^2).

Among participants without prior evidence of SARS-CoV-2 infection before and during the vaccination regimen, VE for at-risk participants was 95.3%, as compared with 94.7% for those not at-risk (Table 16). VE for participants ≥65 years of age and at-risk was 91.7%, as compared with 100% for those ≥65 years of age and not at-risk. VE was similar in obese (95.4%) and non-obese (94.8%) participants. A summary of VE for groups of participants by specific comorbidity is provided in Table 17.

Table 13. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	8	2.214 (17411)	162	2.222 (17511)	95.0	(90.0, 97.9)
Age group (years)						
16 to 55	5	1.234 (9897)	114	1.239 (9955)	95.6	(89.4, 98.6)
>55	3	0.980 (7500)	48	0.983 (7543)	93.7	(80.6, 98.8)
≥65	1	0.508 (3848)	19	0.511 (3880)	94.7	(66.7, 99.9)
Sex						
Male	3	1.124 (8875)	81	1.108 (8762)	96.4	(88.9, 99.3)
Female	5	1.090 (8536)	81	1.114 (8749)	93.7	(84.7, 98.0)
Race						
White	7	1.889 (14504)	146	1.903 (14670)	95.2	(89.8, 98.1)
Black or African American	0	0.165 (1502)	7	0.164 (1486)	100.0	(31.2, 100.0)
All others[f]	1	0.160 (1405)	9	0.155 (1355)	89.3	(22.6, 99.8)
Ethnicity						
Hispanic/Latino	3	0.605 (4764)	53	0.600 (4746)	94.4	(82.7, 98.9)
Non-Hispanic/non-Latino	5	1.596 (12548)	109	1.608 (12661)	95.4	(88.9, 98.5)
Country						
Argentina	1	0.351 (2545)	35	0.346 (2521)	97.2	(83.3, 99.9)
Brazil	1	0.119 (1129)	8	0.117 (1121)	87.7	(8.1, 99.7)
USA	6	1.732 (13359)	119	1.747 (13506)	94.9	(88.6, 98.2)

Table 13. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
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Table 14. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20172)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	9	2.332 (18559)	169	2.345 (18708)	94.6	(89.6, 97.6)
Age group (years)						
16 to 55	6	1.309 (10653)	120	1.317 (10738)	95.0	(88.7, 98.2)
>55	3	1.022 (7892)	49	1.028 (7956)	93.8	(80.9, 98.8)
≥65	1	0.530 (4044)	19	0.532 (4067)	94.7	(66.8, 99.9)
Sex						
Male	4	1.183 (9457)	85	1.170 (9342)	95.3	(87.6, 98.8)
Female	5	1.149 (9102)	84	1.176 (9366)	93.9	(85.2, 98.1)
Race						
White	7	1.975 (15294)	153	1.990 (15473)	95.4	(90.3, 98.2)
Black or African American	0	0.187 (1758)	7	0.188 (1758)	100.0	(30.4, 100.0)
All others[f]	2	0.170 (1507)	9	0.167 (1477)	78.2	(-5.4, 97.7)
Ethnicity						
Hispanic/Latino	3	0.637 (5074)	55	0.638 (5090)	94.5	(83.2, 98.9)
Non-Hispanic/non-Latino	6	1.681 (13380)	114	1.693 (13509)	94.7	(88.1, 98.1)
Country						
Argentina	1	0.366 (2664)	36	0.367 (2684)	97.2	(83.5, 99.9)
Brazil	2	0.134 (1274)	8	0.132 (1257)	75.4	(-23.5, 97.5)
USA	6	1.816 (14141)	124	1.830 (14287)	95.1	(89.1, 98.2)
South Africa	0	0.015 (362)	1	0.015 (363)	100.0	(-3818.9, 100.0)

Table 14. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20172)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Prior SARS-CoV-2 Status						
Positive at baseline[g]	1	0.056 (526)	1	0.060 (567)	-7.1	(-8309.9, 98.6)
Negative at baseline but positive prior to 7 days after Dose 2[h]	0	0.003 (27)	1	0.004 (34)	100.0	(-6004.9, 100.0)
Negative prior to 7 days after Dose 2[i]	8	2.214 (17411)	162	2.222 (17511)	95.0	(90.0, 97.9)
Unknown	0	0.059 (595)	5	0.060 (596)	100.0	(-9.6, 100.0)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
g. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
h. Negative N-binding antibody result and negative NAAT result at Visit 1, positive NAAT result at Visit 2 or at unscheduled visit, if any, prior to 7 days after Dose 2.
i. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1 and Visit 2, and negative NAAT result at unscheduled visit, if any, prior to 7 days after Dose 2.

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Table 15. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Requested Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	8	2.214 (17411)	162	2.222 (17511)	95.0	(90.0, 97.9)
Age group (years)						
12 to 15	0	0.000 (14)	0	0.000 (13)	NE	(NE, NE)
16 to 17	0	0.002 (52)	0	0.003 (55)	NE	(NE, NE)
18 to 64	7	1.703 (13497)	143	1.708 (13563)	95.1	(89.6, 98.1)
65 to 74	1	0.406 (3074)	14	0.406 (3095)	92.9	(53.1, 99.8)
≥75	0	0.102 (774)	5	0.106 (785)	100.0	(-13.1, 100.0)
Race						
White	7	1.889 (14504)	146	1.903 (14670)	95.2	(89.8, 98.1)
Black or African American	0	0.165 (1502)	7	0.164 (1486)	100.0	(31.2, 100.0)
American Indian or Alaska native	0	0.011 (100)	1	0.010 (96)	100.0	(-3429.0, 100.0)
Asian	1	0.092 (764)	4	0.093 (769)	74.6	(-156.6, 99.5)
Native Hawaiian or other Pacific Islander	0	0.006 (46)	1	0.003 (29)	100.0	(-2266.9, 100.0)
Multiracial	0	0.042 (414)	1	0.036 (359)	100.0	(-3231.3, 100.0)
Not reported	0	0.010 (81)	2	0.012 (102)	100.0	(-563.3, 100.0)

Table 15. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Requested Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 23NOV2020 (16:38)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2 unblinded/C4591001 EUA FAEF RR/adc19ef ve cov 7pd2 worq sg eval

Table 16. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	8	2.214 (17411)	162	2.222 (17511)	95.0	(90.0, 97.9)
At risk[f]						
Yes	4	1.025 (8030)	86	1.025 (8029)	95.3	(87.7, 98.8)
No	4	1.189 (9381)	76	1.197 (9482)	94.7	(85.9, 98.6)
Age group (years) and at risk						
16-64 and not at risk	4	0.962 (7671)	69	0.964 (7701)	94.2	(84.4, 98.5)
16-64 and at risk	3	0.744 (5878)	74	0.746 (5917)	95.9	(87.6, 99.2)
≥65 and not at risk	0	0.227 (1701)	7	0.233 (1771)	100.0	(29.0, 100.0)
≥65 and at risk	1	0.281 (2147)	12	0.279 (2109)	91.7	(44.2, 99.8)
Obese[g]						
Yes	3	0.763 (6000)	67	0.782 (6103)	95.4	(86.0, 99.1)
No	5	1.451 (11406)	95	1.439 (11404)	94.8	(87.4, 98.3)
Age group (years) and obese						
16-64 and not obese	4	1.107 (8811)	83	1.101 (8825)	95.2	(87.3, 98.7)
16-64 and obese	3	0.598 (4734)	60	0.609 (4789)	94.9	(84.4, 99.0)
≥65 and not obese	1	0.343 (2582)	12	0.338 (2567)	91.8	(44.5, 99.8)
≥65 and obese	0	0.165 (1265)	7	0.173 (1313)	100.0	(27.1, 100.0)

Table 16. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. At risk is defined as having at least one of the Charlson Comorbidity Index (CMI) category or obesity (BMI ≥30 kg/m^2).
g. Obese is defined as BMI ≥30 kg/m^2.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 24NOV2020 (17:41)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_EUA_FAEF_RR/adc19ef_ve_cov_7pd2_wo_rg_eval

Table 17. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Comorbidity Status – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	8	2.214 (17411)	162	2.222 (17511)	95.0	(90.0, 97.9)
Comorbidity						
No comorbidity	4	1.189 (9381)	76	1.197 (9482)	94.7	(85.9, 98.6)
Any comorbidity[f]	4	1.025 (8030)	86	1.025 (8029)	95.3	(87.7, 98.8)
Any malignancy	1	0.092 (704)	4	0.090 (681)	75.7	(-145.8, 99.5)
Cardiovascular	0	0.067 (534)	5	0.062 (492)	100.0	(-0.8, 100.0)
Chronic pulmonary disease	1	0.175 (1374)	14	0.171 (1358)	93.0	(54.1, 99.8)
Diabetes	1	0.176 (1372)	19	0.176 (1374)	94.7	(66.8, 99.9)
Obese (≥30.0 kg/m^2)	3	0.763 (6000)	67	0.782 (6103)	95.4	(86.0, 99.1)
Hypertension	2	0.567 (4413)	44	0.567 (4437)	95.4	(82.6, 99.5)
Diabetes (including gestational diabetes)	1	0.177 (1381)	20	0.178 (1384)	95.0	(68.7, 99.9)

Table 17. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Comorbidity Status – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Subject who had 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥30 kg/m^2.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 29NOV2020 (21:33)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_EUA_FAEF_RR/adc19ef_ve_cov_7pd2_wo_cg_eval

2.5.4.3.2.1.3. Secondary Efficacy – Final Analysis

2.5.4.3.2.1.3.1. Vaccine Efficacy For COVID-19 Occurring at Least 14 Days After Dose 2 – Final Analysis

Participants Without Evidence of Infection Before and During Vaccination Regimen

For this efficacy endpoint, participants with positive or unknown NAAT results at any illness visit prior to 14 days after Dose 2 were not included in the evaluation for efficacy.

Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, VE against confirmed COVID-19 occurring at least 14 days after Dose 2 was 94.2%, with 8 and 139 cases in the BNT162b2 and placebo groups respectively (Table 18). The posterior probability of >99.99% for the true VE greater than 30% met the prespecified success criterion of >98.6% for this endpoint. The 95% credible interval for the vaccine efficacy was 88.7% to 97.2%, indicating that the true VE is at least 88.7% with a 97.5% probability given the available data.

Table 18. Vaccine Efficacy – First COVID-19 Occurrence From 14 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=18175)		Placebo (N[a]=18261)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 14 days after Dose 2	8	1.887 (16612)	139	1.893 (16663)	94.2	(88.7, 97.2)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 14 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 14 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 14pd2 wo eval

Participants With or Without Evidence of Infection Before and During Vaccination Regimen

Among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen, VE against confirmed COVID-19 occurring at least 14 days after Dose 2 was 94.4%, with 8 and 144 cases in the BNT162b2 and placebo groups respectively (Table 19). The posterior probability of >99.99% for the true VE greater than 30% met the prespecified success criterion of >98.6% for this endpoint. The 95% credible interval for the vaccine efficacy was 89.1% to 97.3%, indicating that the true VE is at least 89.1% with a 97.5% probability given the available data.

Table 19. Vaccine Efficacy – First COVID-19 Occurrence From 14 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20171)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 14 days after Dose 2	8	1.984 (17645)	144	1.995 (17746)	94.4	(89.1, 97.3)	>0.9999

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 14pd2 eval

2.5.4.3.2.1.3.2. Efficacy for Severe COVID-19 Cases – Final Analysis

Efficacy Against Severe COVID-19 (≥7 Days After Dose 2)

Participants Without Evidence of Infection Before and During Vaccination Regimen

For this efficacy endpoint, participants with positive or unknown NAAT results at any illness visit prior to 7 days after Dose 2 were not included in the evaluation for efficacy.

Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against severe COVID-19 occurring at least 7 days after Dose 2 was 66.4%, with 1 and 3 cases in the BNT162b2 and placebo groups respectively (Table 20). The posterior probability for the true vaccine efficacy greater than 30% is 74.29%, which did not meet the prespecified success criterion of >98.6% for this endpoint due to the small number of severe cases observed after Dose 2 in the study. Consequently, statistical testing of subsequent secondary endpoints (ie, the additional secondary endpoints related to severe disease with pre-specified control of overall type 1 error) ended. However, descriptive summaries for the additional endpoints are provided.

Table 20. Vaccine Efficacy – First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)				
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**	**Pr (VE >30% | data)[f]**
First severe COVID-19 occurrence from 7 days after Dose 2	1	2.215 (17411)	3	2.232 (17511)	66.4	(-124.8, 96.3)	0.7429

Table 20. Vaccine Efficacy – First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:47)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve sev cov 7pd2 wo eval

Participants With or Without Evidence of Infection Before and During Vaccination Regimen

Among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen, VE against severe COVID-19 occurring at least 7 days after Dose 2 was 66.3%, with 1 and 3 cases in the BNT162b2 and placebo groups respectively (Table 21). The posterior probability for the true vaccine efficacy greater than 30% is 74.19%.

Table 21. Vaccine Efficacy – First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20172)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First severe COVID-19 occurrence from 7 days after Dose 2	1	2.333 (18566)	3	2.358 (18733)	66.3	(-125.5, 96.3)	0.7419

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_sev_cov_7pd2_eval

All Confirmed Cases of Severe COVID-19 After Dose 1 – All-Available Population

Among participants in the all-available efficacy population, 1 case of severe COVID-19 occurred after Dose 1 in the BNT162b2 group compared to 9 cases in the placebo group (Table 22). The estimated VE against severe COVID-19 occurring after Dose 1 was 88.9% (2-sided 95% CI: 20.1%, 99.7%), with an estimated VE of 75.0% (1 case in BNT162b2 and 4 cases in placebo groups) against severe COVID-19 occurring at least 7 days after Dose 2.

In addition to the C4591001 protocol specified definition of severe COVID-19 (provided in Section 2.5.4.1.1.3), a post hoc efficacy analysis for severe COVID-19 cases was conducted using the CDC definition of severe COVID-19 (hospitalization, admission to the ICU, intubation or mechanical ventilation, or death).[18] In this analysis, the Dose 1 all-available efficacy population, 1 case of severe COVID-19 occurred after Dose 1 in the BNT162b2 group compared to 14 cases in the placebo group (Table 23). The estimated VE against severe COVID-19 occurring after Dose 1 was 92.9% (2-sided 95% CI: 53.2%, 99.8%), with an estimated VE of 100.0% against severe COVID-19 occurring at least 7 days after Dose 2 (no cases in the BNT162b2 group and 5 cases in the placebo group).

Table 22. Vaccine Efficacy – First Severe COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=21669)		Placebo (N[a]=21686)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First severe COVID-19 occurrence after Dose 1	1	4.021 (21314)	9	4.006 (21259)	88.9	(20.1, 99.7)
After Dose 1 to before Dose 2	0		4		100.0	(-51.5, 100.0)
Dose 2 to 7 days after Dose 2	0		1		100.0	(-3800.0, 100.0)
≥7 Days after Dose 2	1		4		75.0	(-152.6, 99.5)

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method (adjusted for surveillance time for overall row).
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 18NOV2020 (17:43)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_sev_cov_pd1_aai

Table 23. Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC-Definition After Dose 1 – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=21669)		Placebo (N[a]=21686)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First Severe COVID-19 occurrence based on CDC-definition after Dose 1	1	4.018 (21299)	14	4.001 (21238)	92.9	(53.2, 99.8)
After Dose 1 to before Dose 2	1		8		87.5	(6.8, 99.7)
Dose 2 to 7 days after Dose 2	0		1		100.0	(-3800.0, 100.0)
≥7 Days after Dose 2	0		5		100.0	(-9.1, 100.0)

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method (adjusted for surveillance time for overall row).
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 03DEC2020 (22:53)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_VRBPAC/adc19ef_ve_sev_cdc_pd1_aai

Participants Without Evidence of Infection Before and During Vaccination Regimen (14 Days) – Severe – Evaluable Efficacy Population

For this efficacy endpoint, participants with positive or unknown NAAT results at any illness visit prior to 14 days after Dose 2 were not included in the evaluation for efficacy.

Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against severe COVID-19 occurring at least 14 days after Dose 2 was 66.4%, with 1 and 3 cases in the BNT162b2 and placebo groups respectively (Table 24). The posterior probability for the true vaccine efficacy greater than 30% is 74.32%.

Table 24. Vaccine Efficacy – First Severe COVID-19 Occurrence From 14 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=18175)		Placebo (N[a]=18261)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First severe COVID-19 occurrence from 14 days after Dose 2	1	1.888 (16612)	3	1.901 (16663)	66.4	(-124.7, 96.3)	0.7432

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 14 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 14 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_sev_cov_14pd2_wo_eval

Participants With or Without Evidence of Infection Before and During Vaccination Regimen (14 Days) – Severe – Evaluable Efficacy Population

Among participants with or without evidence of SARS-CoV-2 infection before and during vaccination phase, VE against severe COVID-19 occurring at least 14 days after Dose 2 was 66.3%, with 1 and 3 cases in the BNT162b2 and placebo groups respectively (Table 25). The posterior probability for the true vaccine efficacy greater than 30% is 74.18%.

Table 25. Vaccine Efficacy – First Severe COVID-19 Occurrence From 14 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20171)				
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**	**Pr (VE >30% | data)[f]**
First severe COVID-19 occurrence from 14 days after Dose 2	1	1.985 (17652)	3	2.007 (17792)	66.3	(-125.6, 96.3)	0.7418

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:47)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_sev_cov_14pd2_eval

2.5.4.3.2.1.3.3. Efficacy for COVID-19 per CDC Definition – Final Analysis

Efficacy Against COVID-19 Based on CDC-Defined Symptoms (≥7 Days After Dose 2)

Participants Without Evidence of Infection Before and During Vaccination Regimen – CDC Defined – 7 Days

For this efficacy endpoint, participants with positive or unknown NAAT results at any illness visit prior to 7 days after Dose 2 were not included in the evaluation for efficacy.

Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, VE against CDC-defined COVID-19 occurring at least 7 days after Dose 2 was 95.1% (2-sided 95% CI: 90.2%, 97.9%), with 8 and 165 cases in the BNT162b2 and placebo groups respectively (Table 26).

Table 26. Vaccine Efficacy – First COVID-19 Occurrence Based on CDC-Defined Symptoms From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**
First COVID-19 occurrence based on CDC-defined symptoms from 7 days after Dose 2	8	2.213 (17399)	165	2.220 (17495)	95.1	(90.2, 97.9)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 18NOV2020 (07:39)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 7pd2 wo cdc eval

Participants With or Without Evidence of Infection Before and During Vaccination Regimen – CDC Defined – 7 Days

Among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen, VE against CDC-defined COVID-19 occurring at least 7 days after Dose 2 was 94.7% (2-sided 95% CI: 89.8%, 97.6%), with 9 and 172 cases in the BNT162b2 and placebo groups respectively (Table 27).

Table 27. Vaccine Efficacy – First COVID-19 Occurrence Based on CDC-Defined Symptoms From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20172)			
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**
First COVID-19 occurrence based on CDC-defined symptoms from 7 days after Dose 2	9	2.330 (18544)	172	2.343 (18690)	94.7	(89.8, 97.6)

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 18NOV2020 (07:39)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 7pd2 cdc eval

Efficacy Against COVID-19 Based on CDC-Defined Symptoms (≥14 Days After Dose 2)

Among participants without and with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen, observed VE results against CDC-defined COVID-19 occurring at least 14 days after Dose 2 were similar to those occurring at least 7 days after Dose 2.

2.5.4.3.2.2. Efficacy Conclusions – Final Analysis

Final Analysis of Efficacy in the Evaluable Efficacy Population

In the final efficacy analysis, among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 95.0%, with 8 COVID-19 cases in the BNT162b2 group compared to 162 COVID-19 cases in the placebo group. The 95% credible interval for the vaccine efficacy was 90.3% to 97.6%.

For the second primary endpoint, VE against confirmed COVID-19 occurring at least 7 days after Dose 2 in participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen was 94.6%, with 9 and 169 cases in the BNT162b2 and placebo groups respectively. The posterior probability of >99.99% for the true VE greater than 30% met the prespecified success criterion of >98.6% for this endpoint. The 95% credible interval for the vaccine efficacy was 89.9% to 97.3%.

Observed VE was very high for the first primary efficacy endpoint across subgroups of age, sex, race, ethnicity, and country, as VE was >93% in all subgroups, with the exception of "all others" race group (89.3% VE) and Brazil (87.7% VE).

For the secondary efficacy endpoint analyses, observed VE against confirmed COVID-19 occurring at least 14 days after Dose 2 in participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, was 94.2%, with 8 and 139 cases in the BNT162b2 and placebo groups respectively. The posterior probability of >99.99% for the true VE >30% met the prespecified success criterion of >98.6% for this endpoint. The 95% credible interval for the vaccine efficacy was 88.7% to 97.2%.

Similarly, among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen, VE against confirmed COVID-19 occurring at least 14 days after Dose 2 was 94.4%, with 8 and 144 cases in the BNT162b2 and placebo groups respectively. The posterior probability of >99.99% for the true VE >30% met the prespecified success criterion of >98.6% for this endpoint. The 95% credible interval for the vaccine efficacy was 89.1% to 97.3%.

Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, observed VE of 66.3% against severe COVID-19 occurring at least 7 days after Dose 2 did not meet the prespecified success criterion of the posterior probability >98.6%, due to the small number of severe cases (1 in the BNT162b2 group, 3 in the placebo group) observed after Dose 2 in the study.

The efficacy analyses using CDC defined symptoms to identify a COVID-19 case gave similar efficacy results as the primary endpoints.

Final Analysis of Efficacy in the All-Available Efficacy Population

The early onset of protection is readily apparent from cumulative incidence curves, which show that disease onset tracks conjointly for BNT162b2 and placebo until approximately 14 days after Dose 1, at which point the curves diverge, with cases steadily accumulating in the placebo group, while remaining virtually flat after BNT162b2.

Among all participants, regardless of evidence of infection before or during the vaccination regimen, 50 cases of COVID-19 occurred after Dose 1 in the BNT162b2 group compared with 275 cases in the placebo group, indicating an estimated VE of 82% (2-sided 95% CI: 75.6%, 86.9%) against confirmed COVID-19 occurring after Dose 1, with VE of 52.4% (95% CI: 29.5%, 68.4%) between Dose 1 and Dose 2.

Among the total of 10 severe COVID-19 cases observed after Dose 1, only 1 severe case was seen in BNT162b2 recipients compared to 9 severe COVID-19 cases in placebo recipients; these results, as well as case splits between Dose 1 and Dose 2 and after Dose 2, were consistent with overall efficacy seen against COVID-19. Similar results were observed when using the CDC definition of severe disease.

Overall Conclusions from Final Analysis of Efficacy

Final efficacy results show that BNT162b2 at 30 µg provided protection against COVID-19 in participants with or without evidence of prior infection with SARS-CoV-2, including across demographic subgroups, with severe cases observed predominantly in the placebo group.

2.5.4.3.3. Updated Analysis of Efficacy in Study C4591001

Updated analyses of 1165 confirmed cases in blinded placebo-controlled follow-up from Dose 1 to the data cutoff date (13 March 2021) evaluated duration of protection. Updated efficacy data for the Phase 3 portion of Study C4591001 were analyzed for all enrolled participants who met the protocol-specified criteria for efficacy evaluation. Data are summarized for the efficacy populations.

COVID-19 case evaluation for primary and secondary efficacy endpoints is discussed in Section 2.5.4.1. Efficacy endpoints evaluated confirmed COVID-19 cases in participants either without or with or without evidence of past SARS-CoV-2 infection before and during the vaccination regimen. Participants with positive or unknown NAAT results at any illness visit prior to either 7 days after Dose 2 were not included in the evaluation for VE. Cases were counted from 7 days after Dose 2.

Efficacy population characteristics in the updated analysis are presented in Section 2.5.4.3.3.1, and results of the updated analysis are presented in Section 2.5.4.3.3.2 and Section 2.5.4.3.3.3 (VE for participants either without or with or without prior evidence of SARS-CoV-2 infection, respectively), Section 2.5.4.3.3.4 (VE in demographic, risk, and comorbidity subgroups), and Section 2.5.4.3.3.5 (VE for severe disease as defined by the FDA and by the CDC).

2.5.4.3.3.1. Efficacy Populations – Updated Analysis

Disposition and Data Sets Analyzed

The proportions of participants included in the updated efficacy populations were similar in the BNT162b2 and placebo groups (Table 28).

Most participants who were excluded from the evaluable efficacy population had not received all vaccinations as randomized or did not receive Dose 2 within the predefined window (ie, 19 to 42 days after Dose 1). There were 240 participants in the BNT162b2 group and 60 participants in the placebo group excluded for having important protocol deviations on or prior to 7 days after Dose 2. In the BNT162b2 group, most of these deviations were related to improper administration of the investigational product (203 participants, as compared with 23 participants in the placebo group). Specifically, in the BNT162b2 group most PDs were due to dosing/administration errors (errors in dilution of the vaccine, 76 participants) or administration of investigational product that was deemed not suitable for use (temperature excursions in shipment or storage at the distributor, 110 participants) that would have not applied to placebo.

Table 28. Efficacy Populations – Blinded Placebo-Controlled Follow-up Period

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Randomized[b]	23219 (100.0)	23210 (100.0)	46429 (100.0)
Dose 1 all-available efficacy population	23140 (99.7)	23137 (99.7)	46277 (99.7)
Subjects without evidence of infection before Dose 1	22200 (95.6)	22191 (95.6)	44391 (95.6)
Subjects excluded from Dose 1 all-available efficacy population	79 (0.3)	73 (0.3)	152 (0.3)
Reason for exclusion[c]			
Did not receive at least 1 vaccination	58 (0.2)	51 (0.2)	109 (0.2)
Data considered potentially unreliable due to lack of PI oversight identified as significant quality event	21 (0.1)	22 (0.1)	43 (0.1)
Dose 2 all-available efficacy population	22771 (98.1)	22741 (98.0)	45512 (98.0)
Subjects without evidence of infection prior to 7 days after Dose 2	21544 (92.8)	21470 (92.5)	43014 (92.6)
Subjects excluded from Dose 2 all-available efficacy population	448 (1.9)	469 (2.0)	917 (2.0)
Reason for exclusion[c]			
Did not receive 2 vaccinations	384 (1.7)	443 (1.9)	827 (1.8)
Data considered potentially unreliable due to lack of PI oversight identified as significant quality event	21 (0.1)	22 (0.1)	43 (0.1)
Unblinded prior to 7 days after Dose 2	45 (0.2)	11 (0.0)	56 (0.1)
Evaluable efficacy (7 days) population	22255 (95.8)	22410 (96.6)	44665 (96.2)
Subjects without evidence of infection prior to 7 days after Dose 2	21069 (90.7)	21175 (91.2)	42244 (91.0)
Subjects excluded from evaluable efficacy (7 days) population	964 (4.2)	800 (3.4)	1764 (3.8)
Reason for exclusion[c]			

Table 28. Efficacy Populations – Blinded Placebo-Controlled Follow-up Period

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Randomized but did not meet all eligibility criteria	33 (0.1)	30 (0.1)	63 (0.1)
Data considered potentially unreliable due to lack of PI oversight identified as significant quality event	21 (0.1)	22 (0.1)	43 (0.1)
Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)	732 (3.2)	748 (3.2)	1480 (3.2)
Unblinded prior to 7 days after Dose 2	45 (0.2)	11 (0.0)	56 (0.1)
Had other important protocol deviations on or prior to 7 days after Dose 2	240 (1.0)	60 (0.3)	300 (0.6)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. n = Number of subjects with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. Subjects may have been excluded for more than 1 reason.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (02:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_eff_pop

Demographics

Demographics of participants in the updated evaluable efficacy population for participants without evidence of infection prior to 7 days after Dose 2 were similar in the BNT162b2 and placebo groups (Table 29). This analysis population had generally similar demographics compared to the safety population (refer to Section 2.5.5.5.1).

Demographic characteristics for the Dose 1 all-available efficacy population and for participants with or without evidence of infection prior to 7 days after Dose 2 (evaluable efficacy [7 days] population) were similar to the evaluable efficacy (7 days) population.

Table 29. Demographic Characteristics – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=21069) n[b] (%)	Placebo (N[a]=21175) n[b] (%)	Total (N[a]=42244) n[b] (%)
Sex			
Male	10824 (51.4)	10689 (50.5)	21513 (50.9)
Female	10245 (48.6)	10486 (49.5)	20731 (49.1)
Race			
White	17458 (82.9)	17604 (83.1)	35062 (83.0)
Black or African American	1799 (8.5)	1812 (8.6)	3611 (8.5)
American Indian or Alaska Native	188 (0.9)	182 (0.9)	370 (0.9)
Asian	959 (4.6)	949 (4.5)	1908 (4.5)
Native Hawaiian or other Pacific Islander	55 (0.3)	31 (0.1)	86 (0.2)
Multiracial	522 (2.5)	489 (2.3)	1011 (2.4)
Not reported	88 (0.4)	108 (0.5)	196 (0.5)
All others[c]	1812 (8.6)	1759 (8.3)	3571 (8.5)
Racial Designation			
Japanese	78 (0.4)	74 (0.3)	152 (0.4)
Ethnicity			
Hispanic/Latino	5241 (24.9)	5217 (24.6)	10458 (24.8)
Non-Hispanic/non-Latino	15725 (74.6)	15846 (74.8)	31571 (74.7)
Not reported	103 (0.5)	112 (0.5)	215 (0.5)
Country			
Argentina	2624 (12.5)	2617 (12.4)	5241 (12.4)
Brazil	1326 (6.3)	1314 (6.2)	2640 (6.2)
Germany	238 (1.1)	242 (1.1)	480 (1.1)
South Africa	307 (1.5)	297 (1.4)	604 (1.4)
Turkey	231 (1.1)	226 (1.1)	457 (1.1)
USA	16343 (77.6)	16479 (77.8)	32822 (77.7)
Age group (years)			
12 to 15	1005 (4.8)	978 (4.6)	1983 (4.7)
16 to 55	11753 (55.8)	11824 (55.8)	23577 (55.8)
>55	8311 (39.4)	8373 (39.5)	16684 (39.5)
≥65	4245 (20.1)	4296 (20.3)	8541 (20.2)
16 to 17	344 (1.6)	334 (1.6)	678 (1.6)
16 to 25	1657 (7.9)	1668 (7.9)	3325 (7.9)
16 to 64	15819 (75.1)	15901 (75.1)	31720 (75.1)
18 to 64	15475 (73.4)	15567 (73.5)	31042 (73.5)
55 to 64	4499 (21.4)	4493 (21.2)	8992 (21.3)
65 to 74	3392 (16.1)	3442 (16.3)	6834 (16.2)
≥75	853 (4.0)	854 (4.0)	1707 (4.0)
75 to 85	848 (4.0)	848 (4.0)	1696 (4.0)
>85	5 (0.0)	6 (0.0)	11 (0.0)

Table 29. Demographic Characteristics – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=21069) n[b] (%)	Placebo (N[a]=21175) n[b] (%)	Total (N[a]=42244) n[b] (%)
Comorbidities[d]			
Yes	9390 (44.6)	9411 (44.4)	18801 (44.5)
No	11679 (55.4)	11764 (55.6)	23443 (55.5)
Age at vaccination (years)			
Mean (SD)	48.3 (17.41)	48.2 (17.41)	48.3 (17.41)
Median	50.0	50.0	50.0
Min, max	(12, 89)	(12, 91)	(12, 91)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
d. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥30 kg/m^2 (≥16 Years of age) or BMI ≥95th percentile (12-15 Years of age).
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 19APR2021 (17:13)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adsl demo 7d eval eff

2.5.4.3.3.2. Vaccine Efficacy Without Prior Evidence of SARS-CoV-2 Infection – 7 Days After Dose 2 – Updated Analysis

Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 91.3%, with 77 COVID-19 cases in the BNT162b2 group compared to 850 cases in the placebo group (Table 30). The 2-sided 95% CI for vaccine efficacy was 89.0% to 93.2%. The posterior probability for the true VE being >30%, given the available data, was >99.99%.

The vaccine efficacy of BNT162b2 for the same efficacy endpoint based on the Dose 2 all-available efficacy population was 91.4 % (2-sided 95% CI: 89.1%, 93.3%), with 78 and 866 cases in the BNT162b2 and placebo group, respectively.

Table 30. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	77	6.247 (20712)	850	6.003 (20713)	91.3	(89.0, 93.2)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (01:59)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adc19ef ve cov 7pd2 wo eval

2.5.4.3.3.3. Vaccine Efficacy With or Without Prior Evidence of SARS-CoV-2 Infection – 7 Days After Dose 2 – Updated Analysis

Among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen, estimated VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 91.1%, with 81 and 873 cases in the BNT162b2 and placebo groups, respectively (Table 31). The 2-sided 95% CI for vaccine efficacy was 88.8% to 93.0%. The posterior probability for the true VE being >30%, given the available data, was >99.99%.

The vaccine efficacy of BNT162b2 for the same efficacy endpoint based on the Dose 2 all-available efficacy population was 91.2 % (2-sided 95% CI: 88.9%, 93.0%), with 82 and 889 cases in the BNT162b2 and placebo group, respectively.

Table 31. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	81	6.509 (21642)	873	6.274 (21689)	91.1	(88.8, 93.0)	>0.9999

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (01:59)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_ve_cov_7pd2_eval

All Confirmed Cases of COVID-19 After Dose 1 – Dose 1 All-Available Efficacy Population

A number of confirmed cases of COVID-19 are not captured in the analyses of the primary endpoints for the evaluable efficacy population because they either occurred in participants who were excluded from the evaluable efficacy population or occurred <7 days after Dose 2.

All reports of COVID-19 with onset at any time after Dose 1 are accounted for in Table 32, which provides a summary of confirmed cases for all participants in the Dose 1 all-available efficacy (modified intention-to-treat) population adjusted for exposure, regardless of evidence of infection before or during the vaccination regimen. Among these participants, 131 cases of COVID-19 occurred after Dose 1 in the BNT162b2 group compared to 1034 cases in the placebo group. The estimated VE against confirmed COVID-19 occurring after Dose 1 was 87.8% (2-sided 95% CI: 85.3%, 89.9%).

In this population, the estimated VE against all cases occurring ≥7 days after Dose 2 was 91.2%. The estimated VE was 91.7% from ≥11 days after Dose 1 to before Dose 2, 96.2% for cases occurring from ≥7 days after Dose 2 to <2 months after Dose 2, 90.1% for the period from ≥2 months to <4 months after Dose 2, and 83.7% for the period ≥4 months after Dose 2.

The early onset of protection is readily apparent in Figure 2, which displays cumulative incidence for the first COVID-19 occurrence after Dose 1 among all vaccinated participants based on Dose 1 all-available efficacy (modified intention-to-treat) population. Disease onset appears to track together for BNT162b2 and placebo until approximately 11 days after Dose 1 (consistent with the data shown in Table 32), at which point the curves diverge with cases steadily accumulating in the placebo group and remaining virtually flat in the BNT162b2 group.

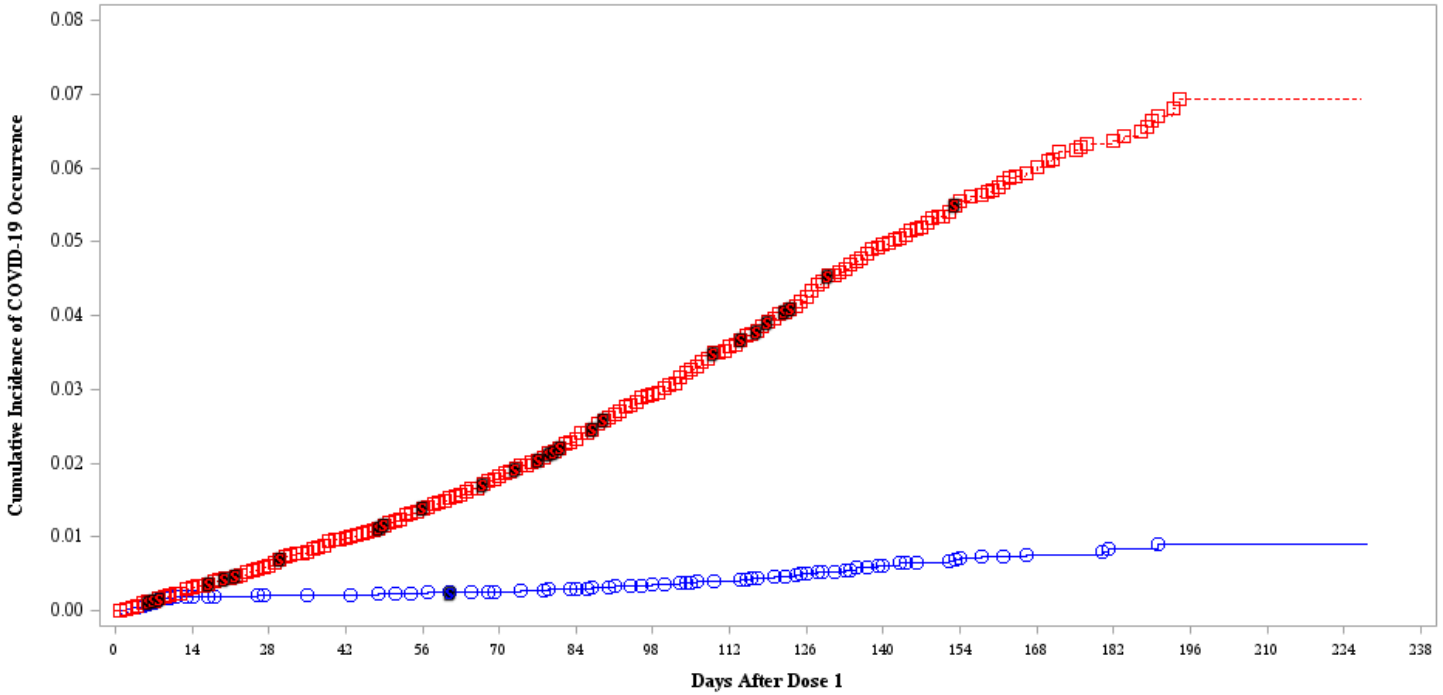
The darker-appearing symbols for both BNT162b2 (blue circles) and placebo (red squares) curves in Figure 2 have an "S" written inside the open symbol, which denotes severe cases. Severe COVID-19 cases reported in the updated analysis are discussed further in Section 2.5.4.3.3.5.

Table 32. Vaccine Efficacy – First COVID-19 Occurrence After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=23040)		Placebo (N[a]=23037)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence after Dose 1	131	8.412 (22505)	1034	8.124 (22434)	87.8	(85.3, 89.9)
After Dose 1 to before Dose 2	46	1.339 (22505)	110	1.331 (22434)	58.4	(40.8, 71.2)
After Dose 1 to <11 days after Dose 1	41	0.677 (22505)	50	0.675 (22434)	18.2	(-26.1, 47.3)
≥11 Days after Dose 1 to before Dose 2	5	0.662 (22399)	60	0.656 (22369)	91.7	(79.6, 97.4)
Dose 2 to 7 days after Dose 2	3	0.424 (22163)	35	0.422 (22057)	91.5	(72.9, 98.3)
≥7 Days after Dose 2	82	6.649 (22132)	889	6.371 (22001)	91.2	(88.9, 93.0)
≥7 days after Dose 2 to <2 Months after Dose 2	12	2.923 (22132)	312	2.884 (22001)	96.2	(93.3, 98.1)
≥2 Months after Dose 2 to <4 Months after Dose 2	46	2.696 (20814)	449	2.593 (20344)	90.1	(86.6, 92.9)
≥4 Months after Dose 2	24	1.030 (12670)	128	0.895 (11802)	83.7	(74.7, 89.9)

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 19APR2021 (17:34)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adc19ef ve cov pd1 aai

Figure 2. Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population – Updated Analysis



Subjects at Risk

A:	22505	22398	22320	22241	22037	21325	20560	19085	17130	14582	11376	7889	4577	2463	1082	158	4
B:	22434	22352	22193	22034	21738	20889	20024	18428	16401	13747	10523	6997	3827	1911	657	38	3

Cumulative Number of Events

A:	0	43	47	48	53	59	66	77	87	102	116	125	128	130	131	131	131
B:	0	70	137	219	309	406	509	630	744	850	939	991	1016	1027	1034	1034	1034

Note: "S" indicates subjects with severe COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adc19ef Table Generation: 27MAR2021 (11:38)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_f001_km_d1_aai

2.5.4.3.3.4. Vaccine Efficacy by Subgroup – Updated Analysis

Subgroup Analyses by Demographics and by Country

For both primary endpoints, VE was also evaluated for subgroups of participants by age, sex, race, ethnicity, country, and baseline SARS-CoV-2 status. Overall, the results show high VE across the subgroups. In the evaluable efficacy population among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE was ≥90% in most subgroups, similar to the estimated 91.3% overall VE (Table 33).

High estimated VE was observed across age ranges/groups:

- 100.0% in participants 12 to 15 years of age
- 90.6% in participants 16 to 64 years of age
- 94.5% in participants ≥65 years of age
- 96.2% in those ≥75 years of age.

Estimated VE was 90.1% and 92.4% in male and female participants, respectively.

Estimated VE among race/ethnicity groups was:

- 91.3% among White participants
- 87.6% among Asian participants
- 88.5% among Hispanic/Latino participants.

Estimated VE by country was:

- 92.6% in the US
- 86.5% in Argentina
- 86.2% in Brazil
- 100.0% in South Africa, Germany, and Turkey.

Similar results were observed for subgroup analyses among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen (Table 34). In analyses for the Dose 1 all-available efficacy population, which included all confirmed cases occurring at any time after Dose 1, no clinically meaningful differences among the subgroups were identified (Table 35).

Subgroup Analyses by Baseline SARS-CoV-2 Status

Subgroup analyses included evaluation of VE by prior SARS-CoV-2 status at baseline. The number of participants with positive prior SARS-CoV-2 status at baseline was relatively small, and the 95% CIs for the estimated VEs in these subgroup analyses were very wide; therefore, the data must be interpreted with caution. However, the results may provide some information regarding the benefits of vaccination for individuals with prior SARS-CoV-2 infection.

Participants with positive prior SARS-CoV-2 status at baseline were defined as those with positive N-binding antibody or NAAT results at Visit 1 or a medical history of COVID-19. In the evaluable efficacy analysis for this subgroup, the estimated VE against cases occurring ≥7 days after Dose 2 was 46.9% (3 cases BNT162b2; 6 cases placebo; Table 34), and in the Dose 1 all-available efficacy analysis the estimated VE against cases occurring at any time after Dose 1 was 19.2% (13 cases BNT162b2, 17 cases placebo; Table 35).

It is important to note that the subgroup defined above includes participants with both past infections (positive for N-binding antibody) and current infections (NAAT-positive). Since it is reasonable to expect that vaccination may be less effective in participants currently infected with SARS-CoV-2 at Visit 1, it may be relevant to examine VE specifically in participants who were positive for N-binding only (and were not NAAT-positive) at Visit 1. In the evaluable efficacy analysis for these participants, the estimated VE against cases occurring ≥7 days after Dose 2 was 58.9% (2 cases BNT162b2; 5 cases placebo); Table 34), and in the all-available efficacy analysis the estimated VE against cases occurring at any time after Dose 1 was 70.5% (2 cases BNT162b2, 7 cases placebo; Table 35). Therefore, estimates of VE are considerably higher in participants who were positive for N-binding antibody only, suggesting that vaccination provides a benefit for individuals with previous SARS-CoV-2 infection.

Subgroup Analyses by Risk Status

Analyses of efficacy by risk status were performed. For these analyses, at-risk participants were defined as those who had at least one Charlson Comorbidity Index condition or who were obese (defined as BMI ≥30 kg/m^2).

Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE was similar for participants at risk (91.6%) and for participants not at risk (91.0%) (Table 36). The estimated VE for participants ≥65 years of age and at risk was 91.8%, as compared with 98.1% for those ≥65 years of age and not at risk. The estimated VE was similar in obese (91.6%) and non-obese (91.1%) participants.

Results were similar among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen (Table 37).

Subgroup Analyses by Comorbidity

Among participants without prior evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE was similar for participants with any comorbidity (91.6% with 2-sided 95% CI of 88.2% to 94.3%) and for those with no comorbidity (91.0% with 2-sided 95% CI of 87.6% to 93.6%) (Table 38). When evaluated by type of comorbidity, the estimated VE was >85% for participants with each comorbidity evaluated, including any malignancy, cardiovascular disease, chronic pulmonary disease, diabetes, obesity, and hypertension.

Results were similar for participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen (Table 39).

Table 33. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	77	6.247 (20712)	850	6.003 (20713)	91.3	(89.0, 93.2)
Age group (years)						
12 to 15	0	0.154 (1001)	16	0.147 (972)	100.0	(75.3, 100.0)
16 to 55	52	3.593 (11517)	568	3.439 (11533)	91.2	(88.3, 93.5)
>55	25	2.499 (8194)	266	2.417 (8208)	90.9	(86.3, 94.2)
≥65	7	1.233 (4192)	124	1.202 (4226)	94.5	(88.3, 97.8)
16 to 17	0	0.061 (342)	10	0.057 (331)	100.0	(58.2, 100.0)
16 to 25	8	0.482 (1629)	80	0.466 (1622)	90.3	(80.0, 96.0)
16 to 64	70	4.859 (15519)	710	4.654 (15515)	90.6	(87.9, 92.7)
18 to 64	70	4.798 (15177)	700	4.597 (15184)	90.4	(87.7, 92.6)
55 to 64	21	1.399 (4426)	157	1.334 (4388)	87.3	(79.8, 92.3)
65 to 74	6	0.994 (3350)	98	0.966 (3379)	94.1	(86.6, 97.9)
≥75	1	0.239 (842)	26	0.237 (847)	96.2	(76.9, 99.9)
75 to 85	1	0.238 (837)	25	0.235 (841)	96.0	(75.9, 99.9)
>85	0	0.001 (5)	1	0.001 (6)	100.0	(-4055.9, 100.0)
Sex						
Male	42	3.246 (10637)	399	3.047 (10433)	90.1	(86.4, 93.0)
Female	35	3.001 (10075)	451	2.956 (10280)	92.4	(89.2, 94.7)

Table 33. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Race						
White	67	5.208 (17186)	747	5.026 (17256)	91.3	(88.9, 93.4)
Black or African American	4	0.545 (1737)	48	0.527 (1737)	91.9	(78.0, 97.9)
American Indian or Alaska Native	0	0.041 (186)	3	0.037 (176)	100.0	(-119.0, 100.0)
Asian	3	0.260 (946)	23	0.248 (934)	87.6	(58.9, 97.6)
Native Hawaiian or other Pacific Islander	0	0.015 (54)	1	0.008 (30)	100.0	(-1961.2, 100.0)
Multiracial	3	0.151 (518)	22	0.128 (476)	88.5	(61.6, 97.8)
Not reported	0	0.026 (85)	6	0.030 (104)	100.0	(2.8, 100.0)
All others[f]	6	0.494 (1789)	55	0.451 (1720)	90.0	(76.9, 96.5)
Ethnicity						
Hispanic/Latino	29	1.786 (5161)	241	1.711 (5120)	88.5	(83.0, 92.4)
Non-Hispanic/non-Latino	47	4.429 (15449)	609	4.259 (15484)	92.6	(90.0, 94.6)
Not reported	1	0.032 (102)	0	0.033 (109)	-∞	(NA, NA)
Country						
Argentina	15	1.012 (2600)	108	0.986 (2586)	86.5	(76.7, 92.7)
Brazil	12	0.406 (1311)	80	0.374 (1293)	86.2	(74.5, 93.1)
Germany	0	0.047 (236)	1	0.048 (242)	100.0	(-3874.2, 100.0)
South Africa	0	0.080 (291)	9	0.074 (276)	100.0	(53.5, 100.0)
Turkey	0	0.027 (228)	5	0.025 (222)	100.0	(-0.1, 100.0)
USA	50	4.674 (16046)	647	4.497 (16094)	92.6	(90.1, 94.5)

Table 33. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 30MAR2021 (22:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adc19ef ve cov 7pd2 wo sg eval

Table 34. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	81	6.509 (21642)	873	6.274 (21689)	91.1	(88.8, 93.0)
Age group (years)						
12 to 15	0	0.170 (1109)	18	0.163 (1094)	100.0	(78.1, 100.0)
16 to 55	56	3.766 (12088)	584	3.619 (12142)	90.8	(87.9, 93.1)
>55	25	2.573 (8445)	271	2.491 (8453)	91.1	(86.5, 94.3)
≥65	7	1.267 (4315)	128	1.232 (4326)	94.7	(88.7, 97.9)
16 to 17	0	0.065 (365)	11	0.061 (355)	100.0	(62.4, 100.0)
16 to 25	10	0.511 (1734)	84	0.498 (1740)	88.4	(77.6, 94.6)
16 to 64	74	5.073 (16218)	727	4.879 (16269)	90.2	(87.6, 92.4)
18 to 64	74	5.008 (15853)	716	4.817 (15914)	90.1	(87.4, 92.3)
55 to 64	21	1.442 (4563)	159	1.386 (4559)	87.3	(79.9, 92.4)
65 to 74	6	1.021 (3450)	102	0.992 (3468)	94.3	(87.1, 98.0)
≥75	1	0.246 (865)	26	0.240 (858)	96.2	(77.2, 99.9)
75 to 85	1	0.244 (860)	25	0.238 (852)	96.1	(76.2, 99.9)
>85	0	0.001 (5)	1	0.001 (6)	100.0	(-4055.9, 100.0)
Sex						
Male	44	3.376 (11103)	411	3.181 (10920)	89.9	(86.2, 92.8)

Table 34. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Female	37	3.133 (10539)	462	3.093 (10769)	92.1	(88.9, 94.5)
Race						
White	69	5.379 (17801)	768	5.191 (17880)	91.3	(88.9, 93.3)
Black or African American	4	0.611 (1958)	49	0.601 (1985)	92.0	(78.1, 97.9)
American Indian or Alaska Native	0	0.044 (200)	3	0.039 (182)	100.0	(-114.5, 100.0)
Asian	3	0.268 (976)	24	0.257 (967)	88.0	(60.5, 97.7)
Native Hawaiian or other Pacific Islander	0	0.016 (57)	1	0.008 (31)	100.0	(-1896.2, 100.0)
Multiracial	5	0.164 (561)	22	0.145 (532)	79.9	(45.7, 94.1)
Not reported	0	0.028 (89)	6	0.033 (112)	100.0	(-0.0, 100.0)
All others[f]	8	0.519 (1883)	56	0.481 (1824)	86.8	(72.1, 94.5)
Ethnicity						
Hispanic/Latino	32	1.862 (5408)	245	1.794 (5391)	87.4	(81.8, 91.6)
Non-Hispanic/non-Latino	48	4.615 (16128)	628	4.445 (16186)	92.6	(90.1, 94.6)
Not reported	1	0.033 (106)	0	0.034 (112)	-∞	(NA, NA)
Country						
Argentina	16	1.033 (2655)	110	1.017 (2670)	85.7	(75.7, 92.1)
Brazil	14	0.441 (1419)	82	0.408 (1401)	84.2	(71.9, 91.7)
Germany	0	0.047 (237)	1	0.048 (243)	100.0	(-3868.6, 100.0)
South Africa	0	0.099 (358)	10	0.096 (358)	100.0	(56.6, 100.0)

Table 34. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)			
Efficacy Endpoint Subgroup	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**
Turkey	0	0.029 (238)	6	0.026 (232)	100.0	(22.2, 100.0)
USA	51	4.861 (16735)	664	4.678 (16785)	92.6	(90.2, 94.6)
Prior SARS-CoV-2 Status						
Positive at baseline[g]	3	0.190 (639)	6	0.201 (689)	46.9	(-148.7, 91.4)
Positive N-binding only	2	0.147 (494)	5	0.151 (516)	58.9	(-151.3, 96.1)
Positive NAAT only	0	0.014 (50)	1	0.015 (58)	100.0	(-3996.1, 100.0)
Positive NAAT and N-binding	1	0.028 (95)	0	0.035 (114)	-∞	(NA, NA)
Negative at baseline but positive prior to 7 days after Dose 2[h]	0	0.011 (43)	3	0.014 (60)	100.0	(-211.3, 100.0)
Negative prior to 7 days after Dose 2[i]	77	6.247 (20712)	850	6.003 (20712)	91.3	(89.0, 93.2)
Unknown	1	0.062 (248)	14	0.055 (228)	93.7	(58.3, 99.9)

Table 34. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
g. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
h. Negative N-binding antibody result and negative NAAT result at Visit 1, positive NAAT result at Visit 2 or at unscheduled visit, if any, prior to 7 days after Dose 2.
i. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1 and Visit 2, and negative NAAT result at unscheduled visit, if any, prior to 7 days after Dose 2.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 30MAR2021 (22:37)
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Table 35. Vaccine Efficacy – First COVID-19 Occurrence After Dose 1, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=23040)		Placebo (N[a]=23037)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[c])
First COVID-19 occurrence after Dose 1						
Overall	131	8.412 (22505)	1034	8.124 (22434)	87.8	(85.3, 89.9)
Age group (years)						
12 to 15	3	0.257 (1120)	35	0.250 (1119)	91.6	(73.5, 98.4)
16 to 55	95	4.845 (12645)	693	4.669 (12626)	86.8	(83.6, 89.5)
>55	33	3.310 (8740)	306	3.204 (8689)	89.6	(85.0, 92.9)
≥65	12	1.645 (4455)	138	1.596 (4437)	91.6	(84.8, 95.7)
16 to 17	3	0.094 (373)	19	0.090 (370)	84.8	(48.4, 97.1)
16 to 25	18	0.661 (1811)	114	0.651 (1836)	84.4	(74.3, 91.1)
16 to 64	116	6.511 (16930)	861	6.278 (16878)	87.0	(84.2, 89.4)
18 to 64	113	6.417 (16557)	842	6.188 (16508)	87.1	(84.2, 89.5)
55 to 64	25	1.840 (4738)	185	1.772 (4697)	87.0	(80.2, 91.8)
65 to 74	10	1.319 (3550)	112	1.285 (3560)	91.3	(83.4, 95.9)
≥75	2	0.326 (905)	26	0.310 (877)	92.7	(70.7, 99.2)
75 to 85	2	0.324 (899)	25	0.309 (871)	92.4	(69.4, 99.1)
>85	0	0.002 (6)	1	0.002 (6)	100.0	(-3408.8, 100.0)
Sex						
Male	70	4.355 (11560)	500	4.115 (11312)	86.8	(83.0, 89.9)
Female	61	4.057 (10945)	534	4.009 (11122)	88.7	(85.3, 91.5)

Table 35. Vaccine Efficacy – First COVID-19 Occurrence After Dose 1, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=23040)		Placebo (N[a]=23037)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Race						
White	115	6.957 (18538)	916	6.719 (18479)	87.9	(85.3, 90.1)
Black or African American	6	0.783 (2042)	53	0.770 (2063)	88.9	(74.1, 96.1)
American Indian or Alaska Native	1	0.061 (216)	7	0.055 (209)	86.9	(-1.6, 99.7)
Asian	4	0.348 (995)	26	0.337 (990)	85.1	(57.0, 96.2)
Native Hawaiian or other Pacific Islander	0	0.021 (58)	1	0.011 (32)	100.0	(-2000.0, 100.0)
Multiracial	5	0.208 (565)	25	0.190 (546)	81.8	(51.6, 94.6)
Not reported	0	0.035 (91)	6	0.042 (115)	100.0	(-0.7, 100.0)
All others[f]	10	0.672 (1925)	65	0.635 (1892)	85.5	(71.5, 93.3)
Ethnicity						
Hispanic/Latino	52	2.351 (5701)	302	2.282 (5673)	83.3	(77.5, 87.8)
Non-Hispanic/non-Latino	78	6.018 (16692)	730	5.799 (16647)	89.7	(87.0, 92.0)
Not reported	1	0.043 (112)	2	0.043 (114)	49.4	(-872.9, 99.1)
Country						
Argentina	32	1.282 (2846)	146	1.269 (2840)	78.3	(68.0, 85.7)
Brazil	14	0.554 (1430)	95	0.520 (1420)	86.1	(75.6, 92.7)
Germany	2	0.067 (246)	1	0.069 (250)	-104.5	(-11965.9, 89.4)
South Africa	0	0.128 (367)	11	0.125 (365)	100.0	(61.1, 100.0)
Turkey	3	0.048 (246)	12	0.045 (244)	76.4	(12.4, 95.7)
USA	80	6.333 (17370)	769	6.095 (17315)	90.0	(87.4, 92.1)
Baseline SARS-CoV-2 status						

Table 35. Vaccine Efficacy – First COVID-19 Occurrence After Dose 1, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=23040)		Placebo (N[a]=23037)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Positive[g]	13	0.250 (692)	17	0.265 (736)	19.2	(-76.6, 63.9)
Positive N-binding only	2	0.192 (521)	7	0.198 (542)	70.5	(-54.7, 97.0)
Positive NAAT only	10	0.020 (66)	9	0.020 (69)	-10.5	(-207.3, 59.7)
Positive NAAT and N-binding	1	0.038 (105)	1	0.046 (124)	-20.5	(-9359.2, 98.5)
Negative[h]	116	8.101 (21615)	1015	7.804 (21521)	89.0	(86.6, 91.0)
Unknown	2	0.061 (198)	2	0.055 (177)	9.7	(-1145.4, 93.5)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
g. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
h. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.

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Table 36. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	77	6.247 (20712)	850	6.003 (20713)	91.3	(89.0, 93.2)
At risk[f]						
Yes	35	2.797 (9167)	401	2.681 (9136)	91.6	(88.2, 94.3)
No	42	3.450 (11545)	449	3.322 (11577)	91.0	(87.6, 93.6)
Age group (years) and at risk						
12-15 and not at risk	0	0.121 (788)	11	0.116 (769)	100.0	(61.9, 100.0)
12-15 and at risk	0	0.034 (213)	5	0.032 (203)	100.0	(-2.0, 100.0)
16-64 and not at risk	41	2.776 (8887)	385	2.661 (8886)	89.8	(85.9, 92.8)
16-64 and at risk	29	2.083 (6632)	325	1.993 (6629)	91.5	(87.5, 94.4)
≥65 and not at risk	1	0.553 (1870)	53	0.546 (1922)	98.1	(89.2, 100.0)
≥65 and at risk	6	0.680 (2322)	71	0.656 (2304)	91.8	(81.4, 97.1)
Obese[g]						
Yes	27	2.103 (6796)	314	2.050 (6875)	91.6	(87.6, 94.6)
No	50	4.143 (13911)	536	3.952 (13833)	91.1	(88.1, 93.5)
Age group (years) and obese						
12-15 and not obese	0	0.135 (878)	13	0.131 (867)	100.0	(68.3, 100.0)
12-15 and obese	0	0.019 (123)	3	0.016 (105)	100.0	(-104.8, 100.0)
16-64 and not obese	46	3.178 (10212)	444	3.028 (10166)	90.1	(86.6, 92.9)
16-64 and obese	24	1.680 (5303)	266	1.624 (5344)	91.3	(86.7, 94.5)
≥65 and not obese	4	0.829 (2821)	79	0.793 (2800)	95.2	(87.1, 98.7)
≥65 and obese	3	0.404 (1370)	45	0.410 (1426)	93.2	(78.9, 98.7)

Table 36. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Includes subjects who had at least one of the Charlson Comorbidity Index (CMI) category or obesity (BMI ≥30 kg/m^2 [≥16 Years of age] or BMI ≥95th percentile [12-15 Years of age]).
g. Subjects (≥16 Years of age) who had BMI ≥30 kg/m^2. For 12 through 15 years age group, obesity is defined as a BMI at or above the 95th percentile. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev htm.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 30MAR2021 (22:35)
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Table 37. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	81	6.509 (21642)	873	6.274 (21689)	91.1	(88.8, 93.0)
At risk[f]						
Yes	36	2.925 (9601)	410	2.807 (9570)	91.6	(88.1, 94.2)
No	45	3.584 (12041)	463	3.466 (12119)	90.6	(87.2, 93.2)
Age group (years) and at risk						
12-15 and not at risk	0	0.132 (867)	11	0.129 (864)	100.0	(61.1, 100.0)
12-15 and at risk	0	0.038 (242)	7	0.035 (230)	100.0	(36.2, 100.0)
16-64 and not at risk	44	2.887 (9254)	397	2.779 (9289)	89.3	(85.4, 92.4)
16-64 and at risk	30	2.186 (6964)	330	2.100 (6980)	91.3	(87.3, 94.2)
≥65 and not at risk	1	0.566 (1920)	55	0.559 (1966)	98.2	(89.6, 100.0)
≥65 and at risk	6	0.701 (2395)	73	0.672 (2360)	92.1	(82.0, 97.2)
Obese[g]						
Yes	28	2.207 (7139)	319	2.158 (7235)	91.4	(87.4, 94.4)
No	53	4.301 (14497)	554	4.114 (14448)	90.8	(87.9, 93.2)
Age group (years) and obese						
12-15 and not obese	0	0.148 (969)	14	0.145 (970)	100.0	(70.5, 100.0)
12-15 and obese	0	0.022 (140)	4	0.019 (124)	100.0	(-31.1, 100.0)
16-64 and not obese	49	3.303 (10629)	458	3.158 (10614)	89.8	(86.2, 92.5)
16-64 and obese	25	1.768 (5584)	269	1.719 (5649)	91.0	(86.4, 94.3)
≥65 and not obese	4	0.850 (2899)	82	0.811 (2864)	95.3	(87.6, 98.8)
≥65 and obese	3	0.417 (1415)	46	0.420 (1462)	93.4	(79.5, 98.7)

Table 37. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Includes subjects who had at least one of the Charlson Comorbidity Index (CMI) category or obesity (BMI ≥30 kg/m^2 [≥16 Years of age] or BMI ≥95th percentile [12-15 Years of age]).
g. Subjects (≥16 Years of age) who had BMI ≥30 kg/m^2. For 12 through 15 years age group, obesity is defined as a BMI at or above the 95th percentile. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html charts/bmiagerev htm.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 30MAR2021 (22:35)
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Table 38. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Comorbidity Status – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	77	6.247 (20712)	850	6.003 (20713)	91.3	(89.0, 93.2)
Comorbidity						
No comorbidity	42	3.450 (11545)	449	3.322 (11577)	91.0	(87.6, 93.6)
Any comorbidity[f]	35	2.797 (9167)	401	2.681 (9136)	91.6	(88.2, 94.3)
Any malignancy	3	0.228 (770)	27	0.214 (748)	89.6	(66.2, 98.0)
Cardiovascular	3	0.172 (584)	23	0.159 (555)	88.0	(60.2, 97.7)
Chronic pulmonary disease	8	0.490 (1684)	69	0.460 (1671)	89.1	(77.3, 95.5)
Diabetes	9	0.465 (1529)	61	0.444 (1517)	85.9	(71.4, 93.8)
Obese (≥30.0 kg/m^2 [≥16 Years of age])	27	2.083 (6673)	311	2.034 (6770)	91.5	(87.4, 94.5)
Obese (≥95th percentile [12-15 Years of age])	0	0.019 (123)	3	0.016 (105)	100.0	(-104.8, 100.0)
Hypertension	15	1.481 (4900)	191	1.427 (4896)	92.4	(87.2, 95.8)
Diabetes (including gestational diabetes)	9	0.468 (1538)	63	0.447 (1531)	86.3	(72.4, 94.0)

Table 38. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Comorbidity Status – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Subject who had 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥30 kg/m^2 (≥16 Years of age) or BMI ≥95th percentile (12-15 Years of age).
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 30MAR2021 (22:39)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adc19ef ve cov 7pd2 wo cg eval

Table 39. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Comorbidity Status – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	81	6.509 (21642)	873	6.274 (21689)	91.1	(88.8, 93.0)
Comorbidity						
No comorbidity	45	3.584 (12041)	463	3.466 (12119)	90.6	(87.2, 93.2)
Any comorbidity[f]	36	2.925 (9601)	410	2.807 (9570)	91.6	(88.1, 94.2)
Any malignancy	3	0.234 (792)	27	0.217 (762)	89.7	(66.5, 98.0)
Cardiovascular	3	0.180 (607)	23	0.163 (569)	88.2	(60.9, 97.7)
Chronic pulmonary disease	8	0.512 (1764)	72	0.480 (1750)	89.6	(78.4, 95.7)
Diabetes	9	0.485 (1597)	62	0.463 (1582)	86.1	(71.9, 93.9)
Obese (≥30.0 kg/m^2 [≥16 Years of age])	28	2.185 (6999)	315	2.139 (7111)	91.3	(87.2, 94.3)
Obese (≥95th percentile [12-15 Years of age])	0	0.022 (140)	4	0.019 (124)	100.0	(-31.1, 100.0)
Hypertension	15	1.535 (5078)	193	1.479 (5077)	92.5	(87.3, 95.9)
Diabetes (including gestational diabetes)	9	0.488 (1606)	64	0.466 (1596)	86.5	(72.8, 94.1)

Table 39. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Comorbidity Status – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Subject who had 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥30 kg/m^2 (≥16 Years of age) or BMI ≥95th percentile (12-15 Years of age).
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 30MAR2021 (22:39)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_ve_cov_7pd2_cg_eval

2.5.4.3.3.5. Vaccine Efficacy for Severe COVID-19 Cases – Updated Analysis

Efficacy Against Severe COVID-19 (≥7 Days After Dose 2)

Participants Without Evidence of Infection Before and During Vaccination Regimen

Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against severe COVID-19 as defined by FDA occurring at least 7 days after Dose 2 was 95.3% (2-sided 95% CI: 71.0%, 99.9%), with 1 and 21 cases in the BNT162b2 and placebo groups, respectively (Table 40). The posterior probability for the true vaccine efficacy being >30%, given the available data, was >99.99%.

Table 40. Vaccine Efficacy – First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First severe COVID-19 occurrence from 7 days after Dose 2	1	6.257 (20712)	21	6.120 (20713)	95.3	(71.0, 99.9)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (02:26)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adc19ef ve sev cov 7pd2 wo eval

In addition, a supportive analysis was conducted for efficacy against severe cases of COVID-19 using the CDC definition of severe COVID-19 (hospitalization, admission to the intensive care unit (ICU), intubation or mechanical ventilation, or death).[18] Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against CDC-defined severe COVID-19 occurring at least 7 days after Dose 2 was 100.0% (2-sided 95% CI: 88.1%, 100.0%), with 0 and 32 cases in the BNT162b2 and placebo groups, respectively (Table 41).

Table 41. Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC-Definition From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First severe COVID-19 occurrence based on CDC-definition from 7 days after Dose 2	0	6.250 (20688)	32	6.108 (20680)	100.0	(88.1, 100.0)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (02:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_ve_sev_7pd2_cdc_wo_eval

Participants With or Without Evidence of Infection Before and During Vaccination Regimen

Among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen, estimated VE against severe COVID-19 as defined by FDA occurring at least 7 days after Dose 2 was 95.3% (2-sided 95% CI: 70.9%, 99.9%), with 1 and 21 cases in the BNT162b2 and placebo groups, respectively (Table 42). The posterior probability for the true vaccine efficacy being >30%, given the available data, was >99.99%.

Table 42. Vaccine Efficacy – First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First severe COVID-19 occurrence from 7 days after Dose 2	1	6.522 (21649)	21	6.404 (21730)	95.3	(70.9, 99.9)	>0.9999

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (02:26)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_ve_sev_cov_7pd2_eval

In a supportive analysis conducted for efficacy against severe cases of COVID-19 using the CDC definition of severe COVID-19, among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against CDC-defined severe COVID-19 occurring at least 7 days after Dose 2 was 100.0% (2-sided 95% CI: 88.0%, 100.0%), with 0 and 32 cases in the BNT162b2 and placebo groups, respectively (Table 43).

Table 43. Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC-Definition From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First severe COVID-19 occurrence based on CDC-definition from 7 days after Dose 2	0	6.514 (21620)	32	6.391 (21693)	100.0	(88.0, 100.0)

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (02:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adc19ef ve sev 7pd2 cdc eval

All Confirmed Cases of Severe COVID-19 After Dose 1 – Dose 1 All-Available Population

Among participants in the Dose 1 all-available efficacy (modified intention-to-treat) population, 1 case of severe COVID-19 as defined by FDA occurred after Dose 1 in the BNT162b2 group compared to 30 cases in the placebo group (Table 44). The estimated VE against severe COVID-19 occurring after Dose 1 was 96.7% (2-sided 95% CI: 80.3%, 99.9%).

In a supportive analysis conducted for efficacy against severe cases of COVID-19 using the CDC definition of severe COVID-19, among participants in the Dose 1 all-available efficacy population, 1 case of CDC-defined severe COVID-19 occurred after Dose 1 in the BNT162b2 group (but before Dose 2) compared to 45 cases in the placebo group. The estimated VE against severe CDC-defined COVID-19 occurring after Dose 1 was 97.8% (2-sided 95% CI: 87.2%, 99.9%).

Table 44. Vaccine Efficacy – First Severe COVID-19 Occurrence After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=23040)		Placebo (N[a]=23037)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First severe COVID-19 occurrence after Dose 1	1	8.439 (22505)	30	8.288 (22435)	96.7	(80.3, 99.9)
After Dose 1 to before Dose 2	0	1.351 (22505)	6	1.360 (22435)	100.0	(14.5, 100.0)
Dose 2 to 7 days after Dose 2	0	0.425 (22170)	1	0.423 (22070)	100.0	(-3783.5, 100.0)
≥7 Days after Dose 2	1	6.663 (22142)	23	6.505 (22048)	95.8	(73.9, 99.9)

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 19APR2021 (18:26)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adc19ef ve sev cov pd1 aai

2.5.4.3.3.6. Efficacy Conclusions – Updated Analysis

Updated Analysis of Efficacy Against Confirmed COVID-19

In the updated descriptive efficacy analysis (data cutoff date: 13 March 2021), among participants in the evaluable efficacy population without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 91.3% (2-sided 95% CI: 89.0%, 93.2%), with 77 cases in the BNT162b2 group and 850 cases in the placebo group. Among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 91.1% (2-sided 95% CI: 88.8%, 93.0%), with 81 and 873 cases in the BNT162b2 and placebo groups, respectively.

All cases of confirmed COVID-19 are accounted for in the analyses of VE in the Dose 1 all-available (modified intention-to-treat) population, regardless of evidence of infection before or during the vaccination regimen. In this analysis, the estimated VE against all cases occurring at any time after Dose 1 was 87.8% (2-sided 95% CI: 85.3%, 89.9%), with 131 cases in the BNT162b2 group and 1034 cases in the placebo group.

In this same Dose 1 all-available (modified intention-to-treat) population, the estimated VE against all cases occurring ≥7 days after Dose 2 was 91.2%. The estimated VE was 91.7% from ≥11 days after Dose 1 to before Dose 2, 96.2% for cases occurring from ≥7 days after Dose 2 to <2 months after Dose 2, 90.1% for the period from ≥2 months to <4 months after Dose 2, and 83.7% for the period ≥4 months after Dose 2.

Updated Analysis of Efficacy in Subgroups

Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen (efficacy evaluable population), VE against COVID-19 occurring at least 7 days after Dose 2 was evaluated for demographic and risk subgroups, as follows:

- Estimated VE was ≥90% in most demographic subgroups, similar to the estimated 91.3% overall VE.

- High estimated VE was observed across age subgroups:
  - 100.0% in participants 12 to 15 years of age
  - 90.6% in participants 16 to 64 years of age
  - 94.5% in participants ≥65 years of age
  - 96.2% in participants ≥75 years of age.

- Estimated VE by country was 86.5% in Argentina; 86.2% in Brazil; 92.6% in the US; and 100.0% in South Africa, Germany, and Turkey.

The estimated VE was similar for participants at risk (91.6%) and those not at risk (91.0%). The estimated VE for participants ≥65 years of age who were at risk was 91.8%, as compared with 98.1% for those ≥65 years of age and not at risk. The estimated VE was similar in obese (91.6%) and non-obese (91.1%) participants. When evaluated by type of comorbidity, the estimated VE was >85% for participants with each comorbidity evaluated, including any malignancy, cardiovascular disease, chronic pulmonary disease, diabetes, obesity, and hypertension.

Updated Analysis of Efficacy Against Severe Disease

Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen (evaluable efficacy population), the estimated VE against FDA-defined severe COVID-19 (protocol definition) occurring at least 7 days after Dose 2 was 95.3% (2-sided 95% CI: 71.0%, 99.9%), with 1 and 21 cases in the BNT162b2 and placebo groups, respectively. Similarly, the estimated VE was also 95.3% [2-sided 95% CI: 70.9%, 99.9%]) among participants with or without evidence of SARS-CoV-2 infection, also with 1 and 21 cases in the BNT162b2 and placebo groups, respectively.

Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen (evaluable efficacy population), the estimated VE against CDC-defined severe COVID-19 occurring at least 7 days after Dose 2 was 100.0% (2-sided 95% CI: 88.1%, 100.0%), with 0 and 32 cases in the BNT162b2 and placebo groups, respectively. Similarly, the estimated VE was also 100.0% [2-sided 95% CI: 88.0%, 100.0%]) among participants with or without evidence of SARS-CoV-2 infection before and during the

vaccination regimen, also with 0 and 32 cases in the BNT162b2 and placebo groups, respectively.

Among participants in the Dose 1 all-available (modified intention-to-treat) population, regardless of evidence of infection before or during the vaccination regimen, the estimated VE against FDA-defined severe cases of COVID-19 occurring at any time after Dose 1 was 96.7% (2-sided 95% CI: 80.3%, 99.9%), with 1 case of severe COVID-19 in the BNT162b2 group compared to 30 cases in the placebo group.

Overall Conclusions from Updated Analysis of Efficacy

Updated efficacy results show that BNT162b2 at 30 µg provided protection against COVID-19 in participants regardless of evidence of past infection with SARS-CoV-2, including across demographic and risk subgroups, with severe cases observed predominantly in the placebo group.

2.5.4.4. Immunogenicity Results

Details of immunogenicity results, including for additional endpoints, are presented as follows:

Study BNT162-01: Module 5.3.5.1 BNT162-01 Interim CSR.

Study C4591001:

Phase 1: immunogenicity results for all candidates and dose levels up to 1 month after Dose 2 are presented in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR; immunogenicity results for Phase 1 participants in the BNT162b2 30 µg up to 6 months after Dose 2 are presented in Module 5.3.5.1 C4591001 6-Month Update Interim CSR.

Phase 2: immunogenicity results up to 1 month after Dose 2 are presented in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR.

Immunogenicity data are also presented in Module 2.7.3 and summarized below.

2.5.4.4.1. Phase 1 Immunogenicity in Study BNT162-01

Details of immunogenicity results from the Phase 1 portion of Study BNT162-01 are presented in Module 5.3.5.1 BNT162-01 Interim CSR Section 10 and Section 11 and summarized below.

This section focuses primarily on Study BNT162-01 immune response data for BNT162b2, which was the candidate selected for further development in Phase 2/3 of pivotal Study C4591001. Summary serology data for the BNT162b1 groups are also presented.

In Study BNT162-01, T cell data are presented for BNT162b2 groups up to 7 days after Dose 2; a subset of participants had blood samples collected on Day 85 (9 weeks, or approximately 2 months, after Dose 2) and Day 184 (approximately 6 months after Dose 2) and analyzed. Immunogenicity data (neutralizing titers) are summarized for both BNT162b1 and BNT162b2 groups up to approximately 2 months after Dose 2. Evaluable ELISPOT data (data cutoff date: 02 March 2021) were available from 76 participants across dose levels of

BNT162b2: 47 younger participants 18 to 55 years of age (dose range: 1 to 30 µg), and 29 older participants 56 to 85 years of age (dose range: 10 to 30 µg).

Evaluable intracellular cytokine staining and FACS data (data cutoff date: 02 March 2021) were available for 76 participants across dose levels of BNT162b2: 47 younger participants (dose range: 1 to 30 µg) and 29 older participants (dose range: 10 to 30 µg).

Serum neutralizing titers (data cutoff date: 23 October 2020) were available for younger participants who received BNT162b1 across dose levels (dose range: 1 to 60 µg; n=12 per group), with no data available for older participants at this time; and for younger participants who received BNT162b2 (dose range: 1 to 30 µg; n=12 per group) and older participants who received BNT162b2 (dose level: 20 µg; n=12 per group).

The immunogenicity set was generally similar to the safety set (refer to Section 2.5.5.2.1).

2.5.4.4.1.1. T Cell Response Data

T cell mediated immune responses were evaluated using ELISPOT and intracellular cytokine staining visualized with FACS, for data available up to a cutoff date of 02 March 2021. BNT162b2 induced poly-functional and pro-inflammatory CD4+ and CD8+ T cell responses in most participants in both the younger and older age groups. Re-stimulation of PBMCs with peptide pools representing the encoded antigen (full-length S protein) demonstrated a helper response characterized by a robust IFNγ and IL-2 response and only minor IL-4 production. This cytokine profile indicates presence of a favorable Th1 response and absence of a potentially deleterious Th2 immune response.

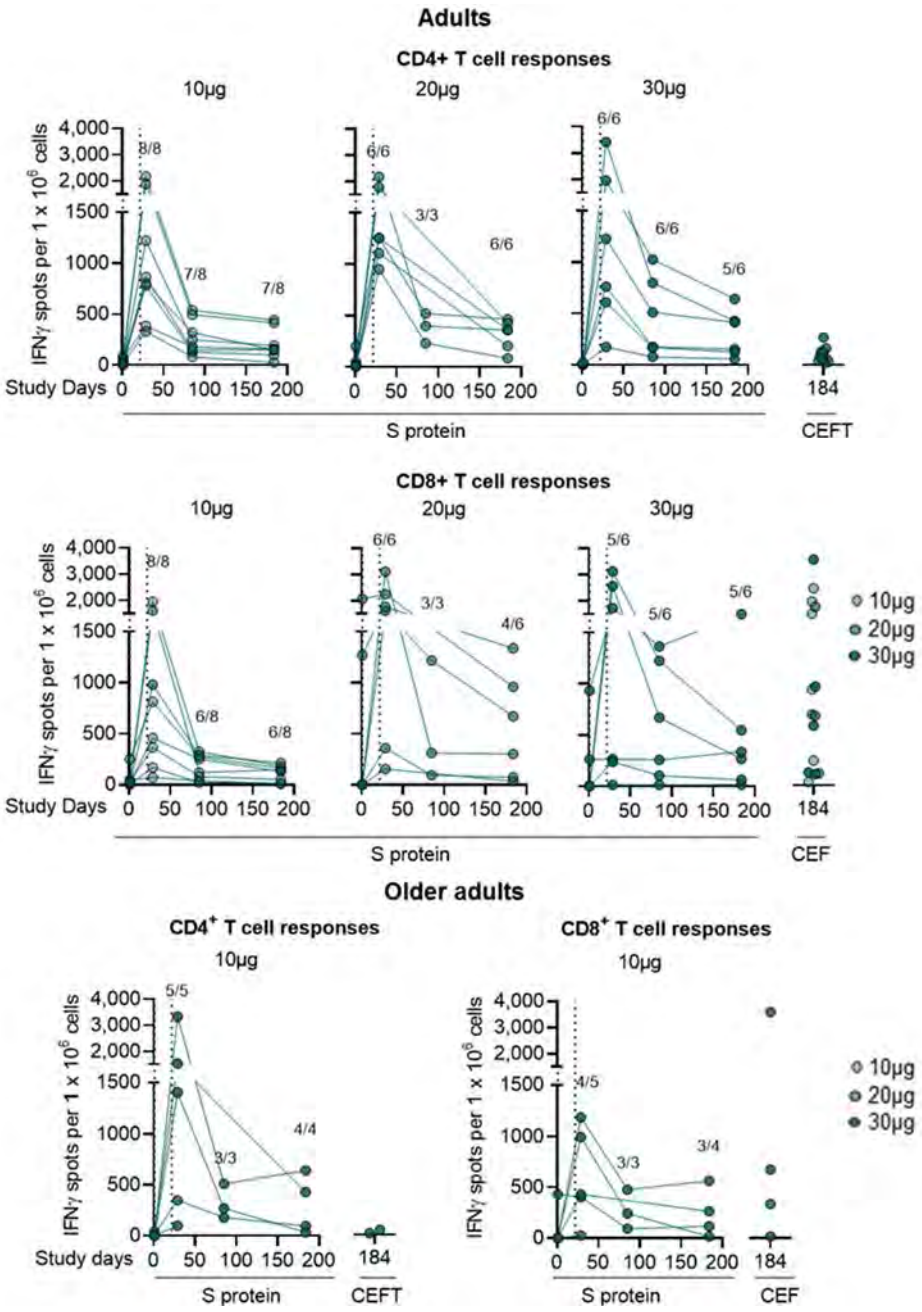
2.5.4.4.1.1.1. ELISPOT Results

BNT162b2 induced strong SARS-CoV-2 S protein-specific CD4+ T cell responses in all participants in all of the dosed younger and older participants (76/76). CD8+ T cell responses were induced in 45/47 younger participants (95.7%) of in 24/29 older participants (82.8%). Overall, the magnitude of the BNT162b2 induced responses was comparable in younger and older participants receiving 30 µg of BNT162b2 (Figure 3). These T cell responses were directed against different parts of the antigen, including non-RBD sequences, indicating the induction of multi-epitopic responses by BNT162b2 in both age groups.

Dosing twice with BNT162b2 led to a substantial increase in incidence and magnitude of T cell responses in both age groups. While the magnitude of responses was similar across BNT162b2 dose levels, the magnitude of CD8+ T cell responses was highest in the 30 µg group. Participants with the strongest CD4+ T cell responses had >10-fold of the memory responses observed in the same individuals against immunodominant peptides from the benchmarking epitope pool, CEFT (Figure 3). CD8+ T cell responses in these same individuals were comparable with memory responses against the epitope benchmarking pool, CEF. BNT162b2 induced CD4+ and CD8+ T cell responses were decreased on Day 85 (approximately 2 months after Dose 2) but remained detectable on Day 184 (approximately 6 months after Dose 2) in almost all participants vaccinated with dose levels >10 µg, at levels higher than or within range of recall antigen memory responses (Figure 3).

BNT162b2 induced de novo RBD and S protein specific T cell responses were observed for CD4+ T cells in 100% of participants and for CD8+ T cells in 96.6% of participants.

Figure 3. Durability of BNT162b2 Induced CD4+ and CD8+ T Cell Responses Against Full-Length S Protein



ELISPOT data are plotted for BNT162b2 groups from Day 1 (before Dose 1), Day 29, Day 85, and Day 184. Vertical dotted lines indicate the time of administration of Dose 2 (on Day 22). Common pathogen epitope pools (CEF, CEFT) assessed T cell reactivity; cell culture medium was a negative control. Each dot represents the sum of normalized mean spot count from duplicate wells stimulated with 2 peptide pools corresponding to full-length wild-type S protein for 1 study participant after subtracting medium-only control. Ratios above the data points represent the number of participants with detectable CD4+ or CD8+ T cell responses within the total number of participants with available data at that timepoint and within that group.

2.5.4.4.1.1.2. Intracellular Cytokine Production

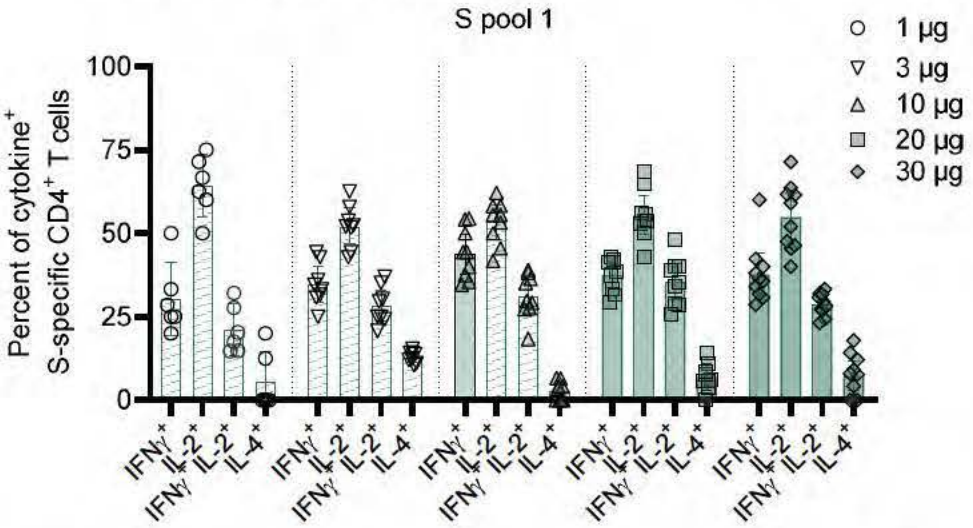
Functionality and polarization of S-specific BNT162b2 induced SARS-CoV-2 T cells were assessed by intracellular accumulation of cytokines IFNγ, IL-2, and IL-4 measured after stimulation with overlapping peptide pools representing the full-length sequence of the whole SARS-CoV-2 S protein. For benchmarking, PBMC fractions from convalescent patients with virologically confirmed COVID-19 were used.

BNT162b2 induced T cell responses, especially for CD8+ T cells, were not limited to the RBD, as pronounced and strong T cell recognition of non-RBD regions of the S protein were observed. BNT162b2 induced poly-functional and pro-inflammatory CD4+ and CD8+ T cell responses in most participants. The Th1 polarization of the T helper response was characterized by robust IFNγ and IL-2, and only minor IL-4, production upon antigen-specific re-stimulation (SARS-CoV-2 S protein peptide pools). No clear BNT162b2 dose dependency was observed, and cytokine responses in older participants were mostly identical in response pattern and intensity with that in younger participants.

Two doses of BNT162b2 induced CD4+ and CD8+ S-specific T cell responses in both age groups. Testing for SARS-CoV-2 S protein specific T cell responses was performed with two different peptide pools: sub-pool 1 comprising overlapping peptides from the N-terminal region (which is not equivalent to structural domains) and sub-pool 2 comprising C-terminal regions of the S protein.

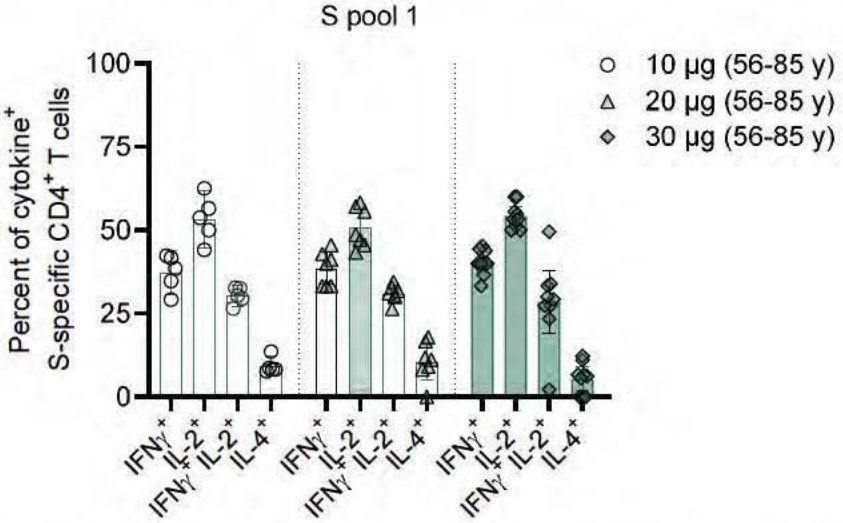
S-specific CD4+ T cells had a Th1-skewed cytokine profile with secretion of IFNγ or IL-2, or both (Figure 4 and Figure 5 for younger and older age groups in response to sub-pool 1 stimulation). Almost no Th2 cytokine IL-4 secreting T cells were detectable in response to S peptide sub-pool stimulations. BNT162b2 induced T cell cytokine production therefore suggested a Th1 profile characterized secreting IFNγ, or IL-2, or both at Day 29 (7 days after Dose 2).

Figure 4. S-Specific CD4+ T Cell Cytokine Production in Response to BNT162b2 – 18 to 55 Years of Age



Bars represent the arithmetic means with 95% CIs. Cytokine production was calculated by summing fractions of all CD4+ T cells positive for IFNγ, IL-2, IFNγ and IL-2, or IL-4 following stimulation with S peptide sub-pool 1, setting this sum to 100%, and calculating the fraction of each cytokine producing subset. CD4+ non-responders (ie, participants with frequency of total cytokine producing CD4+ T cells <0.03%) were excluded from analysis: 1 µg, n=2; 3 µg, n=1; and 10 µg, n=1.

Figure 5. S-Specific CD4+ T Cell Cytokine Production in Response to BNT162b2 – 56 to 85 Years of Age



Bars represent the arithmetic means with 95% CIs. Cytokine production was calculated by summing fractions of all CD4+ T cells positive for IFNγ, IL-2, IFNγ and IL-2, or IL-4 following stimulation with S peptide sub-pool 1, setting this sum to 100%, and calculating the fraction of each cytokine producing subset. CD4+ non-responders (ie, participants with frequency of total cytokine producing CD4+ T cells <0.03%) were excluded from analysis: 10 µg, n=4 and 20 µg, n=1.

S-specific IFNγ secretion was detected in CD8+ T cells at Day 29 in 65/79 participants (43/50 younger participants and 22/29 older participants); IL-2 secreting CD8+ T cells were also detected. Fractions of S-specific IFNγ+ CD8+ T cells targeting the N-terminal domain of the S protein reached up to 1.24% of total peripheral blood CD8+ T cells for the younger participants who received 20 or 30 µg dose levels, and up to 1.57% for older participants who received 30 µg. Preexisting CD8+ T cell responses against the C-terminal region of the S protein were detected in 17/79 dosed participants (range: 0.07 to 5.59% IFNγ-producing CD8+ T cells). In 5/17 participants, these preexisting responses were slightly amplified upon BNT162b2 dosing.

The mean fractions of S-specific CD4+ and CD8+ T cells from BNT162b2 vaccinated participants were substantially higher at Day 29 than that observed in 18 patients who recovered from COVID-19; the S protein sub-pool 1 IFNγ CD8+ response of 30 µg dosed participants was 12.5-fold higher. Importantly, for the clinically targeted 30 µg dose level, cytokine production elicited by BNT162b2 vaccination was mostly identical for older and younger participants with regard to cytokine response patterns and intensity.

For the majority of participants, the strong S-specific IFNγ+ and IL-2+ CD8+ T cell responses and Th1 CD4+ T cell responses contracted by Day 43 (3 weeks after Dose 2), and plateaued at a lower level towards Day 85 (approximately 2 months after Dose 2). This observation held true for all dose groups analyzed, with varying response magnitudes between individuals. For younger participants, the cell mediated immune responses were detectable until Day 184 (approximately 6 months after Dose 2). Note that Day 184 PBMC samples from older participants were not yet available at the time of this submission.

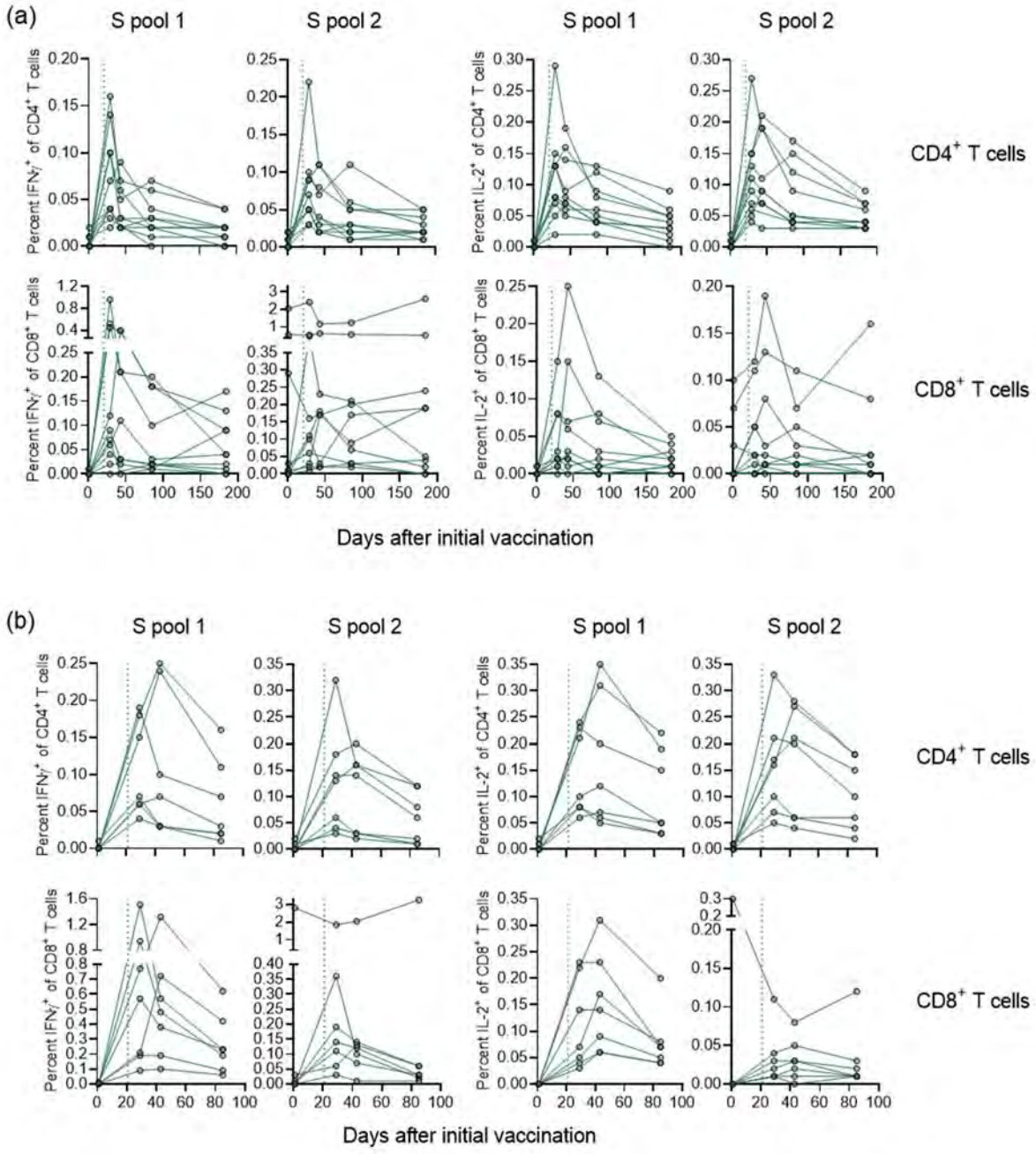
The impact of SARS-CoV-2 infection on persistence of vaccine induced immune response could not be evaluated since participants were not routinely monitored for infection in Study BNT162-01.

Persistence of S-specific CD4+ and CD8+ T cells producing the indicated cytokines (IFNγ and IL-2) as a fraction of the total circulating CD4+ and CD8+ T cells are shown in Figure 6, which includes data for the 30 µg BNT162b2 dose group in younger and older participants and is considered representative of observations for other dose groups.

BNT162b2 induced T cell responses, especially for $CD8^+$ T cells, were not limited to the RBD, and pronounced and strong T cell recognition of non-RBD regions of the S protein were observed indicating a polyvalent immune recognition of multiple independent CD4+ and CD8+ restricted epitopes across the entire S protein.

BNT162b2 induced poly-functional and pro-inflammatory CD4+ and CD8+ T cell responses in nearly all participants and persisted in the majority of participants for up to approximately 6 months. The Th1 polarization of the Th1 T cell response was characterized by robust production of IFNγ and IL-2. Only minor IL-4 production was observed upon antigen-specific (ie, wild-type SARS-CoV-2 S protein peptide pools) re-stimulation, which was reduced in magnitude, at later time points.

Figure 6. Persistence of S-Specific CD4+ T Cell Cytokine Production in Response to BNT162b2



Cytokine release data are plotted for the BNT162b2 30 µg dose level group from Day 1 (before Dose 1), Day 29, Day 43, Day 85, and Day 184. Vertical dotted lines indicate the time of administration of Dose 2 (on Day 22).
(a) Percentage of IFNγ+ CD4+ and CD8+ T cells for younger (n=10) participants who received BNT162b2 30 µg.
(b) Percentage of IFNγ+ CD4+ and CD8+ T cells for older (n=7) participants who received BNT162b2 30 µg.

2.5.4.4.1.2. SARS-CoV-2 Neutralization Titers

Results for serum neutralizing titers available for the immunogenicity set up to the immunogenicity data cutoff date (23 October 2020) as follows:

- **BNT162b1**: younger participants: N=60, n=12 each in 1, 10, 30, 50, and 60 µg groups with data available up to Day 43 for all doses; no data available for older participants.

- **BNT162b2**: younger participants: N=60, n=12 each in 1, 3, 10, 20, and 30 µg groups with data available up to Day 50 for 1 and 3 µg and up to Day 85 for 10, 20, and 30 µg; older participants: N=36, n=12 each in 10, 20, and 30 µg groups; up to Day 29 for 20 µg.

In Study BNT162-01, at 21 days after administration of Dose 1 and prior to administration of Dose 2 (Day 22), both BNT162b1 and BNT162b2 showed modest, dose-dependent increases in SARS-CoV-2 50% neutralizing GMTs over baseline for both age groups.

For BNT162b1, by 7 days after Dose 2 (Day 29) there was a clear dose-level booster response from 10 µg to 50 µg of BNT162b1 for younger participants. Note: the group receiving BNT162b1 at the 60 µg dose level did not receive a second dose per SRC decision based on reactogenicity of the initial 60 µg dose; for this dose group, neutralizing GMTs remained at a lower level, indicating a booster dose is necessary to increase functional antibody titers. No data for the older group are available at this time.

For BNT162b2, by 7 days after Dose 2 (Day 29) GMTs had increased substantially in younger participants who received doses of ≥3 µg and in older participants who received 20 µg. On Day 29 (1 week after Dose 2 of BNT162b2), neutralizing GMTs were comparable in the younger and older age groups at the 20 µg dose level. On Day 43 (3 weeks after Dose 2 of BNT162b2), neutralizing GMTs in the younger groups decreased at the 3, 20, and 30 µg dose levels. Thereafter, neutralizing GMTs remained stable up to Day 85 (approximately 2 months after Dose 2) for younger dose groups of 10, 20, and 30 µg.

Overall, both vaccine candidates elicited a boost effect after receiving Dose 2 that was most pronounced at the 30 µg dose level.

HCS Comparison

For benchmarking, neutralizing GMTs across dose level groups were compared with those of a panel of human convalescent sera (HCS) comprising samples obtained from 38 individuals 18 to 85 years of age at least 14 days after confirmed diagnosis of COVID-19.[19,20]

For younger BNT162b1 recipients, Day 43 (3 weeks after Dose 2) neutralizing GMTs ranged from 0.7- to 3.6-fold that of the HCS panel. Data for the older group are unavailable at this time.

For younger BNT162b2 recipients at 10 to 30 µg dose levels, Day 85 (approximately 2 months after Dose 2) neutralizing GMTs ranged from 1.3- to 1.9-fold that of the HCS panel. Preliminary data for older BNT162b2 recipients were available through Day 29 (1 week after Dose 2) for the 20 µg dose level, which showed neutralizing GMTs exceeding that of the HCS panel.

2.5.4.4.2. Phase 1 Immunogenicity in Study C4591001

Details of immunogenicity results from the Phase 1 portion of Study C4591001 up to 1 month after Dose 2 are presented in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 10 and Section 11.2.

Details of immunogenicity results for Phase 1 participants in the BNT162b2 30 µg up to 6 months after Dose 2 are presented in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 10 and Section 11.2.

This section focuses on immunogenicity for dose level groups for both vaccine candidates that were administered as 2 doses at the same dose level. Note that the group receiving BNT162b1 at the 100 µg dose level received a second dose of 10 µg, per IRC decision based on reactogenicity of the initial 100 µg dose. This dose level was described in detail in the C4591001 Final Analysis Interim CSR but is not discussed further in this section.

The data cutoff date for immunogenicity analyses of Phase 1 participants was 24 August 2020 for up to 1 month after Dose 2 of both vaccine candidates (BNT162b1 and BNT162b2). Data up to 6 months after Dose 2 are available for participants who received BNT162b2 30 µg have a data cutoff of 13 March 2021.

The Phase 1 immunogenicity populations were generally similar to the Phase 1 safety population (refer to Section 2.5.5.3.1).

Results for the all-available immunogenicity population in the younger and older age groups were similar to those observed for the evaluable immunogenicity population.

2.5.4.4.2.1. SARS-CoV-2 Neutralizing Titers and Antigen-Binding IgG Concentrations

Geometric Mean Titers/Concentrations (GMTs/GMCs)

Overall, for both the BNT162b1 and the BNT162b2 recipients in both age groups, SARS-CoV-2 50% neutralizing GMTs modestly increased by at 3 weeks after Dose 1 and prior to receiving Dose 2 (Day 21) and were substantially increased by 7 days after Dose 2 (Day 28).

In the younger age groups, SARS-CoV-2 50% neutralizing GMTs modestly increased by 3 weeks after Dose 1 and prior to Dose 2 (Day 21) and were substantially increased by 7 days after Dose 2 of BNT162b1 (Day 28), with the highest neutralizing GMTs across vaccine candidates observed in the 30 µg dose groups.

Similar trends were observed in the older age groups for both vaccine candidates. Generally, neutralizing GMTs in the older age group tended to be somewhat lower than the GMTs in the younger age group at most time points for both BNT162b1 and BNT162b2 recipients.

Overall, for both the BNT162b1 and the BNT162b2 recipients, and in both age groups, RBD- and S1-binding GMCs increased substantially by 3 weeks after Dose 1 and prior to receiving Dose 2 (Day 21) and were further increased 7 days after Dose 2 (Day 28). Responses were maintained through 1 month after Dose 2 (Day 52).

In the younger age groups, RBD- or S1-binding GMCs increased substantially by Day 21 after Dose 1 of BNT162b1 and further increased 7 days after Dose 2 (Day 28) of BNT162b1, with higher GMCs observed in the 30 µg dose group.

Similar trends were observed in the older age groups, with higher S1-binding GMCs observed in the 20 µg and/or 30 µg dose groups for both vaccine candidates. GMCs in the older age group were generally lower than the GMCs in the younger age group.

HCS Comparison

BNT162b1 and BNT162b2 GMTs were compared with neutralizing antibody levels with an HCS panel, composed of 38 human SARS-CoV-2 infection/COVID-19 convalescent sera, drawn from participants 18 to 83 years of age at least 14 days after PCR-confirmed diagnosis, and at a time when participants were asymptomatic.[19,20] In Phase 1 of Study C4591001, GMTs measured 7 days after Dose 2 (Day 28) of BNT162b1 or BNT162b2 at the 30 µg dose level were 267.1 and 100.8 for younger and older participants who received BNT162b1, and 360.9 and 155.7 for younger and older participants who received BNT162b2. These GMTs were approximately 2.8- to 3.8-times that of the HCS panel GMT for younger participants, and 1.1- to 1.7-times that of the panel for older participants. By 1 month after Dose 2 (Day 52), GMTs were generally stable and were approximately 1.5- to 1.9-times that of the convalescent serum panel GMT for younger participants, and 1.5- to 1.6-times that of the panel for older participants. These comparisons to HCS further support the benefit of both candidates at the 30 µg dose level. The comparison of SARS-CoV-2 neutralizing titers to both study candidates to the HCS panel also showed the benefit of the second dose, with a dose response up to 30 µg.

Persistence of Immune Response Up to 6 Months After Dose 2 of BNT162b2 30 µg

Neutralizing GMTs and S1-binding GMCs were evaluated at 6 months after Dose 2 for the Phase 1 groups of participants who received BNT162b2 at 30 µg and corresponding placebo recipients. Samples from some earlier time points (ie, from Day 1 through Day 52) were re-analyzed with the 6-month post Dose 2 (Day 202) data for consistency in reporting.

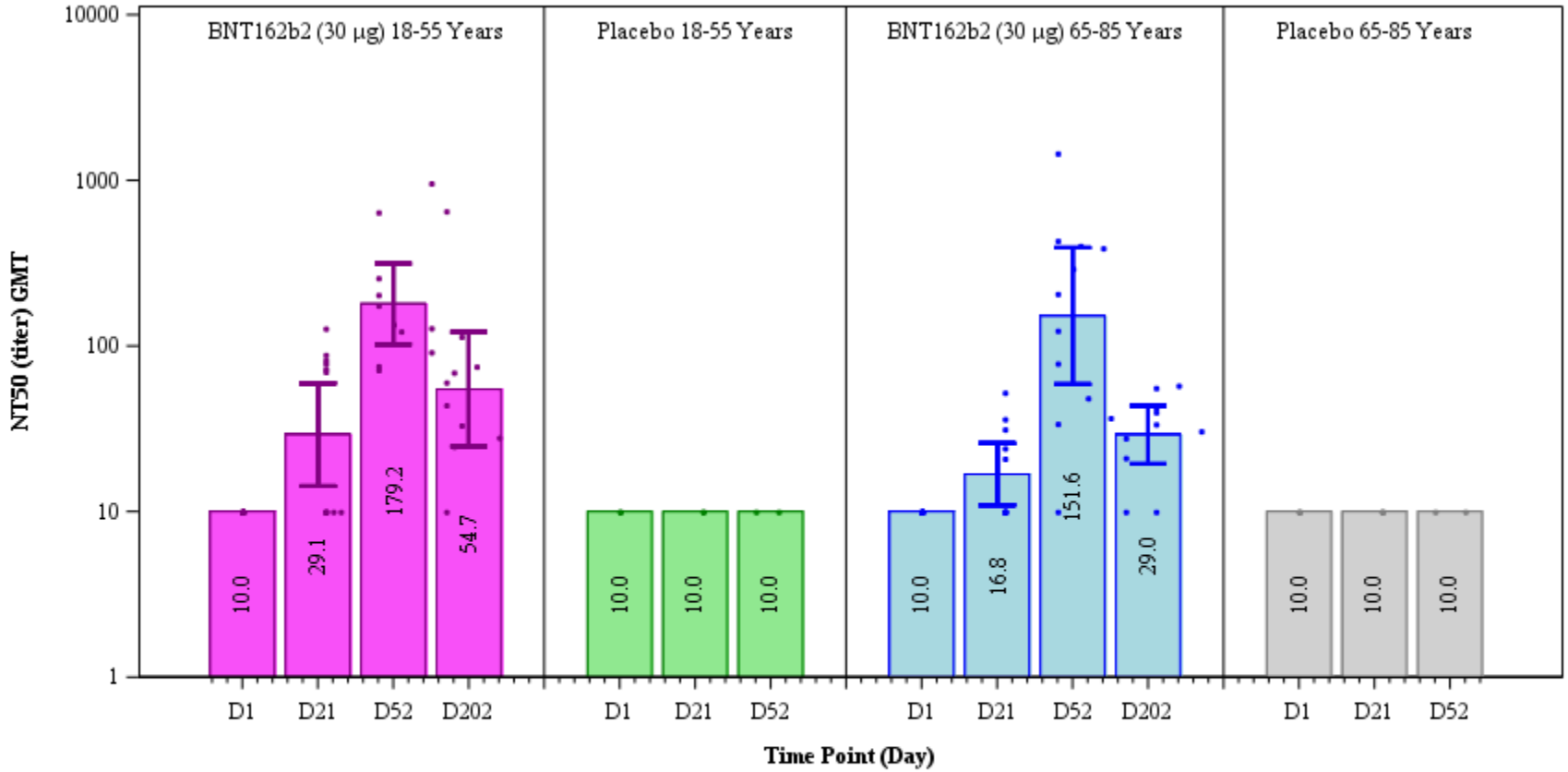
Geometric Mean Titers (GMTs) and Geometric Mean Concentrations (GMCs)

Among participants who received the 30 µg dose level of BNT162b2, in both age groups, the observed SARS-CoV-2 serum 50% neutralizing GMTs declined from 1 month after Dose 2 (Day 52) to 6 months after Dose 2 (Day 202). In the younger age group, GMTs were 179.2 at 1 month after Dose 2 and 54.7 at 6 months after Dose 2; in the older age group GMTs declined from 151.6 to 29.0. Observed S1-binding IgG GMCs at 6 months after Dose 2 also declined.

At 6 months after Dose 2, both GMTs and GMCs remained higher than pre-vaccination and placebo control levels.

For Phase 1 data available up to 6 months after Dose 2, GMTs are shown in Figure 7 and GMCs are shown in Figure 8.

Figure 7. Geometric Mean Titers and 95% CIs: SARS-CoV-2 Neutralization Assay – NT50 – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – Evaluable Immunogenicity Population



Abbreviations: D = day; GMT = geometric mean titer; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

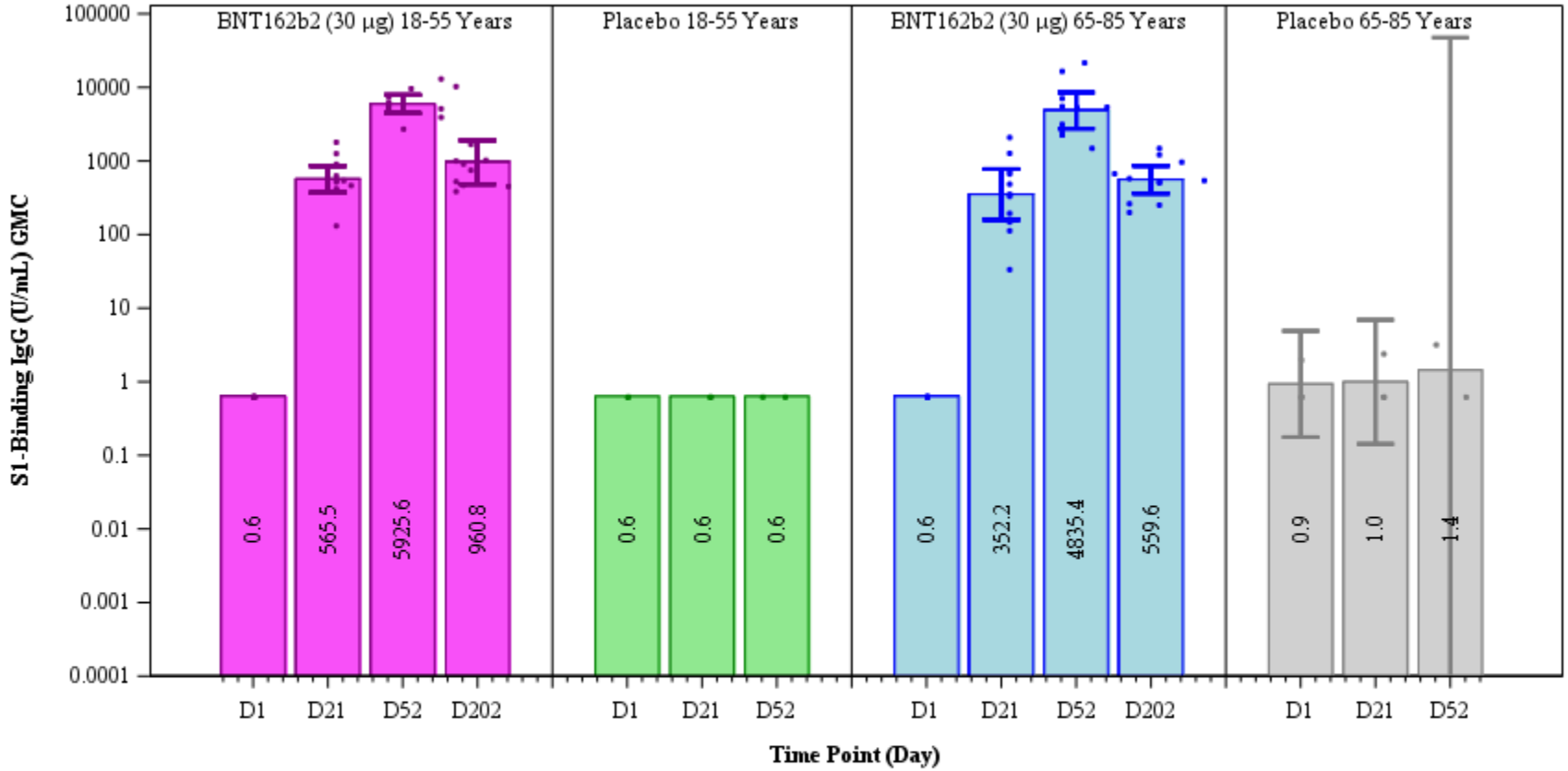
Note: Blood samples from the Day 7 and Day 14 post–Dose 2 visits are not included since these samples were not retested with the 6-month post–Dose 2 samples.

Note: Dots represent individual antibody levels.

Note: Number within each bar denotes geometric mean titer.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 01APR2021 (02:17) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA1/adva_f002_sars_50_b2_p1

Figure 8. Geometric Mean Concentrations and 95% CIs: S1-Binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – Evaluable Immunogenicity Population



Abbreviations: D = day; GMC = geometric mean concentration; IgG = immunoglobulin G; S1 = spike protein S1 subunit.

Note: Blood samples from the Day 7 and Day 14 post–Dose 2 visits are not included since these samples were not retested with the 6-month post–Dose 2 samples.

Note: Dots represent individual antibody levels.

Note: Number within each bar denotes geometric mean titer.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 01APR2021 (02:19) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA1/adva_f002_s1_b2_p1

Geometric Mean Fold Rises (GMFRs)

In the younger and older age groups, respectively, GMFRs of SARS-CoV-2 serum 50% neutralizing titers from before vaccination with BNT162b2 30 µg to each subsequent time point were 2.9 and 1.7 at Day 21 (before Dose 2); 17.9 and 15.2 at 1 month after Dose 2; 5.5 and 2.9 at 6 months after Dose 2. Results for GMFRs of S1-binding IgG concentrations reflected similar trends.

Geometric Mean Ratios (GMRs)

At 6 months after Dose 2 of BNT162b2 30 µg, GMRs of SARS-CoV-2 50% neutralizing titers to S1-binding IgG levels were 0.057 in the younger age group and 0.052 in the older age group. These values are similar to those observed at Day 21.

Number (%) of Participants Achieving a ≥4-Fold Rise from Baseline

In the younger age group, the proportions of participants achieving a ≥4-fold rise in SARS-CoV-2 50% neutralizing titers from before vaccination to each time point were: 50.0% (6/12) at Day 21; 100.0% (11/11) at 1 month after Dose 2; and 60.0% (6/10) at 6 months after Dose 2 of BNT162b2 30 µg. In the older age group, these proportions were 9.1% (1/11) at Day 21; 81.8% (9/11) at 1 month after Dose 2; and 27.3% (3/11) at 6 months after Dose 2 of BNT162b2 30 µg.

With respect to S1-binding IgG concentrations, 100% of participants in both age groups had a ≥4-fold increase from baseline at each of these time points.

2.5.4.4.3. Phase 2 Immunogenicity in Study C4591001

Details of immunogenicity results from the Phase 2 portion of Study C4591001 are presented in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 10 and Section 11 and summarized below.

The data cutoff date for immunogenicity analyses of Phase 2 participants was 12 October 2020 and included data up to 1 month after Dose 2. Data from the 6-month time point were not available at the time of the submission data cutoff date.

2.5.4.4.3.1. Immunogenicity Populations

Disposition and Data Sets Analyzed

The 360 participants enrolled in Phase 2 were randomized 1:1 to the BNT162b2 and placebo groups (180 participants each). Among participants randomized to the BNT162b2 group, 88 participants were in the younger age group (18 to 55 years of age) and 92 participants were in the older age group (56 to 85 years of age) (Table 45).

All 360 participants received both doses of study vaccine, except for 1 participant in the younger age group who was withdrawn from the study after Dose 1 of BNT162b2 but before Dose 2 because of an SAE of gastric adenocarcinoma 23 days after receiving Dose 1.

Immunogenicity results are currently available for the pre-vaccination and 1-month post Dose 2 time point; results for later time points will be reported when available.

A total of 7 participants (3 in the BNT162b2 group and 4 in the placebo group) were excluded from the Dose 2 all-available immunogenicity population because they did not have at least 1 valid and determinate immunogenicity result after Dose 2. The Dose 2 evaluable immunogenicity population included 93.9% of participants who received BNT162b2 and 92.8% of participants who received placebo. The reasons for data exclusion are shown in Table 45. Serology data at 1 month after Dose 2 from 2 participants who had a postbaseline positive SARS-CoV-2 test result were excluded in the analysis based on the Dose 2 evaluable immunogenicity populations, according to the study protocol and SAP.

Demographics

In the Dose 2 evaluable immunogenicity population, 52.1% of participants were male; 84.8% were White and 10.1% were Black or African American; 10.7% were Hispanic; and the median age was 56 years (range: 18 to 85) (Table 46).

Table 45. Immunogenicity Populations – Phase 2

	Vaccine Group (as Randomized)				
	BNT162b2 (30 µg)			Placebo	
	18-55 Years n[a] (%)	56-85 Years n[a] (%)	18-85 Years n[a] (%)	18-85 Years n[a] (%)	Total n[a] (%)
Randomized[b]	88 (100.0)	92 (100.0)	180 (100.0)	180 (100.0)	360 (100.0)
Dose 2 all-available immunogenicity population	85 (96.6)	91 (98.9)	176 (97.8)	176 (97.8)	352 (97.8)
Subjects excluded from Dose 2 all-available immunogenicity population	3 (3.4)	1 (1.1)	4 (2.2)	4 (2.2)	8 (2.2)
Reason for exclusion					
Did not receive Dose 2	1 (1.1)	0	1 (0.6)	0	1 (0.3)
Did not have at least 1 valid and determinate immunogenicity result after Dose 2	2 (2.3)	1 (1.1)	3 (1.7)	4 (2.2)	7 (1.9)
Dose 2 evaluable immunogenicity population	80 (90.9)	89 (96.7)	169 (93.9)	167 (92.8)	336 (93.3)
Subjects excluded from Dose 2 evaluable immunogenicity population	8 (9.1)	3 (3.3)	11 (6.1)	13 (7.2)	24 (6.7)
Reason for exclusion[c]					
Did not receive 2 doses of the vaccine to which they are randomly assigned	1 (1.1)	0	1 (0.6)	0	1 (0.3)
Did not receive Dose 2 within 19-42 days after Dose 1	0	1 (1.1)	1 (0.6)	4 (2.2)	5 (1.4)
Did not have at least 1 valid and determinate immunogenicity result after Dose 2	2 (2.3)	1 (1.1)	3 (1.7)	4 (2.2)	7 (1.9)
Did not have blood collection within 28-42 days after Dose 2	5 (5.7)	2 (2.2)	7 (3.9)	7 (3.9)	14 (3.9)
Had important protocol deviation(s) as determined by the clinician	0	0	0	1 (0.6)	1 (0.3)

a. n = Number of subjects with the specified characteristic, or the total sample.
b. These values are the denominators for the percentage calculations.
c. Subjects may have been excluded for more than 1 reason.
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(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2 unblinded/C4591001 IA P2 Serology/adva s008 imm pop p2

Table 46. Demographic Characteristics – Phase 2 – Dose 2 Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)				
	BNT162b2 (30 µg)			Placebo	
	18-55 Years (N^a=80) n^b (%)	56-85 Years (N^a=89) n^b (%)	18-85 Years (N^a=169) n^b (%)	18-85 Years (N^a=167) n^b (%)	Total (N^a=336) n^b (%)
Sex					
Male	41 (51.3)	49 (55.1)	90 (53.3)	85 (50.9)	175 (52.1)
Female	39 (48.8)	40 (44.9)	79 (46.7)	82 (49.1)	161 (47.9)
Race					
White	64 (80.0)	83 (93.3)	147 (87.0)	138 (82.6)	285 (84.8)
Black or African American	9 (11.3)	3 (3.4)	12 (7.1)	22 (13.2)	34 (10.1)
American Indian or Alaska native	0	1 (1.1)	1 (0.6)	1 (0.6)	2 (0.6)
Asian	5 (6.3)	0	5 (3.0)	4 (2.4)	9 (2.7)
Multiracial	1 (1.3)	1 (1.1)	2 (1.2)	1 (0.6)	3 (0.9)
Not reported	1 (1.3)	1 (1.1)	2 (1.2)	1 (0.6)	3 (0.9)
Ethnicity					
Hispanic/Latino	13 (16.3)	3 (3.4)	16 (9.5)	20 (12.0)	36 (10.7)
Non-Hispanic/non-Latino	66 (82.5)	85 (95.5)	151 (89.3)	145 (86.8)	296 (88.1)
Not reported	1 (1.3)	1 (1.1)	2 (1.2)	2 (1.2)	4 (1.2)
Age at vaccination (years)					
Mean (SD)	41.0 (10.47)	65.9 (6.64)	54.1 (15.18)	51.6 (15.92)	52.8 (15.58)
Median	43.5	65.0	56.0	56.0	56.0
Min, max	(18, 55)	(56, 85)	(18, 85)	(20, 83)	(18, 85)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2 unblinded/C4591001 IA P2 Serology/adsl s005 demo p2 d2 eval

2.5.4.4.3.2. SARS-CoV-2 Neutralizing Titers and S1-Binding IgG Concentrations

Results of immunogenicity analyses reported here are those for the Dose 2 evaluable immunogenicity population; note that baseline positive participants (by SARS-CoV-2 N-binding antibody or positive NAAT at Visit 1) were not excluded from these analyses. Immunogenicity results for the Dose 2 all-available immunogenicity population were similar to those for the evaluable population.

Geometric Mean Titers/Concentrations (GMTs/GMCs)

BNT162b2 elicited robust SARS-CoV-2 immune responses at 1 month after Dose 2 defined by both SARS-CoV-2 50% neutralizing titers (GMTs) (Figure 9) and S1-binding IgG concentrations (GMCs) (Figure 10). GMTs/GMCs were higher in younger participants (18 to 55 years of age) than in older participants (56 to 85 years of age) (Table 47).

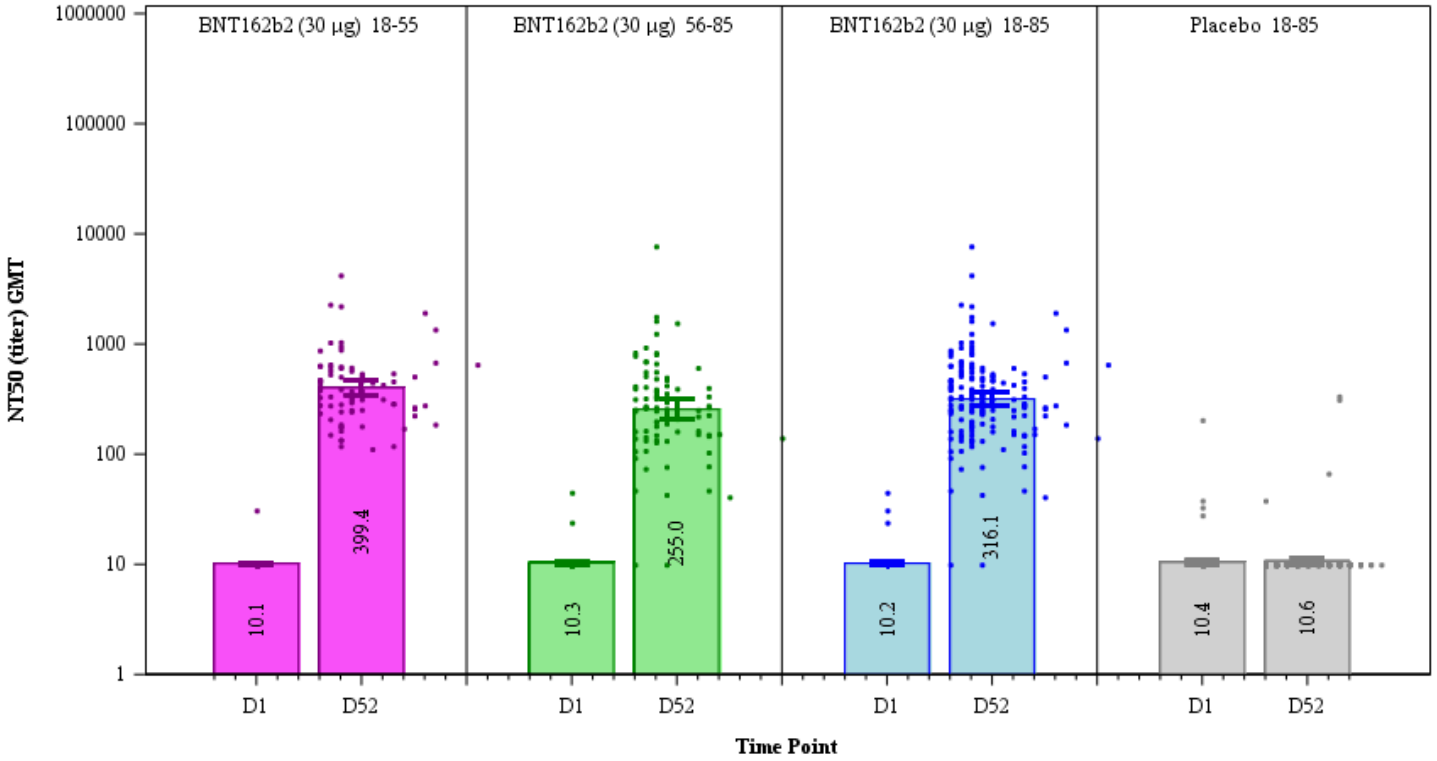
HCS Comparison

Of note, 50% neutralizing GMTs at 1-month post Dose 2 for both younger (GMT=399.4) and older participants (GMT=255.0) in the evaluable immunogenicity population were similar to the GMTs of a comparative panel of HCS (GMT=319).[19] The HCS is the same panel described in Section 2.5.4.2.3.3, except 5 sera from the N=38 serum panel had been depleted.

Geometric Mean Fold-Rise (GMFR) in Titers/Concentrations

Results for GMFRs in SARS-CoV-2 50% neutralizing titers and S1-binding IgG concentrations were robust at 1 month after Dose 2 of BNT162b2, with higher GMFRs observed in younger participants than in older participants (Table 48).

Figure 9. Geometric Mean Titers: SARS-CoV-2 Neutralization Assay – NT50 – Evaluable Immunogenicity Population – Phase 2



Abbreviations: GMT = geometric mean titer; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
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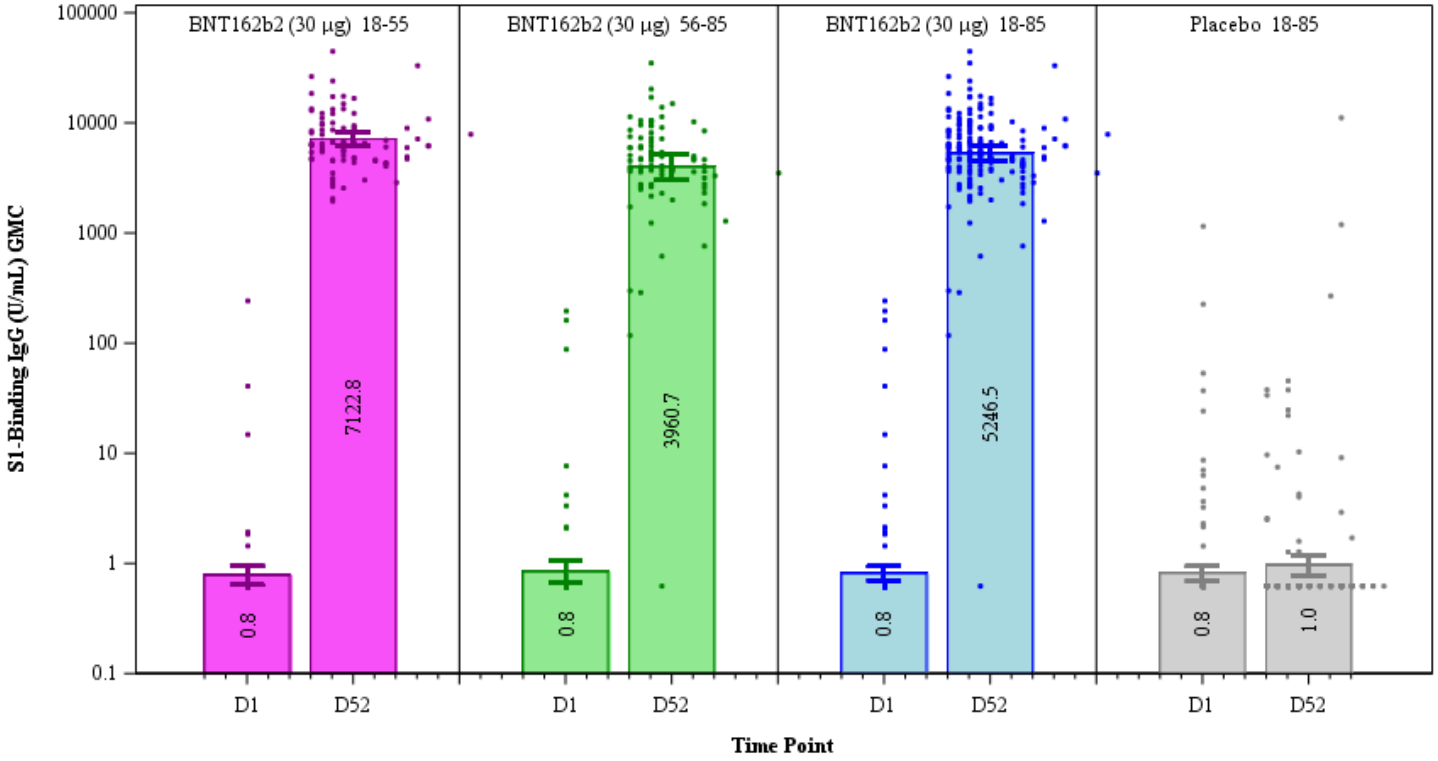
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adva_f002_sars_50_p2

Figure 10. Geometric Mean Concentrations: SARS-CoV-2 S1-Binding IgG Level Assay – Evaluable Immunogenicity Population – Phase 2



Abbreviations: GMC = geometric mean concentration; IgG = immunoglobulin G; S1 = spike protein S1 subunit.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adva_f002_s1_p2

Table 47. Summary of Geometric Mean Titers/Concentrations – Phase 2 – Dose 2 Evaluable Immunogenicity Population

Assay	Dose/ Sampling Time Point[a]	Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)						Placebo	
		18-55 Years		56-85 Years		18-85 Years		18-85 Years	
		n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	80	10.1 (9.9, 10.4)	88	10.3 (9.9, 10.7)	168	10.2 (10.0, 10.5)	167	10.4 (10.0, 10.9)
	2/1 Month	80	399.4 (342.1, 466.2)	87	255.0 (205.7, 316.0)	167	316.1 (275.6, 362.6)	167	10.6 (10.0, 11.3)
S1-binding IgG level assay (U/mL)	1/Prevax	80	0.8 (0.6, 0.9)	88	0.8 (0.7, 1.1)	168	0.8 (0.7, 0.9)	167	0.8 (0.7, 0.9)
	2/1 Month	80	7122.8 (6217.4, 8160.2)	87	3960.7 (3007.2, 5216.6)	167	5246.5 (4460.3, 6171.4)	167	1.0 (0.8, 1.2)

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation;
NT50 = 50% neutralizing titer; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentrations and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
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(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File:
./nda2 unblinded/C4591001 IA P2 Serology/adva s001 gm p2 eval

Table 48. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 2 – Dose 2 Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)						Placebo	
		18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	80	39.4 (34.0, 45.6)	86	24.9 (20.2, 30.9)	166	31.1 (27.2, 35.5)	167	1.0 (1.0, 1.1)
S1-binding IgG level assay (U/mL)	2/1 Month	80	9167.2 (7452.8, 11276.0)	86	4975.5 (3655.9, 6771.4)	166	6679.4 (5511.6, 8094.7)	167	1.2 (1.0, 1.4)

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer;
S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.
c. GMFRs and the corresponding 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adva_s001_gmfr_p2_eval

2.5.4.4.3.3. SARS-CoV-2 Neutralizing Titers and S1-Binding IgG Concentrations by Baseline SARS-CoV-2 Status

Immunogenicity results were summarized by baseline SARS-CoV-2 status (positive or negative; ie, participants with or without serological or virological evidence of SARS-CoV-2 infection before vaccination). Positive baseline SARS-CoV-2 status was defined as positive by N-binding antibody at Visit 1, or positive NAAT at Visit 1, or a medical history of COVID-19; negative baseline SARS-CoV-2 status was defined as negative by N-binding antibody and negative NAAT at Visit 1.

Geometric Mean Titers/Concentrations (GMTs/GMCs)

A few participants in the Dose 2 evaluable immunogenicity population had a positive baseline SARS-CoV-2 status: a total of 9 participants with immunogenicity data at the pre-vaccination time point (5 who received BNT162b2 and 4 who received placebo) and 7 participants (3 who received BNT162b2 and 4 who received placebo) with immunogenicity data at the 1 month post Dose 2 time point. These SARS-CoV-2 status positive participants were analyzed separately from the baseline negative participants (Table 49). In general, at 1 month post Dose 2 among BNT162b2 recipients, SARS-CoV-2 50% neutralizing GMTs in participants with a positive baseline SARS-CoV-2 status (n=3) and S1-binding IgG GMCs in participants with a positive baseline SARS-CoV-2 status were numerically higher than those observed in participants with a negative baseline SARS-CoV-2 status (n=163) (Table 49). Participants with baseline negative SARS-CoV-2 status had SARS-CoV-2 50% neutralizing GMTs and S1-binding IgG GMCs similar to those in the combined baseline positive and negative participant group (Figure 9, Figure 10, and Table 47).

Geometric Mean Fold-Rise (GMFR) in Titers/Concentrations

When analyzing GMFRs stratified by SARS-CoV-2 status at 1 month post Dose 2, among BNT162b2 recipients (Table 50), the GMFRs for SARS-CoV-2 50% neutralizing titers and S1-binding IgG were similar to those in the combined baseline positive and negative participant group (Table 47).

Table 49. Summary of Geometric Mean Titers/Concentrations by Baseline SARS-CoV-2 Status – Phase 2 – Dose 2 Evaluable Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)						Placebo	
			18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	POS	1	31.0 (NE, NE)	4	18.1 (5.6, 58.2)	5	20.2 (8.7, 46.9)	4	38.4 (5.2, 282.5)
		NEG	79	10.0 (10.0, 10.0)	83	10.0 (10.0, 10.0)	162	10.0 (10.0, 10.0)	162	10.1 (9.9, 10.2)
	2/1 Month	POS	1	4233.0 (NE, NE)	2	3469.9 (0.1, 9.247E7)	3	3707.6 (495.5, 27743.3)	4	53.2 (5.5, 515.3)
		NEG	79	387.6 (335.4, 448.0)	84	237.7 (194.4, 290.7)	163	301.3 (264.7, 342.9)	162	10.2 (9.8, 10.7)
S1-binding IgG level assay (U/mL)	1/Prevax	POS	1	246.1 (NE, NE)	4	36.9 (0.5, 2848.7)	5	53.9 (2.4, 1222.0)	4	153.0 (12.7, 1844.4)
		NEG	79	0.7 (0.6, 0.8)	83	0.7 (0.6, 0.8)	162	0.7 (0.7, 0.8)	162	0.7 (0.7, 0.8)
	2/1 Month	POS	1	45474.1 (NE, NE)	2	23255.3 (106.2, 5.092E6)	3	29080.6 (6983.3, 121100.2)	4	144.4 (9.5, 2189.7)
		NEG	79	6957.6 (6113.5, 7918.3)	84	3759.2 (2847.3, 4963.2)	163	5066.1 (4308.9, 5956.5)	162	0.8 (0.7, 1.0)

Table 49. Summary of Geometric Mean Titers/Concentrations by Baseline SARS-CoV-2 Status – Phase 2 – Dose 2 Evaluable Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)						Placebo	
			18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; NE = not estimable; NEG = negative; NT50 = 50% neutralizing titer; POS = positive;
S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined due to missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. Positive = Positive N-binding antibody at Visit 1, or positive NAAT at Visit 1, or had medical history of COVID-19. Negative = Negative N-binding antibody at Visit 1 and negative NAAT at Visit 1.
c. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
d. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentration and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (04:18)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adva_s001_gm_lt_p2_eval

Table 50. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point by Baseline SARS-CoV-2 Status – Phase 2 – Dose 2 Evaluable Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)						Placebo	
			18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	POS	1	136.5 (NE, NE)	2	163.6 (0.0, 6.156E10)	3	154.0 (3.2, 7377.7)	4	1.4 (0.9, 2.0)
		NEG	79	38.8 (33.5, 44.8)	83	23.6 (19.3, 29.0)	162	30.1 (26.4, 34.3)	162	1.0 (1.0, 1.1)
S1-binding IgG level assay (U/mL)	2/1 Month	POS	1	184.7 (NE, NE)	2	191.8 (0.0, 1.993E6)	3	189.4 (31.0, 1156.2)	4	0.9 (0.6, 1.5)
		NEG	79	9631.6 (8008.6, 11583.6)	83	5312.3 (3946.8, 7150.4)	162	7100.7 (5925.1, 8509.7)	162	1.2 (1.0, 1.4)

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; NE = not estimable; NEG = negative; NT50 = 50% neutralizing titer; POS = positive; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Subjects whose baseline SARS-CoV-2 status cannot be determined due to missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.

a. Protocol-specified timing for blood sample collection.

b. Positive = Positive N-binding antibody at Visit 1, or positive NAAT at Visit 1, or had medical history of COVID-19. Negative = Negative N-binding antibody at Visit 1 and negative NAAT at Visit 1.

c. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.

d. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.

PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2 unblinded/C4591001 IA P2 Serology/adva s002 gmfr lt p2 eval

2.5.4.4.4. Immunogenicity Conclusions

Phase 1

Study BNT162-01 provides evidence for robust T cell-mediated immunity, with antigen induced IFNγ expression demonstrating a Th1 CD4+ and CD8+ phenotype following the second dose of either BNT162b1 or BNT162b2. Immunogenicity data from Study BNT162-01 were generally concordant with results in pivotal Study C4591001, showing robust SARS CoV-2 neutralization following the second dose and complimentary T cell immune response data for both younger and older adults. The durability of T cell responses to BNT162b2 vaccination was evident from maintenance of the Th1 phenotype and persistent IFNγ and IL-2 production by CD4+ and CD8+ T cells up to approximately 6 months.

In Study C4591001, both BNT162b1 and BNT162b2 elicited robust SARS-CoV-2 neutralizing antibody response starting from 7 days after Dose 2 in younger and older adults. Responses were generally stronger in younger adults than in older adults. Neutralizing antibody response was maintained through Day 52 and was similar for the candidates within the corresponding age and dose groups. Comparisons of SARS-CoV-2 neutralizing titers for both vaccine candidates with a panel of HCS support the benefit of a two-dose vaccination regimen with a dose response up to 30 µg.

For the groups that received BNT162b2 at 30 µg, persistence of the immune response was observed through 6 months after Dose 2. SARS-CoV-2 serum neutralizing titers and serum S1-binding IgG concentrations at 6 months after Dose 2 had decreased relative to those observed at 1 month after Dose 2 but remained above pre-vaccination and placebo levels.

The Phase 1 immunogenicity data from both the pivotal and supportive study collectively showed robust immunogenicity elicited by BNT162b2 in both younger and older adults at the 30 µg dose level, which was ultimately selected to proceed to Phase 2/3 development.

Phase 2

Based on immunogenicity results from 360 participants in Phase 2 of Study C4591001, BNT162b2 at 30 µg elicited robust SARS-CoV-2 neutralization and S1-binding IgG antibody responses at 1 month after Dose 2 similar to those previously observed in Phase 1 of the study. Notably, SARS-CoV-2 neutralizing titers were higher in the younger adult compared to the older adult cohort. Of note, GMTs for younger and older participants at 1 month after Dose 2 were comparable to the GMTs of a comparative panel of HCS. S1-binding GMCs were generally higher in the younger age cohort compared to the older age cohort, again concordant with observations in the Phase 1 portion of the study.

2.5.5. Overview of Safety

Safety was evaluated in Study BNT162-01 (Phase 1) and in all 3 phases of Study C4591001. The methods for evaluation of safety are provided in Section 2.5.5.1 and results are presented for BNT162-01 Phase 1 (Section 2.5.5.2 and Section 2.5.5.6.1); and all phases of Study C4591001 (Section 2.5.5.3 through Section 2.5.5.5).

Details of safety analysis methods in Study C4591001 are provided in the Module 5.3.5.1 C4591001 Protocol and SAP, and for Study BNT162-01 in the Module 5.3.5.1 BNT162-01 Protocol and SAP.

Details of safety results, including for additional endpoints, are presented as follows:

Study BNT162-01: Module 5.3.5.1 BNT162-01 Interim CSR.

Study C4591001:

Phase 1: safety results for all candidates and dose levels up to 1 month after Dose 2 are presented in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR; safety results for Phase 1 participants in the BNT162b2 30 µg up to 6 months after Dose 2 are presented in Module 5.3.5.1 C4591001 6-Month Update Interim CSR.

Phase 2: safety results up to 1 month after Dose 2 are presented in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR.

Phase 2/3: safety results to 1 month after Dose 2 are presented in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR; safety results to 6 months after Dose 2 and to data cutoff date (blinded and open-label follow-up) are presented in Module 5.3.5.1 C4591001 6-Month Update Interim CSR.

Note that data from Phase 2 participants were included in Phase 3 safety analyses. Safety data are also presented in Module 2.7.4 and summarized below.

2.5.5.1. Safety Endpoints and Analysis Methods

Details of safety methods and analyses are provided in Module 2.7.4 and summarized below. Statistical analyses are provided in Section 2.5.5.1.3.

2.5.5.1.1. Safety Endpoints in Study BNT162-01

In Study BNT162-01, all participants in Phase 1 recorded local reactions, systemic events, and antipyretic/pain medication usage for 7 days, each evening following administration of study intervention using a paper diary. Participants were asked to assess local reactions and systemic events from Day 1 through Day 7 after each dose.

Treatment-emergent AEs were recorded for up to 1 month after Dose 2 and categorized by frequency, maximum severity, seriousness, and relationship to study intervention using System Organ Class (SOC) and Preferred Term (PT) according to the Medical Dictionary for Regulatory Activities (MedDRA). AEs of special interest (AESIs) included enhanced

respiratory disease or flu-like symptomatology that did not resolve after 7 days or with symptom kinetics that were inconsistent with a relationship to RNA immunization.

Clinical laboratory tests were performed and classified as normal or abnormal (lower or higher than reference range) and abnormal results were graded as mild, moderate, severe, or life-threatening. Physical examinations, vital signs, and electrocardiograms (ECGs) were conducted prior to vaccine dose administration.

2.5.5.1.2. Safety Endpoints in Study C4591001

2.5.5.1.2.1. Phase 1 Safety Endpoints

In Phase 1 of Study C4591001, all participants were asked to record reactogenicity:[21] local reactions (pain, redness and swelling at the injection site), systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain), and antipyretic/pain medication usage for 7 days, each evening following administration of study intervention using prompts from an electronic diary (e-diary). This allowed recording of these assessments only within a fixed time window and provided an accurate representation of the participant's experience at that time. Participants were asked to assess local reactions and systemic events from Day 1 through Day 7 after each dose.

In Phase 1, AEs were recorded for up to 1 month after Dose 2 and categorized by frequency, maximum severity, seriousness, and relationship to study intervention using SOC and PT according to MedDRA. SAEs are being recorded for up to 6 months after Dose 2. For longer-term follow-up, AEs and SAEs continue to be reported until end of the study.

In Phase 1 only, abnormal hematology and chemistry laboratory values including grading shifts through Day 7 after Dose 2 were reported; abnormal clinical laboratory data were graded as mild, moderate, severe, or life-threatening. Physical examinations, vital signs, and ECGs were conducted prior to vaccine dose administration.

Stopping rules were in place for all Phase 1 participants, based on review of AE data and e-diary reactogenicity data, until the start of Phase 2/3 or 30 days after the last dose of study intervention in Phase 1, whichever was later. These data were monitored on an ongoing basis by the investigator (or medically qualified designee), Pfizer, and BioNTech in order to promptly identify and flag any event that potentially contributes to a stopping rule.

2.5.5.1.2.2. Phase 2/3 Safety Endpoints

Phase 2

In Phase 2, N~360 participants recorded local reactions, systemic events, and antipyretic/pain medication usage for 7 days, each evening following administration of study intervention using an e-diary from Day 1 through Day 7 after each dose.

In Phase 2, AEs and SAEs were recorded through 7 days after Dose 2 as a prespecified study endpoint and then further (to at least 1 month after Dose 2) for longer-term follow-up. AEs were categorized by frequency, maximum severity, seriousness, and relationship to

study intervention using SOC and PT according to MedDRA. For longer-term follow-up, AEs and SAEs continue to be reported until end of the study.

Note that Phase 2 participants are a subset of those in the Phase 2/3 portion of the study and are therefore included in Phase 3 safety analyses.

Phase 2/3

A subset of participants ≥16 years of age first enrolled in Phase 2/3 recorded local reactions, systemic events, and antipyretic/pain medication usage for 7 days, each evening following administration of study intervention using an e-diary from Day 1 through Day 7 after each dose. For participants who were not in the reactogenicity subset, local reactions and systemic events consistent with reactogenicity were detected and reported as AEs.

For Phase 2/3 safety analyses (which included the N~360 participants analyzed in Phase 2), AEs were reported for up to 1 month after Dose 2 and categorized by frequency, maximum severity, seriousness, and relationship to study intervention using SOC and PT according to MedDRA. SAEs were recorded for up to 6 months after Dose 2. For longer-term follow-up, AEs and SAEs continue to be reported until end of the study.

Phase 2/3 AE data were analyzed for safety population ≥16 years of age subgroups defined by:

- evidence of prior SARS-CoV-2 infection at baseline per NAAT or N-antigen binding assay
- demographics (ie, age, sex, race, and ethnicity).

Subgroups of the safety population for Phase 2/3 participants ≥16 years of age were analyzed and reported for the blinded placebo-controlled follow-up period up to the date of unblinding.

Additional subgroups were analyzed to evaluate safety for participants ≥16 years of age who were originally randomized to placebo, had prior evidence of SARS-CoV-2 infection at study baseline or had COVID-19 illness during the study, and were subsequently unblinded to receive BNT162b2 during open-label follow-up.

The subset of Phase 2/3 participants ≥16 years of age with stable HIV were analyzed separately per protocol as of the most recent cutoff date (13 March 2021).

AEs of special interest (AESIs) were not prespecified in the protocol; instead, Pfizer utilizes a safety review as part of the signal detection processes that highlights specified targeted medical events (TMEs) of clinical interest. These are a dynamic list of specific AE terms reviewed on an ongoing basis by routine safety data review procedures throughout the clinical study. The TME terms are chosen based on review of known pharmacology, toxicology findings, possible class effects, published literature, and potential signals arising from safety data assessments. For this study, the list of TMEs includes events of interest due to their association with COVID-19 and terms of interest for vaccines in general; during safety review, consideration was also given to the CDC defined list of AESIs associated with COVID-19 vaccination.

Data for adolescents 12 to 15 years of age are not included in this submission and will be reported at a later time.

2.5.5.1.2.3. Safety Assessments in All Phases

In Phase 2/3 of Study C4591001, prior infection with SARS-CoV-2 was assessed at baseline (NAAT, serology) and at Dose 2 (NAAT) and is being evaluated for up to 24 months to assess persistence of efficacy, explore efficacy against asymptomatic SARS-CoV-2 infections, and ensure safety in baseline SARS-COV-2 negative and positive participants. Prior infection was determined by virological testing via NAAT on mid-turbinate swab and serological testing for IgG to the SARS-CoV-2 N-antigen.

Participants in all phases were surveilled for potential COVID-19 illness from Visit 1 onwards. In Phase 1, Pfizer and BioNTech conducted unblinded reviews of the data, including for the purpose of safety assessment. Any NAAT-confirmed cases in Phase 1 were reviewed contemporaneously by the IRC and Data Monitoring Committee (DMC). In Phase 2/3, the unblinded team supporting the DMC (including an unblinded medical monitor) reviewed severe COVID-19 cases as they were received, and reviewed AEs at least weekly for additional potential cases of severe COVID-19. At any point, the unblinded team could discuss with the DMC chair whether the DMC should review cases for an adverse imbalance of COVID-19 and/or severe COVID-19 cases in the BNT162b2 and placebo groups.

Pregnancies were reported for participants in any phase of the study.

Narratives

Narratives are located in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 14 Subject Narratives (for data available as of the 14 November 2020 cutoff date) or Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 14 Subject Narratives (for data available as of the 13 March 2021 cutoff date). Narratives were prepared for participants ≥16 years of age if they were determined to meet these criteria:

- Deaths, vaccine-related SAEs, all other SAEs, safety-related withdrawals
- AEs of interest requested by FDA: anaphylaxis, Bell's palsy, lymphadenopathy, appendicitis, and pregnancy exposures and outcomes
- AESIs with a numerical imbalance with a higher frequency (or incidence rate) in the vaccine group vs placebo group that led to withdrawal, were related, or had biological plausibility
- COVID-19 cases (participants with severe and/or multiple episodes).

Note that imbalances in PTs in the BNT162b2 and placebo groups that corresponded to reactogenicity terms reported within 7 days after each dose, such as pain at injection site and headache and that were captured in participants' e-diaries for reactogenicity analysis, were generally excluded as criteria for narratives.

Study Groups and Follow-up Periods Contributing Safety Data

Safety evaluations from Study C4591001 presented in this CO include the following data from a total of approximately 44,000 enrolled participants ≥16 years of age, through a data cutoff date of 13 March 2021:

- Randomized BNT162b2 and placebo groups for period of available blinded follow-up to:
  - at least 6 months after Dose 2 for Phase 1 participants randomized to BNT162b2 30 µg, comparing younger (18 to 55 years of age) and older (65 to 85 years of age) groups
  - 1 month after Dose 2 and until unblinding for Phase 2/3 participants, comparing younger adult (16 to 55 years of age) and older adult (>55 years of age) groups
  - 1 month after Dose 1 and until unblinding for Phase 2/3 participants in HIV+ subset
- Open-label data for Phase 2/3 participants originally randomized to BNT162b2 from the time of unblinding through the data cutoff date
- Cumulative data for Phase 2/3 participants originally randomized to BNT162b2, including at least 3000 per age group (16 to 55, >55 years of age) with follow-up to at least 6 months after Dose 2 (inclusive of blinded and open-label data)
- Open-label data for Phase 2/3 participants originally randomized to placebo from the time of unblinding and vaccination with BNT162b2 (Dose 3) through the data cutoff date

2.5.5.1.3. Safety Analysis Methods

2.5.5.1.3.1. Study BNT162-01

Safety data were analyzed and reported using descriptive summary statistics for the safety set (described in Module 2.7.4). Analyses were performed for endpoints described in Section 2.5.5.1.1, separately by protocol defined age group (younger and older adults).

Reactogenicity: Summary statistics including counts and percentages provided by study group.

Adverse Events: Summary statistics including counts and percentages provided by study group.

Clinical Laboratory Evaluations: Values at each timepoint and change from baseline to post-baseline time points summarized using descriptive summary statistics by study group. Values were flagged as abnormal and/or clinically significant.

2.5.5.1.3.2. Study C4591001

Safety data were analyzed and reported using descriptive summary statistics for the safety population for each study phase (described in Module 2.7.4). Analyses were performed for endpoints described in Section 2.5.5.1.2, separately by protocol defined age groups (adolescents, younger adults, older adults) and for the HIV+ subset and reactogenicity subset. Analyses of subgroups were performed for those described in Section 2.5.5.1.2.2.

Reactogenicity

Descriptive statistics were provided for each reactogenicity endpoint for each dose and vaccine group. Local reactions and systemic events from Day 1 through Day 7 after each vaccination will be presented by severity cumulatively across severity levels. Descriptive summary statistics included counts and percentages of participants with the indicated endpoint and the associated Clopper-Pearson 2-sided 95% confidence intervals (CIs). Missing reactogenicity e-diary data were not imputed.

Adverse Events

Descriptive summary statistics including counts, percentages, and associated Clopper-Pearson 2-sided 95% CIs were provided for AEs for by study group.

AE analyses of participants who had different durations of follow-up time due to unblinding in the study (per protocol) were summarized as incidence rates (IR) adjusted for exposure time. This was calculated as: (number of participants reporting event) / (total exposure time across all participants in the specified group). This accounts for variable exposure since unblinding began for individual participants (as described in Section 2.5.1.2.3.2.2). Two-sided 95% CIs for the IRs were provided based on Poisson distribution.

Clinical Laboratory Evaluations

Descriptive statistics were provided for abnormal hematology and chemistry laboratory values after each vaccine dose (in Phase 1 only). This includes grading shifts in hematology and chemistry laboratory values from baseline to 1 and 7 days after Dose 1, and to before Dose 2 and 7 days after Dose 2. Descriptive summary statistics include counts and percentages of participants with the indicated endpoint and the associated Clopper-Pearson 2-sided 95% CIs.

2.5.5.2. Safety Results – Phase 1 Safety in Study BNT162-01

Details of study population and safety analysis results in Study BNT162-01 are provided in Module 5.3.5.1 BNT162-01 Interim CSR Section 10 and Section 12, in Module 2.7.4, and summarized below.

Safety data (reactogenicity and AE analyses) up to 1 month after Dose 2 are available up through the safety data cutoff date (23 October 2020) and summarized below as follows:

- **BNT162b1**: younger participants: N=84, n=12 each in 1, 3, 10, 20, 30, 50, 60 µg groups (note: 60 µg group received only Dose 1 per SRC decision due to Dose 1 reactogenicity); older participants: N=36, n=12 each in 10, 20, 30 µg groups (note: 10 µg group had data to 1 month after Dose 2; 20 and 30 µg groups had available data to 7 days after Dose 2).

- **BNT162b2**: younger participants: N=60, n=12 each in 1, 3, 10, 20, and 30 µg groups; older participants: N=36, n=12 each in 10, 20, and 30 µg groups.

2.5.5.2.1. Safety Populations – Phase 1

The safety set for Study BNT162-01 is described below; the immunogenicity set was generally similar.

BNT162b1

In the younger group (18 to 55 years of age), BNT162b1 was administered to 84 participants among whom 52% were male and 48% were female, 96% were White and 2% were Hispanic/Latino, with a median 36 years of age.

In the older group (56 to 85 years of age), BNT162b1 was administered to 36 participants among whom 36% were male and 64% were female, all were White and none were Hispanic/Latino, with a median 67 years of age.

Among the BNT162b1 groups in the Phase 1 portion of Study BNT162-01, 80/84 younger and 11/36 older participants completed the study (ie, through the end of treatment visit). Four premature discontinuations have occurred. One younger participant in the 10 µg group discontinued prematurely from the study due to an AE after Dose 1; this AE was assessed as not related to study treatment. Three younger participants discontinued prematurely for other reasons: in the 20 µg group due to withdrawal by participant (n=1) after Dose 1 and due to other/private reason (n=1) after Dose 2; and in the 50 µg group due to other/private reason (n=1) after Dose 1. Another younger participant in the 20 µg group discontinued prematurely after 1 month of follow-up post Dose 2, but did not complete the end of treatment visit. No older participants have prematurely discontinued the study; some have completed the study and the others remain in follow-up.

BNT162b2

In the younger group (18 to 55 years of age), BNT162b2 was administered to 60 participants among whom 43% were male and 57% were female, 100% were White, none were Hispanic/Latino, with a median 42 years of age.

In the older group (56 to 85 years of age), BNT162b2 was administered to 36 participants among whom 50% were male and 50% were female, 100% were White, none were Hispanic/Latino, with a median 65 years of age.

Among the BNT162b2 groups in the Phase 1 portion of Study BNT162-01, 53/60 younger and 30/36 older participants completed the study (ie, through end of treatment visit). Two premature discontinuations have occurred. One younger participant in the 10 µg group discontinued prematurely due to AEs after Dose 1; these AEs were assessed as not related to study treatment. One younger participant in the 1 µg group discontinued prematurely due to withdrawal by the participant after Dose 1. No older participants have prematurely discontinued the study; most have completed the study the others remain in follow-up.

2.5.5.2.2. Reactogenicity – Phase 1

This section summarizes reactogenicity collected in paper diaries from participants in the Phase 1 part of Study BNT162-01 for candidates BNT162b1 and BNT162b2.

Based on all available data from the Phase 1 part of Study BNT162-01, the reactogenicity profile observed for BNT162b2 is more favorable than that of BNT162b1. For BNT162b1, reactogenicity (particularly systemic events) increased after Dose 2 compared to Dose 1. For BNT162b2, dose level- and dose number-dependent increases in reactogenicity were minimal to modest. In general, older participants had milder reactogenicity compared to the younger groups for both vaccine candidates.

2.5.5.2.2.1. Local Reactions

Overall, solicited local reactions following administration across doses of BNT162b2 were milder and less frequent for participants compared with BNT162b1. Local reactions generally increased in frequency and/or severity with increasing dose level and number of doses of BNT162b1 and BNT162b2. Most local reactions were mild or moderate in severity and resolved within several days of onset.

For BNT162b1, the incidence of any local reactions after each dose was similar in younger and older age groups, but local reactions were generally milder in the older group. For BNT162b2, both incidence and severity of local reactions was general decreased after each dose in the older group compared with the younger group.

2.5.5.2.2.2. Systemic Events

Overall, solicited systemic events following administration across doses of BNT162b2 were milder and less frequent for participants compared with BNT162b1. Systemic events generally increased in frequency and/or severity with increasing dose level and number of doses of BNT162b1 and BNT162b2. Most systemic events were mild or moderate, arose within the first 1 to 2 days after dosing, and were short-lived.

For BNT162b1, the incidence of any systemic events after each dose was similar in the younger and older age groups, but systemic events were generally milder in the older group. For BNT162b2, the incidence of systemic events after each dose was similar in the older group compared with the younger group. Reports of severe systemic events were similar in the younger and older BNT162b2 groups and were substantially less frequent than the severe events reported for younger and older BNT162b1 groups.

2.5.5.2.3. Adverse Events – Phase 1

In the Phase 1 part of Study BNT162-01, 40% to 45% of participants who received BNT162b1 and BNT162b2 across age groups and across dose levels reported one or more AEs from Dose 1 through 28 days (ie, 1 month) after Dose 2. There was no overall pattern between vaccine candidates with regard to AE incidence or severity; however, AEs considered by the investigator as related to study intervention (after omitting events captured in paper diaries for reactogenicity) were less frequently reported for BNT162b2 groups compared with BNT162b1. Most AEs were considered by the investigator as not related to study intervention and mild to moderate in severity, and all AEs were reported as resolved.

Among BNT162b1 recipients, 1 younger participant in the 10 µg group discontinued the study due to a moderate AE of malaise (considered as not related to study intervention) after Dose 1 and 1 younger participant in the 60 µg group discontinued due to a dose-limiting toxicity of pyrexia after Dose 1. One older participant in the 20 µg group had an SAE of severe syncope (considered as not related to study intervention) after Dose 1 and study treatment was withdrawn.

Among BNT162b2 recipients, 1 younger participant in the 10 µg group discontinued the study due to a moderate AE of nasopharyngitis (considered as not related to study intervention) after Dose 1. One older participant in the 20 µg group had an SAE of ankle fracture (considered as not related to study intervention) after receiving both doses, was listed as recovering, and remains in follow-up.

No deaths occurred in the Phase 1 part of Study BNT162-01.

2.5.5.3. Safety Results – Phase 1 Safety in Study C4591001

Details of study population and safety analysis results in Phase 1 are provided in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 10 and Section 12.1 (up to 1 month after Dose 2), and Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 10 and Section 12 (up to 6 months after Dose 2).

C4591001 Phase 1 safety data are also presented in Module 2.7.4 and summarized below.

Safety results for Phase 1 vaccine candidates BNT162b1 and BNT162b2 for both adult age groups are presented up to 1 month after Dose 2 (data cutoff date: 24 August 2020) at the 10 µg, 20 µg, and 30 µg dose levels. Note that the younger group of participants 18 to 55 years of age who received 100 µg BNT162b1 did not receive a second dose of 100 µg BNT162b2 per IRC decision, and instead were given 10 µg for Dose 2. These participants were described in the C4591001 Final Analysis Interim CSR and are not detailed here as the dose level was discontinued.

Safety follow-up is also presented up to at least 6 months after Dose 2 (data cutoff date: 13 March 2021) for Phase 1 participants who received BNT162b2 30 µg.

2.5.5.3.1. Safety Populations – Phase 1

In the Phase 1 part of Study C4591001, participants in each dose level and age group were randomized 4:1 to receive vaccine or placebo. The safety population for Study C4591001 is described below; the immunogenicity population was generally similar.

All Phase 1 participants in Study C4591001 received both vaccine doses except for the younger group who received BNT162b1 at the 100 µg dose level which was discontinued after the first dose per IRC decision. Participants in this group were instead able to receive a second dose at the 10 µg dose level, and 11/12 were administered this second dose. No participants discontinued the Phase 1 part of the study as of 1 month after Dose 2.

BNT162b1

BNT162b1 was administered to 45 participants who received up to 30 µg in the younger (18 to 55 years of age) group among whom 62% were male and 38% were female, 82% were White, 4% were Hispanic/Latino, with a median 35 years of age.

BNT162b1 was administered to 45 participants in the older (65 to 85 years of age) group among whom 29% were male and 71% were female, 93% were White, 2% were Hispanic/Latino, with a median 69 years of age.

Further follow-up data on the BNT162b1 groups was not available as of the most recent data cutoff date (13 March 2021).

BNT162b2

In the Phase 1 portion of Study C4591001, BNT162b2 was administered to 45 younger participants among whom 42% were male and 58% were female, 87% were White, 4% were Hispanic/Latino, with a median 37 years of age.

BNT162b2 was administered to 45 older participants among whom 38% were male and 62% were female, 100% were White, none were Hispanic/Latino, with a median 68 years of age.

Safety Follow-Up to at Least 6 Months After Dose 2 in BNT162b2 30 µg Groups

All participants in each age group randomized to receive BNT162b2 completed the visit at 6 months after Dose 2, with most of these 6-month visits occurring during the open-label follow-up period. All participants in each age group randomized to the placebo group received both doses of BNT162b2 (Dose 3 and Dose 4 in the study) during the open-label period and completed the visit at 1 month after Dose 4, as of the data cutoff date of 13 March 2021. No participants were withdrawn from the study up to the data cutoff date.

2.5.5.3.2. Reactogenicity – Phase 1

Based on all available data in the Phase 1 portion of Study C4591001, the reactogenicity profile observed for BNT162b2 is more favorable than that of BNT162b1. For BNT162b1, reactogenicity (particularly systemic events) increased after Dose 2 compared to Dose 1. For BNT162b2, dose level- and dose number-dependent increases in reactogenicity were minimal to modest in younger (18 to 55 years of age) and older (65 to 85 years of age) participants.

2.5.5.3.2.1. Local Reactions

Overall, prompted local reactions following administration of both doses of BNT162b2 in the Phase 1 portion of Study C4591001 were milder and less frequent for participants in both age groups compared with BNT162b1. For both BNT162b1 and BNT162b2, the frequency of local reactions was lower for the older group compared to the younger group. Local reactions were generally infrequent in placebo recipients.

The majority of local reactions in the vaccine groups were mild or moderate in severity and resolved within several days of onset. No grade 4 (potentially life-threatening) reactions were reported.

Pain at the injection site was the most frequent prompted local reaction, increasing in frequency and/or severity with increasing dose level, for both BNT162b1 and BNT162b2.

2.5.5.3.2.2. Systemic Events

Overall, systemic events following administration of both doses of BNT162b2 in the Phase 1 portion of Study C4591001 were milder and less frequent for participants in both age groups compared with BNT162b1. Systemic events were generally infrequent in placebo recipients.

The frequency of systemic events was lower for the older group (65 to 85 years of age) compared to the younger group (18 to 55 years of age). Notably, for older adults who received BNT162b2, frequencies of systemic events after the first dose were similar in BNT162b2 and placebo recipients.

Prompted systemic events generally increased in frequency and/or severity with increasing dose level and number of doses of BNT162b1 and BNT162b2. Use of antipyretic/pain medication also increased in frequency with increasing dose level and number of doses.

Most systemic events were mild or moderate, arose within the first 1-2 days after dosing, and resolved within several days of onset. For participants who received the 30 µg dose level, fever had a median duration of 1 day across vaccine candidates and across age groups, and chills had a median duration of 1 to 2 days across vaccine candidates and age groups.
No grade 4 (potentially life-threatening) events were reported.

2.5.5.3.3. Adverse Events – Phase 1

In the Phase 1 portion of Study C4591001, the majority of participants who received both BNT162b1 and BNT162b2 across age groups and dose levels reported one or more AEs after vaccine dosing (from Dose 1 onwards). AEs were reported at higher frequencies in BNT162b1 and BNT162b2 vaccine groups compared with placebo, across age groups and dose levels. AE incidences were generally lower in the older age groups compared with the younger age groups. Across BNT162b1 dose levels, 42% to 50% of younger participants and 25% to 58% of older participants reported AEs. Across BNT162b2 dose levels, 33% to 42% of younger participants and 8% to 25% of older participants reported AEs. Placebo younger and older groups reported AEs in 22% to 44% of participants.

Overall, most AEs reported were considered by the investigator as not related to study intervention. Most AEs were mild to moderate in severity. No SAEs, deaths, or discontinuations due to AEs were reported in the Phase 1 part of the study up to 1 month after Dose 2.

Safety Follow-Up to at Least 6 Months After Dose 2 in BNT162b2 30 µg Groups

From Dose 1 of BNT162b2 30 µg to the unblinding date, 6 (50.0%) participants in the younger age group and 3 (25.0%) participants in the older age group reported at least 1 AE.

Two (16.7%) participants in the BNT162b2 30 µg younger age group and 1 (8.3%) participant in the BNT162b2 30 µg older age group reported at least 1 severe AE. In the BNT162b2 30 µg younger age group, 3 (25.0%) participants reported at least 1 related AE and 1 (8.3%) participant reported 1 severe SAE.

No AEs were reported in either the younger or older participants in the placebo group. No SAEs or related AEs were reported in the BNT162b2 30 µg older age group. No AEs leading to withdrawal, life-threatening AEs, or deaths were reported in either the younger or older participants in the BNT162b2 30 µg group.

From Dose 1 of BNT162b2 30 µg to the unblinding date, AEs were most commonly reported in the system organ class (SOC) of nervous system disorders (3 [25.0%] participants in the younger age group and 1 [8.3%] participant in the older age group), followed by musculoskeletal and connective tissue disorders (1 [8.3%] participant in each age group). All AEs by preferred term (PT) were reported by no more than 1 participant.

There were no Phase 1 participants randomized to BNT162b2 30 µg or corresponding placebo who died through the data cutoff date of 13 March 2021. From Dose 1 to the unblinding date, 1 participant in the BNT162b2 30 µg younger age group reported a severe SAE (neuritis) that was assessed by the investigator as not related to study intervention. No Phase 1 participants randomized to BNT162b2 30 µg or corresponding placebo reported any AEs leading to withdrawal from the study from Dose 1 to the unblinding date. AEs of special interest were not defined for Phase 1 of this study. Pregnancy was not reported in any Phase 1 participants through the data cutoff date of 13 March 2021.

2.5.5.4. Safety Results – Phase 2 Safety in Study C4591001

Details of study population and safety analysis results in Phase 2 are provided in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 10 and Section 12.2, in Module 2.7.4, and summarized below.

Note that the Phase 2 portion of Study C4591001 included 360 participants randomized 1:1 to receive BNT162b2 (30 µg) or placebo when the Phase 2/3 study commenced.

Safety data (reactogenicity and AE analyses) for the 360 participants in the Phase 2 portion of the study are presented up to Day 7 after Dose 2 (per protocol objective), with a data cutoff date of 02 September 2020. AE data from participants in Phase 2 after this time point are otherwise included with Phase 3 analyses in Section 2.5.5.5.3.

2.5.5.4.1. Safety Populations – Phase 2

Disposition of 360 participants randomized 1:1 in Phase 2 was similar in the BNT162b2 and placebo groups. A total of 2 participants received Dose 1 but did not receive Dose 2: 1 participant each in the BNT162b2 and placebo groups.

Overall, most participants were White (85.8%), followed by Black or African American (9.2%). The proportions of Hispanic/Latino participants were similar in the BNT162b2 (8.9%) and placebo (11.1%) groups. Within the BNT162b2 group, the younger age group had 14.8% of Hispanic/Latino participants and the older age group had 3.3%.

The median age was 56 years overall. Median age was 44 years for the BNT162b2 younger age group and 65 years for the BNT162b2 older age group. The male/female split was approximately 50/50 for both groups and for younger and older participants within the BNT162b2 group.

The participants evaluated in Phase 2 after receiving BNT162b2 included 88 participants in the younger group and 92 participants in the older group.

2.5.5.4.2. Reactogenicity – Phase 2

In Phase 2, reactogenicity (particularly systemic events) increased after Dose 2 compared to Dose 1. Dose number-dependent increases in incidence of local reactions were minimal to modest in the younger and older groups of participants who received BNT162b2.

Most local reactions were mild or moderate in severity, had a median onset between 1 to 3 days after dosing (Day 1 was the day of vaccination), and resolved after a median duration of 1 to 3 days after onset. No grade 4 (potentially life-threatening) reactions were reported.

Most systemic events were mild or moderate in severity, had a median onset of 2 to 3 days after dosing, and resolved after a median duration of 1 day after onset. Fever and chills each had a median duration of 1 day after either dose for both age groups.

2.5.5.4.2.1. Local Reactions

Pain at the injection site was the most frequent prompted local reaction in Phase 2 across doses and age groups (71% to 85%), with higher frequency in the BNT162b2 group compared to placebo (9% to 10%). Local reactions generally had similar incidence in the younger group (N=88 post Dose 1; N=86 post Dose 2) compared with the older group (N=92 post Dose 1; N=91 post Dose 2). Severe pain at injection site was reported by 2 participants, both in the BNT162b2 group: n=1 in the older group had severe injection site pain after Dose 1, and n=1 in the younger age group had severe injection site pain after Dose 2.

Across age groups and both doses, swelling (3% to 12%) and redness (3% to 8%) occurred at low frequencies after Doses 1 and 2. One BNT162b2 recipient in the older group reported severe redness after Dose 2.

Most local reactions were mild or moderate in severity, had a median onset between 1 to 3 days after dosing (Day 1 was the day of vaccination), and resolved after a median duration of 1 to 3 days after onset. No grade 4 (potentially life-threatening) reactions were reported.

2.5.5.4.2.2. Systemic Events

The most frequent prompted systemic events for any dose and age groups in Phase 2 were fatigue (36% to 59%), headache (27% to 51%), muscle pain (14% to 45%), chills (8% to 41%), diarrhea (9% to 20%), joint pain (4% to 17%), fever (0% to 17%), and vomiting (0% to 2%). Systemic events generally had increased frequency and/or severity after Dose 2 compared with after Dose 1. Systemic events were also generally increased in frequency in the younger group (N=88 post Dose 1; N=86 post Dose 2) compared with the older group

(N=92 post Dose 1; N=91 post Dose 2), with frequencies increasing with number of doses (Dose 1 vs Dose 2):

- fatigue: younger group (50.0% vs 59.3%) compared to older group (35.9% vs 52.7%)
- headache: younger group (31.8% vs 51.2%) compared to older group (27.2% vs 36.3%)
- muscle pain: younger group (23.9% vs 45.3%) compared to older group (14.1% vs 28.6%)
- chills: younger group (9.1% vs 40.7%) compared to older group (7.6% vs 20.9%)
- joint pain: younger group (9.1% vs 17.4%) compared to older group (4.3% vs 16.5%)
- fever: younger group (3.4% vs 17.4%) compared to older group (0.0% vs 11.0%)
- vomiting: similar in both age groups and after either dose
- diarrhea: reported less frequently in the older group and was similar after each dose.

Use of antipyretic/pain medication also increased in frequency with increasing number of doses and was used more frequently in the younger group compared with the older group.

Most systemic events were mild or moderate in severity, had a median onset of 2 to 3 days after dosing, and resolved after a median duration of 1 day after onset. Fever and chills each had a median duration of 1 day after either dose for both age groups.

Across age groups, severe systemic events were observed only after Dose 2 of BNT162b2 overall and were reported for fever (1.1%), fatigue (4.0%), headache (2.8%), chills (2.3%), and muscle pain (1.7%). No grade 4 (potentially life-threatening) events were reported.

Systemic events were infrequent in placebo recipients.

2.5.5.4.3. Adverse Events – Phase 2

AE analysis results for 360 participants of Study C4591001 evaluated for Phase 2 were included with the Phase 3 AE analyses, and summarized separately here for data corresponding to the protocol defined objective of 7 days after Dose 2. AE data from participants in Phase 2 after this time point are otherwise included with Phase 3 analyses in Section 2.5.5.5.3.

The proportions of participants who reported any AEs up to 7 days after Dose 2 were similar in the BNT162b2 and placebo groups overall. Incidences in the BNT162b2 and placebo were similar within the age groups for younger (9.1% vs 11.1%) and older (4.3% vs 8.9%) participants. Two severe events of myalgia and gastric adenocarcinoma (which was also an SAE) were reported for 2 participants in the BNT162b2 younger age group, both assessed by the investigator as not related to study intervention. No other SAEs or any deaths were reported up to 7 days after Dose 2. The only discontinuation due to an AE during this time was the participant in the BNT162b2 younger age group who reported an SAE of gastric adenocarcinoma (discontinued from the study on Day 23 after Dose 1 of BNT162b2). There were no immediate AEs after any dose of BNT162b2 30 µg or placebo.

2.5.5.5. Safety Results - Phase 2/3 Safety in Study C4591001

Details of study population and safety analysis results in Phase 2/3 are provided in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 10 and Section 12.3 (up to 1 month after Dose 2), and Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 10 and Section 12.2 (up to 6 months after Dose 2).

C4591001 Phase 2/3 safety data are also presented in Module 2.7.4 and summarized below. Note that Phase 2/3 analyses included the 360 participants who were analyzed in Phase 2.

Safety data (reactogenicity and AE analyses) for participants in the Phase 2/3 portion of Study C4591001 are included up to the most recent data cutoff date of 13 March 2021. Participants ≥16 years of age are included in safety analyses presented in this submission; safety data for adolescents 12 to 15 years of age will be reported at a later time.

2.5.5.5.1. Safety Populations – Phase 2/3

The safety population included a total of 44,050 participants: 22,026 participants in the BNT162b2 group and 22,021 participants in the placebo group (Table 51). Most of the total 115 (0.3%) participants excluded from the safety population were excluded because those participants did not receive study vaccine.

HIV+ participants are included in this summary and summarized separately (per protocol). Safety analysis results of HIV+ participants are presented for adult participants (≥16 years of age) for the reactogenicity set and for other safety endpoints during the blinded placebo-controlled follow-up period.

There were no clinically meaningful differences in the safety population by age group, baseline SARS-CoV-2 status, ethnicity, race, or sex.

Table 51. Safety Population – Phase 2/3 Subjects ≥16 Years of Age

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)
Randomized[b]			44165
Vaccinated	22032	22025	44060 (99.8)
Safety population	22026	22021	44050 (99.7)
HIV-positive	100	100	200 (0.5)
Indeterminate vaccine[c]			3 (0.0)
Excluded from safety population			115 (0.3)
Reason for exclusion			
Subject did not receive study vaccine			105 (0.2)
Unreliable data due to lack of PI oversight			10 (0.0)

Table 51. Safety Population – Phase 2/3 Subjects ≥16 Years of Age

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. n = Number of subjects with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
c. "Indeterminate vaccine" refers to subjects whose vaccine group (as administered) could not be determined. These subjects were not included in the safety analysis but their safety data is listed separately.
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(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_s003_pop_all_p3

2.5.5.5.1.1. Duration of Follow-Up

During the blinded placebo-controlled follow-up period, 51.1% of participants in the BNT162b2 group and 51.4% of participants in the placebo group had follow-up time between ≥4 months to <6 months after Dose 2 (Table 52). Altogether, 25,651 participants (58.2%) ≥16 years of age were followed for ≥4 months after the second dose.

From Dose 2 to the cutoff date, 54.5% of participants in the BNT162b2 group had a total follow-up time of ≥6 months after the second dose.

In the younger age group, 48.5% of participants in the BNT162b2 group and 48.3% of participants in the placebo group had follow-up time between ≥4 months to <6 months after Dose 2 during the blinded placebo-controlled follow-up period. From Dose 2 to the cutoff date, 51.0% of participants in the BNT162b2 group had a total follow-up time of ≥6 months.

In the older age group, 54.8% of participants in the BNT162b2 group and 55.9% of participants in the placebo group had follow-up time between ≥4 months to <6 months after Dose 2 during the blinded placebo-controlled follow-up period. From Dose 2 to the cutoff date, 59.6% of participants in the BNT162b2 group had a total follow-up time of ≥6 months.

During the open-label follow-up period, 47.5% of original placebo participants had follow-up time between ≥1 month to <2 months after Dose 1 of BNT162b2.

Table 52. Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Placebo (N[a]=22021) n[b] (%)	Total (N[a]=44047) n[b] (%)
Subjects (%) with length of follow-up of:			
Original blinded placebo-controlled follow-up period			
<2 Months	1251 (5.7)	1331 (6.0)	2582 (5.9)
≥2 Months to <4 months	7744 (35.2)	8070 (36.6)	15814 (35.9)
≥4 Months to <6 months	11253 (51.1)	11316 (51.4)	22569 (51.2)
≥6 Months	1778 (8.1)	1304 (5.9)	3082 (7.0)
Total exposure from Dose 2 to cutoff date			
<2 Months	390 (1.8)		
≥2 Months to <4 months	679 (3.1)		
≥4 Months to <6 months	8951 (40.6)		
≥6 Months	12006 (54.5)		

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (01:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_fu_d2_p3_saf

Table 53. Follow-up Time After Dose 1 of BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received Placebo) – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=19611) n[b] (%)
Subjects (%) with length of follow-up of:	
Open-label follow-up period	
<1 Month	4934 (25.2)
≥1 Month to <2 months	9323 (47.5)
≥2 Months to <3 months	4145 (21.1)
≥3 Months	1209 (6.2)

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (01:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adsl fu d1 p3 saf

2.5.5.5.1.2. Disposition

The disposition of all Phase 2/3 participants randomized is presented for the blinded placebo-controlled and open-label follow-up periods in Table 54.

Disposition of all randomized participants ≥16 years of age was similar by age group. Disposition of HIV+ participants is included in this summary but summarized separately in safety analyses.

Note, several participants remain in the study but were erroneously reported as withdrawn because of AEs, which was subsequently queried and corrected as described in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Errata.

Blinded Placebo-Controlled Follow-Up Period

During the blinded placebo-controlled follow-up period, most participants randomized received Dose 1 (99.8%) and Dose 2 (98.1%). There were 352 (1.6%) participants in the BNT162b2 group and 528 (2.4%) participants in the placebo group who discontinued from the vaccination period (Dose 1 to 1 month after Dose 2) (Table 54). Most participants completed the visit at 1 month post-Dose 2 (≥96.4%). Few participants in the BNT162b2 and

placebo groups were withdrawn from the study (1.6% and 2.2%, respectively), and most were due to withdrawals by the participant, or they were lost to follow-up.

There were 7 participants with special data issues: 8 participant identification numbers from 4 participants who enrolled into the study more than once and 3 participants whose vaccine assignment was not confirmed in the IRT at the time of data cutoff.

- Three participants who were randomized and vaccinated, but actual vaccine assignment was not confirmed in IRT at the time of data cutoff. Participants were vaccinated as per CRF, but due to the inability to confirm consistency between the data in the CRF and IRT, these participants were not assigned to any actual dosing group. Safety data from these 3 participants were excluded from safety summary tables but their safety data are listed separately (Table 54).

- During the conduct of this study, 4 participants were each randomized twice with different participant identification numbers at 2 different sites. Because the significant misconduct of these participants compromised the integrity of the study data, results from these participants were excluded from all efficacy and safety analyses, including disposition and demographic tabulations. These participants who were discontinued from vaccination and/or from the study are listed separately.

Open-Label Follow-Up Period

Individuals ≥16 years of age have been unblinded as they became locally eligible and wished to know their vaccine assignment to confirm prior vaccination with BNT162b2 (if randomized to this group), or to receive BNT162b2 (if randomized to placebo). Unblinded participants originally randomized to BNT162b2 continue to be followed in an open-label manner. Unblinded participants originally randomized to placebo are offered BNT162b2 vaccination (Doses 3 and 4; first and second dose of BNT162b2 30 µg, respectively) and thereafter followed in an open-label manner.

Most Phase 2/3 participants in the originally randomized BNT162b2 (96.8%) and placebo (96.4%) groups completed the 1 month post-Dose 2 visit before unblinding (Table 54).

A total of 87 (0.4%) original BNT162b2 participants received Dose 1 of BNT162b2 during the blinded placebo-controlled follow-up period and then received Dose 2 of BNT162b2 30 µg during the open-label follow-up period (when they were unblinded). There were 105 (0.5%) participants withdrawn from the study, and most were due to withdrawals by the participant, or they had a protocol deviation.

During the open-label follow-up period, most participants originally randomized in the placebo group received Doses 3 and 4 (88.8% and 72.4%, respectively) of BNT162b2. There were few participants in this group (0.1%) who were withdrawn from the study, and most were due to withdrawals by the participant.

Table 54. Disposition of All Randomized Subjects – Phase 2/3 Subjects ≥16 Years of Age

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=22085) n[b] (%)	Placebo (N[a]=22080) n[b] (%)	Total (N[a]=44165) n[b] (%)
Randomized	22085 (100.0)	22080 (100.0)	44165 (100.0)
Not vaccinated	55 (0.2)	50 (0.2)	105 (0.2)
Original blinded placebo-controlled follow-up period			
Vaccinated	22030 (99.8)	22030 (99.8)	44060 (99.8)
Dose 1	22030 (99.8)	22030 (99.8)	44060 (99.8)
Dose 2	21675 (98.1)	21650 (98.1)	43325 (98.1)
Discontinued from original blinded placebo-controlled vaccination period[c]	352 (1.6)	528 (2.4)	880 (2.0)
Reason for discontinuation			
Lost to follow-up	151 (0.7)	153 (0.7)	304 (0.7)
Withdrawal by subject	109 (0.5)	181 (0.8)	290 (0.7)
No longer meets eligibility criteria	26 (0.1)	120 (0.5)	146 (0.3)
Adverse event	27 (0.1)	26 (0.1)	53 (0.1)
Physician decision	5 (0.0)	8 (0.0)	13 (0.0)
Pregnancy	6 (0.0)	6 (0.0)	12 (0.0)
Protocol deviation	3 (0.0)	8 (0.0)	11 (0.0)
Death	3 (0.0)	4 (0.0)	7 (0.0)
Medication error without associated adverse event	3 (0.0)	2 (0.0)	5 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	18 (0.1)	20 (0.1)	38 (0.1)
Unblinded before 1-month post–Dose 2 visit	253 (1.1)	240 (1.1)	493 (1.1)
Completed 1-month post–Dose 2 visit	21382 (96.8)	21293 (96.4)	42675 (96.6)
Withdrawn from the study	343 (1.6)	484 (2.2)	827 (1.9)
Withdrawn after Dose 1 and before Dose 2	176 (0.8)	211 (1.0)	387 (0.9)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	100 (0.5)	139 (0.6)	239 (0.5)
Withdrawn after 1-month post–Dose 2 visit	67 (0.3)	134 (0.6)	201 (0.5)
Reason for withdrawal from the study			
Lost to follow-up	174 (0.8)	191 (0.9)	365 (0.8)
Withdrawal by subject	122 (0.6)	226 (1.0)	348 (0.8)
Protocol deviation	11 (0.0)	24 (0.1)	35 (0.1)
Death	16 (0.1)	15 (0.1)	31 (0.1)
Adverse event	9 (0.0)	8 (0.0)	17 (0.0)
Physician decision	3 (0.0)	6 (0.0)	9 (0.0)
No longer meets eligibility criteria	1 (0.0)	4 (0.0)	5 (0.0)
Pregnancy	0	1 (0.0)	1 (0.0)
Medication error without associated adverse event	1 (0.0)	0	1 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	5 (0.0)	9 (0.0)	14 (0.0)
Open-label follow-up period			

Table 54. Disposition of All Randomized Subjects – Phase 2/3 Subjects ≥16 Years of Age

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=22085) n[b] (%)	**Placebo (N[a]=22080) n[b] (%)**	**Total (N[a]=44165) n[b] (%)**
Originally randomized to BNT162b2	20404 (92.4)		
Received Dose 2/unplanned dose	87 (0.4)		
Completed 1-month post–Dose 2 visit	210 (1.0)		
Completed 6-month post–Dose 2 visit	6414 (29.0)		
Withdrawn from the study	105 (0.5)		
Withdrawn before 6-month post–Dose 2 visit	103 (0.5)		
Withdrawn after 6-month post–Dose 2 visit	2 (0.0)		
Reason for withdrawal from the study			
Withdrawal by subject	56 (0.3)		
Protocol deviation	35 (0.2)		
Lost to follow-up	4 (0.0)		
Death	3 (0.0)		
Physician decision	2 (0.0)		
Adverse event	1 (0.0)		
No longer meets eligibility criteria	1 (0.0)		
Other	3 (0.0)		
Originally randomized to placebo		20948 (94.9)	
Withdrawn from the study after unblinding and before Dose 3		497 (2.3)	
Received Dose 3 (first dose of BNT162b2 [30 µg])		19612 (88.8)	
Received Dose 4 (second dose of BNT162b2 [30 µg])		15986 (72.4)	
Discontinued from open-label vaccination period[d]		24 (0.1)	
Reason for discontinuation from open-label vaccination period			
Protocol deviation		6 (0.0)	
Adverse event		5 (0.0)	
Withdrawal by subject		5 (0.0)	
Pregnancy		4 (0.0)	
Death		2 (0.0)	
Lost to follow-up		2 (0.0)	
Completed 1-month post–Dose 4 visit		7209 (32.6)	
Withdrawn from the study		14 (0.1)	
Withdrawn after Dose 3 and before Dose 4		11 (0.0)	
Withdrawn after Dose 4 and before 1-month post–Dose 4 visit		2 (0.0)	
Withdrawn after 1-month post–Dose 4 visit		1 (0.0)	
Reason for withdrawal from the study			
Withdrawal by subject		7 (0.0)	
Protocol deviation		3 (0.0)	
Death		2 (0.0)	
Adverse event		1 (0.0)	

Table 54. Disposition of All Randomized Subjects – Phase 2/3 Subjects ≥16 Years of Age

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=22085) n^b (%)	Placebo (N^a=22080) n^b (%)	Total (N^a=44165) n^b (%)
Lost to follow-up		1 (0.0)	

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
Note: Subjects randomized but did not sign informed consent or had a significant quality event due to lack of PI oversight are not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1081 10811053, C4591001 1088 10881077, C4591001 1177 11771089 and C4591001 1231 12311057 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving 1 dose of BNT162b2 (30 µg) and 1 dose of placebo.
a. N = number of randomized subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Original blinded placebo-controlled vaccination period is defined as the time period from Dose 1 to 1 month post–Dose 2.
d. Open-label vaccination period is defined as the time period from Dose 3 (first dose of BNT162b2 [30 µg]) to 1 month post–Dose 4 (second dose of BNT162b2 [30 µg]).
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adds Table Generation: 27MAR2021 (16:34)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adds s002 all p3 rand

2.5.5.5.1.3. Demographics

2.5.5.5.1.3.1. Participants ≥16 Years of Age

Demographic characteristics for all Phase 2/3 participants ≥16 years of age were similar in the BNT162b2 and placebo groups (Table 55). Overall, most participants were White (82.0%), with 9.6% Black or African American participants and 4.3% Asian participants, and all other racial groups were ≤2.5%. There were 25.9% Hispanic/Latino participants. Median age was 51.0 years and 50.9% of participants were male. Obesity was reported in 34.4% of participants in this safety population.

Baseline SARS-CoV-2 status was positive (defined as a positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19) in 3.1% of participants in the BNT162b2 group and 3.3% of participants in the placebo group.

Demographic data for participants 12 to 15 years of age in this study are provided in the Module 5.3.5.1 C4591001 6-Month Update Interim CSR. These participants were included in the efficacy populations, as defined in the protocol, for updated analyses of efficacy; safety data for participants 12 to 15 years of age will be reported separately at a later time.

Table 55. Demographic Characteristics – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Placebo (N[a]=22021) n[b] (%)	Total (N[a]=44047) n[b] (%)
Sex			
Male	11322 (51.4)	11098 (50.4)	22420 (50.9)
Female	10704 (48.6)	10923 (49.6)	21627 (49.1)
Race			
White	18056 (82.0)	18064 (82.0)	36120 (82.0)
Black or African American	2098 (9.5)	2118 (9.6)	4216 (9.6)
American Indian or Alaska Native	221 (1.0)	217 (1.0)	438 (1.0)
Asian	952 (4.3)	942 (4.3)	1894 (4.3)
Native Hawaiian or other Pacific Islander	58 (0.3)	32 (0.1)	90 (0.2)
Multiracial	550 (2.5)	533 (2.4)	1083 (2.5)
Not reported	91 (0.4)	115 (0.5)	206 (0.5)
Racial designation			
Japanese	78 (0.4)	78 (0.4)	156 (0.4)
Ethnicity			
Hispanic/Latino	5704 (25.9)	5695 (25.9)	11399 (25.9)
Non-Hispanic/non-Latino	16211 (73.6)	16212 (73.6)	32423 (73.6)
Not reported	111 (0.5)	114 (0.5)	225 (0.5)
Country			
Argentina	2883 (13.1)	2881 (13.1)	5764 (13.1)
Brazil	1452 (6.6)	1448 (6.6)	2900 (6.6)
Germany	249 (1.1)	250 (1.1)	499 (1.1)
South Africa	401 (1.8)	399 (1.8)	800 (1.8)
Turkey	249 (1.1)	249 (1.1)	498 (1.1)
USA	16792 (76.2)	16794 (76.3)	33586 (76.3)
Age group (at vaccination)			
16-55 Years	13069 (59.3)	13095 (59.5)	26164 (59.4)
>55 Years	8957 (40.7)	8926 (40.5)	17883 (40.6)
Age at vaccination (years)			
Mean (SD)	49.7 (15.99)	49.6 (16.05)	49.7 (16.02)
Median	51.0	51.0	51.0
Min, max	(16, 89)	(16, 91)	(16, 91)
Baseline SARS-CoV-2 status			
Positive[c]	689 (3.1)	716 (3.3)	1405 (3.2)
Negative[d]	21185 (96.2)	21180 (96.2)	42365 (96.2)
Missing	152 (0.7)	125 (0.6)	277 (0.6)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	271 (1.2)	304 (1.4)	575 (1.3)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	6535 (29.7)	6524 (29.6)	13059 (29.6)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	7670 (34.8)	7558 (34.3)	15228 (34.6)

Table 55. Demographic Characteristics – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Placebo (N[a]=22021) n[b] (%)	Total (N[a]=44047) n[b] (%)
Obese (≥30.0 kg/m^2)	7543 (34.2)	7629 (34.6)	15172 (34.4)
Missing	7 (0.0)	6 (0.0)	13 (0.0)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (15:19)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_s005_demo_all_p3_saf

Within each age group, most demographic characteristics were similar in the BNT162b2 group and the placebo group. Overall, 4.0% of participants in the younger age group were SARS-CoV-2 baseline positive, and 1.9% of participants in the older age group were SARS-CoV-2 baseline positive, and the proportions were similar in the BNT162b2 and placebo groups. There was a lower proportion of non-Hispanic/non-Latino participants in the younger BNT162b2 and placebo groups (68.6% and 68.8%, respectively) than in the older BNT162b2 and placebo groups (80.9% and 80.7%, respectively).

Within each baseline SARS-CoV-2 status group, demographic characteristics were similar in the BNT162b2 group and the placebo group. Most participants were White regardless of baseline status; however, there was a higher proportion of White participants among those with a negative baseline status (82.9%) than with a positive baseline status (57.7%). The median age was 43.0 years in participants with a positive baseline status and 51.0 years in participants with a negative baseline status. There were 41.4% and 34.2% of participants who were obese with positive and negative baseline status, respectively.

Participants ≥16 years of age had a diverse medical history profile consistent with that of individuals in the general population in the same age group. In the BNT162b2 group, conditions in the surgical and medical procedures (8430 [38.3%]), metabolism and nutrition disorders (6587[29.9%]), and immune system disorders (5987 [27.2%]; of which 3303 [15.0%] were seasonal allergy) SOCs were most frequently reported.

Overall, 20.7% of participants had any comorbidity (per the Charlson comorbidity index). The most frequently reported comorbidities were diabetes without chronic complications (7.7%), chronic pulmonary disease (8.1%), and any malignancy (3.6%), which were reported at similar frequencies in each vaccine group.

- In the younger age group, 13.3% of participants had any comorbidity. The most frequently reported comorbidities were diabetes without chronic complications (3.7%) and chronic pulmonary disease (7.4%), which were reported at similar frequencies in each vaccine group.

- In the older age group, 31.6% of participants had any comorbidity. The most frequently reported comorbidities were diabetes without chronic complications (13.6%) and chronic pulmonary disease (9.1%), which were reported at similar frequencies in each vaccine group.

HIV+ Participants

Demographic characteristics for participants with confirmed stable HIV disease were similar in the BNT162b2 and the placebo groups. Overall, 54.5% of participants were Black or African American, 40.5% of participants were White, and all other racial groups were ≤1.5%. There were 16.0% Hispanic/Latino participants. Median age was 49.5 years and 67.5% of participants were male. Obese participants made up 39.0% of this population.

2.5.5.5.1.3.2. Participants With at Least 6 Months Follow-Up Time – BNT162b2 Group

Demographic characteristics for all original BNT162b2 Phase 2/3 participants ≥16 years of age and had at least 6 months of follow-up time after Dose 2 are presented in Table 56. Overall, most participants were White (86.4%), with 7.1% Black or African American participants and 3.8% Asian participants, and other racial groups were ≤1.6%. There were 27.8% Hispanic/Latino participants. Median age was 53.0 years and 50.3% of participants were male. Obese participants made up 34.2% of this safety population.

Table 56. Demographic Characteristics – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=12006) n[b] (%)
Sex	
Male	6040 (50.3)
Female	5966 (49.7)
Race	
White	10370 (86.4)
Black or African American	851 (7.1)
American Indian or Alaska Native	55 (0.5)

Table 56. Demographic Characteristics – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=12006) n[b] (%)
Asian	452 (3.8)
Native Hawaiian or other Pacific Islander	31 (0.3)
Multiracial	195 (1.6)
Not reported	52 (0.4)
Racial designation	
Japanese	44 (0.4)
Ethnicity	
Hispanic/Latino	3339 (27.8)
Non-Hispanic/non-Latino	8604 (71.7)
Not reported	63 (0.5)
Country	
Argentina	2118 (17.6)
Brazil	596 (5.0)
USA	9292 (77.4)
Age group (at vaccination)	
16-55 Years	6666 (55.5)
>55 Years	5340 (44.5)
Age at vaccination (years)	
Mean (SD)	51.4 (15.44)
Median	53.0
Min, max	(18, 85)
Baseline SARS-CoV-2 status	
Positive[c]	250 (2.1)
Negative[d]	11678 (97.3)
Missing	78 (0.6)
Body mass index (BMI)	
Underweight (<18.5 kg/m^2)	136 (1.1)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	3527 (29.4)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	4232 (35.2)
Obese (≥30.0 kg/m^2)	4107 (34.2)
Missing	4 (0.0)

Table 56. Demographic Characteristics – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=12006) n[b] (%)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (15:19)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adsl s005 demo 6m p3 saf

2.5.5.5.1.3.3. Placebo Group Who Received BNT162b2

Demographic characteristics for all original placebo Phase 2/3 participants who then received BNT162b2 later during the open-label follow-up period are presented in Table 57. Overall, most participants were White (83.1%), with 8.3% Black or African American participants and 4.3% Asian participants, and all other racial groups were ≤2.6%. There were 25.5% Hispanic/Latino participants. Median age was 51.0 years and 50.2% of participants were male. Obese participants made up 34.4% of this safety population.

Table 57. Demographic Characteristics – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=19611) n[b] (%)
Sex	
Male	9841 (50.2)
Female	9770 (49.8)
Race	
White	16299 (83.1)

Table 57. Demographic Characteristics – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=19611) n[b] (%)
Black or African American	1636 (8.3)
American Indian or Alaska Native	189 (1.0)
Asian	849 (4.3)
Native Hawaiian or other Pacific Islander	28 (0.1)
Multiracial	509 (2.6)
Not reported	101 (0.5)
Racial designation	
Japanese	77 (0.4)
Ethnicity	
Hispanic/Latino	5002 (25.5)
Non-Hispanic/non-Latino	14499 (73.9)
Not reported	110 (0.6)
Country	
Argentina	2612 (13.3)
Brazil	1428 (7.3)
Germany	241 (1.2)
South Africa	362 (1.8)
Turkey	242 (1.2)
USA	14726 (75.1)
Age group (at vaccination)	
16-55 Years	11404 (58.2)
>55 Years	8207 (41.8)
Age at vaccination (years)	
Mean (SD)	50.1 (15.91)
Median	51.0
Min, max	(16, 91)
Baseline SARS-CoV-2 status	
Positive[c]	590 (3.0)
Negative[d]	18909 (96.4)
Missing	112 (0.6)
Body mass index (BMI)	
Underweight (<18.5 kg/m^2)	258 (1.3)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	5805 (29.6)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	6790 (34.6)
Obese (≥30.0 kg/m^2)	6753 (34.4)
Missing	5 (0.0)

Table 57. Demographic Characteristics – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=19611) n[b] (%)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (15:20)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adsl s005 demo cr p3 saf

2.5.5.5.2. Reactogenicity – Phase 2/3

Reactogenicity (local reactions and systemic events) was assessed via e-diary in a subset of participants in up to 7 days after each dose in the blinded placebo-controlled follow-up period.

Local reactions are summarized in Section 2.5.5.4.2.1 and systemic events are summarized in Section 2.5.5.4.2.2 for the reactogenicity subset of the safety population, subgroups of participants defined by baseline SARS-CoV-2 status, and participants with stable HIV.

The reactogenicity subset of the safety population included e-diary data for participants in each group as follows:

- BNT162b2 group:
  - Younger adults 16 to 55 years of age: N=2899 post Dose 1 and N=2682 post Dose 2
  - Older adults >55 years of age: N=2008 post Dose 1 and N=1860 post Dose 2

- Placebo group:
  - Younger adults 16 to 55 years of age: N=2908 post Dose 1 and N=2684 post Dose 2
  - Older adults >55 years of age: N=1989 post Dose 1 and N=1833 post Dose 2

The baseline SARS-CoV-2 positive reactogenicity subset was comprised of adults ≥16 years of age and included e-diary data for the N=177 post Dose 1 and N=153 post Dose 2 in the BNT162b2 group, and N=187 post Dose 1 and N=165 post Dose 2 in the placebo group.

The baseline SARS-CoV-2 negative reactogenicity subset was comprised of adults ≥16 years of age and included e-diary data for the N=4701 post Dose 1 and N=4368 post Dose 2 in the BNT162b2 group, and N=4690 post Dose 1 and N=4334 post Dose 2 in the placebo group.

The HIV+ reactogenicity subset was comprised of adults ≥16 years of age and included e-diary data for the N=54 post Dose 1 and N=60 post Dose 2 in the BNT162b2 group, and N=56 post Dose 1 and N=62 post Dose 2 in the placebo group.

2.5.5.5.2.1. Local Reactions

In the BNT162b2 group, pain at the injection site was reported more frequently in the younger age group than in the older age group and frequency was similar after Dose 1 compared with Dose 2 of BNT162b2 in the younger age group (83.7% vs 78.3%) and in the older age group (70.1% vs 66.1%) (Figure 11 and Figure 12, respectively). In the placebo group, pain at the injection site after Doses 1 and 2 was reported at slightly higher frequencies in the younger age group (14.2% and 11.6%, respectively) than in the older age group (9.3% and 7.8%, respectively).

In the BNT162b2 group, frequencies of redness and swelling were similar in the younger and older age group after Doses 1 and 2. Frequencies of redness were similar after Dose 1 compared with Dose 2 of BNT162b2 in the younger age group (5.4% vs 5.6%) and in the older age group (5.3% vs 7.2%). Frequencies of swelling were similar after Dose 1 compared with Dose 2 of BNT162b2 in the younger age group (6.3% vs 6.8%, respectively) and in the older age group (7.0% vs 7.8%). In the placebo group, redness and swelling were reported infrequently in the younger (≤1.0%) and older (≤1.2%) groups after Doses 1 and 2.

Overall, across age groups, pain at the injection site did not increase after Dose 2, and redness and swelling were generally similar in frequency after Dose 1 and Dose 2. Severe redness and swelling were reported infrequently and were similar in the younger and older age groups (≤0.7%) after any dose. Severe pain at the injection site occurred more frequently in the younger age group compared to the older age group (2.5% vs 0.7%). After the first and second dose and in both age groups, the majority of local reactions were mild or moderate in severity, and no grade 4 local reactions were reported.

The median onset for local reactions after either dose of BNT162b2 was between Day 1.0 and Day 2.0 in the younger age group and between Day 1.0 and Day 3.0 in the older age group (Day 1 was the day of vaccination). Local reactions resolved with median durations between 1.0 and 2.0 days in both age groups.

Subgroup Analyses

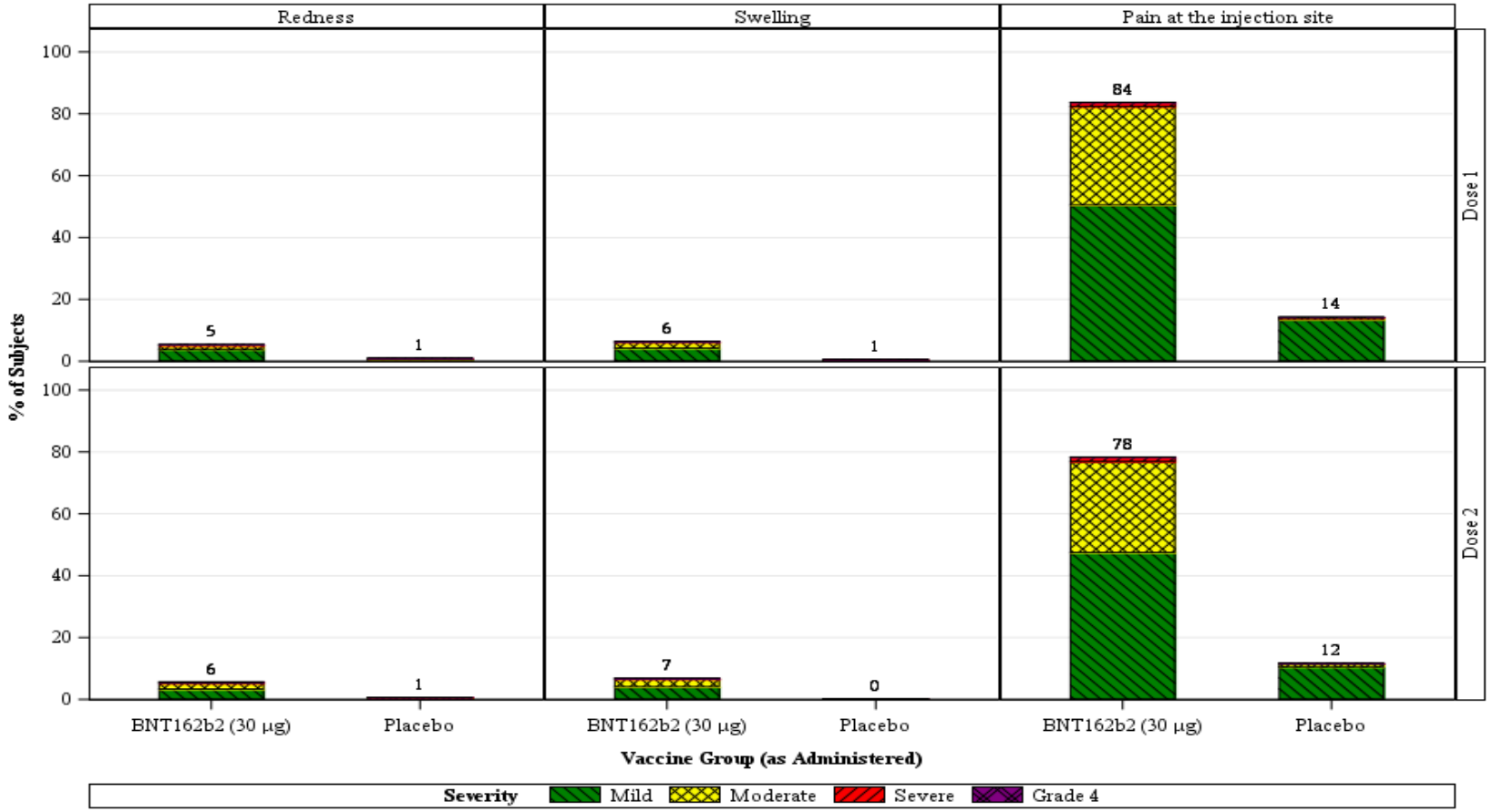
There were 177 BNT162b2 and 187 placebo participants with baseline positive SARS-CoV-2 status, and 4701 BNT162b2 and 4690 placebo participants with baseline negative SARS-CoV-2 status. For local reactions the frequency of redness, swelling, and pain at the injection site after any dose of BNT162b2 was 8.5%, 10.2%, and 80.2% compared with 9.9%, 11.1%, and 84.5% for those positive and negative at baseline, respectively.

While the frequency of local reactions was numerically higher in those negative at baseline, these differences are not clinically meaningful.

HIV+ Participants

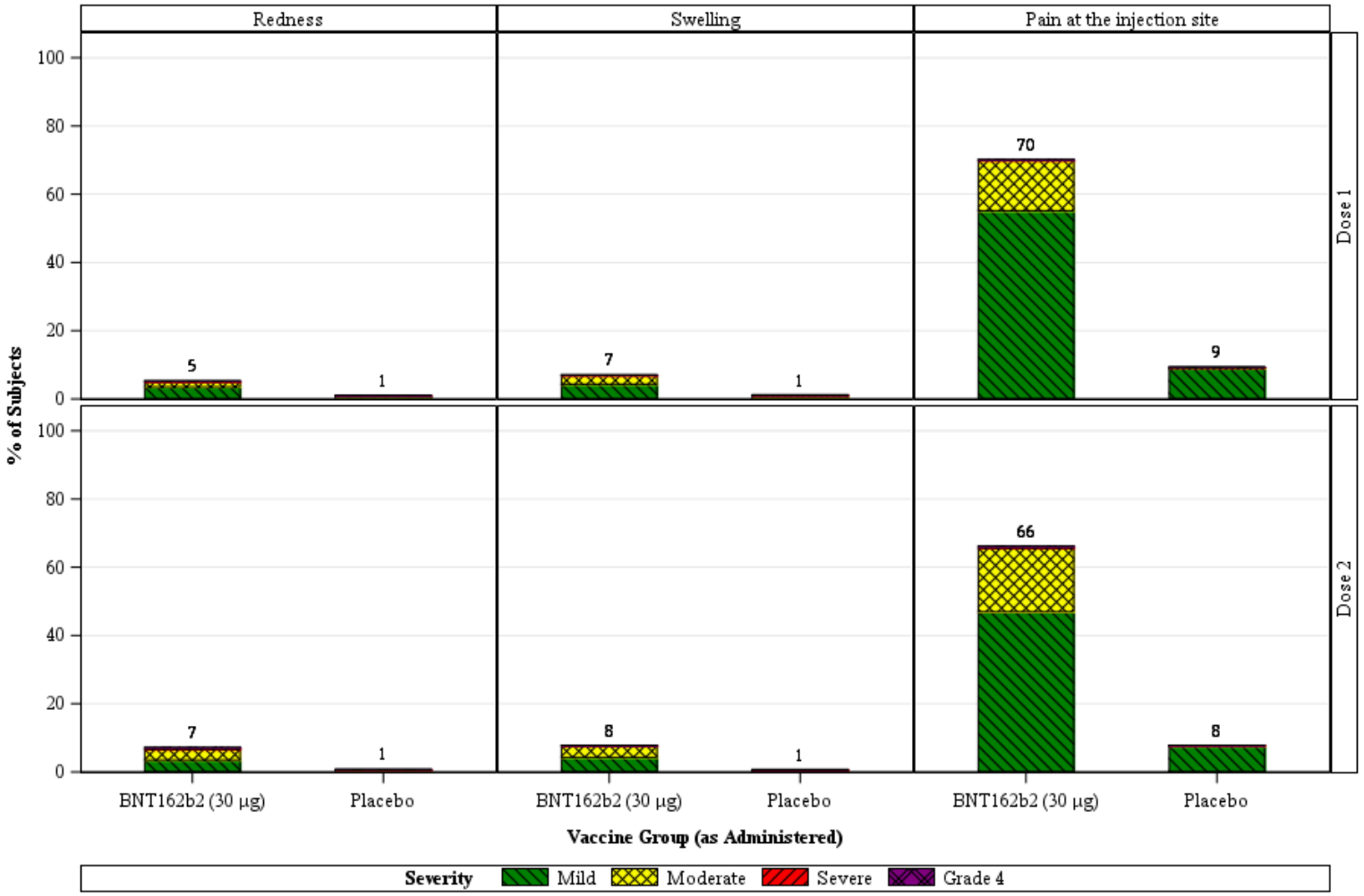
Local reactions in participants with confirmed stable HIV disease were similar to those observed for all participants ≥16 years of age by severity, onset day, and median duration. The frequency of pain at the injection site was similar after Dose 1 compared with Dose 2 of BNT162b2 (63.0% vs 53.3%). The frequency of redness and swelling was similar after Dose 1 compared with Dose 2 of BNT162b2 (redness: 3.7% vs 6.7%; swelling: 5.6% vs 8.3%, respectively). There was 1 (1.7%) severe reaction (pain at the injection site) reported after Dose 2 of BNT162b2 and no grade 4 reactions were reported.

Figure 11. Participants Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years



Note: Number above each bar denotes percentage of subjects reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_f001_lr_max_age_p3

Figure 12. Participants Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population Age Group: >55 Years



Note: Number above each bar denotes percentage of subjects reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_f001_lr_max_age_p3

2.5.5.5.2.2. Systemic Events

Systemic events were generally increased in frequency and severity in the younger group (Figure 13) compared with the older group (Figure 14), with frequencies and severity increasing with number of doses (Dose 1 vs Dose 2). Vomiting and diarrhea were exceptions, with vomiting reported similarly infrequently in both age groups and diarrhea reported at similar incidences after each dose.

Systemic events in the younger group compared with the older group, with frequencies increasing with number of doses (Dose 1 vs Dose 2), were:

- fatigue: younger group (49.4% vs 61.5%) compared to older group (33.7% vs 51.0%)
- headache: younger group (43.5% vs 54.0%) compared to older group (25.0% vs 39.4%)
- muscle pain: younger group (22.9% vs 39.3%) compared to older group (13.6% vs 28.9%)
- chills: younger group (16.5% vs 37.8%) compared to older group (6.5% vs 23.4%)
- joint pain: younger group (11.8% vs 23.8%) compared to older group (8.7% vs 19.0%)
- fever: younger group (4.1% vs 16.4%) compared to older group (1.3% vs 11.8%)
- vomiting: younger group (1.2% vs 2.2%) compared to older group (0.5% vs 0.7%)
- diarrhea: younger group (10.7% vs 10.0%) compared to older group (8.4% vs 8.2%).

Systemic events were generally reported less frequently in the placebo group than in the BNT162b2 group, for both age groups and doses, with some exceptions. In the younger age group, vomiting and diarrhea (after Dose 1 and Dose 2) were reported at similar frequencies in the placebo group and the BNT162b2 group (Figure 13). In the older age group, vomiting and diarrhea (after Dose 1 and Dose 2) were reported at similar frequencies in the placebo group and the BNT162b2 group (Figure 14).

Following both Dose 1 and Dose 2, use of antipyretic/pain medication was slightly less frequent in the older age group (19.0% vs 37.0%) than in the younger age group (27.8% vs 45.2%) after both doses, and medication use increased in both age groups after Dose 2 as compared with after Dose 1. Use of antipyretic/pain medication was less frequent in the placebo group than in the BNT162b2 group and was similar after Dose 1 and Dose 2 in the younger and older placebo groups (ranging from 9.3% to 13.7%).

Severe fever (>38.9 °C to 40.0 °C) increased in frequency with the number of doses (Dose 1 vs Dose 2) in younger (0.3% vs 1.5%) and older (0.0% vs 0.4%) participants who received BNT162b2 and was reported in 0.1% of participants who received placebo in both age group after both doses. One participant in the younger BNT162b2 group reported fever of 41.2 °C only on Day 2 after Dose 2 and was nonfebrile for all other days of the reporting period. Grade 4 fever was not reported in the older BNT162b2 group or in any placebo participants.

After the first and second dose and in both age groups, the majority of systemic events were mild or moderate in severity.

Systemic events in the younger and older age groups after either dose of BNT162b2 had a median onset day between Day 2.0 and Day 4.0 (Day 1.0 was the day of vaccination) and resolved with a median duration of 1 day in both age groups.

Subgroup Analyses

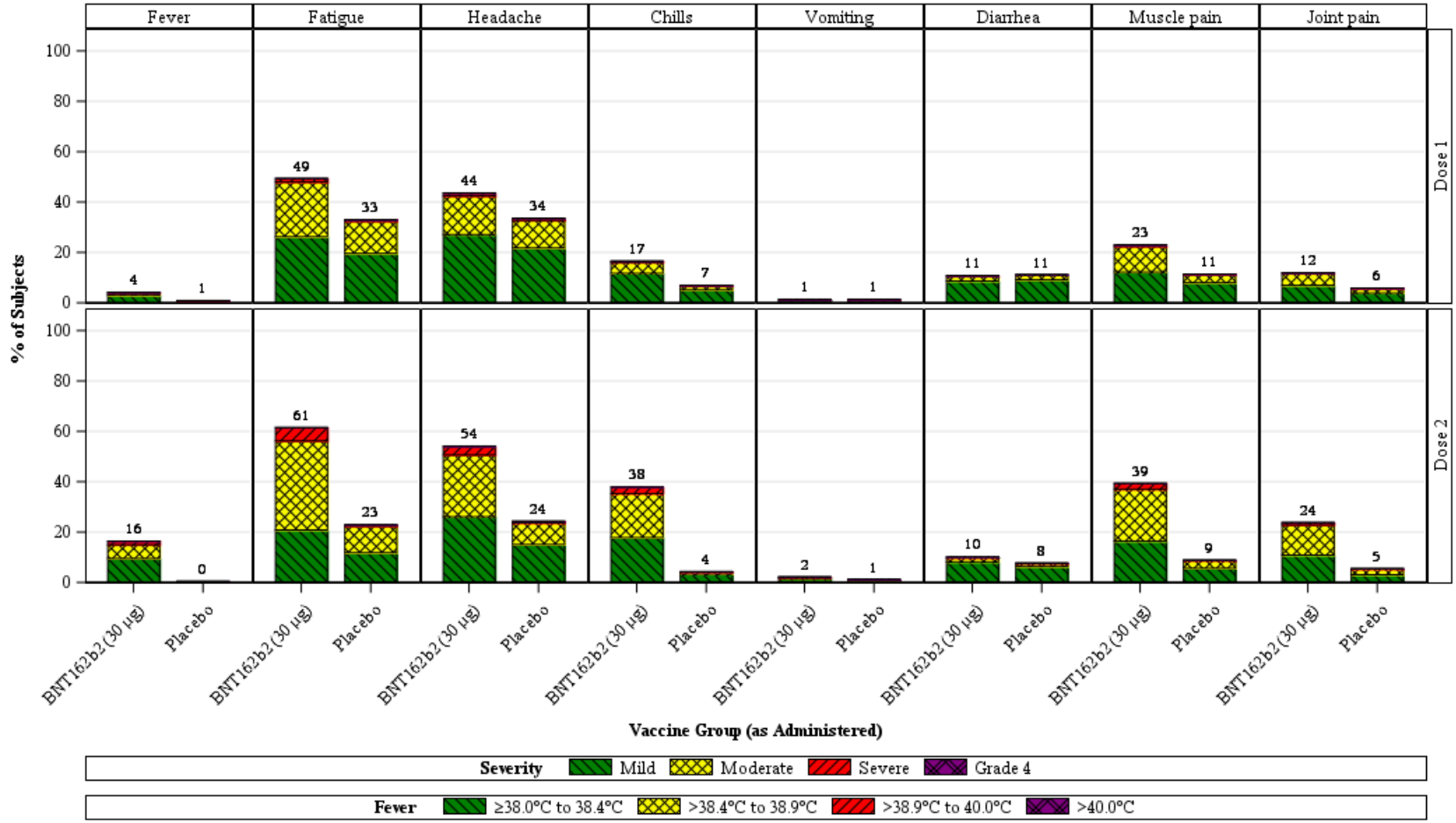
There were 177 BNT162b2 and 187 placebo participants with baseline positive SARS-CoV-2 status, and 4701 BNT162b2 and 4690 placebo participants with baseline negative SARS-CoV-2 status. For any fever after either dose of BNT162b2 there were 31 (17.5%) compared to 714 (15.1%) in those positive and negative for SARS-CoV-2 at baseline, respectively. Severe fever (>38.9 °C to 40.0 °C) was reported in 1 participant (0.6%) and 49 participants (1.0%) in those positive and negative for SARS-CoV-2 at baseline, respectively. The frequency for other systemic events after any dose was numerically lower for those positive at baseline: fatigue, headache and chills the frequency was 54.2%, 49.7% and 32.8% compared with 65%, 57.4%, 34.7% for those positive and negative for SARS-CoV-2 at baseline, respectively. Joint pain was another exception where 27.1% compared to 25.0% were reported in those positive and negative for SARS-CoV-2 at baseline.

Note that the baseline SARS-CoV-2 positive subgroup included far fewer participants the negative subgroup, so their results should be interpreted with caution.

HIV+ Participants

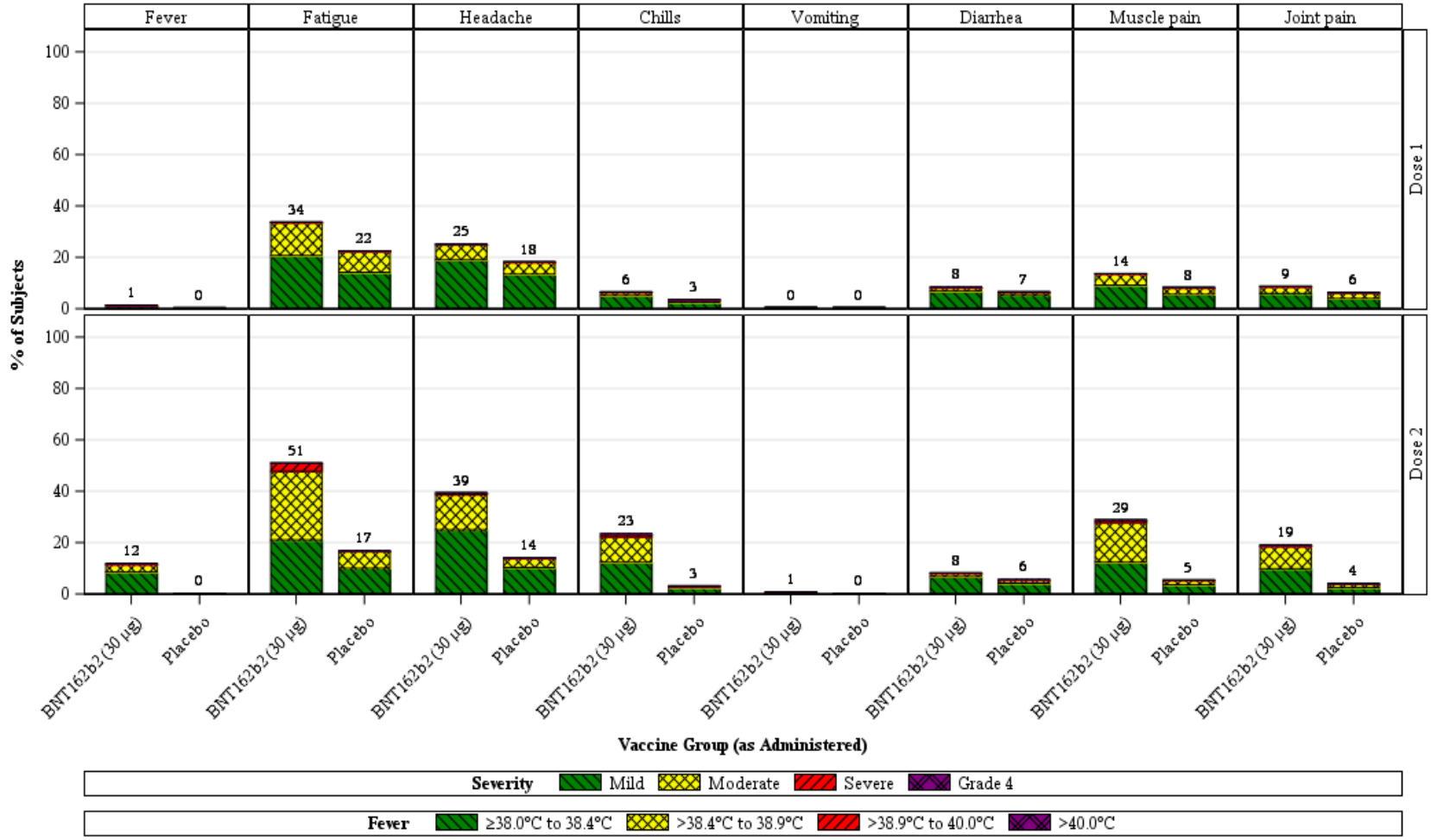
Systemic events from participants with confirmed stable HIV disease were similar to those observed for all participants ≥16 years of age by severity, onset day, and median duration. Fever, headache, chills, and joint pain increased in frequency from Dose 1 to Dose 2 while fatigue, vomiting, diarrhea, and muscle pain were similar after each dose. There were no severe systemic events after Dose 1 of BNT162b2, but after Dose 2, there was 1 (1.7%) severe fever (>38.9 °C to 40.0 °C), 3 participants (5.0%) with severe fatigue, 2 participants (3.3%) with severe headache, 1 participant (1.7%) with severe chills, and 1 participant (1.7%) with severe diarrhea. There were no grade 4 systemic events reported after either dose.

Figure 13. Participants Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population Age Group: 16-55 Years



Note: Number above each bar denotes percentage of subjects reporting the event with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_f001_se_max_age_p3

Figure 14. Participants Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group – Reactogenicity Subset for Phase 2/3 Analysis – Safety Population Age Group: >55 Years



Note: Number above each bar denotes percentage of subjects reporting the event with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_f001_se_max_age_p3

2.5.5.5.3. Adverse Events – Phase 2/3

AEs are presented separately for the blinded and open-label follow-up periods as follows.

Blinded follow-up: participants randomized to BNT162b2 and placebo:

- Younger (16 to 55 years of age) and older (>55 years of age) groups, including HIV+ subset
  - from Dose 1 up to 1 month after Dose 2
  - from Dose 1 up to end of blinded follow-up (date of unblinding)

Open-label follow-up for BNT162b2: participants originally randomized to BNT162b2, from date of unblinding through the data cutoff date.

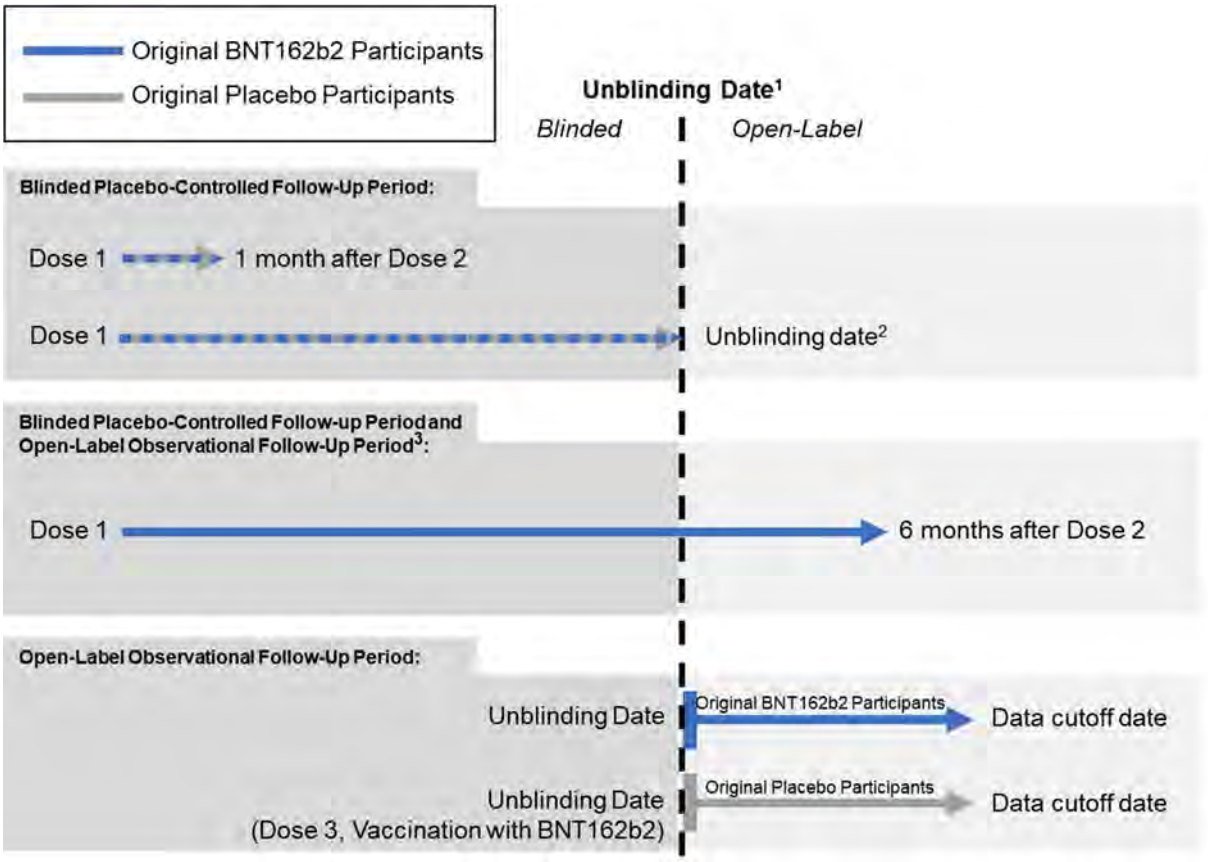
Cumulative blinded and open-label follow-up for BNT162b2: participants originally randomized to BNT162b2, inclusive of blinded and post-unblinding open-label periods, from Dose 1 up to at least 6 months after Dose 2 (at least 3000 participants per age group).

Open-label follow-up for placebo after receiving BNT162b2: participants originally randomized to placebo from time of unblinding/BNT162b2 vaccination (Dose 3) through the data cutoff date.

Note that due to individual study participant unblinding to treatment assignment (per protocol), safety data were calculated as IRs to adjust for variable exposure time in analyses of time intervals either up to, or starting from, the unblinding date.

A schematic of AE analyses by study group and time period is shown in Figure 15.

Figure 15. Study C4591001 Phase 2/3 Safety Analyses: Time Periods and Analysis Groups



[1] AE data analyzed from Dose 1 to unblinding date (on or after 14 December 2020) or from unblinding date to data cutoff date (13 March 2021) reported as IRs per 100 PY adjusted for exposure time; varies per participant.
[2] Blinded placebo-controlled follow-up period duration up to ~6 months after Dose 2.
[3] Cumulative BNT162b2 follow-up to ≥6 months after Dose 2, N≥3000/age group (16 -55, >55 years of age).

2.5.5.5.3.1. Blinded Follow-Up Period from Dose 1 Through 1 Month After Dose 2

2.5.5.5.3.1.1. Summary of Adverse Events

An overview of AEs from Dose 1 to 1 month after Dose 2 for participants during the blinded safety follow-up (including those analyzed in Phase 2) is presented in Table 58.

The numbers of overall participants who reported at least 1 AE and at least 1 related AE were higher in the BNT162b2 group (30.2% and 23.9%, respectively) as compared with the placebo group (13.9% and 6.0%, respectively). The higher frequencies in the BNT162b2 was due to terms consistent with reactogenicity reported at greater frequency in the BNT162b2 group versus the placebo group; this pattern is further analyzed in Section 2.5.5.5.3.1.2. Severe AEs were reported by 1.2% and 0.7% in in the BNT162b2 and placebo groups respectively, and life-threatening AEs were similar (0.1% in both groups).

SAEs and AEs leading to withdrawal were reported by ≤0.6% and ≤0.2%, respectively, in both groups. Discontinuations due to related AEs were reported in 13 participants in the BNT162b2 group and 11 participants in the placebo group (0.1% in both groups).

From Dose 1 to 1 month after Dose 2, there were 3 deaths in the BNT162b2 group and 5 deaths in the placebo group during the blinded follow-up period (Section 2.5.5.5.4.1).

In the younger age group, the number of participants who reported at least 1 AE from Dose 1 to 1 month after Dose 2 was 4233 (32.6%) and 1871 (14.4%) in the BNT162b2 and placebo groups, respectively. In the older age group, the number of participants who reported at least 1 AE from Dose 1 to 1 month after Dose 2 was 2384 (26.7%) and 1177 (13.2%) in the BNT162b2 and placebo groups, respectively.

Table 58. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)	
Adverse Event	BNT162b2 (30 µg) (N[a]=21926) n[b] (%)	Placebo (N[a]=21921) n[b] (%)
Any event	6617 (30.2)	3048 (13.9)
Related[c]	5241 (23.9)	1311 (6.0)
Severe	262 (1.2)	150 (0.7)
Life-threatening	21 (0.1)	26 (0.1)
Any serious adverse event	127 (0.6)	116 (0.5)
Related[c]	3 (0.0)	0
Severe	71 (0.3)	66 (0.3)
Life-threatening	21 (0.1)	26 (0.1)
Any adverse event leading to withdrawal	32 (0.1)	36 (0.2)
Related[c]	13 (0.1)	11 (0.1)
Severe	10 (0.0)	10 (0.0)
Life-threatening	3 (0.0)	7 (0.0)
Death	3 (0.0)	5 (0.0)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s091 all pd2 p3 saf1

HIV+ Participants

From Dose 1 to 1 month after Dose 2, the subset of 200 HIV+ participants during the placebo-controlled follow-up showed generally similar trends as the overall population (likewise attributed to reactogenicity reported in the BNT162b2 group). The numbers of HIV+ participants who reported at least 1 AE and at least 1 related AE were higher in the BNT162b2 group (26.0% and 19.0%, respectively) as compared with the placebo group (13.0% and 3.0%, respectively). In this group, there was 1 severe AE and 1 AE leading to withdrawal (both in the BNT162b2 group), and there were no SAEs or deaths.

2.5.5.5.3.1.2. Analysis of Adverse Events

Adverse Events by System Organ Class and Preferred Term

Most AEs after Dose 1 up to 1 month after Dose 2 were reactogenicity events (Table 59). From Dose 1 to 1 month after Dose 2 during the blinded placebo-controlled follow-up period, 6617 (30.2%) BNT162b2 participants and 3048 (13.9%) placebo participants reported at least 1 AE. AE frequencies for all enrolled participants in these reactogenicity SOCs (BNT162b2 vs placebo) were:

- general disorders and administration site conditions: 4725 (21.5%) vs 993 (4.5%)
- musculoskeletal and connective tissue disorders: 1804 (8.2%) vs 527 (2.4%)
- nervous system disorders: 1565 (7.1%) vs 600 (2.7%)
- gastrointestinal disorders: 699 (3.2%) vs 464 (2.1%).

The number of BNT162b2 participants who reported at least 1 AE from Dose 1 to 1 month after Dose 2 was 4233 (32.6%) and 2384 (26.7%) in the younger and older groups. In the BNT162b2 age groups (younger vs older), AE frequencies in the SOCs were:

- general disorders and administration site conditions: 3161 (24.3%) vs 1564 (17.5%]
- musculoskeletal and connective tissue disorders: 1201 (9.2%) vs 603 (6.8%)
- nervous system disorders: 1067 (8.2%) vs 498 (5.6%)
- gastrointestinal disorders: 440 (3.4%) vs 259 (2.9%).

The most frequently reported AEs in the BNT162b2 group by PT overall were injection site pain (2915 [13.3%]), pyrexia (1517 [6.9%]), fatigue (1463 [6.7%]), chills (1365 [6.2%]), headache (1339 [6.1%]), and myalgia (1239 [5.7%]) (Table 59). During this time period from Dose 1 to 1 month after Dose 2, most of these AEs were reported during the e-diary 7-day reporting period (note, such events occurring in the reactogenicity reporting period are further analyzed below).

The frequency of AEs in the SOC of investigations was higher in the BNT162b2 group (0.8%) as compared with the placebo group (0.2%) mainly due to the higher frequency of the PT Body temperature increased (120 in the BNT162b2 group and 12 in the placebo group).

In the skin and subcutaneous tissue disorders SOC, there were 17 participants who reported night sweats in the BNT162b2 group (compared to 3 in the placebo group), and all but 1 of these participants reported the AE within the first 7 days after Dose 1 or 2, respectively, and

there were 31 participants who reported hyperhidrosis in the BNT162b2 group (compared to 9 in the placebo group), and all but 3 of these participants reported the AE within the first 7 days after Dose 1 or 2.

Nineteen study participants reported events in the hepatobiliary disorders SOC (14 BNT162b2 recipients and 5 placebo recipients) (Table 59). Of the 19 total participants, 3 participants had hepatic events:

- 1 participant in the placebo group reported hepatic cirrhosis
- 1 participant in the placebo group reported nonalcoholic fatty liver disease
- 1 participant in the BNT162b2 group reported alcoholic cirrhosis.

The remaining 16 participants reported biliary events (cholecystitis/cholecystitis acute, biliary colic, bile duct stone, and biliary dyskinesia): 13 participants in the BNT162b2 group and 3 participants in the placebo group.

- In the BNT162b2 group, 8 participants reported cholelithiasis (1 reported an event each of cholelithiasis and cholecystitis), 1 participant reported cholecystitis acute, 2 participants reported biliary colic, and 1 participant each reported bile duct stone/biliary dyskinesia.

- In the placebo group, 1 participant reported an event each of cholecystitis acute and cholelithiasis, 1 participant reported cholecystitis acute, and 1 participant reported cholelithiasis.

In the nervous systems disorder SOC, 3 participants who reported facial paralysis in the BNT162b2 group (compared to none in the placebo group). More details are presented in Section 2.5.5.5.7.

For lymphadenopathy the frequency in the BNT162b2 group was 0.4% compared to the frequency of 0.0% on the placebo group. Most AEs of lymphadenopathy in the BNT162b2 group were judged by the investigator as related to study intervention and are further discussed in Section 2.5.5.5.7.1.

Other events of clinical interest that were evaluated by the sponsor related to cardiac disorders, appendicitis, optic neuritis, and hypersensitivity/anaphylaxis are discussed in Section 2.5.5.5.7.3.

Analysis of Reactogenicity Terms Reported Within 7 Days After Each Dose

Beyond the 9839 participants included in the Phase 2/3 reactogenicity subset, events related to reactogenicity are no longer reported using an e-diary but are instead reported as AEs. An analysis was conducted to evaluate if the imbalance in AEs observed from Dose 1 to 1 month after Dose 2 was attributed to reactogenicity events. The analysis examined the AEs reported within 7 days after each dose, which represented the reactogenicity reporting period. The time period was chosen because many AEs were reported in the SOCs of general disorders and administration site conditions, musculoskeletal and connective tissue disorders, and nervous system disorders, which includes AEs consistent with reactogenicity events

(Section 2.5.5.5.2), and could only be attributed to reactogenicity if they occurred during this time period as opposed to occurring up to 1 month from each dose.

PTs reported from Dose 1 to 7 days after Dose 1 and from Dose 2 to 7 days after Dose 2 in the SOCs of general disorders and administration site conditions (injection site pain, chills, fatigue, and pyrexia), musculoskeletal and connective tissue disorders (myalgia), and nervous system disorders (headache) represented the majority of PTs reported in those SOCs. AEs reported from Dose 1 to 7 days after Dose 1 and from Dose 2 to 7 days after Dose 2 were largely attributable to reactogenicity events. This observation provides a reasonable explanation for the greater rates of AEs observed overall in the BNT162b2 group compared with the placebo group.

In addition to analysis of AEs corresponding to e-diary terms that were reported within 7 days after Dose 1 or Dose 2 that are attributable to reactogenicity, additional consideration was given to AE terms that are reported at higher frequency in the BNT162b2 group compared to placebo. The following additional AEs were identified: pain in extremity, decreased appetite, lethargy, asthenia, malaise, night sweats, and hyperhidrosis. Careful examination of these terms after either dose of BNT162b2 shows that these events are clustered within the 7-day period when reactogenicity events are known to occur. Since the majority of the participants did not have an e-diary and reported reactogenicity as AEs, there is considerable leeway in how symptoms are described by participants from multiple countries, interpreted by investigators, and reported as AEs. As these events are occurring when reactogenicity is being reported, these events are considered to be attributable to the experience of reactogenicity events and are plausibly associated with local reactions and systemic events.

Reactogenicity PTs were reported more frequently in the younger age group than in the older age group, which is consistent with the pattern of reactogenicity observed based on e-diary data (Section 2.5.5.5.2).

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	6617 (30.2)	(29.6, 30.8)	3048 (13.9)	(13.4, 14.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	105 (0.5)	(0.4, 0.6)	19 (0.1)	(0.1, 0.1)
Lymphadenopathy	83 (0.4)	(0.3, 0.5)	7 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Anaemia	4 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Lymph node pain	7 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Blood loss anaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytopenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypochromic anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Leukopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenopathy mediastinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Splenomegaly	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	56 (0.3)	(0.2, 0.3)	50 (0.2)	(0.2, 0.3)
Palpitations	6 (0.0)	(0.0, 0.1)	14 (0.1)	(0.0, 0.1)
Tachycardia	13 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Atrial fibrillation	7 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Coronary artery disease	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Acute myocardial infarction	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Cardiac failure congestive	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Left ventricular hypertrophy	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mitral valve incompetence	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arrhythmia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arteriospasm coronary	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cardiac arrest	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mitral valve prolapse	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial ischaemia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tricuspid valve incompetence	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular extrasystoles	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute left ventricular failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Atrioventricular block complete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrioventricular block first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block left	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac failure acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiovascular disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Junctional ectopic tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left atrial enlargement	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left ventricular dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pericardial effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pericarditis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Congenital bladder neck obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Type V hyperlipidaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	65 (0.3)	(0.2, 0.4)	43 (0.2)	(0.1, 0.3)
Vertigo	25 (0.1)	(0.1, 0.2)	20 (0.1)	(0.1, 0.1)
Ear pain	11 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Tinnitus	9 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Vertigo positional	8 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Deafness unilateral	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ear discomfort	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerumen impaction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Meniere's disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic otitis media	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness neurosensory	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Ear pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eustachian tube dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sudden hearing loss	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	13 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Hypothyroidism	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Hypogonadism	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid mass	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Autoimmune thyroiditis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Goitre	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperprolactinaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	60 (0.3)	(0.2, 0.4)	50 (0.2)	(0.2, 0.3)
Cataract	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Eye pain	7 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Eye irritation	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Vision blurred	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Chalazion	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vitreous detachment	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blepharitis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Conjunctivitis allergic	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry eye	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Keratitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Ocular hyperaemia	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Glaucoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Lacrimation increased	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal detachment	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vitreous floaters	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Asthenopia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blepharospasm	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diplopia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye pruritus	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Amaurosis fugax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Conjunctival hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Corneal irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dacryostenosis acquired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diabetic retinopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Episcleritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye inflammation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelids pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Iritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ocular discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scleral discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ulcerative keratitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Visual acuity reduced	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	699 (3.2)	(3.0, 3.4)	464 (2.1)	(1.9, 2.3)
Diarrhoea	248 (1.1)	(1.0, 1.3)	188 (0.9)	(0.7, 1.0)
Nausea	274 (1.2)	(1.1, 1.4)	87 (0.4)	(0.3, 0.5)
Vomiting	66 (0.3)	(0.2, 0.4)	32 (0.1)	(0.1, 0.2)
Toothache	24 (0.1)	(0.1, 0.2)	27 (0.1)	(0.1, 0.2)
Abdominal pain upper	25 (0.1)	(0.1, 0.2)	15 (0.1)	(0.0, 0.1)
Abdominal pain	19 (0.1)	(0.1, 0.1)	19 (0.1)	(0.1, 0.1)
Gastrooesophageal reflux disease	12 (0.1)	(0.0, 0.1)	16 (0.1)	(0.0, 0.1)
Dyspepsia	12 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Odynophagia	13 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Constipation	7 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Dental caries	8 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Gastritis	3 (0.0)	(0.0, 0.0)	10 (0.0)	(0.0, 0.1)
Haemorrhoids	3 (0.0)	(0.0, 0.0)	10 (0.0)	(0.0, 0.1)
Aphthous ulcer	8 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Abdominal discomfort	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Abdominal distension	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Flatulence	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Irritable bowel syndrome	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Dry mouth	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Large intestine polyp	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Abdominal pain lower	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Dysphagia	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Stomatitis	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Diverticulum	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal disorder	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hiatus hernia	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Retching	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cheilitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Food poisoning	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival pain	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia oral	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Lip swelling	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rectal haemorrhage	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Swollen tongue	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tooth impacted	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Umbilical hernia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Colitis microscopic	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Eructation	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glossodynia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematochezia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Noninfective gingivitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Salivary gland calculus	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal rigidity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abnormal faeces	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute abdomen	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anal pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angular cheilitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Appendix disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colitis ulcerative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal haemorrhagic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Epiploic appendagitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Femoral hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Frequent bowel movements	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastric polyps	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastric ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastritis erosive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal mucosa hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glossitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia teeth	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Impaired gastric emptying	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Incarcerated inguinal hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal spasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Oesophageal ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal varices haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophagitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral lichenoid reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral mucosa haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Palatal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatic failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peptic ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Proctalgia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland mucocoele	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Teething	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Varices oesophageal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Volvulus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4725 (21.5)	(21.0, 22.1)	993 (4.5)	(4.3, 4.8)
Injection site pain	2915 (13.3)	(12.8, 13.8)	397 (1.8)	(1.6, 2.0)
Fatigue	1463 (6.7)	(6.3, 7.0)	379 (1.7)	(1.6, 1.9)
Pyrexia	1517 (6.9)	(6.6, 7.3)	77 (0.4)	(0.3, 0.4)
Chills	1365 (6.2)	(5.9, 6.6)	120 (0.5)	(0.5, 0.7)
Pain	628 (2.9)	(2.6, 3.1)	61 (0.3)	(0.2, 0.4)
Injection site erythema	185 (0.8)	(0.7, 1.0)	28 (0.1)	(0.1, 0.2)
Injection site swelling	140 (0.6)	(0.5, 0.8)	23 (0.1)	(0.1, 0.2)
Malaise	130 (0.6)	(0.5, 0.7)	22 (0.1)	(0.1, 0.2)
Asthenia	76 (0.3)	(0.3, 0.4)	25 (0.1)	(0.1, 0.2)
Injection site pruritus	38 (0.2)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Injection site bruising	13 (0.1)	(0.0, 0.1)	18 (0.1)	(0.0, 0.1)
Influenza like illness	23 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.0)
Chest pain	12 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Injection site warmth	14 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Axillary pain	14 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Injection site induration	10 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site oedema	12 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Non-cardiac chest pain	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Oedema peripheral	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Peripheral swelling	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Chest discomfort	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Feeling hot	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site discomfort	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Swelling face	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Injection site haematoma	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Injection site haemorrhage	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Injection site reaction	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site mass	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Swelling	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Adverse drug reaction	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cyst	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Feeling abnormal	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site nodule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site papule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site rash	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sensation of foreign body	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Face oedema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling cold	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury associated with device	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Medical device pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sluggishness	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thirst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vessel puncture site bruise	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Capsular contracture associated with breast implant	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gait disturbance	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site urticaria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Medical device site granuloma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mucosal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Therapeutic response unexpected	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaccination site pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	14 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Cholelithiasis	8 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Cholecystitis acute	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Biliary colic	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cirrhosis alcoholic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nonalcoholic fatty liver disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
IMMUNE SYSTEM DISORDERS	22 (0.1)	(0.1, 0.2)	25 (0.1)	(0.1, 0.2)
Seasonal allergy	8 (0.0)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Drug hypersensitivity	7 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Food allergy	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Hypersensitivity	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Allergy to arthropod bite	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Milk allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	337 (1.5)	(1.4, 1.7)	365 (1.7)	(1.5, 1.8)
Urinary tract infection	58 (0.3)	(0.2, 0.3)	52 (0.2)	(0.2, 0.3)
Tooth infection	24 (0.1)	(0.1, 0.2)	29 (0.1)	(0.1, 0.2)
Sinusitis	18 (0.1)	(0.0, 0.1)	27 (0.1)	(0.1, 0.2)
Cellulitis	12 (0.1)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Herpes zoster	12 (0.1)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Ear infection	9 (0.0)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Conjunctivitis	9 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Hordeolum	8 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Cystitis	6 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Gastroenteritis	5 (0.0)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Rhinitis	5 (0.0)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Tooth abscess	9 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	9 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Diverticulitis	8 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Otitis externa	6 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Otitis media	7 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	5 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Appendicitis	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Gingivitis	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Oral herpes	4 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Acute sinusitis	1 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Pneumonia	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Skin infection	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Vaginal infection	0	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Fungal skin infection	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Onychomycosis	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Periodontitis	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pyelonephritis	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Folliculitis	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Furuncle	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Localised infection	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Nasopharyngitis	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Otitis media acute	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Paronychia	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tonsillitis	0	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Genital herpes	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Herpes simplex	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Influenza	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Postoperative wound infection	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tinea versicolour	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bacterial vulvovaginitis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bronchitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Chronic sinusitis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye infection	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Gingival abscess	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impetigo	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Infected bite	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parotitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pustule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcutaneous abscess	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tinea infection	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acarodermatitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Anal abscess	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial vaginosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
COVID-19	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Conjunctivitis bacterial	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Erysipelas	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Gastroenteritis viral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Kidney infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Labyrinthitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Laryngitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ophthalmic herpes zoster	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral candidiasis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Papilloma viral infection	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash pustular	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sialoadenitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinusitis bacterial	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Trichomoniasis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess jaw	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess neck	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anal fistula infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial blepharitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Balanitis candida	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bartholin's abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bartholinitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blister infected	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bone abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Campylobacter infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Carbuncle	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cellulitis orbital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clostridium difficile infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coxsackie viral infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis infected	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device related infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Eye infection bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Genital herpes simplex	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gonorrhoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Groin abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Helicobacter infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatitis A	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatitis C	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lyme disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nail infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Orchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis media bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parasitic gastroenteritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pelvic inflammatory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pilonidal cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary tuberculosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Puncture site infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shigella sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Soft tissue infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subacute endocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Syphilis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea cruris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Varicella	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Viral upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	215 (1.0)	(0.9, 1.1)	269 (1.2)	(1.1, 1.4)
Fall	48 (0.2)	(0.2, 0.3)	51 (0.2)	(0.2, 0.3)
Ligament sprain	19 (0.1)	(0.1, 0.1)	22 (0.1)	(0.1, 0.2)
Skin laceration	14 (0.1)	(0.0, 0.1)	22 (0.1)	(0.1, 0.2)
Contusion	12 (0.1)	(0.0, 0.1)	19 (0.1)	(0.1, 0.1)
Exposure during pregnancy	10 (0.0)	(0.0, 0.1)	19 (0.1)	(0.1, 0.1)
Muscle strain	14 (0.1)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Road traffic accident	9 (0.0)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Skin abrasion	8 (0.0)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Arthropod bite	12 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Limb injury	7 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Foot fracture	5 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Joint injury	5 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Tooth fracture	7 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Procedural pain	8 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Meniscus injury	4 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Animal bite	2 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Arthropod sting	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Facial bones fracture	4 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Joint dislocation	7 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Rib fracture	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Ankle fracture	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Concussion	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Muscle rupture	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Wound	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Chest injury	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Corneal abrasion	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ligament rupture	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Thermal burn	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Vaccination complication	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Epicondylitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Fibula fracture	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hand fracture	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Head injury	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Overdose	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Radius fracture	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Wrist fracture	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Bone contusion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle injury	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Spinal compression fracture	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ulna fracture	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Administration related reaction	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns second degree	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical vertebral fracture	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ligament injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Procedural dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Skin injury	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Stress fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tendon injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Upper limb fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaemia postoperative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burn oral cavity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clavicle fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental restoration failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear canal abrasion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Exposure to communicable disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Femur fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foreign body	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Foreign body aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foreign body in eye	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lip injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Maternal exposure during breast feeding	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mouth injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Patella fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngeal perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post concussion syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post procedural swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative ileus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory fume inhalation disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scapula fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Scar	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Soft tissue injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal column injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stab wound	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stoma site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subdural haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sunburn	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tibia fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic haemothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Venom poisoning	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	172 (0.8)	(0.7, 0.9)	37 (0.2)	(0.1, 0.2)
Body temperature increased	120 (0.5)	(0.5, 0.7)	12 (0.1)	(0.0, 0.1)
Blood pressure increased	6 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Blood glucose increased	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Heart rate increased	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blood cholesterol increased	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Low density lipoprotein increased	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood thyroid stimulating hormone increased	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Weight decreased	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
High density lipoprotein increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Mammogram abnormal	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostatic specific antigen increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alanine aminotransferase increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood chloride decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood creatinine increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood glucose fluctuation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood potassium decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood pressure diastolic increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood pressure systolic increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood sodium decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood testosterone decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood testosterone increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood triglycerides increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fractional exhaled nitric oxide increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatitis C antibody positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes simplex test positive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Intraocular pressure increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mean cell volume decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Monocyte count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Platelet count increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SARS-CoV-2 antibody test positive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid function test abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Troponin increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urine ketone body present	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Weight increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
White blood cell count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
White blood cells urine positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	100 (0.5)	(0.4, 0.6)	73 (0.3)	(0.3, 0.4)
Decreased appetite	39 (0.2)	(0.1, 0.2)	9 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	8 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Vitamin D deficiency	9 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Hypercholesterolaemia	4 (0.0)	(0.0, 0.0)	9 (0.0)	(0.0, 0.1)
Hyperlipidaemia	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Hypokalaemia	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dyslipidaemia	4 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Gout	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Dehydration	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Hyperglycaemia	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Glucose tolerance impaired	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Vitamin B12 deficiency	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypoglycaemia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Insulin resistance	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertriglyceridaemia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypocalcaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obesity	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Polydipsia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetes mellitus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Folate deficiency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Food intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hyperkalaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypernatraemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperuricaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypomagnesaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyponatraemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypovolaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impaired fasting glucose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Increased appetite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Iron deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lactic acidosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1804 (8.2)	(7.9, 8.6)	527 (2.4)	(2.2, 2.6)
Myalgia	1239 (5.7)	(5.3, 6.0)	168 (0.8)	(0.7, 0.9)
Arthralgia	268 (1.2)	(1.1, 1.4)	102 (0.5)	(0.4, 0.6)
Pain in extremity	185 (0.8)	(0.7, 1.0)	44 (0.2)	(0.1, 0.3)
Back pain	97 (0.4)	(0.4, 0.5)	85 (0.4)	(0.3, 0.5)
Neck pain	29 (0.1)	(0.1, 0.2)	33 (0.2)	(0.1, 0.2)
Muscle spasms	27 (0.1)	(0.1, 0.2)	15 (0.1)	(0.0, 0.1)
Osteoarthritis	11 (0.1)	(0.0, 0.1)	16 (0.1)	(0.0, 0.1)
Musculoskeletal stiffness	12 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Tendonitis	10 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	8 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Bursitis	10 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Muscular weakness	10 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Musculoskeletal chest pain	10 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Muscle contracture	4 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Rotator cuff syndrome	3 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Plantar fasciitis	4 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Arthritis	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Exostosis	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Flank pain	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Joint swelling	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Joint stiffness	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Musculoskeletal discomfort	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Osteoporosis	0	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Costochondritis	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Muscle twitching	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Musculoskeletal pain	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Intervertebral disc degeneration	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Limb discomfort	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain in jaw	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovial cyst	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Bone pain	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Tendon disorder	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Torticollis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arthropathy	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Axillary mass	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coccydynia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fibromyalgia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Groin pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint effusion	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metatarsalgia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Mobility decreased	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal stenosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spondylitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Trigger finger	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arthritis reactive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bone swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dupuytren's contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint instability	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondrosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Rheumatoid arthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scoliosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Systemic lupus erythematosus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	32 (0.1)	(0.1, 0.2)	36 (0.2)	(0.1, 0.2)
Basal cell carcinoma	3 (0.0)	(0.0, 0.0)	8 (0.0)	(0.0, 0.1)
Lipoma	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Uterine leiomyoma	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Colon adenoma	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Malignant melanoma	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Prostate cancer	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acrochordon	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Fibroadenoma of breast	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Squamous cell carcinoma of skin	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma pancreas	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenoma benign	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Benign breast neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Benign pancreatic neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chondroma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glomus tumour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Infected naevus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphoproliferative disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to liver	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oropharyngeal squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian germ cell teratoma benign	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pancreatic carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer metastatic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Seborrhoeic keratosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Squamous cell carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thyroid cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	1565 (7.1)	(6.8, 7.5)	600 (2.7)	(2.5, 3.0)
Headache	1339 (6.1)	(5.8, 6.4)	424 (1.9)	(1.8, 2.1)
Dizziness	78 (0.4)	(0.3, 0.4)	60 (0.3)	(0.2, 0.4)
Paraesthesia	22 (0.1)	(0.1, 0.2)	23 (0.1)	(0.1, 0.2)
Migraine	24 (0.1)	(0.1, 0.2)	11 (0.1)	(0.0, 0.1)
Lethargy	25 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Syncope	11 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Sciatica	11 (0.1)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Dysgeusia	12 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Somnolence	9 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Tension headache	8 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Presyncope	8 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Hypoaesthesia	5 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Tremor	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Burning sensation	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Parosmia	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Cervical radiculopathy	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Disturbance in attention	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperaesthesia	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neuropathy peripheral	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Sinus headache	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aphasia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebrovascular accident	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dizziness postural	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial paralysis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine without aura	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nerve compression	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Radiculopathy	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amnesia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Head discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post herpetic neuralgia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restless legs syndrome	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Taste disorder	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Transient ischaemic attack	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Trigeminal neuralgia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ageusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amyotrophic lateral sclerosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Balance disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerebellar infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral atrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral capillary telangiectasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervicogenic headache	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depressed level of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug withdrawal headache	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dystonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial paresis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Generalised tonic-clonic seizure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypersomnia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Motor dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myoclonus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nystagmus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parkinsonism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periodic limb movement disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peripheral sensory neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Piriformis syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Sciatic nerve neuropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seizure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal cord compression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VIth nerve paralysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abortion spontaneous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PRODUCT ISSUES	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device breakage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device connection issue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	97 (0.4)	(0.4, 0.5)	75 (0.3)	(0.3, 0.4)
Anxiety	21 (0.1)	(0.1, 0.1)	24 (0.1)	(0.1, 0.2)
Insomnia	25 (0.1)	(0.1, 0.2)	8 (0.0)	(0.0, 0.1)
Depression	17 (0.1)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Attention deficit hyperactivity disorder	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Irritability	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Panic attack	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Anxiety disorder	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Disorientation	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sleep disorder	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abnormal dreams	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Depressed mood	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Alcohol withdrawal syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bruxism	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental disorder	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental status changes	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nightmare	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Confusional state	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depression suicidal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Generalised anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Libido decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Libido increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Listless	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mood swings	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranoia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Schizophrenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stress	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Substance abuse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	34 (0.2)	(0.1, 0.2)	34 (0.2)	(0.1, 0.2)
Nephrolithiasis	6 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Dysuria	7 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Haematuria	4 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Acute kidney injury	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Pollakiuria	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Renal colic	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary retention	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bladder spasm	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic kidney disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Costovertebral angle tenderness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hydronephrosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive nephropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oedematous kidney	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Perinephric oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Renal atrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Renal cyst haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urethral discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary tract obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Urine odour abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	45 (0.2)	(0.1, 0.3)	39 (0.2)	(0.1, 0.2)
Dysmenorrhoea	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Erectile dysfunction	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Ovarian cyst	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic pain	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Amenorrhoea	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Benign prostatic hyperplasia	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast pain	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Breast mass	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Menorrhagia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Prostatitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vaginal haemorrhage	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast cyst	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Genital erythema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhagic ovarian cyst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Menstruation delayed	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Menstruation irregular	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metrorrhagia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Testicular pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine haemorrhage	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Adenomyosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast calcifications	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical polyp	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysfunctional uterine bleeding	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endometriosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematospermia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mammary duct ectasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menometrorrhagia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nipple pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penile vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Polycystic ovaries	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Prostatomegaly	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Scrotal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uterine inflammation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaginal discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	194 (0.9)	(0.8, 1.0)	168 (0.8)	(0.7, 0.9)
Oropharyngeal pain	36 (0.2)	(0.1, 0.2)	31 (0.1)	(0.1, 0.2)
Nasal congestion	25 (0.1)	(0.1, 0.2)	32 (0.1)	(0.1, 0.2)
Cough	23 (0.1)	(0.1, 0.2)	15 (0.1)	(0.0, 0.1)
Rhinorrhoea	20 (0.1)	(0.1, 0.1)	13 (0.1)	(0.0, 0.1)
Rhinitis allergic	12 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Asthma	12 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Dyspnoea	6 (0.0)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Throat irritation	6 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Epistaxis	5 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Sinus congestion	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	4 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Pulmonary embolism	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Sneezing	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Chronic obstructive pulmonary disease	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphonia	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Upper respiratory tract congestion	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bronchospasm	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Productive cough	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Respiratory tract congestion	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sleep apnoea syndrome	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wheezing	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute respiratory failure	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthma exercise induced	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dry throat	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Allergic sinusitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Asthmatic crisis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Oropharyngeal discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Reflux laryngitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic respiratory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atelectasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Emphysema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemoptysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hiccups	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lung infiltration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal polyps	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal septum deviation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleuritic pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinitis perennial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	224 (1.0)	(0.9, 1.2)	158 (0.7)	(0.6, 0.8)
Rash	54 (0.2)	(0.2, 0.3)	41 (0.2)	(0.1, 0.3)
Pruritus	23 (0.1)	(0.1, 0.2)	18 (0.1)	(0.0, 0.1)
Hyperhidrosis	31 (0.1)	(0.1, 0.2)	9 (0.0)	(0.0, 0.1)
Dermatitis contact	14 (0.1)	(0.0, 0.1)	19 (0.1)	(0.1, 0.1)
Urticaria	15 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Night sweats	17 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Rash pruritic	7 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Erythema	9 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Alopecia	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Eczema	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Skin lesion	3 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Rash maculo-papular	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Dermatitis	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Dermatitis allergic	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Angioedema	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dermal cyst	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash erythematous	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Actinic keratosis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Blister	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hand dermatitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Papule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Rash papular	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acne	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alopecia areata	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cold sweat	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug eruption	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pityriasis rosea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Rosacea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seborrhoeic dermatitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Skin mass	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis acneiform	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis bullous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyshidrotic eczema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fixed eruption	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hidradenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ingrowing nail	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Livedo reticularis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Mechanical urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Onychomadesis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pityriasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pseudofolliculitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stasis dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urticaria contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urticaria papular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menopause	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
High risk sexual behaviour	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	28 (0.1)	(0.1, 0.2)	19 (0.1)	(0.1, 0.1)
Tooth extraction	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Dental implantation	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Wisdom teeth removal	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dental care	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Endodontic procedure	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abortion induced	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Apicectomy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Botulinum toxin injection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac pacemaker replacement	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Carpal tunnel decompression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cataract operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug titration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facet joint block	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival operation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia repair	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lacrimal duct procedure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lens extraction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Medical device implantation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Open reduction of fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinoplasty	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sclerotherapy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 59. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Skin neoplasm excision	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Toe operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vasectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wound drainage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	83 (0.4)	(0.3, 0.5)	82 (0.4)	(0.3, 0.5)
Hypertension	42 (0.2)	(0.1, 0.3)	46 (0.2)	(0.2, 0.3)
Hot flush	7 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Flushing	11 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Deep vein thrombosis	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Haematoma	4 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Hypotension	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Orthostatic hypotension	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Varicose vein	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertensive crisis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Accelerated hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic dilatation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Aortic stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diastolic hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Essential hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphoedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pallor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Phlebolith	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Raynaud's phenomenon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subgaleal haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_all_pd2_p3_saf

Related Adverse Events – Blinded Follow-Up to 1 Month After Dose 2

From Dose 1 to 1 month after Dose 2, AEs assessed as related by the investigator during the blinded placebo-controlled follow-up period were reported by 23.9% of participants in the BNT162b2 group and 6.0% of participants in the placebo group (Table 58). Most related AEs were reactogenicity events and in the SOC of general disorders and administration site conditions, reported by 4650 (21.2%) BNT162b2 recipients and 883 (4.0%) placebo recipients. Among BNT162b2 participants who had AEs of lymphadenopathy, 62 of 83 participants had events assessed by the investigator as related to study intervention; the majority of lymphadenopathy events occurred in the arm and neck region and were reported within 2 to 4 days after vaccination (discussed further in Section 2.5.5.5.7).

Immediate Adverse Events – Blinded Follow-Up

After Dose 1, participants with immediate AEs were low in frequency (≤0.5%). Most immediate AEs after Dose 1 were in the SOC of general disorders and administration site conditions, primarily injection site reactions in the BNT162b2 versus placebo groups, with injection site pain (0.3% vs 0.2%) most frequently reported.

After Dose 2, participants with immediate AEs were low in frequency (0.3%). Most immediate AEs after Dose 2 were in the SOC of general disorders and administration site conditions, primarily injection site reactions in the BNT162b2 versus placebo groups, with injection site pain (0.2% vs 0.1%) most frequently reported.

No immediate anaphylactic reactions occurred after either dose.

Severe or Life-Threatening Adverse Events – Blinded Follow-Up to 1 Month After Dose 2

From Dose 1 to 1 month after Dose 2, severe AEs reported during the blinded follow-up period were low in frequency, reported in 1.2% of BNT162b2 recipients and 0.7% of placebo recipients. Severe events were concentrated in the SOCs of general disorders and administration site conditions, generally reflecting terms consistent with reactogenicity, in the BNT162b2 versus placebo groups (0.4% vs 0.0%).

There were 21 participants (0.1%) in the BNT162b2 group and 26 participants (0.1%) in the placebo group who had at least 1 life-threatening AE from Dose 1 to 1 month after Dose 2. None of these AEs were assessed by the investigator as related to study intervention.

No clinically meaningful differences were observed for severe or life-threatening AEs by age group.

HIV+ Participants

From Dose 1 to 1 month after Dose 2, and similar to the overall population, most AEs reported for the subset of 200 HIV+ participants from Dose 1 to 1 month after Dose 2 were in SOCs with reactogenicity events. There were few AEs reported: 26 (26%) in the BNT162b2 group and 13 (13%) in the placebo group, including in the following SOCs (BNT162b2 vs placebo):

- general disorders and administration site conditions: 19.0% vs 2.0%
- musculoskeletal and connective tissue disorders: 6.0% vs 3.0%
- nervous system disorders: 5.0% vs 0.0%
- gastrointestinal disorders: 3.0% vs 4.0%
- infections and infestations: 2.0% vs 2.0%.

2.5.5.5.3.2. Blinded Follow-Up Period from Dose 1 to the Unblinding Date

2.5.5.5.3.2.1. Summary of Adverse Events

An overview of AEs from Dose 1 to the unblinding date for participants during the blinded safety follow-up (including those analyzed in Phase 2) is presented in Table 60.

IRs per 100 PY for participants who reported at least 1 AE were 83.2 in the BNT162b2 group and 43.4 in the placebo group. IRs per 100 PY for related AEs were 62.9 in the BNT162b2 group and 16.0 in the placebo group. IRs of severe AEs, SAEs, and AEs leading to withdrawal were ≤4.3, ≤3.3, and ≤0.6 per 100 PY, respectively, in both groups. IRs for discontinuations because of related AEs were 0.2 per 100 PY in the BNT162b2 group and 0.1 per 100 PY in the placebo group.

From Dose 1 to the unblinding date, there were 15 deaths (0.2 per 100 PY) in the BNT162b2 group and 14 (0.2 per 100 PY) deaths in the placebo group (Section 2.5.5.5.4.1).

In the younger age group, the IRs for participants who reported at least 1 AE from Dose 1 to the unblinding date were 88.4 per 100 PY and 43.5 per 100 PY in the BNT162b2 and placebo groups, respectively. In the older age group, the IRs for participants who reported at least 1 AE from Dose 1 to the unblinding date were 75.7 per 100 PY and 43.3 per 100 PY in the BNT162b2 and placebo groups, respectively.

Table 60. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	6947	83.2	(81.3, 85.2)	3568	43.4	(42.0, 44.9)
Related[f]	5246	62.9	(61.2, 64.6)	1313	16.0	(15.1, 16.9)
Severe	356	4.3	(3.8, 4.7)	256	3.1	(2.7, 3.5)
Life-threatening	48	0.6	(0.4, 0.8)	54	0.7	(0.5, 0.9)
Any serious adverse event	268	3.2	(2.8, 3.6)	268	3.3	(2.9, 3.7)
Related[f]	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Severe	148	1.8	(1.5, 2.1)	156	1.9	(1.6, 2.2)
Life-threatening	48	0.6	(0.4, 0.8)	54	0.7	(0.5, 0.9)

Table 60. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any adverse event leading to withdrawal	45	0.5	(0.4, 0.7)	51	0.6	(0.5, 0.8)
Related[f]	13	0.2	(0.1, 0.3)	12	0.1	(0.1, 0.3)
Severe	10	0.1	(0.1, 0.2)	12	0.1	(0.1, 0.3)
Life-threatening	15	0.2	(0.1, 0.3)	16	0.2	(0.1, 0.3)
Death	15	0.2	(0.1, 0.3)	14	0.2	(0.1, 0.3)

a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s092_all_unb_p3_saf

Subgroup Analyses

Baseline SARS-CoV-2 Status

In the BNT162b2 group, there were 674 baseline SARS-CoV-2 positive and 21,102 baseline SARS-CoV-2 negative participants, and there were 705 baseline SARS-COV-2 positive and 21,092 SARS-CoV-2 negative participants in the placebo group.

Similar to what was observed in the overall AEs irrespective of baseline status (Table 60), IRs of at least 1 AE in the baseline SARS-CoV-2 positive subgroup were 70.7 per 100 PY in the BNT162b2 group and 31.9 per 100 PY in the placebo group, and IRs of at least 1 AE in the baseline SARS-CoV-2 negative subgroup were 83.6 per 100 PY in the BNT162b2 group and 43.8 per 100 PY in the placebo group. IRs of related AEs in the BNT162b2 group were 51.8 per 100 PY (baseline positive) and 63.2 per 100 PY (baseline negative). The IRs of SAEs, related SAEs, severe SAEs, and life threatening SAEs were similar in the BNT162b2 and placebo groups, which support these events are not increased in baseline positive participants. Given the differences in exposure (2.5 vs 80.4) by baseline SARS-CoV-2 positive and negative status, respectively, direct comparisons should be interpreted with caution. Section 2.5.5.5.3.2.2 includes an analysis of AEs for baseline status subgroups,

which shows that there is no evidence that individuals who are positive at baseline report AEs at a higher rate than those who are negative at baseline.

IRs of any AEs and related AEs were similar in those positive and negative at baseline, with the IR for any AE of 70.7 per 100 PY (95% CI: 60.7, 81.9) and 83.6 per 100 PY (95% CI: 81.7, 85.7) and for related AE of 51.8 per 100 PY (95% CI: 43.3, 61.4) and 63.2 per 100 PY (95% CI: 61.5, 65.0), respectively. IRs for SAEs were 4.0 per 100 PY (95% CI: 1.9, 7.3) (baseline positive) and 3.2 per 100 PY (95% CI: 2.8, 3.6) (baseline negative); however, none of the SAEs in the positive baseline group were assessed by the investigator as related to BNT162b2. The death rates were also similar: 0.8 per 100 PY (95% CI: 0.1, 2.9) (baseline positive) and 0.2 per 100 PY (95% CI: 0.1, 0.3) (baseline negative).

Race/Ethnicity

IRs of at least 1 AE in the BNT162b2 group were 78.4 per 100 PY (95% CI: 74.9, 82.0; n=5684) in Hispanic/Latino participants and 85.4 per 100 PY (95% CI: 83.1, 87.8; n=16131) in Non-Hispanic/Non-Latino participants. IRs of SAEs, AEs leading to withdrawal, and death were similar in the Hispanic/Latino and Non-Hispanic/Non-Latino groups. None of the SAEs were considered related to BNT162b2 in the Hispanic/Latino group.

IRs of at least 1 AE in the BNT162b2 group were lower in Black or African American participants (53.5 per 100 PY) compared with White (83.1 per 100 PY) or All Other (120.1 per 100 PY) participants. Other IRs were similar in the groups.

Sex

IRs of at least 1 AE in the BNT162b2 group were greater in female participants (91.0 per 100 PY [95% CI: 88.1, 94.0]) than male participants (76.0 per 100 PY [95% CI: 73.4, 78.6]); that cannot be accounted for by the rates in placebo for female participants (46.8 per 100 PY [95% CI: 44.7, 49.0]) and male participants (40.1 per 100 PY [95% CI: 38.2, 42.1]) IRs for related and severe AEs were also greater in female participants (68.6 per 100 PY [95% CI: 66.1, 71.2] and 4.9 per 100 PY [95% CI: 4.2, 5.6], respectively) than in male participants (57.5 per 100 PY [95% CI: 55.3, 59.8] and 3.7 per 100 PY [95% CI: 3.2, 4.3], respectively). However, life-threatening AEs, SAEs, related SAEs, severe SAEs, life threatening SAEs and death IR were similar in male and female participants.

HIV+ Participants

The subset of 200 HIV+ participants during the blinded placebo-controlled follow-up period showed generally similar trends as the overall population. IRs for HIV+ participants who reported at least 1 AE and at least 1 related AE were 95.8 per 100 PY and 62.8 per 100 PY, respectively, for the BNT162b2 group and 52.0 per 100 PY and 10.4 per 100 PY, respectively, for the placebo group. There were 2 SAEs in the BNT162b2 group (1 severe and 1 life-threatening) and 2 SAEs in the placebo group (1 life-threatening). There were 2 AEs leading to withdrawal in the BNT162b2 group (1 life-threatening) and 1 AE (life-threatening) leading to withdrawal in the placebo group. There were 2 deaths, 1 each in the BNT162b2 and placebo groups; neither were assessed by the investigator as related to study intervention (see Section 2.5.5.5.4.1).

2.5.5.5.3.2.2. Analysis of Adverse Events

Adverse Events by System Organ Class and Preferred Term

AEs reported from Dose 1 to the unblinding date during the blinded placebo-controlled follow-up period are presented in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Supplemental Table 14.119. Results were similar to IRs reported in the Dose 1 to 1 month after Dose 2 follow-up period (Section 2.5.5.5.3.1.2).

From Dose 1 to the unblinding date, the most common AEs by IRs were reactogenicity events and were reported at higher IRs in the BNT162b2 group than in the placebo group. IRs in these SOCs (BNT162b2 vs placebo) were:

- general disorders and administration site conditions: 56.9 per 100 PY vs 12.3 per 100 PY
- musculoskeletal and connective tissue disorders: 22.3 per 100 PY vs 7.6 per 100 PY
- nervous system disorders: 19.2 per 100 PY vs 7.7 per 100 PY
- gastrointestinal disorder: 9.0 per 100 PY vs 6.2 per 100 PY.

In the BNT162b2 age groups (younger versus older), IRs in these SOCs were:

- general disorders and administration site conditions: 63.7 per 100 PY vs 46.9 per 100 PY
- musculoskeletal and connective tissue disorders: 24.6 per 100 PY vs 18.8 per 100 PY
- nervous system disorders: 21.8 per 100 PY vs 15.3 per 100 PY
- gastrointestinal disorders: 9.5 per 100 PY vs 8.2 per 100 PY.

The higher rates of AEs in these SOC is consistent with the reactogenicity analysis that shows greater reactogenicity in the younger age group than in the older age group. AEs with the highest IRs in the BNT162b2 group by PT overall were injection site pain (35.0 per 100 PY), pyrexia (18.2 per 100 PY), fatigue (17.6 per 100 PY), chills (16.4 per 100 PY), headache (16.2 per 100 PY), and myalgia (14.9 per 100 PY).

IRs of AEs in the SOC of investigations was higher in the BNT162b2 group (2.2 per 100 PY) than in the placebo group (0.6 per 100 PY), mainly due to body temperature increased in the BNT162b2 group (IR of 1.5 per 100 PY vs 0.2 per 100 PY for the placebo group).

Analysis of reported night sweats and hyperhidrosis is discussed in Section 2.5.5.5.3.1.2 (most events were reported within 7 days after Dose 1 or 2 and are therefore likely consistent with reactogenicity).

In the nervous systems disorder SOC, there were 4 participants who reported facial paralysis in the BNT162b2 group (compared to 1 in the placebo group). There was 1 case of facial paresis reported in the placebo group. Hence, there are a total of 4 cases of facial paralysis/paresis in the in the BNT162b2 group and 2 in the placebo group. Further details are discussed in Section 2.5.5.5.7.1.

There was 1 case of COVID-19 pneumonia (reported in the BNT162b2 group) which led to death (see Section 2.5.5.5.4.1). This participant had COVID-19 diagnosed based on a local test

that was not protocol-approved and was not subsequently confirmed by a test result from the central laboratory (therefore not included in efficacy analyses).

Among the AEs of lymphadenopathy in the BNT162b2 group, the majority (62 of 87 participants; [0.7 per 100 PY]) were assessed by the investigator as related to study intervention. Most cases occurred in the arm and neck region and were reported within 1 to 4 days after vaccination. See Section 2.5.5.5.7.1 for additional details.

IRs for hepatobiliary disorders was 0.3 per 100 PY and 0.2 per 100 PY in the BNT162b2 and placebo group, respectively. There were 24 participants in the BNT162b2 group who had AEs in the SOC of hepatobiliary disorders compared to 16 participants in the placebo group.

A total of 11 cases of reported PTs associated with deafness in the blinded placebo-controlled follow-up period through the unblinding date included: deafness, deafness unilateral, deafness neurosensory, hypoacusis, and sudden hearing loss. Six participants were randomized to the BNT162b2 group (age range: 43 to 65 years of age), and 5 participants were randomized to placebo (age range: 36 to 74 years of age). For 1 participant in each group, onset was 19 days after Dose 1. Onset ranged from 1 to 55 days after Dose 2 for 5 participants in the BNT162b2, and from 2 to 94 days after Dose 2 for 4 participants in the placebo group. The duration ranged from 9 to 155 days after AE onset with 4 events still ongoing at the time of data cutoff (13 March 2021). The toxicity grades were mostly mild (4 BNT162b2 and 2 placebo) or moderate (1 BNT162b2 group and 3 placebo), with 1 being severe (BNT162b2). In the BNT162b2 group, 2 events were deemed related to study vaccine by the investigator. None of the reported events were SAEs.

Other PTs and further details of events of clinical interest including FDA-requested terms and those that were identified by the sponsor and/or from the CDC list of AESIs are discussed in Section 2.5.5.5.7.

Related Adverse Events – Blinded Follow-Up to Unblinding Date

From Dose 1 to the unblinding date, IRs of AEs assessed as related by the investigator during the blinded follow-up period were 62.9 per 100 PY and 16.0 per 100 PY in the BNT162b2 and in placebo groups, respectively (Table 60). IRs of related AEs were highest for reactogenicity events; in the SOC of general disorders and administration site conditions, IRs were 55.7 per 100 PY and 10.8 per 100 PY for BNT162b2 and placebo recipients, respectively. Additional terms identified as either synonymous with or otherwise plausibly associated with reactogenicity events (ie, secondary to reactogenicity events) occurring within 7 days after each dose were also considered related (pain in extremity, decreased appetite, lethargy, asthenia, malaise, night sweats, and hyperhidrosis) (see discussion of these types of events in Section 2.5.5.5.3.1.2).

For lymphadenopathy cases, IRs of related AEs in the younger and older age groups were 70.0 per 100 PY and 52.3 per 100 PY, respectively for the BNT162b2 group and 18.0 per 100 PY and 13.0 per 100 PY, respectively, for the placebo group. The majority of lymphadenopathy events occurred in the arm and neck region and were reported within 1 to 4 days after vaccination (discussed further as events of clinical interest in Section 2.5.5.5.7.1).

Severe or Life-Threatening Adverse Events – Blinded Follow-Up to Unblinding Date

From Dose 1 to the unblinding date, severe AE IRs during the blinded follow-up period were 4.3 per 100 PY (95% CI: 3.8, 4.7) and 3.1 per 100 PY (95% CI: 2.7, 3.5) in BNT162b2 and placebo recipients, respectively. Severe events in the general disorders and administration site conditions were generally reflecting terms consistent with reactogenicity, in the BNT162b2 versus placebo groups (1.2 per 100 PY vs 0.1 per 100 PY) as well as the Musculoskeletal SOC (0.6 per 100 PY vs 0.3 per 100 PY). The IR in all other SOCs were similar in the BNT162b2 and placebo groups.

IRs for participants who had at least 1 life-threatening AE from Dose 1 to the unblinding date were similar: 0.6 per 100 PY (95% CI: 0.4, 0.8) in the BNT162b2 group and 0.7 per 100 PY (95% CI: 0.5, 0.9) in the placebo group. All of the IRs for the SOCs were similar in the BNT162b2 and placebo groups.

Subgroup Analyses

No clinically meaningful differences in AEs by category or by frequency were observed up from Dose 1 up to the unblinding date for subgroups categorized by race, ethnicity, or baseline SARS-CoV-2 status. Sex-appropriate differences were observed in AE IRs.

Baseline SARS-CoV-2 Status

In the baseline SARS-CoV-2 positive subgroup, differences in IRs in the BNT162b2 (70.7 per 100 PY) and placebo (31.9 per 100 PY) groups were due to reactogenicity events (chills, fatigue, injection site pain, pyrexia, myalgia, and headache). In the baseline SARS-CoV-2 negative subgroup, differences in IRs in the BNT162b2 (83.6 per 100 PY) and placebo (43.8 per 100 PY) groups were due to reactogenicity events (diarrhea, vomiting, chill, fatigue, injection site reactions [pain, erythema, swelling], pyrexia, arthralgia, myalgia, and headache) as well as other AEs (lymphadenopathy, nausea, asthenia, malaise, pain, body temperature increase, and pain in extremity).

Given the differences in exposure (2.5 vs 80.4) by baseline SARS-CoV-2 positive and negative status, respectively, direct comparisons should be interpreted with caution . The overall rate of AEs was 70.7 per 100 PY (95% CI: 60.7, 81.9) (baseline positive) compared with 83.6 per 100 PY (95% CI: 81.7, 85.7) (baseline negative). For other SOCs, the IR were either numerically lower or similar for the baseline positive group compared to the baseline negative group. Overall, there is no evidence that individuals who are positive at baseline report AEs at a higher frequency than those who are negative at baseline.

Race/Ethnicity

In the BNT162b2 group, overall IRs for participants reporting at least 1 AE were highest for participants of all other races (120.1 per 100 PY) compared to White participants (83.1 per 100 PY), with Black or African American participants having the lowest IR (53.5 per 100 PY). The IR for nausea in the BNT162b2 group was higher in participants of all other races (4.7 per 100 PY BNT162b2 vs 1.6 per 100 PY placebo) and White participants (3.4 per 100 PY BNT162b2 vs 1.0 per 100 PY placebo) than in Black or African American participants where the IR was similar in both vaccine groups (1.3 per 100 PY BNT162b2 vs 1.2 per 100 PY placebo).

In the BNT162b2 group, the IR for participants reporting at least 1 AE was higher in non-Hispanic/non-Latino participants (85.4 per 100 PY BNT162b2 and 41.6 per 100 PY placebo) and Hispanic/Latino participants (78.4 per 100 PY BNT162b2 and 47.9 per 100 PY placebo) and lowest in the group where ethnicity was not reported (49.4 per 100 PY BNT162b2 and 43.3 per 100 PY placebo). IRs were higher for mainly reactogenicity events (chills, fatigue, myalgia, diarrhea, injection site reactions [pain, erythema, and swelling], pain, pyrexia, and headache) as well as lymphadenopathy, nausea, influenza like illness, malaise, increased body temperature, and pain in extremity.

Sex

Overall, female participants reported a higher IR of AEs (91.0 per 100 PY BNT162b2, 46.8 per 100 PY placebo) than male participants (76.0 per 100 PY BNT162b2, 40.1 per 100 PY placebo), with a greater difference in BNT162b2 groups than in placebo groups. The higher IRs in female participants were due to reactogenicity AEs (vomiting, chills, fatigue, pyrexia, myalgia, and headache) as well as other AEs (lymphadenopathy, nausea, pain, increased body temperature, and pain in extremity). There were sex-appropriate differences as well, such as higher IRs in the SOC of cardiac disorders in male participants (1.2 per 100 PY) versus female participants (0.9 per 100 PY) and lower IRs in the SOC of reproductive system and breast disorders in male participants (0.3 per 100 PY) versus female participants (0.9 per 100 PY).

HIV+ Participants

From Dose 1 to the unblinding date, and similar to the overall population, most AEs reported for the subset of 200 HIV+ participants from Dose 1 to the unblinding date were in SOCs with reactogenicity events (BNT162b2 vs placebo):

- general disorders and administration site conditions: 66.1 per 100 PY vs 6.9 per 100 PY
- musculoskeletal and connective tissue disorders: 19.8 per 100 PY vs 10.4 per 100 PY
- nervous system disorders: 16.5 per 100 PY vs 0.0 per 100 PY
- gastrointestinal disorders: 9.9 per 100 PY vs 13.9 per 100 PY.

2.5.5.5.3.3. Open-Label Follow-Up Period – Original BNT162b2 Participants

2.5.5.5.3.3.1. Summary of Adverse Events

An overview of AEs from the unblinding date to the data cutoff date for participants originally randomized to BNT162b2 during the open-label follow-up is presented in Table 61.

Note: per protocol, AEs are reported through 1 month after the Dose 2 and within 48 hours after a blood draw and SAEs are reported to approximately 6 months after the last dose of study intervention.

IRs for any AE, at least 1 related AE, and severe AE were 8.8 per 100 PY, 0.7 per 100 PY, and 1.6 per 100 PY, respectively, which is markedly reduced relative to those from Dose 1 to the unblinding date (83.2, 62.9, 4.3 respectively). The IR of life-threatening AEs is 0.4 per 100 PY (95% CI: 0.2, 0.8), which is similar to the IR from Dose 1 to the unblinding date (0.6 per 100 PY [95% CI: 0.4, 0.8]; Table 60).

The IR of SAEs during the open-label follow-up period, 2.0 per 100 PY (95% CI: 1.5, 2.6; Table 61), was lower than the IR from Dose 1 to the unblinding date, 3.2 per 100 PY (95% CI: 2.8, 3.6; Table 60). There was a single related SAE (myocardial infarction) for a participant in the open-label follow-up period (see Section 2.5.5.5.3.3.2 and Section 2.5.5.5.5.3). The IR of AEs leading to withdrawal also decreased (0.1 per 100 PY [95% CI: 0.0, 0.4]) in the open-label follow-up period compared with the blinded placebo-controlled period (0.5 per 100 PY [95% CI: 0.4, 0.7]; Table 60) but the IR of deaths were similar (0.1 per 100 PY vs 0.2 per 100 PY in the open-label and blinded placebo-controlled follow-up periods, respectively).

Three participants originally randomized to BNT162b2 died during open-label follow-up (Section 2.5.5.5.4.2).

Table 61. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021) – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	243	8.8	(7.7, 9.9)
Related[f]	20	0.7	(0.4, 1.1)
Severe	43	1.6	(1.1, 2.1)
Life-threatening	12	0.4	(0.2, 0.8)
Any serious adverse event	55	2.0	(1.5, 2.6)
Related[f]	1	0.0	(0.0, 0.2)

Table 61. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021) – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])
Severe	30	1.1	(0.7, 1.5)
Life-threatening	12	0.4	(0.2, 0.8)
Any adverse event leading to withdrawal	4	0.1	(0.0, 0.4)
Related[f]	0	0.0	(0.0, 0.1)
Severe	0	0.0	(0.0, 0.1)
Life-threatening	4	0.1	(0.0, 0.4)
Death	3	0.1	(0.0, 0.3)

a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from the unblinding date to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s092_unb_cut_p3_saf

2.5.5.5.3.3.2. Analysis of Adverse Events

Adverse Events by System Organ Class and Preferred Term

AEs reported from the unblinding date to the data cutoff date for participants originally randomized to BNT162b2 during the open-label follow-up period are presented in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Supplemental Table 14.142.

From the unblinding date to the data cutoff date, for participants originally randomized to BNT162b2 during the open-label follow-up period, the IRs for participants who reported at least 1 AE was 8.8 per 100 PY, as compared to 83.2 per 100 PY from Dose 1 to the unblinding date (Table 60).

Overall, the rates in all SOCs after the unblinding date decreased or remained similar to those in the blinded placebo-controlled period.

The IR for the SOC of injury, poisoning and procedural complications was 1.4 per 100 PY, with the PT fall having the highest IR (0.4 per 100 PY). The IR for the SOC of vascular disorders was 0.8 per 100 PY, with the PT hypertension having the highest IR (0.6 per 100 PY).

Related Adverse Events – Open-Label Follow-Up for Original BNT162b2 Participants

From the unblinding date to the data cutoff date, for participants originally randomized to BNT162b2, the IR of AEs assessed as related by the investigator during the open-label follow-up period was 0.7 per 100 PY (Table 61). IRs of related AEs were highest for reactogenicity events and in the SOC of general disorders and administration site conditions (0.5 per 100 PY), reflecting AEs from their initial vaccinations.

One younger participant had a life-threatening SAE of myocardial infarction occurring 71 days after Dose 2 that was assessed by the investigator as related to study intervention, which lasted 1 day and resolved the same day (see Section 2.5.5.5.5.3).

2.5.5.5.3.4. Cumulative Blinded and Open-Label Follow-Up Periods from Dose 1 to 6 Months After Dose 2 – BNT162b2 Group

2.5.5.5.3.4.1. Summary of Adverse Events

An overview of AEs from Dose 1 to 6 months after Dose 2 for participants in the BNT162b2 group during the blinded and open-label follow-up is presented in Table 62.

There were 12,006 participants who had at least 6 months of follow-up. Among these, 3454 participants (28.8%) reported at least 1 AE and 2245 participants (18.7%) reported at least 1 related AE. Severe AEs and SAEs were reported by 2.1% and 1.6%, respectively. One participant was reported as discontinued because of an AE (not related); however, this participant remains in the study as the withdrawal was subsequently queried and corrected as described in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Errata. There were no deaths during the blinded and open-label follow-up periods in the group of original BNT162b2 participants with at least 6 months of follow-up after Dose 2.

When frequencies of AEs for participants with at least 6 months of follow-up time are examined by time since the second BNT162b2 dose, the frequency of AEs and related AEs is 25.8% and 18.6% through 1 month after Dose 2 compared with 4.8% and 0.1% from 1 month after Dose 2 to 6 months after Dose 2 (Table 63). In the first month after vaccination, 0.5% of participants reported SAEs (including 1 related) and from 1 month to 6 months after Dose 2 the frequency of SAEs increased to 1.1% (including 1 related SAE).

In the younger age group, the number of participants who reported at least 1 AE and 1 related AE from Dose 1 to 6 months after Dose 2 was 2013 (30.2%) and 1386 (20.8%), respectively. In the older age group, the number of participants who reported at least 1 AE and 1 related AE from Dose 1 to 6 months after Dose 2 was 1441 (27.0%) and 859 (16.1%), respectively.

Table 62. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2 – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=12006)
Adverse Event	n[b] (%)
Any event	3454 (28.8)
Related[c]	2245 (18.7)
Severe	248 (2.1)
Life-threatening	23 (0.2)
Any serious adverse event	190 (1.6)
Related[c]	2 (0.0)
Severe	116 (1.0)
Life-threatening	23 (0.2)
Any adverse event leading to withdrawal	1 (0.0)
Related[c]	0
Severe	0
Life-threatening	0
Death	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (14:48)
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Table 63. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)	After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)
Adverse Event	n[b] (%)	n[b] (%)
Any event	3092 (25.8)	572 (4.8)
Related[c]	2239 (18.6)	12 (0.1)
Severe	143 (1.2)	110 (0.9)
Life-threatening	8 (0.1)	15 (0.1)
Any serious adverse event	58 (0.5)	133 (1.1)
Related[c]	1 (0.0)	1 (0.0)
Severe	34 (0.3)	82 (0.7)
Life-threatening	8 (0.1)	15 (0.1)
Any adverse event leading to withdrawal	0	1 (0.0)
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 14APR2021 (08:45)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA RR/adae s091 all pd2 p3 tp saf2

2.5.5.5.3.4.2. Analysis of Adverse Events

Adverse Events by System Organ Class and Preferred Term

AEs reported during the cumulative period from Dose 1 up to 6 months after Dose 2 (inclusive of blinded and open-label follow-up) in the BNT162b2 group are summarized in Table 64.

From Dose 1 to 6 months after Dose 2 during the blinded and open-label follow-up period, 3454 (28.8%) original BNT162b2 participants reported at least 1 AE (Table 64). The most frequently reported AEs were reactogenicity events:

- general disorders and administration site conditions: 2016 (16.8%)
- musculoskeletal and connective tissue disorders: 905 (7.5%)
- nervous system disorders: 726 (6.0%)
- gastrointestinal disorders: 407 [3.4%).

The number of original BNT162b2 participants who reported at least 1 AE from Dose 1 to 6 months after Dose 2 was 2013 (30.2%) and 1441 (27.0%) in the younger and older groups, respectively.

In the BNT162b2 age groups, AE frequencies in reactogenicity SOCs (younger vs older) were:

- general disorders and administration site conditions: 1246 (18.7%) vs 770 (14.4%)
- musculoskeletal and connective tissue disorders: 539 (8.1%) vs 366 (6.9%)
- nervous system disorders: 449 (6.7%) vs 277 (5.2%)
- gastrointestinal disorders: 231 (3.5%) vs 176 (3.3%).

As shown in Table 64, the most frequently reported AEs in the BNT162b2 group were injection site pain (1191 [9.9%]), pyrexia (633 [5.3%]), chills (606 [5.0%]), fatigue (598 [5.0%]), headache (572 [4.8%]), and myalgia (549 [4.6%]).

When AEs are compared from 1 month after Dose 2 and from 1 month after Dose 2 to 6 months after Dose 2, the frequencies of AEs by most SOCs decreased or remained the same with the additional follow-up time. The overall frequency of any AE for participants from 1 month after Dose 2 to 6 months after Dose 2 (4.8%) was decreased relative to the frequency observed within 1 month of follow-up after Dose 2 (25.8%) for this group.

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	3454 (28.8)	(28.0, 29.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	70 (0.6)	(0.5, 0.7)
Lymphadenopathy	50 (0.4)	(0.3, 0.5)
Anaemia	7 (0.1)	(0.0, 0.1)
Iron deficiency anaemia	5 (0.0)	(0.0, 0.1)
Lymph node pain	3 (0.0)	(0.0, 0.1)
Leukopenia	2 (0.0)	(0.0, 0.1)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Blood loss anaemia	1 (0.0)	(0.0, 0.0)
Coagulopathy	1 (0.0)	(0.0, 0.0)
Lymphadenopathy mediastinal	1 (0.0)	(0.0, 0.0)
Lymphocytosis	1 (0.0)	(0.0, 0.0)
Lymphopenia	1 (0.0)	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)
Pancytopenia	1 (0.0)	(0.0, 0.0)
Splenic infarction	1 (0.0)	(0.0, 0.0)
Splenomegaly	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	59 (0.5)	(0.4, 0.6)
Atrial fibrillation	9 (0.1)	(0.0, 0.1)
Tachycardia	9 (0.1)	(0.0, 0.1)
Palpitations	7 (0.1)	(0.0, 0.1)
Coronary artery disease	6 (0.0)	(0.0, 0.1)
Acute myocardial infarction	4 (0.0)	(0.0, 0.1)
Angina pectoris	4 (0.0)	(0.0, 0.1)
Myocardial infarction	4 (0.0)	(0.0, 0.1)
Cardiac failure congestive	3 (0.0)	(0.0, 0.1)
Angina unstable	2 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)
Arrhythmia	1 (0.0)	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)
Atrial flutter	1 (0.0)	(0.0, 0.0)
Atrioventricular block first degree	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.0)
Cardiac arrest	1 (0.0)	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.0)
Cardiomegaly	1 (0.0)	(0.0, 0.0)
Coronary artery occlusion	1 (0.0)	(0.0, 0.0)
Left ventricular dysfunction	1 (0.0)	(0.0, 0.0)
Mitral valve prolapse	1 (0.0)	(0.0, 0.0)
Pericarditis	1 (0.0)	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)
Ventricular tachycardia	1 (0.0)	(0.0, 0.0)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	3 (0.0)	(0.0, 0.1)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.0)
Gastrointestinal arteriovenous malformation	1 (0.0)	(0.0, 0.0)
Protein S deficiency	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	49 (0.4)	(0.3, 0.5)
Vertigo	21 (0.2)	(0.1, 0.3)
Ear pain	8 (0.1)	(0.0, 0.1)
Tinnitus	6 (0.0)	(0.0, 0.1)
Vertigo positional	4 (0.0)	(0.0, 0.1)
Cerumen impaction	3 (0.0)	(0.0, 0.1)
Deafness neurosensory	2 (0.0)	(0.0, 0.1)
Ear discomfort	2 (0.0)	(0.0, 0.1)
Deafness unilateral	1 (0.0)	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.0)
Sudden hearing loss	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	15 (0.1)	(0.1, 0.2)
Hypothyroidism	6 (0.0)	(0.0, 0.1)
Hyperthyroidism	2 (0.0)	(0.0, 0.1)
Hypogonadism	2 (0.0)	(0.0, 0.1)
Thyroid mass	2 (0.0)	(0.0, 0.1)
Goitre	1 (0.0)	(0.0, 0.0)
Hyperprolactinaemia	1 (0.0)	(0.0, 0.0)
Oestrogen deficiency	1 (0.0)	(0.0, 0.0)
Pituitary cyst	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	47 (0.4)	(0.3, 0.5)
Cataract	5 (0.0)	(0.0, 0.1)
Vision blurred	5 (0.0)	(0.0, 0.1)
Chalazion	3 (0.0)	(0.0, 0.1)
Eye irritation	3 (0.0)	(0.0, 0.1)
Eye pain	3 (0.0)	(0.0, 0.1)
Macular oedema	3 (0.0)	(0.0, 0.1)
Vitreous detachment	3 (0.0)	(0.0, 0.1)
Blepharitis	2 (0.0)	(0.0, 0.1)
Diplopia	2 (0.0)	(0.0, 0.1)
Dry eye	2 (0.0)	(0.0, 0.1)
Glaucoma	2 (0.0)	(0.0, 0.1)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Retinal tear	2 (0.0)	(0.0, 0.1)
Asthenopia	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.0)
Corneal irritation	1 (0.0)	(0.0, 0.0)
Episcleritis	1 (0.0)	(0.0, 0.0)
Eye pruritus	1 (0.0)	(0.0, 0.0)
Eyelid oedema	1 (0.0)	(0.0, 0.0)
Eyelid pain	1 (0.0)	(0.0, 0.0)
Eyelids pruritus	1 (0.0)	(0.0, 0.0)
Keratitis	1 (0.0)	(0.0, 0.0)
Ophthalmic vein thrombosis	1 (0.0)	(0.0, 0.0)
Photophobia	1 (0.0)	(0.0, 0.0)
Retinal artery occlusion	1 (0.0)	(0.0, 0.0)
Scleral discolouration	1 (0.0)	(0.0, 0.0)
Vitreous floaters	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	407 (3.4)	(3.1, 3.7)
Nausea	140 (1.2)	(1.0, 1.4)
Diarrhoea	123 (1.0)	(0.9, 1.2)
Vomiting	35 (0.3)	(0.2, 0.4)
Toothache	18 (0.1)	(0.1, 0.2)
Abdominal pain	15 (0.1)	(0.1, 0.2)
Gastrooesophageal reflux disease	14 (0.1)	(0.1, 0.2)
Dyspepsia	13 (0.1)	(0.1, 0.2)
Abdominal pain upper	10 (0.1)	(0.0, 0.2)
Odynophagia	10 (0.1)	(0.0, 0.2)
Constipation	7 (0.1)	(0.0, 0.1)
Dental caries	6 (0.0)	(0.0, 0.1)
Irritable bowel syndrome	5 (0.0)	(0.0, 0.1)
Abdominal distension	4 (0.0)	(0.0, 0.1)
Flatulence	4 (0.0)	(0.0, 0.1)
Gastritis	4 (0.0)	(0.0, 0.1)
Hiatus hernia	4 (0.0)	(0.0, 0.1)
Large intestine polyp	4 (0.0)	(0.0, 0.1)
Aphthous ulcer	3 (0.0)	(0.0, 0.1)
Diverticulum	3 (0.0)	(0.0, 0.1)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Food poisoning	3 (0.0)	(0.0, 0.1)
Haemorrhoids	3 (0.0)	(0.0, 0.1)
Colitis	2 (0.0)	(0.0, 0.1)
Gastritis erosive	2 (0.0)	(0.0, 0.1)
Gastrointestinal disorder	2 (0.0)	(0.0, 0.1)
Glossodynia	2 (0.0)	(0.0, 0.1)
Haematochezia	2 (0.0)	(0.0, 0.1)
Impaired gastric emptying	2 (0.0)	(0.0, 0.1)
Oral pain	2 (0.0)	(0.0, 0.1)
Small intestinal obstruction	2 (0.0)	(0.0, 0.1)
Abdominal discomfort	1 (0.0)	(0.0, 0.0)
Abdominal pain lower	1 (0.0)	(0.0, 0.0)
Abdominal rigidity	1 (0.0)	(0.0, 0.0)
Angular cheilitis	1 (0.0)	(0.0, 0.0)
Cheilitis	1 (0.0)	(0.0, 0.0)
Coeliac disease	1 (0.0)	(0.0, 0.0)
Colitis microscopic	1 (0.0)	(0.0, 0.0)
Colitis ulcerative	1 (0.0)	(0.0, 0.0)
Crohn's disease	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal	1 (0.0)	(0.0, 0.0)
Dry mouth	1 (0.0)	(0.0, 0.0)
Dysphagia	1 (0.0)	(0.0, 0.0)
Epiploic appendagitis	1 (0.0)	(0.0, 0.0)
Eructation	1 (0.0)	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)
Femoral hernia	1 (0.0)	(0.0, 0.0)
Gastric antral vascular ectasia	1 (0.0)	(0.0, 0.0)
Gastric ulcer	1 (0.0)	(0.0, 0.0)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.0)
Gingival pain	1 (0.0)	(0.0, 0.0)
Glossitis	1 (0.0)	(0.0, 0.0)
Haematemesis	1 (0.0)	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.0)
Hypoaesthesia oral	1 (0.0)	(0.0, 0.0)
Hypoaesthesia teeth	1 (0.0)	(0.0, 0.0)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Inguinal hernia	1 (0.0)	(0.0, 0.0)
Internal hernia	1 (0.0)	(0.0, 0.0)
Intestinal obstruction	1 (0.0)	(0.0, 0.0)
Intestinal polyp	1 (0.0)	(0.0, 0.0)
Intra-abdominal fluid collection	1 (0.0)	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)
Oesophageal spasm	1 (0.0)	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.0)
Oral lichenoid reaction	1 (0.0)	(0.0, 0.0)
Pancreatic calcification	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.0)
Rectal haemorrhage	1 (0.0)	(0.0, 0.0)
Rectal polyp	1 (0.0)	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.0)
Stomatitis	1 (0.0)	(0.0, 0.0)
Swollen tongue	1 (0.0)	(0.0, 0.0)
Tongue oedema	1 (0.0)	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2016 (16.8)	(16.1, 17.5)
Injection site pain	1191 (9.9)	(9.4, 10.5)
Pyrexia	633 (5.3)	(4.9, 5.7)
Chills	606 (5.0)	(4.7, 5.5)
Fatigue	598 (5.0)	(4.6, 5.4)
Pain	277 (2.3)	(2.0, 2.6)
Injection site erythema	91 (0.8)	(0.6, 0.9)
Injection site swelling	60 (0.5)	(0.4, 0.6)
Malaise	46 (0.4)	(0.3, 0.5)
Asthenia	20 (0.2)	(0.1, 0.3)
Injection site pruritus	19 (0.2)	(0.1, 0.2)
Chest pain	14 (0.1)	(0.1, 0.2)
Influenza like illness	10 (0.1)	(0.0, 0.2)
Injection site bruising	8 (0.1)	(0.0, 0.1)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Axillary pain	6 (0.0)	(0.0, 0.1)
Injection site warmth	6 (0.0)	(0.0, 0.1)
Feeling hot	5 (0.0)	(0.0, 0.1)
Injection site induration	5 (0.0)	(0.0, 0.1)
Oedema peripheral	5 (0.0)	(0.0, 0.1)
Peripheral swelling	4 (0.0)	(0.0, 0.1)
Injection site oedema	3 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	3 (0.0)	(0.0, 0.1)
Adverse drug reaction	2 (0.0)	(0.0, 0.1)
Cyst	2 (0.0)	(0.0, 0.1)
Face oedema	2 (0.0)	(0.0, 0.1)
Injection site discomfort	2 (0.0)	(0.0, 0.1)
Injection site haematoma	2 (0.0)	(0.0, 0.1)
Injection site nodule	2 (0.0)	(0.0, 0.1)
Injection site papule	2 (0.0)	(0.0, 0.1)
Swelling	2 (0.0)	(0.0, 0.1)
Application site erythema	1 (0.0)	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)
Chest discomfort	1 (0.0)	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)
Induration	1 (0.0)	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.0)
Injection site discolouration	1 (0.0)	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)
Injection site mass	1 (0.0)	(0.0, 0.0)
Injection site paraesthesia	1 (0.0)	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.0)
Injection site reaction	1 (0.0)	(0.0, 0.0)
Medical device pain	1 (0.0)	(0.0, 0.0)
Sensation of foreign body	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Sluggishness	1 (0.0)	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.0)
Thirst	1 (0.0)	(0.0, 0.0)
Vaccination site induration	1 (0.0)	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.0)
Vessel puncture site haematoma	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	21 (0.2)	(0.1, 0.3)
Cholelithiasis	7 (0.1)	(0.0, 0.1)
Biliary colic	4 (0.0)	(0.0, 0.1)
Cholecystitis acute	3 (0.0)	(0.0, 0.1)
Bile duct stone	2 (0.0)	(0.0, 0.1)
Biliary dyskinesia	1 (0.0)	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)
Cholelithiasis obstructive	1 (0.0)	(0.0, 0.0)
Gallbladder disorder	1 (0.0)	(0.0, 0.0)
Hepatic steatosis	1 (0.0)	(0.0, 0.0)
Jaundice	1 (0.0)	(0.0, 0.0)
Portosplenomesenteric venous thrombosis	1 (0.0)	(0.0, 0.0)
Steatohepatitis	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	15 (0.1)	(0.1, 0.2)
Seasonal allergy	6 (0.0)	(0.0, 0.1)
Drug hypersensitivity	2 (0.0)	(0.0, 0.1)
Hypersensitivity	2 (0.0)	(0.0, 0.1)
Allergy to arthropod bite	1 (0.0)	(0.0, 0.0)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)
Food allergy	1 (0.0)	(0.0, 0.0)
Jarisch-Herxheimer reaction	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	295 (2.5)	(2.2, 2.7)
Urinary tract infection	57 (0.5)	(0.4, 0.6)
Tooth infection	20 (0.2)	(0.1, 0.3)
Sinusitis	16 (0.1)	(0.1, 0.2)
Appendicitis	10 (0.1)	(0.0, 0.2)
Herpes zoster	10 (0.1)	(0.0, 0.2)
Cellulitis	9 (0.1)	(0.0, 0.1)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Conjunctivitis	8 (0.1)	(0.0, 0.1)
Cystitis	8 (0.1)	(0.0, 0.1)
Ear infection	8 (0.1)	(0.0, 0.1)
Diverticulitis	7 (0.1)	(0.0, 0.1)
Gastroenteritis	7 (0.1)	(0.0, 0.1)
Tooth abscess	7 (0.1)	(0.0, 0.1)
Hordeolum	6 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	6 (0.0)	(0.0, 0.1)
Folliculitis	5 (0.0)	(0.0, 0.1)
Rhinitis	5 (0.0)	(0.0, 0.1)
Nasopharyngitis	4 (0.0)	(0.0, 0.1)
Oral herpes	4 (0.0)	(0.0, 0.1)
Otitis externa	4 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	4 (0.0)	(0.0, 0.1)
Fungal skin infection	3 (0.0)	(0.0, 0.1)
Gingivitis	3 (0.0)	(0.0, 0.1)
Onychomycosis	3 (0.0)	(0.0, 0.1)
Paronychia	3 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	3 (0.0)	(0.0, 0.1)
Pneumonia	3 (0.0)	(0.0, 0.1)
Pyelonephritis	3 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	3 (0.0)	(0.0, 0.1)
Device related infection	2 (0.0)	(0.0, 0.1)
Herpes simplex	2 (0.0)	(0.0, 0.1)
Influenza	2 (0.0)	(0.0, 0.1)
Kidney infection	2 (0.0)	(0.0, 0.1)
Laryngitis	2 (0.0)	(0.0, 0.1)
Localised infection	2 (0.0)	(0.0, 0.1)
Oral candidiasis	2 (0.0)	(0.0, 0.1)
Otitis media	2 (0.0)	(0.0, 0.1)
Otitis media acute	2 (0.0)	(0.0, 0.1)
Periodontitis	2 (0.0)	(0.0, 0.1)
Pustule	2 (0.0)	(0.0, 0.1)
Rash pustular	2 (0.0)	(0.0, 0.1)
Sepsis	2 (0.0)	(0.0, 0.1)
Sinusitis bacterial	2 (0.0)	(0.0, 0.1)
Skin infection	2 (0.0)	(0.0, 0.1)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Viral infection	2 (0.0)	(0.0, 0.1)
Abscess	1 (0.0)	(0.0, 0.0)
Abscess neck	1 (0.0)	(0.0, 0.0)
Abscess oral	1 (0.0)	(0.0, 0.0)
Acute sinusitis	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)
Arthritis bacterial	1 (0.0)	(0.0, 0.0)
Bacteraemia	1 (0.0)	(0.0, 0.0)
Bacterial blepharitis	1 (0.0)	(0.0, 0.0)
Bacterial sepsis	1 (0.0)	(0.0, 0.0)
Bacterial vaginosis	1 (0.0)	(0.0, 0.0)
Bacterial vulvovaginitis	1 (0.0)	(0.0, 0.0)
Bartholinitis	1 (0.0)	(0.0, 0.0)
Bone abscess	1 (0.0)	(0.0, 0.0)
Bronchitis	1 (0.0)	(0.0, 0.0)
Cellulitis orbital	1 (0.0)	(0.0, 0.0)
Chronic sinusitis	1 (0.0)	(0.0, 0.0)
Clostridium difficile colitis	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)
Endocarditis	1 (0.0)	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)
Eye infection	1 (0.0)	(0.0, 0.0)
Fungal infection	1 (0.0)	(0.0, 0.0)
Furuncle	1 (0.0)	(0.0, 0.0)
Gangrene	1 (0.0)	(0.0, 0.0)
Gastroenteritis viral	1 (0.0)	(0.0, 0.0)
Gastrointestinal infection	1 (0.0)	(0.0, 0.0)
Genital herpes simplex	1 (0.0)	(0.0, 0.0)
Helicobacter gastritis	1 (0.0)	(0.0, 0.0)
Helicobacter infection	1 (0.0)	(0.0, 0.0)
Herpes zoster oticus	1 (0.0)	(0.0, 0.0)
Impetigo	1 (0.0)	(0.0, 0.0)
Infected bite	1 (0.0)	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.0)
Mastoiditis	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	1 (0.0)	(0.0, 0.0)
Mumps	1 (0.0)	(0.0, 0.0)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Papilloma viral infection	1 (0.0)	(0.0, 0.0)
Parasitic gastroenteritis	1 (0.0)	(0.0, 0.0)
Penile infection	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)
Peritonitis	1 (0.0)	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.0)
Pharyngitis	1 (0.0)	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.0)
Pilonidal cyst	1 (0.0)	(0.0, 0.0)
Postoperative abscess	1 (0.0)	(0.0, 0.0)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.0)
Sialoadenitis	1 (0.0)	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)
Subcutaneous abscess	1 (0.0)	(0.0, 0.0)
Tinea versicolour	1 (0.0)	(0.0, 0.0)
Varicella	1 (0.0)	(0.0, 0.0)
Vulval abscess	1 (0.0)	(0.0, 0.0)
Vulvovaginitis	1 (0.0)	(0.0, 0.0)
Wound infection	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	207 (1.7)	(1.5, 2.0)
Fall	47 (0.4)	(0.3, 0.5)
Exposure during pregnancy	22 (0.2)	(0.1, 0.3)
Muscle strain	15 (0.1)	(0.1, 0.2)
Ligament sprain	13 (0.1)	(0.1, 0.2)
Contusion	12 (0.1)	(0.1, 0.2)
Procedural pain	11 (0.1)	(0.0, 0.2)
Road traffic accident	11 (0.1)	(0.0, 0.2)
Skin laceration	11 (0.1)	(0.0, 0.2)
Arthropod bite	7 (0.1)	(0.0, 0.1)
Limb injury	7 (0.1)	(0.0, 0.1)
Tooth fracture	6 (0.0)	(0.0, 0.1)
Ankle fracture	5 (0.0)	(0.0, 0.1)
Chest injury	5 (0.0)	(0.0, 0.1)
Foot fracture	5 (0.0)	(0.0, 0.1)
Hand fracture	5 (0.0)	(0.0, 0.1)
Joint dislocation	5 (0.0)	(0.0, 0.1)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Skin abrasion	5 (0.0)	(0.0, 0.1)
Joint injury	4 (0.0)	(0.0, 0.1)
Meniscus injury	4 (0.0)	(0.0, 0.1)
Wrist fracture	4 (0.0)	(0.0, 0.1)
Animal bite	3 (0.0)	(0.0, 0.1)
Arthropod sting	3 (0.0)	(0.0, 0.1)
Burns second degree	3 (0.0)	(0.0, 0.1)
Cervical vertebral fracture	3 (0.0)	(0.0, 0.1)
Facial bones fracture	3 (0.0)	(0.0, 0.1)
Humerus fracture	3 (0.0)	(0.0, 0.1)
Patella fracture	3 (0.0)	(0.0, 0.1)
Tibia fracture	3 (0.0)	(0.0, 0.1)
Upper limb fracture	3 (0.0)	(0.0, 0.1)
Vaccination complication	3 (0.0)	(0.0, 0.1)
Concussion	2 (0.0)	(0.0, 0.1)
Craniocerebral injury	2 (0.0)	(0.0, 0.1)
Ligament rupture	2 (0.0)	(0.0, 0.1)
Radius fracture	2 (0.0)	(0.0, 0.1)
Rib fracture	2 (0.0)	(0.0, 0.1)
Thermal burn	2 (0.0)	(0.0, 0.1)
Bone contusion	1 (0.0)	(0.0, 0.0)
Bone fissure	1 (0.0)	(0.0, 0.0)
Burn oral cavity	1 (0.0)	(0.0, 0.0)
Burns first degree	1 (0.0)	(0.0, 0.0)
Burns third degree	1 (0.0)	(0.0, 0.0)
Cartilage injury	1 (0.0)	(0.0, 0.0)
Chemical burns of eye	1 (0.0)	(0.0, 0.0)
Corneal abrasion	1 (0.0)	(0.0, 0.0)
Eyelid injury	1 (0.0)	(0.0, 0.0)
Fibula fracture	1 (0.0)	(0.0, 0.0)
Foreign body in eye	1 (0.0)	(0.0, 0.0)
Fractured sacrum	1 (0.0)	(0.0, 0.0)
Head injury	1 (0.0)	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)
Jaw fracture	1 (0.0)	(0.0, 0.0)
Limb fracture	1 (0.0)	(0.0, 0.0)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Maternal exposure before pregnancy	1 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	1 (0.0)	(0.0, 0.0)
Muscle contusion	1 (0.0)	(0.0, 0.0)
Muscle rupture	1 (0.0)	(0.0, 0.0)
Overdose	1 (0.0)	(0.0, 0.0)
Pelvic fracture	1 (0.0)	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.0)
Post concussion syndrome	1 (0.0)	(0.0, 0.0)
Post procedural discomfort	1 (0.0)	(0.0, 0.0)
Post procedural swelling	1 (0.0)	(0.0, 0.0)
Procedural dizziness	1 (0.0)	(0.0, 0.0)
Spinal compression fracture	1 (0.0)	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)
Spinal fracture	1 (0.0)	(0.0, 0.0)
Stress fracture	1 (0.0)	(0.0, 0.0)
Subdural haematoma	1 (0.0)	(0.0, 0.0)
Sunburn	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)
Ulna fracture	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	94 (0.8)	(0.6, 1.0)
Body temperature increased	50 (0.4)	(0.3, 0.5)
Blood glucose increased	8 (0.1)	(0.0, 0.1)
SARS-CoV-2 antibody test positive	5 (0.0)	(0.0, 0.1)
Blood pressure increased	4 (0.0)	(0.0, 0.1)
Blood cholesterol increased	3 (0.0)	(0.0, 0.1)
Alanine aminotransferase increased	2 (0.0)	(0.0, 0.1)
Blood thyroid stimulating hormone increased	2 (0.0)	(0.0, 0.1)
Weight increased	2 (0.0)	(0.0, 0.1)
Aspartate aminotransferase increased	1 (0.0)	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)
Blood immunoglobulin E increased	1 (0.0)	(0.0, 0.0)
Blood potassium decreased	1 (0.0)	(0.0, 0.0)
Blood triglycerides increased	1 (0.0)	(0.0, 0.0)
Body temperature decreased	1 (0.0)	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.0)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.0)
Fractional exhaled nitric oxide increased	1 (0.0)	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.0)
Haemoglobin decreased	1 (0.0)	(0.0, 0.0)
Heart rate increased	1 (0.0)	(0.0, 0.0)
Intraocular pressure increased	1 (0.0)	(0.0, 0.0)
Liver function test increased	1 (0.0)	(0.0, 0.0)
Lymphocyte count decreased	1 (0.0)	(0.0, 0.0)
Mean cell volume decreased	1 (0.0)	(0.0, 0.0)
Platelet count decreased	1 (0.0)	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.0)
Troponin increased	1 (0.0)	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	81 (0.7)	(0.5, 0.8)
Decreased appetite	15 (0.1)	(0.1, 0.2)
Hyperlipidaemia	9 (0.1)	(0.0, 0.1)
Type 2 diabetes mellitus	9 (0.1)	(0.0, 0.1)
Vitamin D deficiency	8 (0.1)	(0.0, 0.1)
Hypercholesterolaemia	6 (0.0)	(0.0, 0.1)
Dyslipidaemia	5 (0.0)	(0.0, 0.1)
Glucose tolerance impaired	4 (0.0)	(0.0, 0.1)
Gout	3 (0.0)	(0.0, 0.1)
Hyperglycaemia	3 (0.0)	(0.0, 0.1)
Hypertriglyceridaemia	3 (0.0)	(0.0, 0.1)
Hypoglycaemia	3 (0.0)	(0.0, 0.1)
Hypokalaemia	3 (0.0)	(0.0, 0.1)
Dehydration	2 (0.0)	(0.0, 0.1)
Hyperkalaemia	2 (0.0)	(0.0, 0.1)
Hyperuricaemia	2 (0.0)	(0.0, 0.1)
Obesity	2 (0.0)	(0.0, 0.1)
Diabetes mellitus	1 (0.0)	(0.0, 0.0)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.0)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)
Hypocalcaemia	1 (0.0)	(0.0, 0.0)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.0)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Insulin resistance	1 (0.0)	(0.0, 0.0)
Metabolic syndrome	1 (0.0)	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	905 (7.5)	(7.1, 8.0)
Myalgia	549 (4.6)	(4.2, 5.0)
Arthralgia	153 (1.3)	(1.1, 1.5)
Pain in extremity	93 (0.8)	(0.6, 0.9)
Back pain	62 (0.5)	(0.4, 0.7)
Neck pain	20 (0.2)	(0.1, 0.3)
Muscle spasms	19 (0.2)	(0.1, 0.2)
Osteoarthritis	14 (0.1)	(0.1, 0.2)
Tendonitis	9 (0.1)	(0.0, 0.1)
Musculoskeletal stiffness	8 (0.1)	(0.0, 0.1)
Intervertebral disc protrusion	6 (0.0)	(0.0, 0.1)
Arthritis	5 (0.0)	(0.0, 0.1)
Bursitis	5 (0.0)	(0.0, 0.1)
Muscular weakness	5 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	5 (0.0)	(0.0, 0.1)
Periarthritis	5 (0.0)	(0.0, 0.1)
Musculoskeletal discomfort	4 (0.0)	(0.0, 0.1)
Intervertebral disc degeneration	3 (0.0)	(0.0, 0.1)
Joint stiffness	3 (0.0)	(0.0, 0.1)
Muscle contracture	3 (0.0)	(0.0, 0.1)
Rotator cuff syndrome	3 (0.0)	(0.0, 0.1)
Arthropathy	2 (0.0)	(0.0, 0.1)
Coccydynia	2 (0.0)	(0.0, 0.1)
Costochondritis	2 (0.0)	(0.0, 0.1)
Flank pain	2 (0.0)	(0.0, 0.1)
Joint range of motion decreased	2 (0.0)	(0.0, 0.1)
Limb discomfort	2 (0.0)	(0.0, 0.1)
Muscle twitching	2 (0.0)	(0.0, 0.1)
Musculoskeletal pain	2 (0.0)	(0.0, 0.1)
Pain in jaw	2 (0.0)	(0.0, 0.1)
Plantar fasciitis	2 (0.0)	(0.0, 0.1)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.1)
Tenosynovitis stenosans	2 (0.0)	(0.0, 0.1)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Bone disorder	1 (0.0)	(0.0, 0.0)
Bone pain	1 (0.0)	(0.0, 0.0)
Groin pain	1 (0.0)	(0.0, 0.0)
Intervertebral disc compression	1 (0.0)	(0.0, 0.0)
Joint effusion	1 (0.0)	(0.0, 0.0)
Joint instability	1 (0.0)	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)
Mobility decreased	1 (0.0)	(0.0, 0.0)
Muscle fatigue	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)
Osteopenia	1 (0.0)	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.0)
Spinal stenosis	1 (0.0)	(0.0, 0.0)
Spondylitis	1 (0.0)	(0.0, 0.0)
Synovial cyst	1 (0.0)	(0.0, 0.0)
Temporomandibular joint syndrome	1 (0.0)	(0.0, 0.0)
Torticollis	1 (0.0)	(0.0, 0.0)
Trigger finger	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	53 (0.4)	(0.3, 0.6)
Prostate cancer	5 (0.0)	(0.0, 0.1)
Basal cell carcinoma	4 (0.0)	(0.0, 0.1)
Lipoma	4 (0.0)	(0.0, 0.1)
Malignant melanoma	4 (0.0)	(0.0, 0.1)
Breast cancer	3 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	2 (0.0)	(0.0, 0.1)
Skin papilloma	2 (0.0)	(0.0, 0.1)
Transitional cell carcinoma	2 (0.0)	(0.0, 0.1)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.0)
Adenocarcinoma pancreas	1 (0.0)	(0.0, 0.0)
Adenoma benign	1 (0.0)	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)
Benign breast neoplasm	1 (0.0)	(0.0, 0.0)
Benign hydatidiform mole	1 (0.0)	(0.0, 0.0)
Benign uterine neoplasm	1 (0.0)	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.0)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.0)
Brain cancer metastatic	1 (0.0)	(0.0, 0.0)
Breast cancer in situ	1 (0.0)	(0.0, 0.0)
Carcinoid tumour of the stomach	1 (0.0)	(0.0, 0.0)
Chondroma	1 (0.0)	(0.0, 0.0)
Colon adenoma	1 (0.0)	(0.0, 0.0)
Fibroma	1 (0.0)	(0.0, 0.0)
Gallbladder cancer stage II	1 (0.0)	(0.0, 0.0)
Gastric cancer	1 (0.0)	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.0)
Meningioma benign	1 (0.0)	(0.0, 0.0)
Non-small cell lung cancer stage IV	1 (0.0)	(0.0, 0.0)
Seborrhoeic keratosis	1 (0.0)	(0.0, 0.0)
Skin cancer	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma of skin	1 (0.0)	(0.0, 0.0)
Thyroid cancer	1 (0.0)	(0.0, 0.0)
Uterine cancer	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	726 (6.0)	(5.6, 6.5)
Headache	572 (4.8)	(4.4, 5.2)
Dizziness	43 (0.4)	(0.3, 0.5)
Paraesthesia	15 (0.1)	(0.1, 0.2)
Lethargy	14 (0.1)	(0.1, 0.2)
Migraine	14 (0.1)	(0.1, 0.2)
Sciatica	9 (0.1)	(0.0, 0.1)
Tension headache	9 (0.1)	(0.0, 0.1)
Syncope	8 (0.1)	(0.0, 0.1)
Presyncope	6 (0.0)	(0.0, 0.1)
Tremor	6 (0.0)	(0.0, 0.1)
Dysgeusia	5 (0.0)	(0.0, 0.1)
Somnolence	4 (0.0)	(0.0, 0.1)
Disturbance in attention	3 (0.0)	(0.0, 0.1)
Facial paralysis	3 (0.0)	(0.0, 0.1)
Hypoaesthesia	3 (0.0)	(0.0, 0.1)
Sinus headache	3 (0.0)	(0.0, 0.1)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Subarachnoid haemorrhage	3 (0.0)	(0.0, 0.1)
Burning sensation	2 (0.0)	(0.0, 0.1)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)
Cervical radiculopathy	2 (0.0)	(0.0, 0.1)
Dizziness postural	2 (0.0)	(0.0, 0.1)
Migraine without aura	2 (0.0)	(0.0, 0.1)
Nerve compression	2 (0.0)	(0.0, 0.1)
Optic neuritis	2 (0.0)	(0.0, 0.1)
Restless legs syndrome	2 (0.0)	(0.0, 0.1)
Seizure	2 (0.0)	(0.0, 0.1)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)
Aphasia	1 (0.0)	(0.0, 0.0)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.0)
Depressed level of consciousness	1 (0.0)	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.0)
Hyperaesthesia	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)
Intracranial aneurysm	1 (0.0)	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)
Neuralgia	1 (0.0)	(0.0, 0.0)
Parosmia	1 (0.0)	(0.0, 0.0)
Periodic limb movement disorder	1 (0.0)	(0.0, 0.0)
Peripheral nerve lesion	1 (0.0)	(0.0, 0.0)
Peripheral sensory neuropathy	1 (0.0)	(0.0, 0.0)
Post herpetic neuralgia	1 (0.0)	(0.0, 0.0)
Radiculopathy	1 (0.0)	(0.0, 0.0)
Seizure like phenomena	1 (0.0)	(0.0, 0.0)
Toxic encephalopathy	1 (0.0)	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)
Vocal cord paralysis	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	3 (0.0)	(0.0, 0.1)
Abortion spontaneous	2 (0.0)	(0.0, 0.1)
Exposure during pregnancy	1 (0.0)	(0.0, 0.0)
PRODUCT ISSUES	1 (0.0)	(0.0, 0.0)
Device connection issue	1 (0.0)	(0.0, 0.0)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
PSYCHIATRIC DISORDERS	65 (0.5)	(0.4, 0.7)
Insomnia	17 (0.1)	(0.1, 0.2)
Anxiety	16 (0.1)	(0.1, 0.2)
Depression	11 (0.1)	(0.0, 0.2)
Anxiety disorder	4 (0.0)	(0.0, 0.1)
Abnormal dreams	3 (0.0)	(0.0, 0.1)
Attention deficit hyperactivity disorder	3 (0.0)	(0.0, 0.1)
Irritability	3 (0.0)	(0.0, 0.1)
Sleep disorder	3 (0.0)	(0.0, 0.1)
Disorientation	2 (0.0)	(0.0, 0.1)
Nightmare	2 (0.0)	(0.0, 0.1)
Generalised anxiety disorder	1 (0.0)	(0.0, 0.0)
Libido increased	1 (0.0)	(0.0, 0.0)
Panic attack	1 (0.0)	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.0)
Suicide attempt	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	42 (0.3)	(0.3, 0.5)
Nephrolithiasis	11 (0.1)	(0.0, 0.2)
Dysuria	6 (0.0)	(0.0, 0.1)
Pollakiuria	5 (0.0)	(0.0, 0.1)
Haematuria	3 (0.0)	(0.0, 0.1)
Acute kidney injury	2 (0.0)	(0.0, 0.1)
Bladder spasm	2 (0.0)	(0.0, 0.1)
Renal colic	2 (0.0)	(0.0, 0.1)
Urinary retention	2 (0.0)	(0.0, 0.1)
Bladder irritation	1 (0.0)	(0.0, 0.0)
Chronic kidney disease	1 (0.0)	(0.0, 0.0)
Hypertonic bladder	1 (0.0)	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.0)
Obstructive nephropathy	1 (0.0)	(0.0, 0.0)
Renal cyst	1 (0.0)	(0.0, 0.0)
Renal haematoma	1 (0.0)	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)
Urethral stenosis	1 (0.0)	(0.0, 0.0)
Urinary tract obstruction	1 (0.0)	(0.0, 0.0)
Vesical fistula	1 (0.0)	(0.0, 0.0)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	36 (0.3)	(0.2, 0.4)
Dysmenorrhoea	4 (0.0)	(0.0, 0.1)
Ovarian cyst	3 (0.0)	(0.0, 0.1)
Benign prostatic hyperplasia	2 (0.0)	(0.0, 0.1)
Breast pain	2 (0.0)	(0.0, 0.1)
Endometriosis	2 (0.0)	(0.0, 0.1)
Genital erythema	2 (0.0)	(0.0, 0.1)
Menorrhagia	2 (0.0)	(0.0, 0.1)
Menstruation irregular	2 (0.0)	(0.0, 0.1)
Amenorrhoea	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.0)
Dysfunctional uterine bleeding	1 (0.0)	(0.0, 0.0)
Endometrial thickening	1 (0.0)	(0.0, 0.0)
Haematospermia	1 (0.0)	(0.0, 0.0)
Mammary duct ectasia	1 (0.0)	(0.0, 0.0)
Menometrorrhagia	1 (0.0)	(0.0, 0.0)
Metrorrhagia	1 (0.0)	(0.0, 0.0)
Pelvic pain	1 (0.0)	(0.0, 0.0)
Polycystic ovaries	1 (0.0)	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.0)
Prostatitis	1 (0.0)	(0.0, 0.0)
Prostatomegaly	1 (0.0)	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.0)
Scrotal pain	1 (0.0)	(0.0, 0.0)
Testicular pain	1 (0.0)	(0.0, 0.0)
Testicular torsion	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)
Vaginal haemorrhage	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	145 (1.2)	(1.0, 1.4)
Oropharyngeal pain	24 (0.2)	(0.1, 0.3)
Nasal congestion	21 (0.2)	(0.1, 0.3)
Cough	17 (0.1)	(0.1, 0.2)
Rhinorrhoea	12 (0.1)	(0.1, 0.2)
Rhinitis allergic	9 (0.1)	(0.0, 0.1)
Asthma	8 (0.1)	(0.0, 0.1)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Dyspnoea	6 (0.0)	(0.0, 0.1)
Pulmonary embolism	6 (0.0)	(0.0, 0.1)
Sleep apnoea syndrome	5 (0.0)	(0.0, 0.1)
Throat irritation	5 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	5 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	4 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	3 (0.0)	(0.0, 0.1)
Epistaxis	3 (0.0)	(0.0, 0.1)
Asthmatic crisis	2 (0.0)	(0.0, 0.1)
Bronchospasm	2 (0.0)	(0.0, 0.1)
Nasal polyps	2 (0.0)	(0.0, 0.1)
Productive cough	2 (0.0)	(0.0, 0.1)
Respiratory tract congestion	2 (0.0)	(0.0, 0.1)
Sinus congestion	2 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.1)
Wheezing	2 (0.0)	(0.0, 0.1)
Allergic sinusitis	1 (0.0)	(0.0, 0.0)
Atelectasis	1 (0.0)	(0.0, 0.0)
Dry throat	1 (0.0)	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)
Emphysema	1 (0.0)	(0.0, 0.0)
Haemoptysis	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)
Nasal septum deviation	1 (0.0)	(0.0, 0.0)
Oropharyngeal discomfort	1 (0.0)	(0.0, 0.0)
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)
Pneumothorax	1 (0.0)	(0.0, 0.0)
Reflux laryngitis	1 (0.0)	(0.0, 0.0)
Respiratory failure	1 (0.0)	(0.0, 0.0)
Sneezing	1 (0.0)	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	153 (1.3)	(1.1, 1.5)
Rash	35 (0.3)	(0.2, 0.4)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Hyperhidrosis	16 (0.1)	(0.1, 0.2)
Pruritus	15 (0.1)	(0.1, 0.2)
Dermatitis contact	11 (0.1)	(0.0, 0.2)
Urticaria	11 (0.1)	(0.0, 0.2)
Night sweats	8 (0.1)	(0.0, 0.1)
Rash pruritic	6 (0.0)	(0.0, 0.1)
Erythema	5 (0.0)	(0.0, 0.1)
Dermal cyst	4 (0.0)	(0.0, 0.1)
Dermatitis	4 (0.0)	(0.0, 0.1)
Eczema	4 (0.0)	(0.0, 0.1)
Acne	3 (0.0)	(0.0, 0.1)
Actinic keratosis	3 (0.0)	(0.0, 0.1)
Dermatitis allergic	3 (0.0)	(0.0, 0.1)
Rash maculo-papular	3 (0.0)	(0.0, 0.1)
Alopecia	2 (0.0)	(0.0, 0.1)
Acne cystic	1 (0.0)	(0.0, 0.0)
Angioedema	1 (0.0)	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.0)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)
Dry skin	1 (0.0)	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.0)
Erythema nodosum	1 (0.0)	(0.0, 0.0)
Hand dermatitis	1 (0.0)	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.0)
Intertrigo	1 (0.0)	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.0)
Onycholysis	1 (0.0)	(0.0, 0.0)
Onychomadesis	1 (0.0)	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.0)
Papule	1 (0.0)	(0.0, 0.0)
Pityriasis	1 (0.0)	(0.0, 0.0)
Pseudofolliculitis	1 (0.0)	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.0)
Purpura	1 (0.0)	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.0)
Rash papular	1 (0.0)	(0.0, 0.0)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Rosacea	1 (0.0)	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.0)
Skin irritation	1 (0.0)	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.0)
Transient acantholytic dermatosis	1 (0.0)	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	2 (0.0)	(0.0, 0.1)
High risk sexual behaviour	1 (0.0)	(0.0, 0.0)
Miscarriage of partner	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	29 (0.2)	(0.2, 0.3)
Dental implantation	5 (0.0)	(0.0, 0.1)
Tooth extraction	3 (0.0)	(0.0, 0.1)
Wisdom teeth removal	2 (0.0)	(0.0, 0.1)
Botulinum toxin injection	1 (0.0)	(0.0, 0.0)
Cardioversion	1 (0.0)	(0.0, 0.0)
Carpal tunnel decompression	1 (0.0)	(0.0, 0.0)
Drug titration	1 (0.0)	(0.0, 0.0)
Endodontic procedure	1 (0.0)	(0.0, 0.0)
Facet joint block	1 (0.0)	(0.0, 0.0)
Finger amputation	1 (0.0)	(0.0, 0.0)
Gingival operation	1 (0.0)	(0.0, 0.0)
Inguinal hernia repair	1 (0.0)	(0.0, 0.0)
Lacrimal duct procedure	1 (0.0)	(0.0, 0.0)
Mammoplasty	1 (0.0)	(0.0, 0.0)
Meniscus operation	1 (0.0)	(0.0, 0.0)
Metabolic surgery	1 (0.0)	(0.0, 0.0)
Open reduction of fracture	1 (0.0)	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.0)
Radioactive iodine therapy	1 (0.0)	(0.0, 0.0)
Retinal operation	1 (0.0)	(0.0, 0.0)
Rotator cuff repair	1 (0.0)	(0.0, 0.0)
Sclerotherapy	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	78 (0.6)	(0.5, 0.8)
Hypertension	48 (0.4)	(0.3, 0.5)
Deep vein thrombosis	6 (0.0)	(0.0, 0.1)
Hot flush	6 (0.0)	(0.0, 0.1)
Aortic aneurysm	3 (0.0)	(0.0, 0.1)

Table 64. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Haematoma	3 (0.0)	(0.0, 0.1)
Flushing	2 (0.0)	(0.0, 0.1)
Hypotension	2 (0.0)	(0.0, 0.1)
Aortic dilatation	1 (0.0)	(0.0, 0.0)
Arterial occlusive disease	1 (0.0)	(0.0, 0.0)
Essential hypertension	1 (0.0)	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.0)
Lymphorrhoea	1 (0.0)	(0.0, 0.0)
Peripheral vascular disorder	1 (0.0)	(0.0, 0.0)
Systolic hypertension	1 (0.0)	(0.0, 0.0)
Thrombophlebitis superficial	1 (0.0)	(0.0, 0.0)
Varicose vein	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_all_bnt_pd2_p3_saf

Related Adverse Events – Cumulative Follow-Up to 6 Months After Dose 2 for BNT162b2 Group

From Dose 1 to 6 months after Dose 2, AEs assessed as related by the investigator during the cumulative blinded and open-label follow-up period were reported by 18.7% of participants in the BNT162b2 group (Table 62). Most related AEs were reactogenicity events and in the SOC of general disorders and administration site conditions (1944 [16.2%]).

The AE of lymphadenopathy in 29 (0.2%) participants was assessed by the investigator as related to study intervention.

Related AEs in the younger and older age groups were reported in 20.8% and 16.1% of original BNT162b2 participants.

2.5.5.5.3.5. Open-Label Follow-Up Period – Original Placebo Participants Who Received BNT162b2

2.5.5.5.3.5.1. Summary of Adverse Events

An overview of AEs for participants originally randomized to placebo from the time of vaccination with BNT162b2 (Dose 3) up to the data cutoff date during the open-label follow-up period is presented in Table 65.

Overall, there are 19,525 original placebo participants who then were unblinded and received open-label BNT162b2. IRs for any AE and at least 1 related AE were 205.4 per 100 PY and 189.5 per 100 PY, respectively. IRs of severe AEs, SAEs, and AEs leading to withdrawal were 6.0 per 100 PY, 2.7 per 100 PY, and 0.8 per 100 PY. The IR for discontinuations because of related AEs was 0.5 per 100 PY, and 2 participants died (Section 2.5.5.5.4.4).

IRs in Table 60 include all AEs reported for these participants including AEs reported while on placebo (in the blinded follow-up period). Additionally, all of these placebo participants received open-label BNT162b2, with shorter exposure time compared with participants who were originally randomized to BNT162b2 (23.8 per 100 PY vs 83.4 per 100 PY, respectively (Table 65 vs Table 60). As expected, in comparison to participants randomized to BNT162b2 from Dose 1 to the unblinding date, IRs for any AE and at least 1 related AE and severe AE for participants who originally received placebo and then received BNT162b2 are greater (205.4 per 100 PY, 189.5 per 100 PY, 6.0 per 100 PY) than IRs for participants who originally were randomized to BNT162b2, respectively (83.2 per 100 PY, 62.9 per 100 PY, 4.3 per 100 PY). However, IRs for life-threatening AEs, SAEs, AEs leading to withdrawal, and deaths were similar (0.5 per 100 PY, 2.7 per 100 PY, 0.8 per 100 PY, 0.1 per 100 PY vs 0.6 per 100 PY, 3.2 per 100 PY, 0.5 per 100 PY, 0.2 per 100 PY, respectively). There was 1 related SAE of anaphylactoid reaction for a placebo participant who was vaccinated with BNT162b2 (see details in Section 2.5.5.5.7.1).

Table 65. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021) – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	4885	205.4	(199.6, 211.2)
Related[f]	4508	189.5	(184.0, 195.1)
Severe	142	6.0	(5.0, 7.0)
Life-threatening	11	0.5	(0.2, 0.8)
Any serious adverse event	65	2.7	(2.1, 3.5)
Related[f]	1	0.0	(0.0, 0.2)

Table 65. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021) – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
Adverse Event	**n[c]**	**IR (/100 PY)[d]**	**(95% CI[e])**
Severe	37	1.6	(1.1, 2.1)
Life-threatening	11	0.5	(0.2, 0.8)
Any adverse event leading to withdrawal	19	0.8	(0.5, 1.2)
Related[f]	12	0.5	(0.3, 0.9)
Severe	2	0.1	(0.0, 0.3)
Life-threatening	4	0.2	(0.0, 0.4)
Death	2	0.1	(0.0, 0.3)

Note: Dose 3 = First dose of BNT162b2 (30 µg).
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s092_cr_cut_p3x_saf

Subgroup Analyses

IRs of AEs for original placebo participants who then received BNT162b2 were observed by baseline SARS CoV-2 positive and negative status subgroups. Overall, IRs for AEs were similar in the participants who were baseline positive (222.9 per 100 PY [95% CI: 186.5, 264.3]) compared to baseline negative (205 per 100 PY [95% CI 199.6, 211.3]). There were 2 SAEs (considered not related), 1 AE leading to withdrawal, and no deaths reported in the baseline positive group.

Open-Label Follow-Up Period – Original Placebo Participants who had COVID-19 Occurrence After Dose 1 and Then Received BNT162b2

The subset of participants originally randomized to placebo, who had a COVID-19 case after Dose 1 of placebo and were later unblinded to receive BNT162b2 (Dose 3), were evaluated for safety. Overall, a similar safety profile was observed for this participant group, compared to those originally randomized to BNT162b2.

There were 853 original placebo participants who developed COVID-19 and subsequently were vaccinated with BNT162b2. For original placebo participants who had COVID-19 occurrence after Dose 1 and then received BNT162b2, IRs for any AE and at least 1 related AE from Dose 3 (first dose of BNT162b2 30 µg) were 256.8 per 100 PY and 240.9 per 100 PY, respectively. IRs of severe AEs, SAEs, and AEs leading to withdrawal were 4.6 per 100 PY, 3.4 per 100 PY, and 3.4 per 100 PY. The IR for discontinuations because of related AEs was 3.4 per 100 PY.

IRs for SAEs were similar for the placebo participants who developed COVID-19 and subsequently were vaccinated with BNT162b2 (3.4 per 100 P [95% CI: 0.7, 10.0]) and participants originally randomized to BNT162b2 (3.2 per 100 PY [95% CI: 2.8, 3.6]), respectively. None of the SAEs in the placebo participants who developed COVID-19 and subsequently were vaccinated with BNT162b2 were considered related to BNT162b2. Three participants in this group had AEs leading to withdrawal that were assessed as related to BNT162b2: 1 participant with an AE of allergy to vaccine, 1 participant with an AE of pain, and 1 participant with 5 AEs (chills, injection site pain, myalgia, headache, and diarrhea). No deaths were reported in placebo participants who developed COVID-19 and subsequently were vaccinated with BNT162b2.

The exposure time for the group of placebo participants who developed COVID-19 and were subsequently vaccinated with BNT162b2 is small (0.9) compared to the exposure time in blinded placebo-controlled period (83.4; see Table 60), therefore direct comparisons must be interpreted with caution. In this context, rates of SAEs were similar in the groups (3.4 per 100 PY vs 3.2 per 100 PY, respectively).

2.5.5.5.3.5.2. Analysis of Adverse Events

Adverse Events by System Organ Class and Preferred Term

Among participants originally randomized to placebo from the time of vaccination with BNT162b2 (Dose 3) to the data cutoff date during open-label follow-up, the IR for participants who reported at least 1 AE was 205.4 per 100 PY (Table 66). Most AEs reported from Dose 3 (first dose of BNT162b2) to the data cutoff date were in SOCs with reactogenicity events:

- general disorders and administration site conditions: 175.3 per 100 PY
- musculoskeletal and connective tissue disorders: 52.3 per 100 PY
- nervous system disorders: 50.5 per 100 PY
- gastrointestinal disorders: 14.3 per 100 PY

As shown in Table 66, the most frequently reported AEs (IRs) overall were injection site pain (123.8 per 100 PY), fatigue (58.0 per 100 PY), headache (46.6 per 100 PY), chills (41.8 per 100 PY), myalgia (38.9 per 100 PY), and pyrexia (38.1 per 100 PY).

After participants who originally received placebo were unblinded and then received BNT162b2 after unblinding, events related to reactogenicity were not reported using an e diary but were instead reported as AEs. An analysis was conducted to evaluate if the imbalance in AEs observed from Dose 3 to the unblinding date was attributed to reactogenicity events. The analysis examined the AEs reported within 7 days after each dose (Dose 3 and Dose 4), which represented the reactogenicity reporting period.

PTs reported from Dose 3 to 7 days after Dose 3 and from Dose 4 to 7 days after Dose 4 in the SOCs of general disorders and administration site conditions (injection site pain, chills, fatigue, and pyrexia), musculoskeletal and connective tissue disorders (myalgia), and nervous system disorders (headache) represented the majority of PTs reported in those SOCs.

Allergy to vaccine, anaphylactoid reaction, and deep vein thrombosis were reported in 1 participant each from Dose 3 to 7 days after Dose 3:

- One participant reported an AE of grade 2 allergy to vaccine, which occurred on the day of Dose 3 vaccination, had a duration of 2 days, and resolved; this AE was assessed by the investigator as related to the study intervention.

- One participant with an ongoing medical history significant for drug hypersensitivity and food and seasonal allergies reported a life-threatening SAE of anaphylactoid reaction, which occurred 2 days after Dose 3 and was resolved that same day; this SAE was assessed by the investigator as related to the study intervention (detailed in Section 2.5.5.5.7.1).

- One participant with a past medical history significant for deep vein thrombosis, hypertension, pulmonary arterial hypertension, right ventricular enlargement, hypercholesteremia, atherosclerosis and bilateral peripheral neuropathy reported a grade 2 SAE of deep vein thrombosis (lower right extremity) and grade 1 SAE of pulmonary embolism, which both occurred 2 days after Dose 3, had both resolved with a duration of 3 days; both SAEs were assessed by the investigator as not related to the study intervention.

Analysis of Reactogenicity Terms Reported Within 7 Days After Each Dose

An analysis of AEs reported within 7 days after each dose of open-label BNT162b2, which represented the reactogenicity reporting period in the study, evaluated AEs consistent with reactogenicity events (Section 2.5.5.5.2). In addition to analysis of AEs corresponding to e-diary terms, consideration was given to additional AEs that were reported within 7 days after Dose 3 or Dose 4 such as pain in extremity, decreased appetite, lethargy, asthenia, malaise, night sweats, and hyperhidrosis. Similar to the analysis that examined these events 7 days within Dose 1 and Dose 2 of BNT162b2 in blinded follow-up (2.5.5.5.3.1.2), these events reported in open-label follow-up are interpreted as attributable to the experience of local

reactions and systemic events after vaccination with Dose 3 and Dose 4 (first and second dose of BNT162b2).

These results are consistent with the pattern seen during the blinded placebo-controlled follow-up period from Dose 1 to 1 month after Dose 2 (Section 2.5.5.5.3.1.2), which confirms that the greater rates of AEs observed overall in the BNT162b2 group compared with the placebo group were largely attributable to reactogenicity events for that time period.

Table 66. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	4885	205.4	(199.6, 211.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	88	3.7	(3.0, 4.6)
Anaemia	2	0.1	(0.0, 0.3)
Coagulopathy	1	0.0	(0.0, 0.2)
Iron deficiency anaemia	2	0.1	(0.0, 0.3)
Lymph node pain	6	0.3	(0.1, 0.5)
Lymphadenitis	2	0.1	(0.0, 0.3)
Lymphadenopathy	76	3.2	(2.5, 4.0)
CARDIAC DISORDERS	17	0.7	(0.4, 1.1)
Acute myocardial infarction	1	0.0	(0.0, 0.2)
Angina pectoris	1	0.0	(0.0, 0.2)
Arrhythmia	1	0.0	(0.0, 0.2)
Arteriospasm coronary	1	0.0	(0.0, 0.2)
Atrial fibrillation	5	0.2	(0.1, 0.5)
Atrial flutter	1	0.0	(0.0, 0.2)
Cardiac failure congestive	1	0.0	(0.0, 0.2)
Cardio-respiratory arrest	1	0.0	(0.0, 0.2)
Cardiovascular disorder	1	0.0	(0.0, 0.2)
Coronary artery disease	1	0.0	(0.0, 0.2)
Ischaemic cardiomyopathy	1	0.0	(0.0, 0.2)
Myocardial infarction	1	0.0	(0.0, 0.2)
Palpitations	1	0.0	(0.0, 0.2)
Supraventricular tachycardia	1	0.0	(0.0, 0.2)
Tachycardia	2	0.1	(0.0, 0.3)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	4	0.2	(0.0, 0.4)
Atrial septal defect	1	0.0	(0.0, 0.2)

Table 66. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
BRCA2 gene mutation	1	0.0	(0.0, 0.2)
Factor II mutation	1	0.0	(0.0, 0.2)
Hypertrophic cardiomyopathy	1	0.0	(0.0, 0.2)
EAR AND LABYRINTH DISORDERS	18	0.8	(0.4, 1.2)
Cerumen impaction	1	0.0	(0.0, 0.2)
Deafness neurosensory	1	0.0	(0.0, 0.2)
Deafness unilateral	1	0.0	(0.0, 0.2)
Ear discomfort	1	0.0	(0.0, 0.2)
Ear pain	4	0.2	(0.0, 0.4)
Eustachian tube dysfunction	2	0.1	(0.0, 0.3)
Hypoacusis	1	0.0	(0.0, 0.2)
Meniere's disease	1	0.0	(0.0, 0.2)
Sudden hearing loss	1	0.0	(0.0, 0.2)
Tinnitus	2	0.1	(0.0, 0.3)
Vertigo	6	0.3	(0.1, 0.5)
ENDOCRINE DISORDERS	4	0.2	(0.0, 0.4)
Hypothyroidism	2	0.1	(0.0, 0.3)
Thyroid disorder	1	0.0	(0.0, 0.2)
Thyroid mass	1	0.0	(0.0, 0.2)
EYE DISORDERS	26	1.1	(0.7, 1.6)
Blepharitis	1	0.0	(0.0, 0.2)
Cataract	4	0.2	(0.0, 0.4)
Conjunctival haemorrhage	1	0.0	(0.0, 0.2)
Dacryostenosis acquired	1	0.0	(0.0, 0.2)
Diplopia	1	0.0	(0.0, 0.2)
Dry eye	1	0.0	(0.0, 0.2)
Erythema of eyelid	1	0.0	(0.0, 0.2)
Eye irritation	1	0.0	(0.0, 0.2)
Eye pain	5	0.2	(0.1, 0.5)
Eye swelling	1	0.0	(0.0, 0.2)
Keratitis	2	0.1	(0.0, 0.3)
Lacrimation increased	3	0.1	(0.0, 0.4)
Meibomianitis	1	0.0	(0.0, 0.2)
Ocular discomfort	1	0.0	(0.0, 0.2)
Visual impairment	1	0.0	(0.0, 0.2)
Vitreous floaters	1	0.0	(0.0, 0.2)

Table 66. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
GASTROINTESTINAL DISORDERS	339	14.3	(12.8, 15.9)
Abdominal discomfort	4	0.2	(0.0, 0.4)
Abdominal distension	1	0.0	(0.0, 0.2)
Abdominal pain	12	0.5	(0.3, 0.9)
Abdominal pain lower	2	0.1	(0.0, 0.3)
Abdominal pain upper	13	0.5	(0.3, 0.9)
Anal fistula	2	0.1	(0.0, 0.3)
Anal prolapse	1	0.0	(0.0, 0.2)
Chronic gastritis	1	0.0	(0.0, 0.2)
Constipation	4	0.2	(0.0, 0.4)
Dental caries	1	0.0	(0.0, 0.2)
Diarrhoea	91	3.8	(3.1, 4.7)
Dry mouth	3	0.1	(0.0, 0.4)
Duodenitis	1	0.0	(0.0, 0.2)
Dyspepsia	5	0.2	(0.1, 0.5)
Gastric ulcer	1	0.0	(0.0, 0.2)
Gastritis	5	0.2	(0.1, 0.5)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.2)
Gastrointestinal necrosis	1	0.0	(0.0, 0.2)
Gastrointestinal sounds abnormal	1	0.0	(0.0, 0.2)
Gastrooesophageal reflux disease	7	0.3	(0.1, 0.6)
Gingival bleeding	1	0.0	(0.0, 0.2)
Haemorrhoids	1	0.0	(0.0, 0.2)
Hiatus hernia	2	0.1	(0.0, 0.3)
Hyperaesthesia teeth	1	0.0	(0.0, 0.2)
Hypoaesthesia oral	1	0.0	(0.0, 0.2)
Intestinal obstruction	1	0.0	(0.0, 0.2)
Intestinal ulcer perforation	1	0.0	(0.0, 0.2)
Irritable bowel syndrome	2	0.1	(0.0, 0.3)
Large intestine polyp	1	0.0	(0.0, 0.2)
Nausea	160	6.7	(5.7, 7.9)
Oedema mouth	1	0.0	(0.0, 0.2)
Oral mucosal blistering	1	0.0	(0.0, 0.2)
Oral pain	1	0.0	(0.0, 0.2)
Oral pruritus	1	0.0	(0.0, 0.2)
Pancreatitis acute	2	0.1	(0.0, 0.3)
Retching	1	0.0	(0.0, 0.2)

Table 66. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Small intestinal obstruction	1	0.0	(0.0, 0.2)
Stomatitis	2	0.1	(0.0, 0.3)
Submaxillary gland enlargement	1	0.0	(0.0, 0.2)
Tongue disorder	1	0.0	(0.0, 0.2)
Tongue oedema	1	0.0	(0.0, 0.2)
Toothache	1	0.0	(0.0, 0.2)
Umbilical hernia	1	0.0	(0.0, 0.2)
Vomiting	48	2.0	(1.5, 2.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4169	175.3	(170.0, 180.7)
Application site pain	2	0.1	(0.0, 0.3)
Asthenia	36	1.5	(1.1, 2.1)
Axillary pain	3	0.1	(0.0, 0.4)
Chest discomfort	2	0.1	(0.0, 0.3)
Chest pain	4	0.2	(0.0, 0.4)
Chills	994	41.8	(39.2, 44.5)
Crying	1	0.0	(0.0, 0.2)
Discomfort	2	0.1	(0.0, 0.3)
Drug withdrawal syndrome	1	0.0	(0.0, 0.2)
Facial pain	1	0.0	(0.0, 0.2)
Fatigue	1379	58.0	(55.0, 61.1)
Feeling abnormal	6	0.3	(0.1, 0.5)
Feeling cold	2	0.1	(0.0, 0.3)
Feeling hot	6	0.3	(0.1, 0.5)
Gait disturbance	1	0.0	(0.0, 0.2)
Implant site pain	1	0.0	(0.0, 0.2)
Inflammation	1	0.0	(0.0, 0.2)
Influenza like illness	1	0.0	(0.0, 0.2)
Injection site bruising	16	0.7	(0.4, 1.1)
Injection site discomfort	3	0.1	(0.0, 0.4)
Injection site erythema	66	2.8	(2.1, 3.5)
Injection site haematoma	2	0.1	(0.0, 0.3)
Injection site haemorrhage	1	0.0	(0.0, 0.2)
Injection site hypersensitivity	1	0.0	(0.0, 0.2)
Injection site hypoaesthesia	2	0.1	(0.0, 0.3)
Injection site induration	1	0.0	(0.0, 0.2)
Injection site irritation	1	0.0	(0.0, 0.2)

Table 66. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Injection site lymphadenopathy	1	0.0	(0.0, 0.2)
Injection site mass	1	0.0	(0.0, 0.2)
Injection site nodule	2	0.1	(0.0, 0.3)
Injection site oedema	2	0.1	(0.0, 0.3)
Injection site pain	2944	123.8	(119.3, 128.3)
Injection site pruritus	18	0.8	(0.4, 1.2)
Injection site rash	4	0.2	(0.0, 0.4)
Injection site reaction	2	0.1	(0.0, 0.3)
Injection site swelling	65	2.7	(2.1, 3.5)
Injection site urticaria	1	0.0	(0.0, 0.2)
Injection site warmth	3	0.1	(0.0, 0.4)
Malaise	83	3.5	(2.8, 4.3)
Non-cardiac chest pain	1	0.0	(0.0, 0.2)
Oedema peripheral	2	0.1	(0.0, 0.3)
Pain	394	16.6	(15.0, 18.3)
Pelvic mass	1	0.0	(0.0, 0.2)
Peripheral swelling	7	0.3	(0.1, 0.6)
Pyrexia	906	38.1	(35.6, 40.6)
Swelling	3	0.1	(0.0, 0.4)
Swelling face	4	0.2	(0.0, 0.4)
Vaccination site pain	3	0.1	(0.0, 0.4)
Vaccination site reaction	1	0.0	(0.0, 0.2)
Vessel puncture site haematoma	1	0.0	(0.0, 0.2)
HEPATOBILIARY DISORDERS	3	0.1	(0.0, 0.4)
Cholecystitis	1	0.0	(0.0, 0.2)
Cholelithiasis	1	0.0	(0.0, 0.2)
Hepatitis acute	1	0.0	(0.0, 0.2)
IMMUNE SYSTEM DISORDERS	7	0.3	(0.1, 0.6)
Allergy to vaccine	1	0.0	(0.0, 0.2)
Anaphylactoid reaction	1	0.0	(0.0, 0.2)
Hypersensitivity	1	0.0	(0.0, 0.2)
Seasonal allergy	4	0.2	(0.0, 0.4)
INFECTIONS AND INFESTATIONS	136	5.7	(4.8, 6.8)
Abscess	1	0.0	(0.0, 0.2)
Appendicitis perforated	1	0.0	(0.0, 0.2)
Asymptomatic bacteriuria	1	0.0	(0.0, 0.2)

Table 66. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
COVID-19 pneumonia	1	0.0	(0.0, 0.2)
Candida infection	1	0.0	(0.0, 0.2)
Cellulitis	3	0.1	(0.0, 0.4)
Chlamydial infection	1	0.0	(0.0, 0.2)
Clostridium difficile infection	1	0.0	(0.0, 0.2)
Conjunctivitis	6	0.3	(0.1, 0.5)
Cystitis	1	0.0	(0.0, 0.2)
Demodicidosis	1	0.0	(0.0, 0.2)
Diverticulitis	2	0.1	(0.0, 0.3)
Ear infection	8	0.3	(0.1, 0.7)
Eye infection	1	0.0	(0.0, 0.2)
Focal peritonitis	1	0.0	(0.0, 0.2)
Folliculitis	1	0.0	(0.0, 0.2)
Fungal skin infection	3	0.1	(0.0, 0.4)
Genital herpes	1	0.0	(0.0, 0.2)
Genital herpes simplex	2	0.1	(0.0, 0.3)
Helicobacter gastritis	1	0.0	(0.0, 0.2)
Herpes simplex	2	0.1	(0.0, 0.3)
Herpes zoster	8	0.3	(0.1, 0.7)
Hordeolum	2	0.1	(0.0, 0.3)
Infected cyst	1	0.0	(0.0, 0.2)
Infection	1	0.0	(0.0, 0.2)
Labyrinthitis	1	0.0	(0.0, 0.2)
Localised infection	2	0.1	(0.0, 0.3)
Mastitis	1	0.0	(0.0, 0.2)
Onychomycosis	1	0.0	(0.0, 0.2)
Oral candidiasis	1	0.0	(0.0, 0.2)
Oral herpes	3	0.1	(0.0, 0.4)
Osteomyelitis	1	0.0	(0.0, 0.2)
Otitis externa	2	0.1	(0.0, 0.3)
Otitis media	2	0.1	(0.0, 0.3)
Pelvic abscess	1	0.0	(0.0, 0.2)
Pneumonia	2	0.1	(0.0, 0.3)
Postoperative wound infection	1	0.0	(0.0, 0.2)
Rhinitis	2	0.1	(0.0, 0.3)
Sinusitis	7	0.3	(0.1, 0.6)
Subcutaneous abscess	2	0.1	(0.0, 0.3)

Table 66. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Suspected COVID-19	1	0.0	(0.0, 0.2)
Taeniasis	1	0.0	(0.0, 0.2)
Tinea infection	1	0.0	(0.0, 0.2)
Tinea pedis	2	0.1	(0.0, 0.3)
Tonsillitis	2	0.1	(0.0, 0.3)
Tooth abscess	4	0.2	(0.0, 0.4)
Tooth infection	12	0.5	(0.3, 0.9)
Urinary tract infection	30	1.3	(0.9, 1.8)
Urosepsis	1	0.0	(0.0, 0.2)
Vulvitis	1	0.0	(0.0, 0.2)
Vulvovaginal candidiasis	3	0.1	(0.0, 0.4)
Vulvovaginal mycotic infection	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	90	3.8	(3.0, 4.7)
Animal bite	1	0.0	(0.0, 0.2)
Ankle fracture	2	0.1	(0.0, 0.3)
Arthropod bite	3	0.1	(0.0, 0.4)
Chest injury	1	0.0	(0.0, 0.2)
Contusion	9	0.4	(0.2, 0.7)
Corneal abrasion	1	0.0	(0.0, 0.2)
Exposure during pregnancy	5	0.2	(0.1, 0.5)
Eye contusion	1	0.0	(0.0, 0.2)
Facial bones fracture	1	0.0	(0.0, 0.2)
Fall	20	0.8	(0.5, 1.3)
Fibula fracture	2	0.1	(0.0, 0.3)
Foot fracture	4	0.2	(0.0, 0.4)
Frostbite	1	0.0	(0.0, 0.2)
Hand fracture	3	0.1	(0.0, 0.4)
Head injury	1	0.0	(0.0, 0.2)
Injection related reaction	1	0.0	(0.0, 0.2)
Joint dislocation	1	0.0	(0.0, 0.2)
Ligament injury	1	0.0	(0.0, 0.2)
Ligament sprain	6	0.3	(0.1, 0.5)
Limb injury	4	0.2	(0.0, 0.4)
Lip injury	1	0.0	(0.0, 0.2)
Lower limb fracture	1	0.0	(0.0, 0.2)
Maternal exposure during pregnancy	3	0.1	(0.0, 0.4)

Table 66. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Meniscus injury	1	0.0	(0.0, 0.2)
Muscle rupture	1	0.0	(0.0, 0.2)
Muscle strain	2	0.1	(0.0, 0.3)
Postoperative ileus	1	0.0	(0.0, 0.2)
Procedural pain	6	0.3	(0.1, 0.5)
Radius fracture	1	0.0	(0.0, 0.2)
Road traffic accident	2	0.1	(0.0, 0.3)
Scapula fracture	1	0.0	(0.0, 0.2)
Seroma	1	0.0	(0.0, 0.2)
Skin abrasion	2	0.1	(0.0, 0.3)
Skin laceration	10	0.4	(0.2, 0.8)
Spinal fracture	1	0.0	(0.0, 0.2)
Subdural haematoma	1	0.0	(0.0, 0.2)
Tendon injury	1	0.0	(0.0, 0.2)
Tendon rupture	1	0.0	(0.0, 0.2)
Thermal burn	2	0.1	(0.0, 0.3)
Tooth fracture	6	0.3	(0.1, 0.5)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.2)
Upper limb fracture	2	0.1	(0.0, 0.3)
Wound	1	0.0	(0.0, 0.2)
Wrist fracture	1	0.0	(0.0, 0.2)
INVESTIGATIONS	107	4.5	(3.7, 5.4)
Alanine aminotransferase increased	2	0.1	(0.0, 0.3)
Antinuclear antibody positive	1	0.0	(0.0, 0.2)
Aspartate aminotransferase increased	2	0.1	(0.0, 0.3)
Blood cholesterol increased	3	0.1	(0.0, 0.4)
Blood pressure increased	6	0.3	(0.1, 0.5)
Blood testosterone decreased	2	0.1	(0.0, 0.3)
Body temperature increased	91	3.8	(3.1, 4.7)
C-reactive protein increased	1	0.0	(0.0, 0.2)
Heart rate increased	1	0.0	(0.0, 0.2)
SARS-CoV-2 antibody test positive	1	0.0	(0.0, 0.2)
Troponin increased	1	0.0	(0.0, 0.2)
METABOLISM AND NUTRITION DISORDERS	29	1.2	(0.8, 1.8)
Decreased appetite	14	0.6	(0.3, 1.0)
Diabetes mellitus	1	0.0	(0.0, 0.2)

Table 66. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Diabetes mellitus inadequate control	1	0.0	(0.0, 0.2)
Dyslipidaemia	2	0.1	(0.0, 0.3)
Glucose tolerance impaired	2	0.1	(0.0, 0.3)
Gout	1	0.0	(0.0, 0.2)
Hypercholesterolaemia	1	0.0	(0.0, 0.2)
Hyperglycaemia	2	0.1	(0.0, 0.3)
Insulin resistance	2	0.1	(0.0, 0.3)
Lactic acidosis	1	0.0	(0.0, 0.2)
Type 2 diabetes mellitus	2	0.1	(0.0, 0.3)
Vitamin D deficiency	1	0.0	(0.0, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1245	52.3	(49.5, 55.3)
Arthralgia	149	6.3	(5.3, 7.4)
Arthritis	3	0.1	(0.0, 0.4)
Back pain	32	1.3	(0.9, 1.9)
Bursitis	1	0.0	(0.0, 0.2)
Flank pain	2	0.1	(0.0, 0.3)
Foot deformity	1	0.0	(0.0, 0.2)
Groin pain	1	0.0	(0.0, 0.2)
Intervertebral disc protrusion	2	0.1	(0.0, 0.3)
Joint range of motion decreased	2	0.1	(0.0, 0.3)
Joint swelling	1	0.0	(0.0, 0.2)
Limb discomfort	1	0.0	(0.0, 0.2)
Mobility decreased	1	0.0	(0.0, 0.2)
Muscle fatigue	2	0.1	(0.0, 0.3)
Muscle spasms	1	0.0	(0.0, 0.2)
Muscular weakness	4	0.2	(0.0, 0.4)
Musculoskeletal chest pain	1	0.0	(0.0, 0.2)
Musculoskeletal pain	1	0.0	(0.0, 0.2)
Musculoskeletal stiffness	12	0.5	(0.3, 0.9)
Myalgia	925	38.9	(36.4, 41.5)
Neck pain	11	0.5	(0.2, 0.8)
Osteoarthritis	9	0.4	(0.2, 0.7)
Osteoporosis	1	0.0	(0.0, 0.2)
Pain in extremity	154	6.5	(5.5, 7.6)
Periarthritis	1	0.0	(0.0, 0.2)
Plantar fasciitis	3	0.1	(0.0, 0.4)

Table 66. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Rheumatoid arthritis	1	0.0	(0.0, 0.2)
Rotator cuff syndrome	2	0.1	(0.0, 0.3)
Sacroiliitis	1	0.0	(0.0, 0.2)
Sjogren's syndrome	1	0.0	(0.0, 0.2)
Synovial cyst	1	0.0	(0.0, 0.2)
Temporomandibular joint syndrome	1	0.0	(0.0, 0.2)
Tendonitis	1	0.0	(0.0, 0.2)
Trigger finger	1	0.0	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	13	0.5	(0.3, 0.9)
Bladder neoplasm	1	0.0	(0.0, 0.2)
Bowen's disease	1	0.0	(0.0, 0.2)
Brain neoplasm	1	0.0	(0.0, 0.2)
Breast cancer	1	0.0	(0.0, 0.2)
Breast cancer stage II	1	0.0	(0.0, 0.2)
Hepatic cancer	1	0.0	(0.0, 0.2)
Lipoma	1	0.0	(0.0, 0.2)
Meningioma	1	0.0	(0.0, 0.2)
Neoplasm	1	0.0	(0.0, 0.2)
Non-small cell lung cancer stage III	1	0.0	(0.0, 0.2)
Rectal cancer	1	0.0	(0.0, 0.2)
Seborrhoeic keratosis	1	0.0	(0.0, 0.2)
Skin papilloma	1	0.0	(0.0, 0.2)
Squamous cell carcinoma	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	1201	50.5	(47.7, 53.4)
Amnesia	1	0.0	(0.0, 0.2)
Arachnoid cyst	1	0.0	(0.0, 0.2)
Balance disorder	2	0.1	(0.0, 0.3)
Brachial plexopathy	1	0.0	(0.0, 0.2)
Carpal tunnel syndrome	1	0.0	(0.0, 0.2)
Cerebrovascular accident	4	0.2	(0.0, 0.4)
Cervical radiculopathy	1	0.0	(0.0, 0.2)
Cognitive disorder	1	0.0	(0.0, 0.2)
Disturbance in attention	4	0.2	(0.0, 0.4)
Dizziness	47	2.0	(1.5, 2.6)
Dysgeusia	2	0.1	(0.0, 0.3)

Table 66. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Encephalopathy	1	0.0	(0.0, 0.2)
Facial paralysis	3	0.1	(0.0, 0.4)
Head discomfort	1	0.0	(0.0, 0.2)
Headache	1108	46.6	(43.9, 49.4)
Hemiplegia	1	0.0	(0.0, 0.2)
Hyperaesthesia	2	0.1	(0.0, 0.3)
Hypoaesthesia	2	0.1	(0.0, 0.3)
Hypogeusia	1	0.0	(0.0, 0.2)
Lethargy	9	0.4	(0.2, 0.7)
Loss of consciousness	1	0.0	(0.0, 0.2)
Mental impairment	2	0.1	(0.0, 0.3)
Migraine	6	0.3	(0.1, 0.5)
Migraine with aura	1	0.0	(0.0, 0.2)
Nerve compression	1	0.0	(0.0, 0.2)
Paraesthesia	14	0.6	(0.3, 1.0)
Parosmia	1	0.0	(0.0, 0.2)
Piriformis syndrome	1	0.0	(0.0, 0.2)
Presyncope	1	0.0	(0.0, 0.2)
Radiculopathy	1	0.0	(0.0, 0.2)
Sciatica	1	0.0	(0.0, 0.2)
Seizure	1	0.0	(0.0, 0.2)
Somnolence	13	0.5	(0.3, 0.9)
Speech disorder	1	0.0	(0.0, 0.2)
Syncope	4	0.2	(0.0, 0.4)
Transient ischaemic attack	2	0.1	(0.0, 0.3)
Tremor	2	0.1	(0.0, 0.3)
Visual field defect	1	0.0	(0.0, 0.2)
PSYCHIATRIC DISORDERS	43	1.8	(1.3, 2.4)
Abnormal dreams	1	0.0	(0.0, 0.2)
Alcohol withdrawal syndrome	1	0.0	(0.0, 0.2)
Anxiety	9	0.4	(0.2, 0.7)
Attention deficit hyperactivity disorder	3	0.1	(0.0, 0.4)
Bipolar disorder	1	0.0	(0.0, 0.2)
Completed suicide	1	0.0	(0.0, 0.2)
Confusional state	2	0.1	(0.0, 0.3)
Depression	3	0.1	(0.0, 0.4)

Table 66. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Generalised anxiety disorder	1	0.0	(0.0, 0.2)
Insomnia	12	0.5	(0.3, 0.9)
Irritability	2	0.1	(0.0, 0.3)
Major depression	1	0.0	(0.0, 0.2)
Mental fatigue	1	0.0	(0.0, 0.2)
Mental status changes	1	0.0	(0.0, 0.2)
Restlessness	2	0.1	(0.0, 0.3)
Sleep disorder	2	0.1	(0.0, 0.3)
Suicidal ideation	1	0.0	(0.0, 0.2)
Suicide attempt	1	0.0	(0.0, 0.2)
Thinking abnormal	1	0.0	(0.0, 0.2)
RENAL AND URINARY DISORDERS	21	0.9	(0.5, 1.3)
Acute kidney injury	1	0.0	(0.0, 0.2)
Bladder neck obstruction	1	0.0	(0.0, 0.2)
Chronic kidney disease	1	0.0	(0.0, 0.2)
Dysuria	6	0.3	(0.1, 0.5)
Haematuria	1	0.0	(0.0, 0.2)
Hypertonic bladder	2	0.1	(0.0, 0.3)
Nephrolithiasis	4	0.2	(0.0, 0.4)
Pollakiuria	1	0.0	(0.0, 0.2)
Urinary bladder polyp	1	0.0	(0.0, 0.2)
Urinary hesitation	1	0.0	(0.0, 0.2)
Urinary retention	1	0.0	(0.0, 0.2)
Urinary tract obstruction	1	0.0	(0.0, 0.2)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	12	0.5	(0.3, 0.9)
Benign prostatic hyperplasia	3	0.1	(0.0, 0.4)
Breast cyst	1	0.0	(0.0, 0.2)
Breast discharge	1	0.0	(0.0, 0.2)
Endometriosis	1	0.0	(0.0, 0.2)
Metrorrhagia	2	0.1	(0.0, 0.3)
Ovarian cyst	1	0.0	(0.0, 0.2)
Pelvic pain	1	0.0	(0.0, 0.2)
Sexual dysfunction	1	0.0	(0.0, 0.2)
Testicular pain	1	0.0	(0.0, 0.2)
Uterine haemorrhage	1	0.0	(0.0, 0.2)
Vaginal lesion	1	0.0	(0.0, 0.2)

Table 66. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	37	1.6	(1.1, 2.1)
Acute respiratory failure	2	0.1	(0.0, 0.3)
Asthma	1	0.0	(0.0, 0.2)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.2)
Cough	3	0.1	(0.0, 0.4)
Dyspnoea	2	0.1	(0.0, 0.3)
Epistaxis	3	0.1	(0.0, 0.4)
Immune-mediated pneumonitis	1	0.0	(0.0, 0.2)
Nasal congestion	5	0.2	(0.1, 0.5)
Nasal septum deviation	1	0.0	(0.0, 0.2)
Oropharyngeal pain	1	0.0	(0.0, 0.2)
Paranasal sinus discomfort	1	0.0	(0.0, 0.2)
Pleuritic pain	1	0.0	(0.0, 0.2)
Pulmonary embolism	4	0.2	(0.0, 0.4)
Rhinitis allergic	4	0.2	(0.0, 0.4)
Rhinorrhoea	6	0.3	(0.1, 0.5)
Sinus congestion	1	0.0	(0.0, 0.2)
Upper respiratory tract congestion	1	0.0	(0.0, 0.2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	85	3.6	(2.9, 4.4)
Acne	1	0.0	(0.0, 0.2)
Actinic keratosis	3	0.1	(0.0, 0.4)
Alopecia	2	0.1	(0.0, 0.3)
Angioedema	1	0.0	(0.0, 0.2)
Cold sweat	1	0.0	(0.0, 0.2)
Dermatitis	2	0.1	(0.0, 0.3)
Dermatitis contact	6	0.3	(0.1, 0.5)
Dry skin	1	0.0	(0.0, 0.2)
Ecchymosis	3	0.1	(0.0, 0.4)
Erythema	2	0.1	(0.0, 0.3)
Erythema nodosum	1	0.0	(0.0, 0.2)
Hyperhidrosis	15	0.6	(0.4, 1.0)
Ingrowing nail	3	0.1	(0.0, 0.4)
Lichen sclerosus	1	0.0	(0.0, 0.2)
Night sweats	7	0.3	(0.1, 0.6)
Petechiae	1	0.0	(0.0, 0.2)
Pruritus	6	0.3	(0.1, 0.5)

Table 66. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Rash	16	0.7	(0.4, 1.1)
Rash erythematous	2	0.1	(0.0, 0.3)
Rash pruritic	1	0.0	(0.0, 0.2)
Rash vesicular	1	0.0	(0.0, 0.2)
Skin lesion	4	0.2	(0.0, 0.4)
Skin ulcer	1	0.0	(0.0, 0.2)
Urticaria	7	0.3	(0.1, 0.6)
SURGICAL AND MEDICAL PROCEDURES	9	0.4	(0.2, 0.7)
Blepharoplasty	1	0.0	(0.0, 0.2)
Chondroplasty	1	0.0	(0.0, 0.2)
Finger repair operation	1	0.0	(0.0, 0.2)
Hysterectomy	2	0.1	(0.0, 0.3)
Injection	1	0.0	(0.0, 0.2)
Spinal fusion surgery	1	0.0	(0.0, 0.2)
Tooth extraction	2	0.1	(0.0, 0.3)
VASCULAR DISORDERS	45	1.9	(1.4, 2.5)
Aortic aneurysm	1	0.0	(0.0, 0.2)
Aortic arteriosclerosis	1	0.0	(0.0, 0.2)
Aortic stenosis	1	0.0	(0.0, 0.2)
Blood pressure fluctuation	1	0.0	(0.0, 0.2)
Deep vein thrombosis	3	0.1	(0.0, 0.4)
Flushing	5	0.2	(0.1, 0.5)
Haematoma	2	0.1	(0.0, 0.3)
Hot flush	2	0.1	(0.0, 0.3)
Hypertension	25	1.1	(0.7, 1.6)
Hypotension	1	0.0	(0.0, 0.2)
Peripheral coldness	1	0.0	(0.0, 0.2)
Thrombosis	1	0.0	(0.0, 0.2)
Venous thrombosis limb	1	0.0	(0.0, 0.2)

Table 66. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])

Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (17:36)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_exp_age_p3x_saf

Related Adverse Events – Open-Label Follow-Up for Original Placebo Participants Who Received BNT162b2

From vaccination with BNT162b2 (Dose 3) to the data cutoff date for placebo participants, the IR of AEs assessed as related by the investigator during the open-label follow-up period was 189.5 per 100 PY (Table 65). IRs of related AEs were highest for reactogenicity events and in the SOC of general disorders and administration site conditions (4147 [174.3 per 100 PY]) for the following PTs:

- injection site pain: 2938 (123.5 per 100 PY)
- pyrexia: 905 (38.0 per 100 PY)
- fatigue: 1373 (57.7 per 100 PY)
- chills: 993 (41.7 per 100 PY).

Immediate Adverse Events – Open-Label Follow-Up for Original Placebo Participants Who Received BNT162b2

After vaccination with BNT162b2 (Dose 3/4), placebo participants who received BNT162b2 with immediate AEs were low in frequency (0.6%). Most immediate AEs after BNT162b2

doses were in the SOC of general disorders and administration site conditions, primarily injection site reactions, with injection site pain (0.4%) most frequently reported.

Other immediate AEs assessed by the investigator as related to study intervention included:

- 1 participant in the younger age group reported 2 immediate AEs of edema mouth and tongue edema (both mild in severity) after Dose 4. The AE of tongue edema resolved the same day and the AE of edema mouth resolved the following day.

- 1 participant in the younger age group reported an immediate AE of hypoesthesia oral (mild in severity) after Dose 3 and resolved the same day.

- 1 participant in the younger age group reported 3 immediate AEs of swelling face, allergy to vaccine, and flushing after Dose 3, which were all were moderate in severity. All 3 AEs resolved the following day. The participant also reported nausea and urticaria (hives abdomen) (both mild in severity) on the same day but were not immediate. The AE of nausea resolved the same day and the AE of urticaria resolved the following day. These 2 AEs were also assessed by the investigator as related to study intervention.

- 1 participant in the older age group reported an immediate AE of urticaria (hive on back of neck; moderate in severity) after Dose 4 and was ongoing at the time of the data cutoff date.

Severe or Life-Threatening Adverse Events – Open-Label Follow-Up for Original Placebo Participants Who Received BNT162b2

Severe Adverse Events

From Dose 3 (first Dose of BNT162b2) to the data cutoff date, the severe AE IR was 6.0 per 100 PY in original placebo participants. Those events reported as SAEs are discussed further in Section 2.5.5.5.5.5. Severe AEs included:

- 1 participant in the younger age group reported a severe AE of hypersensitivity 13 days after Dose 3, which resolved the following day and assessed by the investigator as not related to study intervention.

- 1 participant in the older age group reported a severe SAE of COVID-19 pneumonia 8 days after Dose 3, which resolved 4 days later and was assessed by the investigator as not related to study intervention.

- 1 participant in the older age group reported a severe SAE of cerebrovascular accident 16 days after Dose 4, which was assessed by the investigator as not related to study intervention and ongoing at the time of the data cutoff date.

- 1 participant in the younger age group reported a severe SAE of pulmonary embolism 5 days after Dose 4, which resolved the following day and was assessed by the investigator as not related to study intervention.

- 1 participant in the older age group reported severe SAEs of pulmonary embolism and thrombosis (occlusive thrombus in the right calf) 2 days after Dose 3. Both events resolved the following day, and both were assessed by the investigator as not related to study intervention.

- 1 participant in the younger age group reported 2 AEs of urticaria (moderate and severe) at 3 and 4 days after Dose 3, respectively. The moderate AE of urticaria (intermittent generalized) resolved the same day, and the severe AE of urticaria (left arm) resolved after 8 days. Both events were assessed by the investigator as related to study intervention.

Life-Threatening Adverse Events

The IR for original placebo participants who had at least 1 life-threatening AE from Dose 3 to the data cutoff date was 0.5 per 100 PY. The following life-threatening events were reported and were considered unrelated to vaccine as assessed by the investigator, with the exception of anaphylactoid reaction. Those reported as SAEs are discussed further in Section 2.5.5.5.5.5. Grade 4 life-threatening events included:

- 1 participant in the older age group had a grade 4 life-threatening SAE of cardio-respiratory arrest. The event occurred (b) (6) days after Dose 3 and the outcome was fatal.

- 1 participant in the younger age group had a grade 4 life-threatening SAE of gastrointestinal necrosis 29 days after Dose 4. The outcome was not recovered/not resolved at the time of this report.

- 1 participant in the younger age group had a grade 4 life-threatening SAE of pulmonary embolism and a grade 4 life-threatening SAE of deep vein thrombosis. Both events occurred 11 days after Dose 4 and the outcome for both events was recovering/resolving.

- 1 participant in the younger age group had a grade 4 life-threatening SAE of anaphylactoid reaction 2 days after Dose 3. The outcome was recovered/resolved and the event was considered related to vaccine. This participant is also discussed in Section 2.5.5.5.7.1.

Subgroup Analyses

No clinically meaningful differences in IRs of AEs for original placebo participants who then received BNT162b2 were observed by baseline SARS-CoV-2 positive (222.9 per 100 PY) and negative (205.4 per 100 PY) status subgroups. The IR for original baseline positive placebo participants who then received BNT162b2 (222.9 per 100 PY [95% CI: 186.5, 264.3]) was similar to baseline negative participants (205.4 per 100 PY [95% CI: 199.6, 211.3]). IRs in other SOCs were similar in the baseline positive and baseline negative groups, except for the musculoskeletal SOC which was higher in the baseline positive group. However, this was driven by a higher rate of myalgia (64.2 per 100 PY [95% CI: 45.4, 88.1]) in baseline positive participants compared to baseline negative participants (38.3 per 100 PY [95% CI: 35.8, 40.9])

Open-Label Follow-Up Period – Original Placebo Participants who had COVID-19 Occurrence After Dose 1 and Then Received BNT162b2

AEs reported from the unblinding date to the data cutoff date for original placebo participants who had COVID-19 occurrence after Dose 1 and then received BNT162b2 in the open-label follow-up period are presented in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Supplemental Table 14.163.

For original placebo participants who had COVID-19 occurrence after Dose 1 and then received BNT162b2, the IR for at least 1 AE was 256.8 per 100 PY. Most AEs reported from Dose 3 (the first dose of BNT162b2) to the data cutoff date were in SOCs with reactogenicity events.

- general disorders and administration site conditions: 236.3 per 100 PY
- musculoskeletal and connective tissue disorders: 47.9 per 100 PY
- nervous system disorders: 66.2 per 100 PY
- gastrointestinal disorders: 17.1 per 100 PY.

2.5.5.5.4. Deaths – Phase 2/3

2.5.5.5.4.1. Blinded Follow-Up Period from Dose 1 to Unblinding Date

There were 15 deaths in the BNT162b2 group and 14 deaths in the placebo group from Dose 1 to the unblinding date during the blinded placebo-controlled follow-up period (Table 67). None of these deaths were assessed by the investigator as related to study intervention.

Table 67. Incidence Rates of Deaths From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Deaths	15	0.2	(0.1, 0.3)	14	0.2	(0.1, 0.3)
Cause of death[f]						
Acute respiratory failure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Aortic rupture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Arteriosclerosis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Biliary cancer metastatic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardiac arrest	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiac failure congestive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

Table 67. Incidence Rates of Deaths From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Death	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dementia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Emphysematous cholecystitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haemorrhagic stroke	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hypertensive heart disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Metastases to liver	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Missing	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Myocardial infarction	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Overdose	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pneumonia	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Septic shock	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Shigella sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Unevaluable event	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified cause of death.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Multiple causes of death can be reported for each subject.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: dd Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/addd_s001_p3_saf

HIV+ Participants

Among participants with confirmed stable HIV disease, 2 deaths were reported as of the data cutoff date. Neither death was assessed by the investigator as related to study intervention.

- 1 female participant died due to COVID-19 pneumonia reported (b) (6) days after receiving Dose 2 of placebo. This participant was diagnosed based on a local COVID-19 test that could not be confirmed as protocol-approved and was not confirmed by a test result from

the central laboratory (case was not evaluable for efficacy analyses). This participant had unrelated SAEs that were diagnosed and reported prior to their death that are discussed further in Section 2.5.5.5.5.2.

- 1 female participant died due to a road traffic accident occurring (b) (6) days after receiving Dose 2.

2.5.5.5.4.2. Open-Label Follow-Up Period – Original BNT162b2 Participants

From the unblinding date to the data cutoff date of the open-label follow-up period, there were 3 deaths among original BNT162b2 participants, all in the older age group: 1 each due to road traffic accident, lung metastases, and myocardial infarction. None of these deaths were assessed by the investigator as related to study intervention.

2.5.5.5.4.3. Participants With at Least 6 Months Follow-Up Time – BNT162b2 Group

No deaths were reported among the participants originally randomized to BNT162b2 who had a cumulative ≥6 months (inclusive of blinded and open-label) follow-up.

2.5.5.5.4.4. Placebo Group Who Received BNT162b2

From the unblinding date to the data cutoff date of the open-label follow-up period, there were 2 deaths among original placebo participants who then received BNT162b2 , all in the older age group: 1 each due to cardiorespiratory arrest or completed suicide. Neither of these deaths were assessed by the investigator as related to study intervention

2.5.5.5.5. Serious Adverse Events – Phase 2/3

2.5.5.5.5.1. Blinded Follow-Up Period from Dose 1 Through 1 Month After Dose 2

From Dose 1 to 1 month after Dose 2 the proportions of participants who reported at least 1 SAE was similar in the BNT162b2 group (0.6%) and in the placebo group (0.5%) (Table 68).

The numbers of participants who reported at least 1 SAE were lower in the younger age group (52 [0.4%] and 49 [0.4%] for the BNT162b2 and placebo groups, respectively) than in the older age group (75 [0.8%] and 67 [0.8%] for the BNT162b2 and placebo groups, respectively).

Three of the SAEs in the BNT162b2 group and none in the placebo group were assessed by the investigator as related to study intervention (Table 58).

In the BNT162b2 group, 2 participants in the younger age group and 1 participant in the older age group had an SAE each assessed by the investigator as related to study intervention:

- 1 participant in the younger age group had an SAE of lymphadenopathy (right axilla) 13 days after Dose 1 which lasted 66 days and resolved. The participant was a 48-year-old woman with a relevant medical history of eczema and topical crisaborole use who was administered BNT162b2 vaccine in the left deltoid and had right axillary pain and lymphadenopathy. She had no injuries to the right arm, no fever, and no history of a similar incident. Her white blood cell count was normal with a normal lymphocyte count

and a right axilla ultrasound showed 4 enlarged lymph nodes (largest 2.5 × 1.1 × 2.4 cm). A biopsy was performed and was reported to be normal and without markers for lymphoma or other cancer. A follow-up visit with oncology (and possible repeat ultrasound) was planned for 3 months' time.

- 1 participant in the younger age group had an SAE of shoulder injury related to vaccine administration (SIRVA; erroneously administered into or near the shoulder joint capsule) after Dose 2, which lasted 153 days and resolved.

- 1 participant in the older age group with a past medical history significant for AV block with pacemaker, sinus node dysfunction, atrial fibrillation, and supraventricular tachycardia had an SAE of ventricular arrhythmia that occurred 1 day after Dose 2 and lasted for 8 days and resolved.

Table 68. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	127 (0.6)	(0.5, 0.7)	116 (0.5)	(0.4, 0.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytopenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	20 (0.1)	(0.1, 0.1)	21 (0.1)	(0.1, 0.1)
Atrial fibrillation	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Acute myocardial infarction	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Coronary artery disease	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac arrest	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac failure congestive	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute left ventricular failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac failure acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 68. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Junctional ectopic tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial ischaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pericarditis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Congenital bladder neck obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EYE DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	9 (0.0)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Small intestinal obstruction	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain upper	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal mucosa hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Incarcerated inguinal hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal varices haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 68. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Umbilical hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Volvulus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Cholecystitis acute	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cholelithiasis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	27 (0.1)	(0.1, 0.2)	21 (0.1)	(0.1, 0.1)
Appendicitis	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Pneumonia	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Cellulitis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Urinary tract infection	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
COVID-19	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diverticulitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative wound infection	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 68. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shigella sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subacute endocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	8 (0.0)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Overdose	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial bones fracture	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Road traffic accident	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fall	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Femur fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foot fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Head injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rib fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal column injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subdural haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic haemothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 68. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blood glucose abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	7 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Osteoarthritis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arthralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Back pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscular weakness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	13 (0.1)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Prostate cancer	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malignant melanoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma pancreas	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to liver	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oropharyngeal squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatic carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 68. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Penile neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer metastatic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	14 (0.1)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Subarachnoid haemorrhage	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Cerebrovascular accident	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient ischaemic attack	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amyotrophic lateral sclerosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervicogenic headache	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord compression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abortion spontaneous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depression suicidal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Nephrolithiasis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute kidney injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 68. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	7 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Pulmonary embolism	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Acute respiratory failure	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonia aspiration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	7 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Deep vein thrombosis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypertension	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Aortic stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive crisis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 ser all pd2 p3 saf

HIV+ Participants

No participants with confirmed stable HIV disease reported an SAE from Dose 1 to 1 month after Dose 2.

2.5.5.5.5.2. Blinded Follow-Up Period from Dose 1 to the Unblinding Date

SAEs reported from Dose 1 to the unblinding date during the blinded placebo-controlled follow-up period are presented in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Supplemental Table 14.166.

From Dose 1 to the unblinding date, IRs of at least 1 SAE were similar in the BNT162b2 group (3.2 per 100 PY) and in the placebo group (3.3 per 100 PY). The IR was lower in the younger age groups (2.1 per 100 PY and 2.4 per 100 PY for the BNT162b2 and placebo groups, respectively) than in the older age groups (4.9 per 100 PY and 4.6 per 100 PY for the BNT162b2 and placebo groups respectively).

Four SAEs in the BNT162b2 group and 1 in the placebo group were assessed by the investigator as related to study intervention. In addition to 3 related SAEs in the BNT162b2 group described in Section 2.5.5.5.5.1, 2 related SAEs occurred from 1 month after Dose 2 to the unblinding date:

- 1 participant in the BNT162b2 younger age group with a medical history significant for occipital neuralgia, and migraines had an SAE of paresthesia (right leg) 47 days after Dose 2 which was recovering/resolving at the data cutoff date.

- 1 participant in the placebo younger age group had an SAE of psoriatic arthropathy 38 days after Dose 2 which was continuing at the data cutoff date.

Subgroup Analyses

Overall, no clinically meaningful differences in IRs of SAEs were observed by baseline SARS-CoV-2 status, ethnicity, race, or sex subgroups.

Baseline SARS-CoV-2 Status

IRs of SAEs were similar by baseline SARS-CoV-2 status in the BNT162b2 and placebo groups for baseline positive (4.0 per 100 PY [95% CI: 1.9, 7.3] and 1.9 per 100 PY [95% CI: 0.6, 4.4]) and baseline negative (3.2 per 100 PY [95% CI: 2.8, 3.6] and 3.3 per 100 PY [95% CI: 2.9, 3.7]) participants. IRs of SAEs in the baseline positive BNT162b2 group were similar (4.0 per 100 PY [95% CI: 1.9, 7.3]) to those in the baseline negative BNT162b2 group (3.2 per 100 PY [95% CI: 2.8, 3.6]), and similar to what was observed in the overall SAE analysis irrespective of baseline status (Table 60).

While there are differences in exposure (2.5 vs 80.4) by baseline SARS-CoV-2 positive and negative status, respectively, IRs were numerically low or similar by baseline SARS-CoV-2 status, so there is no evidence that individuals who are positive at baseline report AEs at a higher frequency than those who are negative at baseline.

Race/Ethnicity

IRs of SAEs were similar in the BNT162b2 and placebo groups for Hispanic/Latino participants (3.5 per 100 PY [95% CI: 2.8, 4.3] and 3.6 per 100 PY [95% CI: 2.9, 4.5]), Non-Hispanic/Non-Latino participants (3.1 per 100 PY [95% CI: 2.7, 3.6] for each), and not reported (2.4 per 100 PY [95% CI: 0.1, 13.1] and 2.3 per 100 PY [95% CI: 0.1, 12.7]) participants.

IRs of SAEs were similar in the BNT162b2 and placebo groups for White participants (3.3 per 100 PY [95% CI: 2.9, 3.8] and 3.5 per 100 PY [95% CI: 3.1, 4.0]), Black or African American participants (2.5 per 100 PY [95% CI: 1.6, 3.9] and 2.6 per 100 PY [95% CI: 1.6, 4.0]), and greater in the BNT162b2 group for All Other participants compared to placebo (2.7 per 100 PY [95% CI: 1.6, 4.3] and 1.4 per 100 PY [95% CI: 0.6, 2.7]).

Sex

IRs of SAEs were similar by sex in the BNT162b2 and placebo groups for male participants (3.5 per 100 PY[95% CI: 3.0, 4.1] and 3.4 per 100 PY [95% CI: 2.8, 4.0]) and female participants (2.9 per 100 PY [95% CI: 2.4, 3.5] and 3.2 per 100 PY [95% CI: 2.6, 3.7]).

HIV+ Participants

From Dose 1 to the unblinding date, IRs of at least 1 SAE in participants with stable HIV disease were similar in the BNT162b2 group (6.6 per 100 PY [95% CI: 0.8, 23.9]) and the placebo group (6.9 per 100 PY [95% CI: 0.8, 25.1]) with 2 participants reporting at least 1 SAE in each group.

- 1 participant in the BNT162b2 group had an SAE of pneumonia 86 days after Dose 2 which lasted 8 days and resolved
- 1 participant in the BNT162b2 group had a fatal SAE of road traffic accident (b) (6) days after Dose 2
- 1 participant in the placebo group had an SAE of breast cancer 71 days after Dose 2 that was continuing at the data cutoff date.
- 1 participant in the placebo group had an SAE of diabetes mellitus 68 days after Dose 2, and then had COVID-19 pneumonia 72 days after Dose 2 which lasted (b) (6) days and resulted in death (see Section 2.5.5.5.4.1). The participant had a history of asthma, HIV, hypertension, and obesity and then was diagnosed with diabetes mellitus 68 days after Dose 2; 4 days after the diagnosis, the participant presented in the emergency room with an elevated blood glucose level and was admitted. Laboratory tests on the following day included a SARS-CoV-2 PCR test, which was positive; 2 days later, a second test confirmed the COVID-19 positive diagnosis. The following day (b) (6) days after Dose 2), the participant died due to disease progression and COVID-19 pneumonia. The investigator concluded that the events of diabetes mellitus and COVID-19 pneumonia were not related to study intervention. Note, this participant had COVID-19 diagnosed based on a local test that could not be confirmed as protocol-approved and was not subsequently confirmed by a test result from the central laboratory (therefore not included in efficacy analyses).

2.5.5.5.5.3. Open-Label Follow-Up Period – Original BNT162b2 Participants

SAEs reported from the unblinding date to the data cutoff date for the originally randomized BNT162b2 group during the open-label follow-up period are presented in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Supplemental Table 14.180.

From the unblinding date to the data cutoff date, the IR of at least 1 SAE was 2.0 per 100 PY (95% CI: 1.5, 2.6) in original BNT162b2 participants.

One younger participant with no past medical history had a life-threatening SAE of myocardial infarction 71 days after Dose 2 that was assessed by the investigator as related to study intervention, which lasted 1 day and resolved the same day.

2.5.5.5.5.4. Cumulative Blinded and Open-Label Follow-Up Periods from Dose 1 to 6 Months After Dose 2 – BNT162b2 Group

From Dose 1 to 6 months after Dose 2, during the blinded and open-label follow-up periods, 190 (1.6%) participants in the BNT162b2 group reported at least 1 SAE (Table 69).

Two of the SAEs in the BNT162b2 group (SIRVA and paresthesia; see Section 2.5.5.5.5.1 and Section 2.5.5.5.5.2, respectively) were assessed by the investigator as related to study intervention (Table 60).

The number of participants who reported at least 1 SAE was 73 (1.1%) and 117 (2.2%) in the younger and older age groups, respectively.

Comparison of SAEs reported from Dose 1 to 1 month after Dose 2 to SAEs reported from 1 month after Dose 2 to 6 months after Dose 2 shows that the frequency of SAEs increased from 0.5% to 1.1%, respectively. The following SOCs had the largest increase in SAEs (from Dose 1 to 1 month after Dose 2 vs 1 month after Dose 2 to 6 months after Dose 2):

- Neoplasms, benign, malignant, unspecified including cysts and polyps: 4 (0.0%) vs 21 (0.2%)
- Injury, poisoning, and procedural complications: 2 (0.0%) vs 14 (0.1%)
- Infections and infestations: 14 (0.1%) vs 22 (0.2%)
- Gastrointestinal disorders: 4 (0.0%) vs 10 (0.1%)
- Respiratory, thoracic, and mediastinal disorders: 2 (0.0%) vs 8 (0.1%)
- Hepatobiliary disorders: 3 (0.0%) vs 8 (0.1%)

Table 69. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	190 (1.6)	(1.4, 1.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)
Pancytopenia	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	27 (0.2)	(0.1, 0.3)
Acute myocardial infarction	4 (0.0)	(0.0, 0.1)
Atrial fibrillation	4 (0.0)	(0.0, 0.1)
Myocardial infarction	4 (0.0)	(0.0, 0.1)
Angina pectoris	3 (0.0)	(0.0, 0.1)
Angina unstable	2 (0.0)	(0.0, 0.1)
Cardiac failure congestive	2 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)
Atrial flutter	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)
Cardiac arrest	1 (0.0)	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.0)
Coronary artery occlusion	1 (0.0)	(0.0, 0.0)
Pericarditis	1 (0.0)	(0.0, 0.0)
Ventricular tachycardia	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	4 (0.0)	(0.0, 0.1)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)
Ophthalmic vein thrombosis	1 (0.0)	(0.0, 0.0)
Retinal tear	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	14 (0.1)	(0.1, 0.2)
Colitis	2 (0.0)	(0.0, 0.1)
Gastritis	2 (0.0)	(0.0, 0.1)
Small intestinal obstruction	2 (0.0)	(0.0, 0.1)
Abdominal pain upper	1 (0.0)	(0.0, 0.0)
Food poisoning	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)
Haematemesis	1 (0.0)	(0.0, 0.0)
Haemorrhoids	1 (0.0)	(0.0, 0.0)

Table 69. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Impaired gastric emptying	1 (0.0)	(0.0, 0.0)
Intestinal obstruction	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	7 (0.1)	(0.0, 0.1)
Chest pain	2 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.1)
Asthenia	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	11 (0.1)	(0.0, 0.2)
Cholecystitis acute	3 (0.0)	(0.0, 0.1)
Cholelithiasis	3 (0.0)	(0.0, 0.1)
Bile duct stone	2 (0.0)	(0.0, 0.1)
Biliary colic	2 (0.0)	(0.0, 0.1)
Cholecystitis	1 (0.0)	(0.0, 0.0)
Cholelithiasis obstructive	1 (0.0)	(0.0, 0.0)
Portosplenomesenteric venous thrombosis	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	36 (0.3)	(0.2, 0.4)
Appendicitis	10 (0.1)	(0.0, 0.2)
Diverticulitis	3 (0.0)	(0.0, 0.1)
Pneumonia	3 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.1)
Pyelonephritis	2 (0.0)	(0.0, 0.1)
Abscess	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)
Arthritis bacterial	1 (0.0)	(0.0, 0.0)
Bacteraemia	1 (0.0)	(0.0, 0.0)
Bacterial sepsis	1 (0.0)	(0.0, 0.0)
Clostridium difficile colitis	1 (0.0)	(0.0, 0.0)
Device related infection	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)

Table 69. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Endocarditis	1 (0.0)	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)
Gangrene	1 (0.0)	(0.0, 0.0)
Gastroenteritis	1 (0.0)	(0.0, 0.0)
Herpes zoster oticus	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	1 (0.0)	(0.0, 0.0)
Penile infection	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)
Peritonitis	1 (0.0)	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.0)
Postoperative abscess	1 (0.0)	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.0)
Subcutaneous abscess	1 (0.0)	(0.0, 0.0)
Urinary tract infection	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	16 (0.1)	(0.1, 0.2)
Ankle fracture	2 (0.0)	(0.0, 0.1)
Road traffic accident	2 (0.0)	(0.0, 0.1)
Wrist fracture	2 (0.0)	(0.0, 0.1)
Burns second degree	1 (0.0)	(0.0, 0.0)
Burns third degree	1 (0.0)	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	1 (0.0)	(0.0, 0.0)
Facial bones fracture	1 (0.0)	(0.0, 0.0)
Fall	1 (0.0)	(0.0, 0.0)
Head injury	1 (0.0)	(0.0, 0.0)
Humerus fracture	1 (0.0)	(0.0, 0.0)
Patella fracture	1 (0.0)	(0.0, 0.0)
Pelvic fracture	1 (0.0)	(0.0, 0.0)
Procedural dizziness	1 (0.0)	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)
Tibia fracture	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)
Upper limb fracture	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	1 (0.0)	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)

Table 69. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
METABOLISM AND NUTRITION DISORDERS	3 (0.0)	(0.0, 0.1)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)
Hypoglycaemia	1 (0.0)	(0.0, 0.0)
Hypokalaemia	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	9 (0.1)	(0.0, 0.1)
Osteoarthritis	4 (0.0)	(0.0, 0.1)
Arthritis	1 (0.0)	(0.0, 0.0)
Intervertebral disc compression	1 (0.0)	(0.0, 0.0)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.0)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	25 (0.2)	(0.1, 0.3)
Breast cancer	2 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	2 (0.0)	(0.0, 0.1)
Prostate cancer	2 (0.0)	(0.0, 0.1)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.0)
Adenocarcinoma pancreas	1 (0.0)	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)
Benign hydatidiform mole	1 (0.0)	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.0)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.0)
Brain cancer metastatic	1 (0.0)	(0.0, 0.0)
Breast cancer in situ	1 (0.0)	(0.0, 0.0)
Carcinoid tumour of the stomach	1 (0.0)	(0.0, 0.0)
Colon adenoma	1 (0.0)	(0.0, 0.0)
Gallbladder cancer stage II	1 (0.0)	(0.0, 0.0)
Gastric cancer	1 (0.0)	(0.0, 0.0)
Malignant melanoma	1 (0.0)	(0.0, 0.0)
Non-small cell lung cancer stage IV	1 (0.0)	(0.0, 0.0)
Skin cancer	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.0)
Thyroid cancer	1 (0.0)	(0.0, 0.0)
Transitional cell carcinoma	1 (0.0)	(0.0, 0.0)
Uterine cancer	1 (0.0)	(0.0, 0.0)

Table 69. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
NERVOUS SYSTEM DISORDERS	23 (0.2)	(0.1, 0.3)
Subarachnoid haemorrhage	3 (0.0)	(0.0, 0.1)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)
Dizziness	2 (0.0)	(0.0, 0.1)
Optic neuritis	2 (0.0)	(0.0, 0.1)
Syncope	2 (0.0)	(0.0, 0.1)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)
Intracranial aneurysm	1 (0.0)	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)
Paraesthesia	1 (0.0)	(0.0, 0.0)
Peripheral nerve lesion	1 (0.0)	(0.0, 0.0)
Seizure	1 (0.0)	(0.0, 0.0)
Toxic encephalopathy	1 (0.0)	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2 (0.0)	(0.0, 0.1)
Abortion spontaneous	2 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.0)
Suicide attempt	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	9 (0.1)	(0.0, 0.1)
Nephrolithiasis	5 (0.0)	(0.0, 0.1)
Acute kidney injury	2 (0.0)	(0.0, 0.1)
Renal colic	1 (0.0)	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	3 (0.0)	(0.0, 0.1)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)
Endometrial thickening	1 (0.0)	(0.0, 0.0)
Endometriosis	1 (0.0)	(0.0, 0.0)
Ovarian cyst	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	10 (0.1)	(0.0, 0.2)
Pulmonary embolism	4 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	2 (0.0)	(0.0, 0.1)

Table 69. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Dyspnoea	1 (0.0)	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	1 (0.0)	(0.0, 0.0)
Miscarriage of partner	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.0)
Finger amputation	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	6 (0.0)	(0.0, 0.1)
Aortic aneurysm	3 (0.0)	(0.0, 0.1)
Deep vein thrombosis	2 (0.0)	(0.0, 0.1)
Arterial occlusive disease	1 (0.0)	(0.0, 0.0)
Hypertension	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 pd2 ser p3 saf

2.5.5.5.5.5. Open-Label Follow-Up Period – Original Placebo Participants Who Received BNT162b2

From Dose 3 (first dose of BNT162b2) to the data cutoff date, the IR of at least 1 SAE in original placebo participants who then received BNT162b2 was 2.7 per 100 PY (95% CI: 2.1, 3.5) (Table 70).

One SAE was assessed by the investigator as related to study intervention (Table 65). This participant in the younger age group had an ongoing medical history of seasonal and food allergies and drug hypersensitivity, had an anaphylactoid reaction 2 days post Dose 3, with

an event duration of 1 day; the event was reported as an SAE, reported as resolved, and the participant withdrew from the study (also described in Section 2.5.5.5.7.1).

Table 70. Incidence Rates of at Least 1 Serious Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	65	2.7	(2.1, 3.5)
CARDIAC DISORDERS	8	0.3	(0.1, 0.7)
Acute myocardial infarction	1	0.0	(0.0, 0.2)
Arrhythmia	1	0.0	(0.0, 0.2)
Arteriospasm coronary	1	0.0	(0.0, 0.2)
Atrial fibrillation	2	0.1	(0.0, 0.3)
Cardiac failure congestive	1	0.0	(0.0, 0.2)
Cardio-respiratory arrest	1	0.0	(0.0, 0.2)
Cardiovascular disorder	1	0.0	(0.0, 0.2)
Ischaemic cardiomyopathy	1	0.0	(0.0, 0.2)
Myocardial infarction	1	0.0	(0.0, 0.2)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	0.0	(0.0, 0.2)
Hypertrophic cardiomyopathy	1	0.0	(0.0, 0.2)
EAR AND LABYRINTH DISORDERS	1	0.0	(0.0, 0.2)
Vertigo	1	0.0	(0.0, 0.2)
EYE DISORDERS	1	0.0	(0.0, 0.2)
Diplopia	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	8	0.3	(0.1, 0.7)
Anal prolapse	1	0.0	(0.0, 0.2)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.2)
Gastrointestinal necrosis	1	0.0	(0.0, 0.2)
Gastrooesophageal reflux disease	1	0.0	(0.0, 0.2)
Intestinal obstruction	1	0.0	(0.0, 0.2)
Intestinal ulcer perforation	1	0.0	(0.0, 0.2)
Pancreatitis acute	2	0.1	(0.0, 0.3)
Small intestinal obstruction	1	0.0	(0.0, 0.2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3	0.1	(0.0, 0.4)
Drug withdrawal syndrome	1	0.0	(0.0, 0.2)
Fatigue	1	0.0	(0.0, 0.2)
Pelvic mass	1	0.0	(0.0, 0.2)

Table 70. Incidence Rates of at Least 1 Serious Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
HEPATOBILIARY DISORDERS	2	0.1	(0.0, 0.3)
Cholecystitis	1	0.0	(0.0, 0.2)
Hepatitis acute	1	0.0	(0.0, 0.2)
IMMUNE SYSTEM DISORDERS	1	0.0	(0.0, 0.2)
Anaphylactoid reaction	1	0.0	(0.0, 0.2)
INFECTIONS AND INFESTATIONS	4	0.2	(0.0, 0.4)
Appendicitis perforated	1	0.0	(0.0, 0.2)
COVID-19 pneumonia	1	0.0	(0.0, 0.2)
Clostridium difficile infection	1	0.0	(0.0, 0.2)
Focal peritonitis	1	0.0	(0.0, 0.2)
Pelvic abscess	1	0.0	(0.0, 0.2)
Pneumonia	1	0.0	(0.0, 0.2)
Urosepsis	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	6	0.3	(0.1, 0.5)
Ankle fracture	1	0.0	(0.0, 0.2)
Fall	1	0.0	(0.0, 0.2)
Lower limb fracture	1	0.0	(0.0, 0.2)
Postoperative ileus	1	0.0	(0.0, 0.2)
Scapula fracture	1	0.0	(0.0, 0.2)
Spinal fracture	1	0.0	(0.0, 0.2)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.2)
METABOLISM AND NUTRITION DISORDERS	1	0.0	(0.0, 0.2)
Diabetes mellitus inadequate control	1	0.0	(0.0, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4	0.2	(0.0, 0.4)
Myalgia	1	0.0	(0.0, 0.2)
Osteoarthritis	3	0.1	(0.0, 0.4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	5	0.2	(0.1, 0.5)
Brain neoplasm	1	0.0	(0.0, 0.2)
Breast cancer	1	0.0	(0.0, 0.2)
Breast cancer stage II	1	0.0	(0.0, 0.2)
Hepatic cancer	1	0.0	(0.0, 0.2)
Non-small cell lung cancer stage III	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	9	0.4	(0.2, 0.7)
Brachial plexopathy	1	0.0	(0.0, 0.2)

Table 70. Incidence Rates of at Least 1 Serious Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Cerebrovascular accident	4	0.2	(0.0, 0.4)
Seizure	1	0.0	(0.0, 0.2)
Syncope	1	0.0	(0.0, 0.2)
Transient ischaemic attack	2	0.1	(0.0, 0.3)
PSYCHIATRIC DISORDERS	5	0.2	(0.1, 0.5)
Alcohol withdrawal syndrome	1	0.0	(0.0, 0.2)
Anxiety	1	0.0	(0.0, 0.2)
Bipolar disorder	1	0.0	(0.0, 0.2)
Completed suicide	1	0.0	(0.0, 0.2)
Depression	1	0.0	(0.0, 0.2)
Major depression	1	0.0	(0.0, 0.2)
Suicide attempt	1	0.0	(0.0, 0.2)
RENAL AND URINARY DISORDERS	2	0.1	(0.0, 0.3)
Nephrolithiasis	1	0.0	(0.0, 0.2)
Urinary tract obstruction	1	0.0	(0.0, 0.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	8	0.3	(0.1, 0.7)
Acute respiratory failure	2	0.1	(0.0, 0.3)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.2)
Dyspnoea	1	0.0	(0.0, 0.2)
Pulmonary embolism	4	0.2	(0.0, 0.4)
VASCULAR DISORDERS	5	0.2	(0.1, 0.5)
Aortic stenosis	1	0.0	(0.0, 0.2)
Deep vein thrombosis	2	0.1	(0.0, 0.3)
Hypertension	1	0.0	(0.0, 0.2)
Thrombosis	1	0.0	(0.0, 0.2)

Table 70. Incidence Rates of at Least 1 Serious Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])

Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_sae_exp_p3x_saf

Subgroup Analyses

Two participants reported SAEs among baseline SARS-CoV-2 positive original placebo participants who then received BNT162b2. Based on this small number, meaningful comparison with baseline negative participants is not possible.

Open-Label Follow-Up Period – Original Placebo Participants who had COVID-19 Occurrence After Dose 1 and Then Received BNT162b2

SAEs reported among original placebo participants who had COVID-19 occurrence after Dose 1 and then received BNT162b2 in the open-label follow-up period are presented in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Supplemental Table 14.186.

For original placebo participants who had COVID-19 occurrence after Dose 1 and then received BNT162b2, the IR for at least 1 SAE was 3.4 per 100 PY (95% CI: 0.7, 10.0). These SAEs occurred in 3 participants.

- 1 participant with a significant past medical history of deep vein thrombosis and COVID-19 in the placebo-controlled follow-up period, and had a grade 3 SAE of

pulmonary embolism 6 days post Dose 4, which lasted 2 days and resolved with sequelae. The SAE was assessed as not related to the study intervention by the investigator.

- 1 participant with a past medical history of hypertension, hypercholesterolemia, coronary artery disease, and a coronary artery bypass in 2006, had a grade 3 SAE of myocardial infarction 16 days post Dose 3, which lasted 4 days and resolved with sequelae. The SAE was assessed and not related to the study intervention by the investigator.

- 1 participant in the older age group had 4 SAEs, all assessed by the investigator as not related to study intervention:

  - 2 grade 3 SAEs of urosepsis and acute hypoxic respiratory failure; both occurred 7 days post Dose 3, lasted 5 days, and resolved.

  - grade 3 SAE of non-small cell lung cancer (stage III), occurred 31 days post Dose 4, and was continuing at the data cutoff date.

  - grade 2 SAE of *Clostridium difficile* infection occurred 47 days post Dose 4 and was continuing at the data cutoff date.

2.5.5.5.6. Adverse Events Leading to Withdrawal – Phase 2/3

Note, several participants remain in the study but were erroneously reported as withdrawn because of AEs, which was subsequently queried and corrected as described in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Errata.

2.5.5.5.6.1. Blinded Follow-Up Period from Dose 1 Through 1 Month After Dose 2

From Dose 1 to 1 month after Dose 2, few participants in the BNT162b2 group (0.1%) and in the placebo group (0.2%) were withdrawn because of AEs (Table 71).

There were 32 participants in the BNT162b2 group and 36 participants in the placebo group had an AE leading to withdrawal (Table 71). The most common SOCs with PTs leading to withdrawal in either vaccine group included:

- 6 participants in the BNT162b2 group and 2 participants in the placebo group who withdrew from the study due to AEs in the SOC of general disorders and administration site conditions (BNT162b2 group: injection site pain [2 participants] and chills, facial pain, injection site dermatitis, injection site swelling, pyrexia, and swelling face [1 participant each]; placebo group: death and fatigue [1 participant each]).

- 5 participants in the BNT162b2 group and 6 participants in the placebo group withdrew from the study due to AEs in the SOC of injury, poisoning and procedural complications (BNT162b2 group: exposure during pregnancy, maternal exposure during pregnancy [2 participants each] and alcohol poisoning [1 participant]; placebo group: exposure during pregnancy [5 participants] and overdose [1 participant].

- 3 participants in the BNT162b2 group and 5 participants in the placebo group withdrew from the study due to AEs in the SOC cardiac disorders (BNT162b2 group: cardiac

arrest, coronary artery disease and tachycardia [1 participant each]; placebo group: atrial fibrillation [2 participants], cardiac failure congestive, coronary artery occlusion, and myocardial infarction [1 participant each]).

- 3 participants in the BNT162b2 group and 6 participants in the placebo group withdrew from the study due to AEs in the SOC of nervous system disorders (BNT162b2 group: headache [3 participants]; placebo group: dizziness [2 participants], amnesia, cerebral infarction, hemorrhagic stroke, paraparesis, and Parkinsonism [1 participant each]).

- 3 participants in the BNT162b2 group and 6 participants in the placebo group withdrew from the study due to AEs in the SOC of gastrointestinal disorders (BNT162b2 group: abdominal pain upper, gastrointestinal hemorrhage, and paresthesia oral [1 participant each]; placebo group: diarrhea [2 participants], diverticular perforation, dry mouth, dysphagia, and nausea [1 participant each]).

No clinically meaningful differences in AEs leading to withdrawal were observed by age subgroups.

Table 71. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	32 (0.1)	(0.1, 0.2)	36 (0.2)	(0.1, 0.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cardiac arrest	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac failure congestive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 71. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
EYE DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	3 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Diarrhoea	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abdominal pain upper	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nausea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Injection site pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chills	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyrexia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Drug hypersensitivity	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shigella sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Exposure during pregnancy	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Overdose	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myalgia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 71. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphoproliferative disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to liver	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	3 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Headache	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parkinsonism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Depression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Depression suicidal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic attack	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pulmonary embolism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Urticaria	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eczema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypertension	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 71. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 1md2 wd p3 saf

2.5.5.5.6.2. Blinded Follow-Up Period from Dose 1 to the Unblinding Date

AEs leading to withdrawal reported from Dose 1 to the unblinding date during the blinded placebo-controlled follow-up period are presented in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Supplemental Table 14.189.

From Dose 1 to the unblinding date, the IRs of participants withdrawn because of AEs were 0.5 per 100 PY in the BNT162b2 group and 0.6 per 100 PY in the placebo group.

There were 45 participants in the BNT162b2 group and 51 participants in the placebo group had an AE leading to withdrawal, which included:

- 9 participants in the BNT162b2 group and 8 participants in the placebo group withdrew from the study due to AEs in the SOC cardiac disorders (BNT162b2 group: cardiac arrest [4 participants], cardiac failure congestive, cardio-respiratory arrest, coronary artery disease, hypertensive heart disease and tachycardia [1 participant each]; placebo group: atrial fibrillation [2 participants], cardiac arrest, cardiac failure congestive, cardio-respiratory arrest, coronary artery occlusion, [1 participant each] and myocardial infarction [2 participants]).

- 3 participants in the BNT162b2 group and 6 participants in the placebo group withdrew from the study due to AEs in the SOC of gastrointestinal disorders (BNT162b2 group: abdominal pain upper, gastrointestinal hemorrhage, and paresthesia oral [1 participant each]; placebo group: diarrhea [2 participants], diverticular perforation, dry mouth, dysphagia, and nausea [1 participant each]).

- 7 participants in the BNT162b2 group and 2 participants in the placebo group withdrew from the study due to AEs in the SOC of general disorders and administration site conditions (BNT162b2 group: injection site pain [2 participants], chills, facial pain, injection site dermatitis, injection site swelling, pyrexia, sudden cardiac death and swelling face [1 participant each]; placebo group: death and fatigue [1 participant each]).

- 4 participants in the BNT162b2 group and 3 participants in the placebo group withdrew from study due to AEs in the SOC infections and infestations (BNT162b2 group: COVID-19 pneumonia, emphysematous cholecystitis, sepsis, septic shock and Shigella sepsis [1 participant each]; placebo group: COVID-19, pneumonia, and septic shock [1 participant each]).

No clinically meaningful differences in IRs of AEs leading to withdrawal were observed in the younger and older age groups.

2.5.5.5.6.3. Open-Label Follow-Up Period – Original BNT162b2 Participants

AEs leading to withdrawal in the originally randomized BNT162b2 group reported from the unblinding date to the data cutoff date during open-label follow-up are presented in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Supplemental Table 14.192.

From the unblinding data to the data cutoff date, IRs of original BNT162b2 participants withdrawn because of AEs were 0.1.

2.5.5.5.6.4. Cumulative Blinded and Open-Label Follow-Up Periods from Dose 1 to 6 Months After Dose 2 – BNT162b2 Group

From Dose 1 to 6 months after Dose 2 during the blinded and open-label follow-up period, 1 participant in the older BNT162b2 group was reported as withdrawn because of AEs (dermatitis). However, this participant remains in the study as the withdrawal was subsequently queried and corrected, as described in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Errata.

2.5.5.5.6.5. Open-Label Follow-Up Period – Original Placebo Participants Who Received BNT162b2

From unblinding to receive BNT162b2 (Dose 3) up to the data cutoff date, IR of original placebo participants withdrawn because of AEs was 0.8 per 100 PY (Table 72).

Table 72. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	19	0.8	(0.5, 1.2)
CARDIAC DISORDERS	2	0.1	(0.0, 0.3)
Angina pectoris	1	0.0	(0.0, 0.2)
Cardio-respiratory arrest	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	2	0.1	(0.0, 0.3)
Diarrhoea	1	0.0	(0.0, 0.2)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	7	0.3	(0.1, 0.6)
Chills	2	0.1	(0.0, 0.3)

Table 72. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Fatigue	2	0.1	(0.0, 0.3)
Injection site pain	3	0.1	(0.0, 0.4)
Pain	1	0.0	(0.0, 0.2)
IMMUNE SYSTEM DISORDERS	2	0.1	(0.0, 0.3)
Allergy to vaccine	1	0.0	(0.0, 0.2)
Anaphylactoid reaction	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	3	0.1	(0.0, 0.4)
Maternal exposure during pregnancy	3	0.1	(0.0, 0.4)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1	0.0	(0.0, 0.2)
Myalgia	1	0.0	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1	0.0	(0.0, 0.2)
Hepatic cancer	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	2	0.1	(0.0, 0.3)
Headache	2	0.1	(0.0, 0.3)
PSYCHIATRIC DISORDERS	1	0.0	(0.0, 0.2)
Completed suicide	1	0.0	(0.0, 0.2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1	0.0	(0.0, 0.2)
Angioedema	1	0.0	(0.0, 0.2)
Urticaria	1	0.0	(0.0, 0.2)

Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 31MAR2021 (18:33)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA1/adae_s131_wd_exp_p3x_saf

Open-Label Follow-Up Period – Original Placebo Participants who had COVID-19 Occurrence After Dose 1 and Then Received BNT162b2

The subset of participants originally randomized to placebo, who had a COVID-19 case after Dose 1 of placebo and were later unblinded to receive BNT162b2 (Dose 3), were evaluated. Three participants in this group had AEs leading to withdrawal that were assessed as related to BNT162b2 (also summarized in Section 2.5.5.5.3.5.1): 1 participant with an AE of allergy to vaccine, 1 participant with an AE of pain, and 1 participant with 5 AEs (chills, injection site pain, myalgia, headache, and diarrhea).

2.5.5.5.7. Other Significant Adverse Events – Phase 2/3

AEs of clinical interest were evaluated based on regulatory agency feedback and sponsor medical review. Terms requested for analysis by the FDA were summarize and detailed for any such cases reported. Other terms of clinical interest, such as the CDC's list of AESIs for COVID-19 vaccines, which both include terms potentially indicative of severe COVID-19 or serious autoimmune and neuroinflammatory disorders, were considered in the review of reported events. Numerical imbalances for AESIs were based on the evaluation of AEs in the blinded placebo-controlled period. These safety evaluations are summarized below.

Narratives were prepared for a defined set of events as described in Section 2.5.5.1.2.3.

2.5.5.5.7.1. FDA-Requested Adverse Events of Clinical Interest

Safety evaluations were conducted for AEs of clinical interest: anaphylaxis, Bell's Palsy, lymphadenopathy, and appendicitis based on feedback from the FDA.

Participants ≥16 years of age reporting these terms during blinded placebo-controlled follow-up (unless otherwise noted as occurring during open-label follow-up) are summarized below.

Hypersensitivity/Anaphylaxis

During the blinded placebo-controlled follow-up period of Study C4591001 in participants ≥16 years of age, there were 3 allergic reactions reported as SAEs (all reported at the time of the 14 November 2020 data cutoff date). All 3 cases of allergic reaction were considered by the investigator as not related to study treatment.

- Anaphylactic reaction following a bee sting in a BNT162b2 recipient (8 days after Dose 2)
- Drug hypersensitivity to an antibiotic in a BNT162b2 recipient (9 days after Dose 2)
- Anaphylactic shock due to an ant bite in a placebo recipient (18 days after Dose 2).

During the open-label follow-up period, 1 participant who received BNT162b2 as Dose 3 (after originally being randomized to placebo and unblinded to receive BNT162b2) had an SAE of anaphylactoid reaction, which was assessed as related to study intervention. This participant was a female adolescent with a medical history significant for multiple allergies since infancy. Two days after Dose 3, she experienced hives on the left arm (deltoid) and self-administered an epinephrine pen 24 minutes later (given the history of anaphylaxis to

multiple allergens). Six minutes after injection, she experienced shortness of breath. Hives and shortness of breath resolved within 10 and 30 minutes, respectively, of epinephrine treatment. The participant did not seek additional medical attention. As a result of the anaphylactoid reaction, the participant was permanently withdrawn from the study.

Hypersensitivity is also assessed as a CDC-defined AESI in Section 2.5.5.5.7.2.

Bell's Palsy/Facial Paralysis

During the blinded placebo-controlled follow-up period, 6 participants developed one-sided facial paralysis (Bell's palsy): 4 were randomized to BNT162b2 (all male) and 2 were randomized to placebo (1 male; 1 female). Regarding the 4 vaccinated participants (previously reported at 14 November 2020 cutoff date), their ages ranged from 40 to 70 years of age (compared to 71 to 73 years of age in placebo participants). Events began from 3 to 48 days after their last dose, were mild to moderate in severity (moderate in the placebo participants), and duration ranged from 3 to 68 days (15 days in 1 placebo participant and ongoing in the other). Of the 4 cases in participants randomized to BNT162b2, 2 were considered by the investigator to be related to study intervention. The remaining 4 cases (2 in participants originally randomized to BNT162b2 and 2 in participants originally randomized to placebo) were assessed as not related to study intervention.

During the open-label follow-up period, 3 participants who received BNT162b2 as Dose 3 or Dose 4 (after originally being randomized to placebo) experienced facial paralysis. All were female and their ages ranged from 19 to 34 years. Events began 2 to 8 days after Dose 3 and were mild to severe in severity. One case involved a duration of 12 days while the other 2 were ongoing as of the data cutoff date. All these events of facial paralysis were considered by the investigator as related to study intervention.

During the open-label follow-up period for participants originally randomized to BNT162b2, a male participant 51 years of age developed Bell's palsy 154 days after receiving Dose 2.

Bell's palsy is also assessed as an AESI in Section 2.5.5.5.7.3.

Lymphadenopathy

In participants ≥16 years of age, during the blinded placebo-controlled follow-up period, lymphadenopathy was reported in 87 participants (1.0 per 100 PY) in the BNT162b2 group compared to 8 participants (0.1 per 100 PY) in the placebo group. The majority of events were mild to moderate; only 3 severe events of lymphadenopathy were reported (all in the BNT162b2 group). The median onset of lymphadenopathy after Dose 1 and before Dose 2 was 5.5 days in the BNT162b2 group and 5.0 days in the placebo group; median onset after Dose 2 was shorter in the BNT162b2 group versus the placebo group (2.0 days vs 7.0 days). The median duration of lymphadenopathy was 5.5 days in the BNT162b2 group and 4.0 days in the placebo group. One case (previously reported at 14 November 2020 cutoff date) was reported as a related SAE (see Section 2.5.5.5.5.1).

Appendicitis

Cases of appendicitis were examined in the placebo-controlled follow-up period of the study including PTs of appendicitis perforated and complicated appendicitis). There were 14 cases of appendicitis and 1 case of appendicitis perforated in the BNT162b2 group; and 9 cases of appendicitis, 2 cases of complicated appendicitis, and 1 appendicitis perforated in the placebo group. Appendicitis cases were all reported as SAEs (see Section 2.5.5.5.5.1 and Section 2.5.5.5.5.2), and none of the cases were considered related to study intervention.

2.5.5.5.7.2. CDC-Defined Adverse Events of Special Interest

CDC-defined AESIs associated with COVID-19 vaccination were evaluated in the blinded placebo-controlled follow-up period, where reported in the Phase 2/3 safety population.

After a review of AEs using the CDC's AESI list, the following terms were not found reported in the study: acute disseminated encephalomyelitis, transverse myelitis, multiple sclerosis, chronic inflammatory demyelinating polyneuropathy, encephalitis, myelitis, encephalomyelitis, meningoencephalitis, ataxia, narcolepsy, cataplexy, immune thrombocytopenia, thrombotic thrombocytopenic purpura, disseminated intravascular coagulation, Kawasaki disease, multisystem inflammatory syndrome in children (MIS-C) and in adults (MIS-A), and acute respiratory distress syndrome.

There were 2 cases of bacterial meningitis reported but they were not analyzed further as there is an immediate and self-evident cause to their illness.

Terms that were present in the safety population are summarized below. For a given SMQ, if there was no imbalance in the BNT162b2 group versus placebo, the PTs within the SMQ were not further examined. In the case of an imbalance, the PTs responsible for the imbalance are further described and the nature of the events characterized with regard to plausible associated with vaccination.

Overall, the number and percentage of participants with any unsolicited AEs within the selected SMQs was similar in the BNT162b2 (224 [1.02%]) and placebo (217 [0.99%]) groups from Dose 1 to the unblinding date (Table 73). From analysis of terms corresponding to AESIs from the CDC's list, individual SMQs are discussed below.

Table 73. Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=21926)	Placebo (N[a]=21921)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)
	Subjects with any unsolicited adverse events within SMQ	224 (1.02)	217 (0.99)
Angioedema (SMQ)	Any unsolicited adverse events within Angioedema (SMQ)	30 (0.14)	29 (0.13)
	Eye disorders	2 (0.01)	2 (0.01)
	Conjunctival oedema	0	1 (0.00)
	Eye swelling	0	1 (0.00)
	Eyelid oedema	1 (0.00)	0
	Swelling of eyelid	1 (0.00)	0
	Gastrointestinal disorders	6 (0.03)	3 (0.01)
	Gingival swelling	0	1 (0.00)
	Lip oedema	1 (0.00)	0
	Lip swelling	2 (0.01)	1 (0.00)
	Swollen tongue	2 (0.01)	1 (0.00)
	Tongue oedema	1 (0.00)	0
	General disorders and administration site conditions	4 (0.02)	7 (0.03)
	Face oedema	2 (0.01)	0
	Swelling face	2 (0.01)	7 (0.03)
	Respiratory, thoracic and mediastinal disorders	1 (0.00)	3 (0.01)
	Pharyngeal swelling	1 (0.00)	3 (0.01)
	Skin and subcutaneous tissue disorders	21 (0.10)	18 (0.08)
	Angioedema	3 (0.01)	2 (0.01)
	Urticaria	18 (0.08)	15 (0.07)
	Urticaria papular	0	1 (0.00)
Arthritis (SMQ)	Any unsolicited adverse events within Arthritis (SMQ)	35 (0.16)	48 (0.22)
	Infections and infestations	1 (0.00)	0
	Arthritis bacterial	1 (0.00)	0
	Metabolism and nutrition disorders	5 (0.02)	3 (0.01)
	Gout	5 (0.02)	3 (0.01)
	Musculoskeletal and connective tissue disorders	29 (0.13)	45 (0.21)
	Arthritis	6 (0.03)	6 (0.03)
	Arthritis reactive	1 (0.00)	0
	Osteoarthritis	15 (0.07)	23 (0.10)
	Patellofemoral pain syndrome	0	1 (0.00)

Table 73. Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=21926)	Placebo (N[a]=21921)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)
	Periarthritis	4 (0.02)	1 (0.00)
	Polyarthritis	0	1 (0.00)
	Rheumatoid arthritis	0	2 (0.01)
	Spinal osteoarthritis	2 (0.01)	4 (0.02)
	Spondylitis	1 (0.00)	1 (0.00)
	Synovitis	0	2 (0.01)
	Temporomandibular joint syndrome	1 (0.00)	4 (0.02)
Convulsions (SMQ)	Any unsolicited adverse events within Convulsions (SMQ)	2 (0.01)	2 (0.01)
	Nervous system disorders	2 (0.01)	2 (0.01)
	Generalised tonic-clonic seizure	0	1 (0.00)
	Seizure	2 (0.01)	1 (0.00)
Demyelination (SMQ)	Any unsolicited adverse events within Demyelination (SMQ)	2 (0.01)	1 (0.00)
	Nervous system disorders	2 (0.01)	1 (0.00)
	Guillain-Barre syndrome	0	1 (0.00)
	Optic neuritis	2 (0.01)	0
Hypersensitivity (SMQ)	Any unsolicited adverse events within Hypersensitivity (SMQ)	182 (0.83)	161 (0.73)
	Ear and labyrinth disorders	0	1 (0.00)
	Allergic otitis media	0	1 (0.00)
	Eye disorders	5 (0.02)	5 (0.02)
	Conjunctival oedema	0	1 (0.00)
	Conjunctivitis allergic	3 (0.01)	2 (0.01)
	Eye allergy	0	1 (0.00)
	Eye swelling	0	1 (0.00)
	Eyelid oedema	1 (0.00)	0
	Swelling of eyelid	1 (0.00)	0
	Gastrointestinal disorders	6 (0.03)	3 (0.01)
	Gingival swelling	0	1 (0.00)
	Lip oedema	1 (0.00)	0
	Lip swelling	2 (0.01)	1 (0.00)
	Swollen tongue	2 (0.01)	1 (0.00)
	Tongue oedema	1 (0.00)	0

Table 73. Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=21926)	Placebo (N[a]=21921)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)
	General disorders and administration site conditions	8 (0.04)	9 (0.04)
	Application site rash	0	1 (0.00)
	Face oedema	2 (0.01)	0
	Injection site dermatitis	1 (0.00)	0
	Injection site rash	2 (0.01)	1 (0.00)
	Injection site urticaria	1 (0.00)	0
	Swelling face	2 (0.01)	7 (0.03)
	Immune system disorders	10 (0.05)	13 (0.06)
	Anaphylactic reaction	1 (0.00)	0
	Anaphylactic shock	0	1 (0.00)
	Drug hypersensitivity	7 (0.03)	7 (0.03)
	Hypersensitivity	2 (0.01)	5 (0.02)
	Infections and infestations	5 (0.02)	1 (0.00)
	Dermatitis infected	0	1 (0.00)
	Pustule	3 (0.01)	0
	Rash pustular	2 (0.01)	0
	Injury, poisoning and procedural complications	3 (0.01)	0
	Administration related reaction	2 (0.01)	0
	Stoma site rash	1 (0.00)	0
	Investigations	1 (0.00)	0
	Blood immunoglobulin E increased	1 (0.00)	0
	Respiratory, thoracic and mediastinal disorders	19 (0.09)	21 (0.10)
	Allergic respiratory disease	0	1 (0.00)
	Allergic sinusitis	2 (0.01)	0
	Bronchospasm	3 (0.01)	3 (0.01)
	Pharyngeal swelling	1 (0.00)	3 (0.01)
	Rhinitis allergic	13 (0.06)	14 (0.06)
	Skin and subcutaneous tissue disorders	134 (0.61)	119 (0.54)
	Angioedema	3 (0.01)	2 (0.01)
	Dermatitis	5 (0.02)	4 (0.02)
	Dermatitis acneiform	1 (0.00)	0
	Dermatitis allergic	3 (0.01)	5 (0.02)
	Dermatitis atopic	0	1 (0.00)

Table 73. Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=21926)	Placebo (N[a]=21921)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)
	Dermatitis bullous	0	1 (0.00)
	Dermatitis contact	14 (0.06)	21 (0.10)
	Dermatitis exfoliative	1 (0.00)	0
	Drug eruption	0	2 (0.01)
	Eczema	7 (0.03)	3 (0.01)
	Erythema nodosum	1 (0.00)	0
	Fixed eruption	1 (0.00)	0
	Hand dermatitis	2 (0.01)	2 (0.01)
	Perioral dermatitis	0	1 (0.00)
	Pruritus allergic	0	2 (0.01)
	Rash	62 (0.28)	52 (0.24)
	Rash erythematous	2 (0.01)	3 (0.01)
	Rash maculo-papular	7 (0.03)	4 (0.02)
	Rash papular	1 (0.00)	0
	Rash pruritic	8 (0.04)	6 (0.03)
	Urticaria	18 (0.08)	15 (0.07)
	Urticaria contact	0	1 (0.00)
	Urticaria papular	0	1 (0.00)
Peripheral neuropathy (SMQ)	Any unsolicited adverse events within Peripheral neuropathy (SMQ)	3 (0.01)	6 (0.03)
	Nervous system disorders	3 (0.01)	6 (0.03)
	Guillain-Barre syndrome	0	1 (0.00)
	Neuralgia	1 (0.00)	1 (0.00)
	Neuritis	0	1 (0.00)
	Neuropathy peripheral	1 (0.00)	3 (0.01)
	Peripheral sensory neuropathy	1 (0.00)	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = the number of subjects reporting at least 1 occurrence of any event.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 14APR2021 (10:22)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA RR/adae smq nzud 16 saf

Angioedema

Overall, the number and percentage of participants with any unsolicited AE within the SMQ of angioedema were low and similar in the BNT162b2 group (30 [0.14%]) and placebo group (29 [0.13%]) (Table 73). AEs were most frequently reported in the SOC of skin and subcutaneous tissue disorders (21 [0.10%] BNT162b2 vs 18 [0.08%] placebo) with urticaria the most frequently reported PT.

In the SOC of gastrointestinal disorders within the SMQ of angioedema, lip edema, or lip swelling was observed in 3 participants in the BNT162b2 group versus 1 participant in the placebo group. Swollen tongue or tongue edema was observed in 3 participants in the BNT162b2 group versus 1 participant in the placebo group. Lip swelling in 1 participant in the BNT162b2 group and swollen tongue in 1 participant in the placebo group were considered as related to the study intervention:

- In the BNT162b2 group, 1 participant experienced mild upper and lower lip swelling 14 and 19 days after Dose 1 which lasted 2 days before resolving and was considered as related to the study intervention. This same participant also experienced upper lip swelling and drug hypersensitivity 2 days after Dose 2, which were recovering/resolving as of the data cutoff date and were considered related to study intervention by the investigator.

- In the placebo group, 1 participant experienced moderate swollen tongue as well as moderate pharyngeal swelling 21 days after Dose 2; both resolved after 9 days; this participant also experienced moderate drug hypersensitivity and mild rash (on chin, elbows, knees, neck and back) 2 days after Dose 2 which lasted for 28 days and 30 days, respectively, and resolved. Swollen tongue as well as these other AEs were all considered related to the study intervention by the investigator.

Angioedema events in the other SMQs were all reported at low percentages in the BNT162b2 (≤0.02) and placebo groups (≤0.03%) (Table 73).

Arthritis

Overall, the number and percentage of participants with any unsolicited AE within the SMQ of arthritis was lower in the BNT162b2 group (35 [0.16%]) than in placebo group (48 [0.22%]) (Table 73). AEs were most frequently reported in the SOC of musculoskeletal and connective tissue disorders (0.13% BNT162b2 vs 0.21% placebo) with osteoarthritis the most frequently reported PT.

Convulsions

Overall, the number and percentage of participants with any unsolicited AE within the SMQ of convulsions was low and equal in the BNT162b2 group and placebo group (2 participants [0.01%] in each group) (Table 73). All events were in the SOC of nervous system disorders: seizure (2 participants in the BNT162b2 group) and generalized tonic-clonic seizure (1 participant in the placebo group).

Demyelination

Overall, the number and percentage of participants with any unsolicited AE within the SMQ of demyelination was low: 2 (0.01%) participants in the BNT162b2 group and 1 (0.00%) participant in the placebo group. All events were in the SOC of nervous system disorders.

Optic neuritis was observed in 2 participants in the BNT162b2 group and none in the placebo group; 1 case occurring in a male participant and 1 case occurring in a female participant. Both participants were in the younger age group. These events occurred 79 and 81 days after their last vaccination of BNT162b2. Both were considered not related to BNT162b2. Both events were reported as SAEs.

Guillain-Barre syndrome was reported as an SAE in 1 participant in the placebo group.

These events of optic neuritis and Guillain-Barre syndrome are also included in AESI analyses in Section 2.5.5.5.7.3.

Hypersensitivity

Overall, the number and percentage of participants with any unsolicited AE within the SMQ of hypersensitivity was higher in the BNT162b2 group (182 [0.83%]) than in the placebo group (161 [0.73%]) (Table 73). The difference was mainly due to skin and subcutaneous tissue disorders (134 [0.61%] BNT162b2 vs 119 [0.54%] placebo):

- rash (62 [0.28%] BNT162b2 vs 52 [0.24%] placebo)
- rash maculo-papular (7 [0.03%] BNT162b2 vs 4 [0.02%] placebo)
- rash papular (1 [0.00%] BNT162b2 vs 0 placebo).

Rash was assessed as related to study intervention at a higher IR in the BNT162b2 group (0.3) than in the placebo group (0.1).

In the SMQ of hypersensitivity in the SOC of infections and infestations: pustule and rash pustular were reported only in the BNT162b2 group by 3 participants (0.01%) and 2 participants (0.01%), respectively. In the SOC of injury, poisoning and procedural complications, administration related reaction (2 participants) and stoma site rash (1 participant) were reported only in the BNT162b2 group.

Additionally, in the SMQ of hypersensitivity in the SOC of gastrointestinal disorders, lip edema, lip swelling, swollen tongue, and tongue edema were observed more frequently in the BNT162b2 group versus the placebo group. Refer to the Angioedema section above for details.

Anaphylactic reaction was observed in 1 participant in the BNT162b2 group (refer to Section 2.5.5.5.7.1 for more detail).

In the SMQ of hypersensitivity in the SOC of investigations, increased blood IgE was observed in 1 participant in the BNT162b2 group.

Peripheral Neuropathy

Overall, the number and percentage of participants with any unsolicited AE within the SMQ of peripheral neuropathy was lower in the BNT162b2 group (3 [0.01%]) than in the placebo group (6 [0.03%]). All PTs were in the SOC of nervous system disorders (Table 73).

2.5.5.5.7.3. Other Sponsor-Identified Adverse Events of Special Interest

Additional terms beyond those designated by the CDC as AESIs were evaluated to assess potential imbalances in the BNT162b2 and placebo groups, and further characterized such an imbalance. PTs associated with these AE categories and by SOC/PT were identified during the blinded placebo-controlled follow-up period and presented (Table 74). These events are summarized below.

One death in the placebo group was captured as a potential AESI as there was no reported primary cause of death at the time of the data cutoff. This death is also captured in Table 67 in the analysis of deaths reported from Dose 1 to the unblinding date (Section 2.5.5.5.4.1).

From analysis of additional designated AESIs, individual categories are discussed below.

Table 74. Incidence Rates of at Least 1 Adverse Event Category of Special Interest From Dose 1 to Unblinding Date, by Adverse Event Category and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)			Difference	
Adverse Event Category Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])	IRD (/100 PY)[f]	(95% CI[g])
ACUTE MYOCARDIAL INFARCTION								
Acute coronary syndrome	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)	-0.04	(-0.09, 0.02)
Acute myocardial infarction	6	0.1	(0.0, 0.2)	4	0.0	(0.0, 0.1)	0.02	(-0.05, 0.10)
Coronary artery occlusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Myocardial infarction	4	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)	-0.05	(-0.13, 0.03)
ANAPHYLAXIS								
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
Anaphylactic shock	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
APPENDICITIS								
Appendicitis	14	0.2	(0.1, 0.3)	9	0.1	(0.1, 0.2)	0.06	(-0.06, 0.17)
Appendicitis perforated	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	-0.00	(-0.03, 0.03)
Complicated appendicitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)	-0.02	(-0.06, 0.01)

Table 74. Incidence Rates of at Least 1 Adverse Event Category of Special Interest From Dose 1 to Unblinding Date, by Adverse Event Category and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)			Difference	
Adverse Event Category Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])	IRD (/100 PY)[f]	(95% CI[g])
ARTHRITIS/ARTHRALGIA								
Arthralgia	281	3.4	(3.0, 3.8)	122	1.5	(1.2, 1.8)	1.88	(1.41, 2.36)
Arthritis	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)	-0.00	(-0.08, 0.08)
Arthritis reactive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
BELL'S PALSY								
Facial paralysis	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.04	(-0.02, 0.09)
Facial paresis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
COVID-19 DISEASE								
COVID-19	0	0.0	(0.0, 0.0)	13	0.2	(0.1, 0.3)	-0.16	(-0.24, -0.07)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	-0.00	(-0.03, 0.03)
DEATH								
Death	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
ENCEPHALOPATHY								
Toxic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
Uraemic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
GUILLAIN-BARRE SYNDROME								
Guillain-Barre syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (MIS-C) AND IN ADULTS (MIS-A)								
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
MYOCARDITIS								
Myocarditis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
NON-ANAPHYLACTIC ALLERGIC REACTIONS								
Angioedema	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)	0.01	(-0.04, 0.06)
Hypersensitivity	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)	-0.04	(-0.10, 0.03)
Lip swelling	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.01	(-0.03, 0.05)
Pruritus	24	0.3	(0.2, 0.4)	20	0.2	(0.1, 0.4)	0.04	(-0.11, 0.20)
Rash	62	0.7	(0.6, 1.0)	52	0.6	(0.5, 0.8)	0.11	(-0.14, 0.36)
Rash pruritic	8	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)	0.02	(-0.07, 0.11)

Table 74. Incidence Rates of at Least 1 Adverse Event Category of Special Interest From Dose 1 to Unblinding Date, by Adverse Event Category and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)			Difference	
Adverse Event Category Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])	IRD (/100 PY)[f]	(95% CI[g])
Swelling face	2	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)	-0.06	(-0.13, 0.01)
Swollen tongue	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.01	(-0.03, 0.05)
Urticaria	18	0.2	(0.1, 0.3)	15	0.2	(0.1, 0.3)	0.03	(-0.10, 0.17)
OPTIC NEURITIS								
Optic neuritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.02	(-0.01, 0.06)
PERICARDITIS								
Pericarditis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
PULMONARY EMBOLISM								
Pulmonary embolism	8	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)	-0.00	(-0.10, 0.09)
SEIZURE/CONVULSION								
Generalised tonic-clonic seizure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Seizure	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.01	(-0.03, 0.05)
STROKE, HEMORRHAGIC								
Haemorrhagic stroke	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Intraventricular haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Subarachnoid haemorrhage	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.04	(-0.02, 0.09)
STROKE, ISCHEMIC								
Cerebellar infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Cerebral infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Cerebrovascular accident	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.04	(-0.02, 0.09)
Ischaemic stroke	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)	-0.00	(-0.05, 0.05)
Transient ischaemic attack	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)	-0.01	(-0.07, 0.04)
THROMBOCYTOPENIA								
Platelet count decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
Thrombocytopenia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)	-0.01	(-0.05, 0.03)
VACCINATION DURING PREGNANCY AND ADVERSE PREGNANCY OUTCOMES								
Abortion incomplete	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Abortion spontaneous	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)	-0.01	(-0.07, 0.04)
Abortion spontaneous incomplete	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Exposure during pregnancy	30	0.4	(0.2, 0.5)	42	0.5	(0.4, 0.7)	-0.15	(-0.35, 0.05)

Table 74. Incidence Rates of at Least 1 Adverse Event Category of Special Interest From Dose 1 to Unblinding Date, by Adverse Event Category and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)			Difference	
Adverse Event Category Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])	IRD (/100 PY)[f]	(95% CI[g])
Retained products of conception	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
VENOUS THROMBOEMBOLISM								
Coagulopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
Deep vein thrombosis	7	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)	-0.00	(-0.09, 0.09)
Ophthalmic vein thrombosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
Penile vein thrombosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Venous thrombosis limb	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)

Note: MedDRA (v23.1) coding dictionary applied.
Note: The 95% confidence interval quantifies the precision of the incidence rate difference estimate. Confidence intervals are not adjusted for multiplicity. They should only be used to identify potentially important adverse events.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Difference in incidence rate (BNT162b2 [30 µg] - placebo).
g. 2-sided Wald CI for the incidence rate difference.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 16APR2021 (13:49)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA1/adae s131 aesi cat p3 saf

Acute Myocardial Infarction

Acute myocardial infarctions were searched with the PTs of acute myocardial infarction, acute coronary syndrome, coronary artery occlusion, and myocardial infarction. A total of 11 events were identified in the BNT162b2 group (6 acute myocardial infarctions, 4 myocardial infarctions group, and 1 acute coronary syndrome) and a total of 17 event were identified in the placebo group (4 acute myocardial infarctions, 8 myocardial infarctions, 4 acute coronary syndromes, and 1 coronary artery occlusion). Most of these events had onset distant (ie, >30 days following) to receipt of vaccine or placebo. None of these events were assessed by the investigator as related to study intervention. Outcome was resolved in all participants in the BNT162b2 group; in the placebo group, outcome was fatal in 2 participants and resolved in remaining participants.

Anaphylaxis

Overall, the category of anaphylaxis included 1 participant with anaphylactic reaction in the BNT162b2 group and 1 participant with anaphylactic shock in the placebo group. These events are further described in Section 2.5.5.5.7.1.

Appendicitis

Overall, the category of appendicitis (including appendicitis perforated and complicated appendicitis) included 15 participants in the BNT162b2 group and 12 participants in the placebo group. These events are further described in Section 2.5.5.5.7.1.

Arthritis/Arthralgia

Arthralgia not associated with reactogenicity was evaluated starting from Day 8 after either dose of BNT162b2. The IR of arthralgia assessed from Day 8 (ie, beyond the 7-day reactogenicity period in which arthralgia is recorded in e-dairies for the reactogenicity subset) after each dose was lower in the BNT162b2 group (0.6) than in the placebo group (0.8).

Autoimmune Disease

There are no search term SMQ that would reliably capture all potential autoimmune diseases. Hence a comprehensive manual medical review of all reported AEs in the blinded placebo-controlled period was undertaken to identify PTs potentially indicative of autoimmune disease. These PTs are summarized by vaccine group.

In the BNT162b2 group there were 10 autoimmune disease cases identified. There were 1 case each in the BNT162b2 group: autoimmune thyroiditis, ulcerative colitis, Crohn's disease, reactive arthritis, fibromyalgia, systemic lupus erythematosus, alopecia areata, psoriasis, and 2 cases of psoriatic arthropathy.

In the placebo group there were 15 autoimmune cases identified. There were 1 case each in the placebo group: autoimmune thyroiditis, celiac disease, alopecia areata, psoriasis, Raynaud's phenomenon, and 2 cases of psoriatic arthropathy, 2 cases of psoriasis, 2 cases of ulcerative colitis, 2 cases of rheumatoid arthritis, 3 cases of fibromyalgia.

Bell's Palsy/Facial Paralysis

Overall, the category of Bell's Palsy (facial paralysis and facial paresis) included 4 participants in the BNT162b2 group and 2 participants in the placebo group during blinded placebo-controlled follow-up. These events are further described in Section 2.5.5.5.7.1.

Multiple Cases of COVID-19

There were 5 participants, all randomized to placebo, who developed 2 separate and clinically symptomatic instances of COVID-19 confirmed by NAAT at the central laboratory. All of the second confirmed COVID-19 cases occurred during the blinded period before their first dose of BNT162b2 (Dose 3), except for 1 participant who had a second COVID-19 diagnosis 4

days after receiving their second dose of BNT162b2. All participants were N-binding antibody negative prior to their first instance of COVID-19. The time interval between the first and second COVID-19 episode generally varied from 1 to 3 months.

Death

One death (placebo group) was captured as a potential AESI as there was no reported primary cause of death at the time of the data cutoff. This death is also captured in Table 67 in the analysis of deaths reported from Dose 1 to the unblinding date (Section 2.5.5.5.4.1).

Encephalopathy

Overall, the category of encephalopathy included 2 participants in the BNT162b2 group and none in the placebo group. One participant reported an SAE of toxic encephalopathy 64 days after Dose 2 in the setting of diverticulosis and a urinary tract infection, which resolved 8 days later, and the other participant reported an SAE of uremic encephalopathy 36 days after Dose 2, which resolved 3 days later. Both events were assessed by the investigator as not related to study intervention.

Guillain-Barre Syndrome

One participant in the placebo group reported an SAE of Guillain-Barre syndrome. This case was also captured as a CDC AESI in Section 2.5.5.5.7.2..

Multisystem Inflammatory Syndrome

One participant in the placebo group reported an SAE of multiple organ dysfunction syndrome.

Myocarditis

One case in the placebo group was reported.

Non-Anaphylactic Allergic Reactions

Overall, there was no imbalance in each of the PTs in non-anaphylactic allergic reactions (123 in the BNT162b2 group and 109 in the placebo group). Selected events are also captured as CDC AESIs under SMQ of Angioedema and Hypersensitivity in Section 2.5.5.5.7.2.

Optic Neuritis

Two participants in the BNT162b2 group reported an SAE each of optic neuritis. This case was also captured as a CDC AESI in Section 2.5.5.5.7.2.

Pericarditis

There was 1 participant in the older BNT162b2 age group with pericarditis. The event had an onset of 28 days after Dose 2, was ongoing at the data cutoff date, and was assessed by the investigator as not related to the study intervention.

Pulmonary Embolism

PTs associated with pulmonary embolism were searched in the blinded placebo-controlled period: pulmonary embolism, pulmonary thrombosis, pulmonary venous thrombosis, and pulmonary artery thrombosis. There were 8 cases of pulmonary embolism in the BNT162b2 group and 8 cases in the placebo group.

Stroke, Hemorrhagic

PTs associated with hemorrhagic stroke were searched in the blinded placebo-controlled follow-up period: hemorrhagic stroke, cerebral hemorrhage, hemorrhagic cerebral infarction, basal ganglia hemorrhage, brain stem hemorrhage, cerebellar hemorrhage, subarachnoid hemorrhage, and intraventricular hemorrhage.

Overall, there were 4 hemorrhagic strokes in the BNT162b2 and 3 in the placebo group. In the BNT162b2 group there were 4 subarachnoid hemorrhages and in the placebo group there was 1 subarachnoid hemorrhage, 1 intraventricular hemorrhage, and 1 hemorrhagic stroke.

Stroke, Ischemic

PTs associated with ischemic stroke were searched in the blinded placebo-controlled follow-up period: ischemic stroke, ischemic cerebral infarction, cerebral infarction, lacunar infarction, cerebral ischemia, cerebellar stroke, brain stem stroke, vertebrobasilar stroke, embolic stroke, thrombotic stroke, thrombotic and cerebral infarction, cerebral vascular accident, transient ischemic attack, and cerebellar infarction.

There were a total of 8 of these PTs in the BNT162b2 group and 8 in the placebo group. There were 2 ischemic strokes, 4 cerebral vascular accidents, 2 transient ischemic attacks identified in the BNT162b2 group. In the placebo group there are 2 ischemic strokes, 3 transient ischemic attacks, 1 cerebral vascular accident, 1 cerebral infarction and 1 cerebellar infarction.

Thrombocytopenia

PTs associated with thrombocytopenia were searched in the blinded placebo-controlled period and included thrombocytopenia and platelet count decreased. The BNT162b2 group had 1 case of thrombocytopenia and 1 case of platelet count decreased, and the placebo group had 2 cases of thrombocytopenia.

Vaccination During Pregnancy and Pregnancy Outcomes

There was no imbalance in the BNT162b2 group versus the placebo group with regard to pregnancy and maternal exposure. Pregnancy and maternal exposure reported during the study is discussed in Section 2.5.5.7.2.

Venous Thromboembolism

PTs associated with venous thromboembolism were searched in the blinded placebo-controlled period: cerebral venous sinus thrombosis, cerebral venous thrombosis, cerebral

thrombosis, superior sagittal sinus thrombosis, deep vein thrombosis, venous thrombosis limb, retinal vein thrombosis, retinal vein occlusion, mesenteric vein thrombosis, thrombosis mesenteric vessel, splenic thrombosis, splenic vein thrombosis, splenic embolism, visceral venous thrombosis, hepatic vein thrombosis, hepatic vein embolism, vena cava thrombosis, vena cava embolism, renal vein thrombosis, renal vein embolism, venous thrombosis, thrombosis, embolism, and thrombotic microangiopathy.

Overall, there were 9 thrombotic events in the BNT162b2 group and 9 in the placebo group. In the BNT162b2 group included 7 deep vein thromboses, 1 coagulopathy, and 1 ophthalmic vein thrombosis; and in the placebo group included 7 deep vein thromboses, 1 penile vein thrombosis, and 1 venous thrombosis limb (Table 74). None of the venous events were associated with thrombocytopenia.

2.5.5.6. Clinical Laboratory Evaluations

Clinical laboratory evaluations were conducted routinely during the Phase 1 part of Studies BNT162-01 and C4591001. No post-dose laboratory abnormalities were associated with clinical findings.

2.5.5.6.1. Clinical Laboratory Evaluations in Study BNT162-01

Details of clinical laboratory evaluations are provided in Module 5.3.5.1 BNT162-01 Interim CSR Section 12 and Module 2.7.4 and summarized below.

Clinical laboratory evaluations were performed in the Phase 1 part of Study BNT162-01 after Dose 1 and after Dose 2 for each vaccine candidate and dose level.

Clinical Chemistry

Clinical chemistry abnormalities were observed infrequently. No clinically relevant abnormalities were observed, except for slight elevations in C-reactive protein reported on Day 2 by 1 participant each in the 30 µg and 50 µg dose groups for BNT162b1 and on Day 8 by 1 participant in the 1 µg dose group for BNT162b2. These values returned to normal at the subsequent visit without any clinical consequences.

Hematology

The most commonly observed hematologic laboratory changes were transient decreases in lymphocytes noted 1-2 days after Dose 1. These decreases returned to normal by the subsequent study visit (by Day 8), without any clinical consequences or sequelae. Overall, the incidence of decreased lymphocyte counts was lower for BNT162b2 recipients compared with BNT162b1 recipients.

No additional clinically relevant hematologic laboratory changes were observed, except for a high lymphocyte count reported on Day 29 by 1 participant in the 1 µg dose group for BNT162b1, which was assessed as an AE considered as related to study intervention and as a clinically significant event. The event resolved 8 days after the second dose without any medication.

2.5.5.6.2. Clinical Laboratory Evaluations in Study C4591001

Details of clinical laboratory evaluations are provided in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 12.1.5 and Module 2.7.4 and summarized below.

Clinical laboratory evaluations were performed in the Phase 1 part of Study after Dose 1 and after Dose 2 for each vaccine candidate, dose level, and age group. Note that the younger group of participants (18 to 55 years of age) who received BNT162b1 at the 100 µg dose level did not receive a second dose at this level per IRC decision due to reactogenicity. This group instead received a second dose of 10 µg, and the 100 µg dose level was discontinued.

Clinical Chemistry

Clinical chemistry abnormalities were observed infrequently. No abnormalities were observed for BNT162b1, and only one abnormality was observed for BNT162b2: one younger participant in the 10 µg group had a grade 2 bilirubin abnormality at screening that was noted as grade 3 at 1 to 3 days after Dose 1 and then recovered to grade 1 by 6 to 8 days.

Hematology

The most commonly observed hematology laboratory changes were transient decreases in lymphocytes (<0.8 × LLN) noted 1 to 3 days after Dose 1. These decreases returned to normal by the next measurement, within 6 to 8 days of the first dose. Overall, the incidence of decreased lymphocyte counts was lower for BNT162b2 recipients compared with BNT162b1 recipients, and most decreases in lymphocyte counts were grade 1 or 2.

2.5.5.7. Other Safety Assessments

Details of other safety analysis results in Study C4591001 are provided in Module 2.7.4 and summarized below.

2.5.5.7.1. Severe COVID-19 Illness

Cases of COVID-19, both overall and those considered as severe, were evaluated per criteria described in Section 2.5.4.1.1.3. A description of severe COVID-19 cases evaluated for efficacy in Phase 2/3 is presented in Section 2.5.4.3.1.3.2 (interim analysis), Section 2.5.4.3.2.1.3.2 (final analysis), and Section 2.5.4.3.3 (updated analysis). The protocol had prespecified stopping rules that included monitoring of severe COVID-19 cases, and these stopping criteria were not met. These data show confinement of severe cases predominantly to the placebo group, suggesting no evidence for vaccine-associated enhanced disease (VAED) including vaccine-associated enhanced respiratory disease (VAERD).

2.5.5.7.2. Pregnancies

At the time of the data cutoff date (13 March 2021), a total of 50 participants who had received BNT162b2 had reported pregnancies, including 42 participants originally randomized to the BNT162b2 group and 8 participants originally randomized to the placebo group who then received BNT162b2. In total, 12 participants (n=6 each in the randomized BNT162b2 and placebo groups) withdrew from the blinded placebo-controlled vaccination period of the study due to pregnancy, and 4 participants originally randomized to placebo

who then received BNT162b2 withdrew from the open-label vaccination period due to pregnancy (Table 54). These participants continue to be followed for pregnancy outcomes. No births have been reported from individuals who have become pregnant in Study C4591001 as of the time of this submission.

2.5.5.7.3. Adverse Drug Reactions

Adverse reactions (ADRs) were identified from Study C4591001 Phase 2/3 safety data and are detailed in Module 2.7.4. ADRs are defined as AEs for which there is reason to conclude the vaccine was the cause of the event; this ADR review also included reactogenicity terms.

The CIOMS frequency categories for adverse reactions are as follows:

- Very common: ≥10%
- Common: ≥1% and <10%
- Uncommon: ≥0.1% and <1%
- Rare: ≥0.01% and <0.1%
- Very rare: <0.01%.

Reactogenicity ADRs that occurred with a very common frequency, based on any dose in the BNT162b2 group from the reactogenicity subset of data as of 13 March 2021, are:

- Injection site pain: 4153/4924 (84.3%)
- Fatigue: 3185/4924 (64.7%)
- Headache: 2814/4924 (57.1%)
- Muscle pain: 1980/4924 (40.2%)
- Chills: 1707/4924 (34.7%)
- Joint pain: 1232/4924 (25.0%)
- Fever: 749/4924 (15.2%)
- Injection site swelling: 546/4924 (11.1%).

A reactogenicity ADR that occurred with a common frequency, based on any dose in the BNT162b2 group from the reactogenicity subset of data as of 13 March 2021, was:

- Injection site redness: 486/4924 (9.9%)

ADRs considered as common (nausea) and uncommon (lymphadenopathy and malaise) in the BNT162b2 group were identified from AE data in the safety population as of 13 March 2021, compared to placebo for reference:

- Nausea: 274/21,926 (1.2%) in BNT162b2 vs 87/21,921 (0.4%) in placebo
- Lymphadenopathy: 83/21,926 (0.4%) in BNT162b2 vs 7/21,921 (0.0%) in placebo
- Malaise: 130/21,926 (0.6%) in BNT162b2 vs 22/21,921 (0.1%) in placebo

The following additional ADRs were identified in the post-authorization setting. Frequencies for these ADRs were obtained from clinical study data (Study C4591001) when possible, as per labeling guidance.

- Diarrhea (very common)
- Vomiting (common)
- Pain in Extremity (uncommon)
- Rash (uncommon)
- Pruritus (uncommon)
- Urticaria (uncommon)
- Angioedema (rare)
- Anaphylaxis (unknown).

It should be noted that at the time of conditional approval of BNT162b2 by the EMA, the sponsor was requested to include the following as ADRs in the Summary of Product Characteristics (SmPC) even though they were not considered ADRs in the Core Data Sheet (CDS). The frequencies in the initial EMA-approved SmPC reflected data from the initial conditional approval submission (data cutoff date: 14 November 2020):

- Acute peripheral facial paralysis 3/18801 = 0.02% (rare)
- Injection site pruritus 27/18801 = 0.1% (uncommon)
- Insomnia 23/18801 = 0.1% (uncommon).

The following ADRs have been identified from the clinical study data and are supported by reports in the post-authorization setting; the CIOMS frequency category for these reactions is uncommon (based on clinical data from Study C4591001): lethargy, asthenia, decreased appetite, hyperhidrosis, and night sweats. These ADRs will be added to the CDS and subsequently proposed for all BNT162b2 labels. The additional ADRs further characterize the safety profile of BNT162b2 but do not impact its favorable risk:benefit profile.

2.5.5.8. Safety in Special Groups and Situations

Details of safety in special groups and situations are provided in Module 2.7.4 and summarized below.

2.5.5.8.1. Geriatric Use

Clinical studies of BNT162b2 (30 µg) include participants ≥65 years of age whose data contribute to overall assessment of safety and efficacy. The clinical data have demonstrated a predominantly mild reactogenicity profile in older adults, overall and compared with younger adults. This is coupled with evidence of robust immune response following the two-dose vaccination regimen, and overwhelming efficacy comparable to younger adults (>90%).

2.5.5.8.2. Pediatric Use

Further study of pediatric use of the vaccine and/or immunobridging study will be undertaken to characterize the vaccine response in children.

2.5.5.8.3. Use During Pregnancy and Lactation

Women who were pregnant or breastfeeding were not eligible to participate in Studies BNT162-01 or C4591001.

There were no pregnancies reported in Study BNT162-01 as of the data cutoff date for the BNT162-01 Phase 1 Interim CSR. At the time of the most recent data cutoff in Study C4591001 (13 March 2021), a total of 50 participants had reported pregnancies in the safety database (Section 2.5.5.7.2). These participants continue to be followed for pregnancy outcomes.

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. Available data on BNT162b2 administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. In a DART study, no vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for vaccination with BNT162b2 and any potential adverse effects on the breastfed child from BNT162b2 or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

2.5.5.8.4. Use in Immunocompromised Individuals

Individuals who are immunocompromised or taking immunosuppressive therapy at the time of vaccine administration may have diminished response to immunization. Study C4591001 included enrollment of individuals with medical history of immunocompromised condition or immunosuppressive therapy (Section 2.5.5.5.1). There are limited data on the safety and effectiveness of the vaccine in this patient population at the time of this submission.

2.5.5.8.5. Other Safety Considerations

Overdose

In Study C4591001, any dose of study intervention exceeding 30 µg within a 24-hour time period was considered an overdose (refer to Module 5.3.5.1 C4591001 Protocol Section 8.4). An error in dilution during the study resulted in 52 participants receiving a higher than intended dose of BNT162b2: instead of receiving 30 µg, an actual dose of 58 µg BNT162b2 was administered. These participants did not report an increase in reactogenicity or AEs.

Drug Abuse and Withdrawal and Rebound

Not applicable for BNT162b2.

Effects on Ability to Drive or Operate Machinery or Impairment of Mental Ability

BNT162b2 has no or negligible influence on the ability to drive and use machines.

2.5.5.9. Post-Authorization Safety Summary

Post-authorization safety data are continually monitored by Pfizer and BioNTech for pharmacovigilance and risk management purposes. Pfizer's safety database contains cases of AEs reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious AEs reported from clinical studies regardless of causality assessment. Through 28 February 2021, there were a total of 42,086 case reports

(25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. Cases were received from 63 countries.

Consistent with events in Phase 2/3 of Study C4591001, most reported AEs were in SOCs with reactogenicity events: general disorders and administration site conditions (51,335), nervous system disorders (25,957), musculoskeletal and connective tissue disorders (17,283), and gastrointestinal disorders (14,096). Post-authorization data have also informed the addition of ADRs related to the experience of reactogenicity to product labeling (see Section 2.5.5.7.3 for additional information regarding ADRs).

Aside from addition of anaphylaxis and hypersensitivity, the analyses of cumulative post-authorization safety data, including a review of AESIs, are consistent with the analysis of the pivotal clinical study (C4591001). Review of post-authorization data has not revealed any novel safety concerns except for anaphylaxis and has confirmed the favorable benefit-risk profile of the vaccine.

Further details regarding the cumulative analysis of post-authorization safety data are presented in Module 5.3.6.

2.5.5.10. Safety Conclusions

Phase 1

Based on Phase 1 data from the FIH Study BNT162-01, BNT162b1 and BNT162b2 were safe and well-tolerated in healthy adults 18 to 55 years of age, with no unanticipated safety findings. Reactogenicity and AEs tended to increase in incidence and/or severity with increasing dose of BNT162b2. Reactogenicity was mostly mild to moderate and short-lived after dosing (eg, arose and resolved within the first 1 to 2 days after dosing), and the AE profile and clinical laboratory results did not suggest any safety concerns.

Based on Phase 1 data from Study C4591001 and Study BNT162-01, BNT162b1 and BNT162b2 were safe and well-tolerated in younger healthy adults 18 to 85 years of age, with no unanticipated safety findings. Reactogenicity and AEs were generally milder and less frequent in participants in the older group compared with the younger group and overall tended to increase with increasing BNT162b2 dose. Reactogenicity was mostly mild to moderate and short-lived after dosing, and the AE profile did not suggest any safety concerns, including up to approximately 6 months after Dose 2 for BNT162b2 30 µg groups. Clinical laboratory evaluations showed a transient decrease in lymphocytes that was observed in all age and dose groups after Dose 1, which resolved within approximately 1 week, were not associated with any other clinical sequelae, and were not considered clinically relevant.

RNA vaccines are known to induce type I interferon,[22] and type I interferons regulate lymphocyte recirculation and are associated with transient migration and/or redistribution of lymphocytes.[23] This rapid rebound of lymphocytes supports that the lymphocytes are not depleted, but temporarily migrated out of the peripheral blood, and subsequently re-entered the bloodstream by the time of the next assessment.

Phase 2/3

Based on Phase 2/3 data from approximately 44,000 participants ≥16 years of age with up to at least 6 months of follow-up after Dose 2 in Study C4591001, BNT162b2 at 30 µg was safe and well-tolerated across age groups. Reactogenicity and AEs were generally milder and less frequent in participants in the older group (>55 years of age) compared with the younger group (≤55 years of age). Reactogenicity was mostly mild to moderate and short-lived after dosing for both younger and older age groups (ie, median onset between 1 to 4 days after dosing and resolution within 1 to 2 days after onset), and the AE profile did not suggest any serious safety concerns. The incidence of SAEs and deaths were low in the context of the number of participants enrolled and comparable in BNT162b2 and placebo. The incidence of discontinuations due to AEs was also generally low and similar between BNT162b2 and placebo groups.

Cumulative safety follow-up to at least 6 months after Dose 2 for approximately 12,000 Phase 2/3 participants originally randomized to BNT162b2, comprising the combined blinded and open-label periods, showed no new safety signals or suggested and new safety concerns arising from this period of follow-up.

Similarly, open-label follow-up of participants originally randomized to placebo from the time of unblinding to receive BNT162b2 until the data cutoff date showed no new safety signals or concerns.

Safety analysis results for subgroups based on demographics (age, race, ethnicity, and sex) and by baseline SARS-CoV-2 status (positive vs negative) have not shown any clinically important differences in the BNT162b2 safety profile. Analysis of the subset of individuals with stable HIV did not suggest any safety concerns in this population. Analysis of participants originally randomized to placebo who then received BNT162b2 (Dose 3) by demographic subgroups and based on prior evidence of SARS-CoV-2 infection or prior COVID-19 illness did not suggest any safety concerns.

Phase 2/3 safety data were generally concordant with safety data in Phase 1 of the study, both overall and with regard to younger and older participants.

2.5.6. Benefits and Risks Conclusions

2.5.6.1. Benefits

COVID-19 is a serious and potentially fatal or life-threatening human infection. Based on clinical data to date, it is expected that BNT162b2 (30 µg) will elicit an immune response that is likely to protect against COVID-19. The total duration of any such protection is currently unknown.

Vaccine Efficacy

Efficacy of BNT162b2 (30 µg) to prevent COVID-19 was overwhelmingly demonstrated at the first interim analysis of 94 cases (data cutoff date: 04 November 2020), with a VE of 95.5% (with a 2-sided 95% credible interval of 88.8% to 98.4%) in pivotal Study C4591001 Phase 3 participants who had no prior evidence of SARS-CoV-2 infection, which met the

protocol prespecified success criteria for the first primary endpoint. This was confirmed in the final analyses of 170 cases reported in participants without evidence of past SARS-CoV-2 infection before or during the vaccination regimen, with VE of 95.0% (data cutoff date: 14 November 2020).

Overall, the observed VE in each demographic subgroup in the final analysis, as defined by age, sex, race, ethnicity, and country, was >90% in the interim and final analyses, and additional post hoc analyses of at-risk subgroups also showed high VE, consistent with broad effectiveness of BNT162b2 to protect vaccinees against COVID-19. Severe cases were predominantly confined to the placebo group.

In the final analysis, among participants without evidence of past SARS-CoV-2 infection before and during the vaccination regimen, observed VE of 66.3% against severe COVID-19 occurring at least 7 days after Dose 2 did not meet the prespecified success criterion of the posterior probability >98.6%, due to the small number of severe cases (1 in the BNT162b2 group, 3 in the placebo group) observed after Dose 2 in the study.

In the all-available population of the final analysis, among the total of 10 severe COVID-19 cases observed after Dose 1, only 1 severe case was seen in BNT162b2 recipients compared to 9 severe COVID-19 cases in placebo recipients; these results, as well as case splits between Dose 1 and Dose 2 and after Dose 2, were consistent with overall efficacy seen against COVID-19. Efficacy against severe COVID-19 was similar when applying the CDC definition of severe, which includes a general criterion of hospitalization.

Efficacy final analyses counting COVID-19 occurring at least 14 days after Dose 2 resulted in similar efficacy estimates as the 7-day efficacy analyses. Moreover, the analyses of efficacy using CDC-defined symptoms gave similar efficacy estimates as the definition used in other primary and secondary endpoints.

Duration of Protection

Updated analyses of efficacy for cases occurring confirmed from at least 7 days after Dose 2 and accrued up to the submission cutoff date (13 March 2021), which represents up to approximately 6 months of blinded follow-up after Dose 2, included estimated VE of 91.3% and 91.1% for evaluable efficacy populations without and with or without past evidence of SARS-CoV-2 infection before or during the vaccination regimen. During this same follow-up period, VE against severe COVID-19 occurring at least 7 days after Dose 2 was 95.3% in participants with or without prior evidence of SARS-CoV-2 infection when applying FDA criteria for severe disease and was 100.0% when applying the CDC definition of severe disease.

High VE (>90%) has continued to be observed for participants across most subgroups defined by demographics, at-risk status (including obesity and Charlson comorbidities), and geography (including in countries where SARS-CoV-2 variants are in predominant circulation). Note that sequencing of SARS-CoV-2 strains from breakthrough cases in the BNT162b2 group is in progress to determine which strains were the cause of COVID-19 as compared to the placebo group and will be submitted at a later time. Few confirmed cases

were reported in the subgroup of baseline SARS-CoV-2 positive participants, precluding a meaningful determination of VE in this subset.

Vaccine-Elicited Immune Response

Immunogenicity data from Phase 1 and Phase 2 participants have shown robust humoral and T cell-mediated immune responses after vaccination with 2 doses of BNT162b2 at 30 µg in both younger and older adults. This immunogenicity has been shown to be maintained up to 6 months after the second dose for Phase 1 participants inclusive of functional neutralizing and antigen-binding antibodies and T cell responses and was evident up to 1 month after Dose 2 in Phase 2 adult participants. Analyses of Phase 2 participants included a small number of individuals with evidence of prior SARS-CoV-2 infection, for whom vaccine induced neutralizing and antigen-binding antibodies were substantially further boosted after BNT162b2 vaccination.

Overall Benefits

Taken together, efficacy and immunogenicity data suggest the BNT162b2 (30 µg) 2-dose regimen induces a strong immune response and provides durable protection from COVID-19 across a spectrum of individuals representative of the population at large for individuals ≥16 years of age: those with or without prior exposure to SARS-CoV-2 and those in higher risk categories based on age, race, ethnicity, and/or comorbidity.

2.5.6.2. Risks

Reactogenicity Profile

The Phase 2/3 reactogenicity profile was typically mild to moderate, arose within the first 1 to 4 days after dosing, and reactions were short-lived. The most common prompted local reaction was injection site pain. The most common prompted systemic events reported in Phase 2/3 included fatigue, headache, muscle and joint pain, and chills.

Adverse Event Profile

The AE profile among approximately 44,000 participants ≥16 years of age enrolled to date as of the most recent safety cutoff date (13 March 2021), was mostly reflective of reactogenicity events with low incidences of severe and/or related events. The incidence of SAEs was low and similar in the vaccine and placebo groups. Few participants withdrew from the study due to AEs. Few deaths occurred overall in both the vaccine and placebo groups with no imbalance. Review of AEs of clinical interest have suggested no clear patterns or safety concerns.

Safety analyses up to at least 6 months after Dose 2 for participants who were randomized to BNT162b2, inclusive of cumulative blinded and open-label data, showed no new safety findings or signals over a longer duration of follow-up.

For participants randomized to placebo and then unblinded to receive BNT162b2 vaccination, open-label data from the time of unblinding to the data cutoff date (13 March 2021) showed no new safety findings or signals. Open-label safety data for participants originally

randomized to placebo who were unblinded to receive BNT162b2 followed generally similar patterns relative to those who were originally randomized to BNT162b2 during blinded follow-up. This supports the overall consistency of the safety profile of the BNT162b2 30 µg two-dose vaccination regimen across study phases and follow-up periods.

Safety analyses of study participants across various demographic subgroups, by baseline SARS-CoV-2 prior infection status, and with stable HIV have not shown any clinically important differences in the BNT162b2 safety profile for the duration of blinded follow-up.

Study participants will continue to be followed for 2 years or end of study.

Severe Disease

As of the most recent safety cutoff date (13 March 2021), representing up to 6 months of follow-up after Dose 2, the reported cases of COVID-19 considered per FDA criteria as severe from Dose 1 onwards included 1 case in the BNT162b2 group and 30 cases in the placebo group; according to CDC criteria, from Dose 1 onwards this included 1 case in the BNT162b2 group and 45 cases in the placebo group. The case split between the study groups using either definition for severe disease suggests no evidence of VAED or VAERD.

Post-Authorization Safety

From December 2020 until April 2021, >100 million doses of BNT162b2 have been administered to individuals ≥16 years of age in the US under EUA.[24,25] It is reassuring that the most commonly reported AEs in the post-authorization review (which includes global reporting; see Section 2.5.5.9) reflect the same profile observed in the blinded placebo-controlled follow-up period of the pivotal clinical study, primarily reflecting short-lived and resolving reactogenicity events. Further, the same pattern was observed for pivotal study participants originally randomized to the placebo group who were unblinded (per protocol) to receive BNT162b2: these participants, in the open-label setting, also reported mostly reactogenicity events similar to those in the blinded follow-up. AEs of clinical interest were not reported frequently in the controlled clinical study and continue to be evaluated in the post-authorization setting.

Overall Safety Profile

Overall, BNT162b2 recipients had a similar or more favorable systemic reactogenicity profile compared with other vaccines that are widely used in clinical settings. Local reactions for BNT162b2 are comparable or less than those seen with other licensed vaccines (eg, Shingrix®, Trumenba®, pneumococcal polysaccharide and pneumococcal conjugate vaccines) in matching age groups; systemic events, particularly chills and fever, were observed more frequently after BNT162b2 compared to the other vaccines, but in a tolerable range with very few withdrawals related to such events (see Section 2.5.5.5.2).

2.5.6.3. Benefit-Risk Conclusions

The available clinical evidence for BNT162b2 (30 µg) effectiveness includes induction of strong immune responses and overwhelmingly high vaccine efficacy, suggesting the vaccine confers protection against COVID-19 in individuals ≥16 years of age.

The potential risks are based on the observed safety profile to date, which shows mostly mild reactogenicity, low incidence of severe or serious events, and no clinically concerning safety observations or safety concerns. The vaccine appears to be safe and well-tolerated across the safety population comprising approximately 44,000 study participants ≥16 years of age, among whom approximately 12,000 have been followed for at least 6 months after completing the two-dose regimen. Safety analyses have also included demographic subgroups based on age, sex, race, ethnicity, and baseline SARS-CoV-2 status and the subset with stable HIV. The confinement of severe cases of COVID-19 predominantly to the placebo group versus the BNT162b2 group suggests no evidence of VAED. Post-authorization safety review reinforces that BNT162b2 is safe and tolerable.

Vaccine efficacy was remarkably high, ≥95% for participants without prior evidence of SARS-CoV-2 infection and >94% for those with or without prior infection, in the prespecified interim and/or final analyses. Updated analyses with all confirmed cases accrued up to approximately 6 months after Dose 2 showed persistence of protection with estimated VE of ≥91.1%. Overall, observed VE was >90% across subgroups identified by age, sex, race, ethnicity, country, and risk factors and remained high in the updated analysis. Severe cases have been confined overwhelmingly to the placebo group in all efficacy analyses. Efficacy data suggest highly effective protection against COVID-19 in a broad population of individuals across demographic characteristics, with durable immune responses and protection from COVID-19 disease observed up to approximately 6 months after completing the vaccination regimen.

Mass immunization with a safe and effective vaccine against COVID-19 can dramatically alter the trajectory of the pandemic. According to policy briefing by the Institute for Health Metrics and Evaluation published on 31 March 2021, COVID-19 remains a leading cause of death in the US with up to 100,000 additional deaths per month projected in the US between March and July 2021, many of which can likely be prevented with COVID-19 vaccination.[26,27]

Vaccination against COVID-19 began with EUA/conditional approvals in December 2020, in a phased rollout defined by national/regional guidance. However, there continue to be concerning trends that may counteract the impacts of this vaccination effort, including:

- limitations in access to obtaining a vaccine due to infrastructure challenges (ie, clinic and appointment capacity and systems)[28]
- increasing viral transmission fueled by relaxed compliance with mitigations as the pandemic surpasses the 1-year mark (ie, masks, physical distancing, limiting travel)[26,28]
- increasing circulation of emerging variants of concern (which are currently driving continued spread of viral infection in Europe despite extensive mitigation mandates).[26,28]

A vaccine program must be implemented expediently and rapidly expanded to have a significant impact on the pandemic course.[27,29] Licensure of BNT162b2 is likely to enhance vaccine uptake by facilitating supply of vaccine from Pfizer/BioNTech directly to pharmacies and healthcare providers/facilities. The greatest impact of BNT162b2 licensure may be direct supply to healthcare providers who serve vulnerable populations such as elderly patients and those who live in rural and underserved communities (ie, individuals who might be unable to navigate the challenges of securing vaccine access using the systems in place for EUA). Expansion of vaccine via licensure would ultimately improve the prospect of achieving population herd immunity to bring the pandemic under control.[30]

Overall, the potential risks and benefits, as assessed by the safety profile and the efficacy and immunogenicity of BNT162b2 (30 µg), are balanced in favor of the potential benefits to prevent COVID-19 in immunized individuals. Likewise, the BNT162b2 30 µg benefit and risk profile supports further development in pediatric, maternal, and other at-risk populations.

2.5.7. References

1 Virus Pathogen Database and Analysis Resource (ViPR). Available at: https://www.viprbrc.org/brc/viprStrainDetails.spg?ncbiAccession=MN908947&decorator=corona. Accessed 11 August 2020.

2 Zhu N, Zhang D, Wang W, et al. A novel coronavirus from patients with pneumonia in China, 2019. N Engl J Med 2020;382:727-33.

3 Johns Hopkins University Coronavirus Resource Center. Available at: https://coronavirus.jhu.edu/map.html. Accessed 23 April 2021.

4 Wiersinga WJ, Rhodes A, Cheng AC, et al. Pathophysiology, transmission, diagnosis, and treatment of Coronavirus Disease 2019 (COVID-19). JAMA 2020; [ePub]doi:10.1001/jama.2020.12839.

5 Centers for Disease Control and Prevention (CDC). Coronavirus Disease (COVID-19). Available at: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html. Accessed 11 August 2020.

6 Onder G, Rezza G, Brusaferro S. Case-fatality rate and COVID-19 death characteristics in Italy. JAMA 2020;[ePub]:doi:10.1001/jama.2020.4683.

7 Wu Z, McGoogan JM. Characteristics of and important lessons from the Coronavirus Disease 2019 (COVID-19) outbreak in China. JAMA 2020; [ePub]:doi:10.1001/jama.2020.2648.

8 Infectious Diseases Society of America Guidelines on the Treatment and Management of Patients with COVID-19. Available at: https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management. Accessed 02 March 2021.

9 Vogel AB, Lambert L, Kinnear E, et al. Self-amplifying RNA vaccines give equivalent protection against influenza to mRNA vaccines but at much lower doses. Mol Ther 2018;26(2):446-55.

10 Moyo N, Vogel AB, Buus S, et al. Efficient induction of T cells against conserved HIV-1 regions by mosaic vaccines delivered as self-amplifying mRNA. Mol Ther Methods 2019;12:32-46.

11 Pardi N, Hogan MJ, Pelc RS, et al. Zika virus protection by a single low-dose nucleoside-modified mRNA vaccination. Nature 2017;543(7644):248-51.

12 Kirchdoerfer RN, Wang N, Pallesen J, et al. Stabilized coronavirus spikes are resistant to conformational changes induced by receptor recognition or proteolysis. Sci Rep 2018;8(1):15701.

13 Wrapp D, Wang N, Corbett KS, et al. Cryo-EM structure of the 2019-nCoV spike in the prefusion conformation. Science 2020;367(6483):1260-63.

14 Pallesen J, Wang N, Corbett KS, et al. Immunogenicity and structures of a rationally designed prefusion MERS-CoV spike antigen. Proc Natl Acad Sci 2017;114(35):E7348-57.

15 Lambert, P-H, Ambrosino DM, Andersen SR, et al. Consensus summary report for CEPI/BC March 12-13, 2020 meeting: Assessment of risk of disease enhancement with COVID-19 vaccines. Vaccine 2020; 38:4783-91; doi:10.1016/j.vaccine.2020.05.064.

16 Vogel AB, Kanevsky I, Che Y, et al. A prefusion SARS-CoV-2 spike RNA vaccine is highly immunogenic and prevents lung infection in non-human primate. 2020; published online at https://www.biorxiv.org/content/10.1101/2020.09.08.280818v1.

17 US Food and Drug Administration. Development and Licensure of Vaccines to Prevent COVID-19. Guidance for Industry. June 2020. Available at: https://www.fda.gov/media/139638/download

18 Centers for Disease Control and Prevention (CDC). Coronavirus Disease (COVID-19). Available at: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html. Accessed 09 December 2020.

19 Walsh EE, Frenck RW Jr, Falsey AR, et al. Safety and immunogenicity of two RNA-based Covid-19 vaccine candidates. N Engl J Med. 2020;[ePub]:doi: 10.1056/NEJMoa2027906.

20 Mulligan MJ, Lyke KE, Kitchin N, et al. Phase I/II study of COVID-19 RNA vaccine BNT162b1 in adults. Nature 2020;586(7830):589-93. [ePub]doi:10.1038/s41586-020-2639-4.

21 US Food and Drug Administration, Guidance for Industry Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trial. Available at: https://www.fda.gov/media/73679/download

22 Kranz LM, Diken M, Haas H, et al. Systemic RNA delivery to dendritic cells exploits antiviral defence for cancer immunotherapy. Nature 2016;534, 396-401.

23 Kamphuis E, Junt T, Waibler Z, et al. Type I interferons directly regulate lymphocyte recirculation and cause transient blood lymphopenia. Blood 2006;108(10):3253-61.

24 Centers for Disease Control and Prevention (CDC). COVID-19 Data Tracker. Available at: https://covid.cdc.gov/covid-data-tracker/#vaccinations. Accessed 23 April 2021.

[25] Coronavirus (COVID-19) Vaccinations – Statistics and Research – Our World in Data. Available at: https://ourworldindata.org/covid-vaccinations#which-vaccines-have-been-administered-in-each-country. Accessed 23 April 2021.

[26] Institute for Health Metrics and Evaluation. COVID-19 policy briefings: United States of America COVID-19 results briefing. 31 March 2021. Available at: http://www.healthdata.org/sites/default/files/files/Projects/COVID/2021/102_briefing_United_States_of_America_11.pdf. Accessed 07 April 2021.

[27] Biggerstaff M. Oct 2020 ACIP meeting. Available at: https://www.cdc.gov/vaccines/acip/meetings/slides-2020-10.html

[28] Coronavirus (COVID-19) Vaccinations – Statistics and Research – Our World in Data. Available at: https://ourworldindata.org/covid-vaccinations#vaccination-policies. Accessed 07 April 2021.

[29] Biggerstaff M, Reed C, Swerdlow D, et al. Estimating the potential effects of a vaccine program against an emerging influenza pandemic—United States. Clinical Infectious Diseases 2015;60(S1):S20-9.

[30] Anderson R, Vegvari C, Truscott J, Collyer BS. Challenges in creating herd immunity to SARS-CoV-2 infection by mass vaccination. Lancet 2020;[ePub]:doi.org/10.1016/S0140-6736(20)32318-7.

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2.7.3 SUMMARY OF CLINICAL EFFICACY

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LIST OF ABBREVIATIONS

Abbreviation	Definition
BMI	body mass index
CDC	(US) Centers for Disease Control and Prevention
CEF	MHC-class I restricted peptides originating from CMV, EBV, and flu (influenza) virus
CEFT	MHC-class II restricted peptides originating from CMV, EBV, Flu (influenza) virus and tetanus toxin
CI	confidence interval
CMV	cytomegalovirus
CoV	coronavirus
COVID-19	coronavirus disease 2019
CSR	clinical study report
DBP	diastolic blood pressure
EBV	Epstein-Barr-virus
ECMO	extracorporeal membrane oxygenation
ELISpot	enzyme-linked immuno-spot
FACS	fluorescence-activated cell sorting
FDA	(US) Food and Drug Administration
FIH	first-in-human
FiO_2	fraction of inspired oxygen
GMC	geometric mean concentration
GMFR	geometric mean-fold rise
GMT	geometric mean titer
HBV	hepatitis B virus
HCV	hepatitis C virus
HCS	human convalescent serum
HIV	human immunodeficiency virus
HLA	human leukocyte antigen
ICS	intracellular cytokine staining
ICU	intensive care unit
IFN	interferon
IgG	immunoglobulin G
IgM	immunoglobulin M
IL	interleukin
IMM	Immunogenicity set, defined as all participants who received at least one dose of study vaccine and had at least one post-baseline immunogenicity assessment
IRC	(US Study C4591001) internal review committee
IRR	illness rate ratio
LLOQ	lower limit of quantitation
LNP	lipid nanoparticle
MHC	major histocompatibility complex
modRNA	nucleoside-modified messenger RNA
mRNA	messenger RNA
NAAT	nucleic acid amplification test
N-binding	SARS-CoV-2 nucleoprotein binding

Abbreviation	Definition
P2 S	SARS-CoV-2 full-length, P2 mutant, prefusion spike glycoprotein
PaO_2	partial pressure of oxygen, arterial
PBMC	peripheral blood mononuclear cell
Pr	posterior probability
RBD	receptor binding domain
RNA	ribonucleic acid
RNA-LNP	RNA lipid nanoparticle
RR	respiratory rate
RT-PCR	reverse transcription–polymerase chain reaction
S protein, S	SARS-CoV-2 spike protein
SAP	statistical analysis plan
SARS	severe acute respiratory syndrome
SARS-CoV-2	SARS coronavirus-2; virus causing the disease COVID-19
SBP	systolic blood pressure
SCE	summary of clinical efficacy
SPO_2	oxygen saturation as measured by pulse oximetry
USA	United States
Th1/Th2	helper T cell type 1/type 2
VE	vaccine efficacy

2.7.3. SUMMARY OF CLINICAL EFFICACY

Pfizer and BioNTech have developed an investigational vaccine intended to prevent Coronavirus Disease 2019 (COVID-19) caused by the virus, SARS-CoV-2. The vaccine, BNT162b2, is a nucleoside-modified mRNA-based vaccine formulated in lipid nanoparticles (LNPs) that encodes the SARS-CoV-2 full-length, P2 mutant, prefusion spike glycoprotein (P2 S).

This Summary of Clinical Efficacy (SCE) summarizes data from evaluations of efficacy and immunogenicity performed in 2 clinical studies of BNT162b2 that support the present marketing application. The proposed indication and dosing administration for BNT162b2 (30 μg) are:

Proposed indication: Active immunization to prevent COVID-19 in individuals 16 years of age and older

Dosing administration: administered intramuscularly as a series of two doses (0.3 mL each) 3 weeks apart.

The present submission comprises 2 studies conducted in individuals ≥12 years of age. The submission includes data from:

- Phase 1 of the first-in-human (FIH) dose-ranging study, BNT162-01; and
- Phase 1, 2, and 3 of the pivotal efficacy study, C4591001.

The studies are currently ongoing, and therefore data included in the submission and presented in this SCE are interim. Additional data will be provided in subsequent submissions.

2.7.3.1. Background and Overview of Clinical Efficacy/Immunogenicity

The core innovation of mRNA-based vaccines is based on in vivo delivery of a pharmacologically optimized, antigen-encoding RNA to induce robust neutralizing antibodies and a concomitant T cell response to achieve protective immunization with minimal vaccine doses.[1,2,3] BioNTech has developed multiple RNA-LNP platforms, including nucleoside-modified RNA (modRNA), which has blunted innate immune sensor activating capacity and thus augmented antigen expression. Two modRNA vaccine candidates were evaluated in both the FIH dose-ranging study, conducted in Germany (BNT162-01), and in the Phase 1, dose-ranging portion of Study C4591001, conducted in the United States. The vaccines were:

- BNT162b1, which encodes a fragment of the SARS-CoV-2 S glycoprotein that contains the receptor binding domain (RBD); and
- BNT162b2, which encodes the full-length SARS-CoV-2 S glycoprotein with mutations that stabilize S in an antigenically optimal prefusion conformation that exposes neutralization-sensitive sites (P2 S).

Based on safety and immunogenicity results from both of these studies, as well as nonclinical data, a single candidate and dose level (BNT162b2, at 30 μg) was selected for further development.

In Phase 2/3 of Study C4591001, the efficacy of BNT162b2 was evaluated using a case accrual design. Based on initial assumptions regarding the COVID-19 attack rate in the placebo group and the anticipated non-evaluable rate among all participants, it was estimated that efficacy could be demonstrated in a population of approximately 43,998 participants (21,999 per group). Recruitment was expanded beyond the United States to include study centers in Argentina, Brazil, Germany, Turkey, and South Africa. Initially, 4 interim analyses were planned after accrual of 32, 62, 92, and 120 confirmed COVID-19 cases for the first primary efficacy endpoint. At each interim analysis, Vaccine efficacy (VE) was to be evaluated for the first primary objective only (ie, VE for the subgroup of participants with no serological or virological evidence of SARS-CoV-2 infection prior to vaccination and up to 7 days after receipt of the second dose). Overwhelming efficacy could be declared if the success criterion for the first primary endpoint was met at any of the 4 interim analyses, or the study could be stopped for lack of benefit if the futility criterion was met at any of the first 3 interim analyses. The final analysis was to be performed with accrual of 164 confirmed cases for the first primary efficacy endpoint.

For operational reasons, the first planned IA was not performed. Amendment 9 to the C4591001 protocol eliminated the planned interim analysis at 32 cases and provided for 3 interim analyses to be performed after accrual of *at least* 62, 92, and 120 cases. Thereafter, case accumulation was so rapid that the planned analysis at 62 cases was performed after 94 cases had been confirmed, and accrual of the 164 cases for the final analysis followed soon thereafter.

At the interim analysis (data cutoff date: 04 November 2020), the success criterion for the first primary endpoint was met, confirming the efficacy of BNT162b2 in preventing disease caused by SARS-CoV-2 virus in individuals ≥16 years of age. The results from this interim analysis of the first primary endpoint are included in this SCE, along with the results from analyses of all the other primary and secondary efficacy endpoints, which were conducted after accrual of at least 164 cases (final analysis data cutoff date: 14 November 2020). In addition, updated descriptive efficacy analyses based on an accrued 1165 confirmed cases of COVID-19 during blinded placebo-controlled follow-up (data cutoff date: 13 March 2021) were conducted.

Analyses of immunogenicity in Study C4591001 include data from adults ≥18 years of age up to 6 months after Dose 2 in Phase 1 and up to 1 month after Dose 2 in Phase 2.

Content of the Summary of Clinical Efficacy

This SCE provides an overview of the 2 studies included in the submission, describing study design and conduct, methods for evaluating vaccine efficacy and immunogenicity, and results from the efficacy and immunogenicity analyses, as outlined below.

Content	Section
Overview of study design and conduct for both studies	Section 2.7.3.1.1
Methods for the evaluation of efficacy (Study C4591001)	Section 2.7.3.1.2
Methods for the evaluation of immunogenicity for both studies	Section 2.7.3.1.3
Results of efficacy evaluations (Study C4591001)	Section 2.7.3.2.1
Results of immunogenicity evaluations	
Phase 1 Candidate and dose selection (BNT162-01, C4591001)	Section 2.7.3.2.2.1
Phase 2 Immunogenicity results (C4591001)	Section 2.7.3.2.2.2

2.7.3.1.1. Overview of the Clinical Development Program

This section provides an overview of study design and conduct for Phase 1/2 study BNT162-01 (Section 2.7.3.1.1.1) and Phase 1/2/3 study C4591001 (Section 2.7.3.1.1.2). Methods for the evaluation of efficacy, including the statistical analyses performed, are described for Study C4591001 in Section 2.7.3.1.2; and methods for the evaluation of immunogenicity, including the statistical analyses performed, are described for both studies in Section 2.7.3.1.3.

2.7.3.1.1.1. Phase 1/2 Study BNT162-01 – Study Design and Conduct

Study BNT162-01, conducted in Germany, is an ongoing, FIH, open-label, dose-level finding study designed to evaluate the safety and immunogenicity of several different candidate vaccines at various dose levels in order to identify vaccine candidates and dose levels for further evaluation.

The study initially enrolled healthy adults 18 to 55 years of age, but the protocol was later amended to include adults 56 to 85 years of age, with data evaluated separately for the 2 age groups. Healthy participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks prior to enrollment, were eligible for the study. Individuals with certain medical conditions that could affect participant safety or evaluation of vaccine safety or immunogenicity were excluded. A complete list of inclusion and exclusion criteria is available in the protocol (Module 5.3.5.1 BNT162-01 Protocol Section 5).

Study BNT162-01 evaluated 4 different vaccine candidates using various mRNA platforms. However, because only the 2 modRNA candidates were ultimately selected for progression in the development program, the 2 candidates based on other RNA platforms are not discussed further herein.

For each vaccine candidate, participants were to receive escalating/de-escalating dose levels (12 participants per dose level), with progression to subsequent dose levels based on review of safety data by a Safety Review Committee. Each modRNA vaccine was administered as a 2-dose regimen, given 21 days apart, with dose levels as follows:

For adults 18 to 55 years of age:

- BNT162b1: 1, 3, 10, 20, 30, 50, and 60 µg
- BNT162b2: 1, 3, 10, 20, and 30 µg

Note that based on the tolerability profile after the first dose of BNT162b1 at 60 µg, the Safety Review Committee recommended that a second dose at 60 µg not be administered.

For adults 56 to 85 years of age:

- BNT162b1: 10, 20, 30 µg
- BNT162b2: 10, 20, 30 µg

Blood samples for evaluation of immunogenicity were to be collected at baseline (immediately before Dose 1); 7 and 21 days after Dose 1; and 7, 14, 21, 28, 63, and 162 days after Dose 2.

Immune responses were principally evaluated based on functional antibody titers determined using the SARS-CoV-2 neutralization assay. In addition, cell-mediated immune response assays were used to characterize T cell responses at baseline and approximately 7 days after Dose 2. For information on immunogenicity evaluation methods, refer to Section 2.7.3.1.3.

2.7.3.1.1.2. Phase 1/2/3 Pivotal Efficacy Study C4591001 – Study Design and Conduct

Study C4591001 is the ongoing Phase 1/2/3, randomized, placebo-controlled, observer-blind study in healthy individuals ≥12 years of age. Phase 1, conducted in the United States, comprised the dose-finding, vaccine candidate–selection portion of the study, while efficacy was evaluated in the Phase 2/3 portion of the study, in which enrollment was expanded to include sites in Argentina, Brazil, Germany, Turkey, and South Africa.

The study is observer-blinded, as the physical appearance of the investigational vaccine candidates and the placebo may differ. The participant, investigator, study coordinator, and other site staff are blinded; at the study site, only the dispenser(s)/administrator(s) of the study vaccines are unblinded. To facilitate rapid review of data in real time, sponsor staff were unblinded to vaccine allocation for the participants in Phase 1.

2.7.3.1.1.2.1. Phase 1 of Study C4591001

Initiated shortly after the FIH study BNT162-01, Phase 1 of Study C4591001 evaluated escalating dose levels of BNT162b1 and BNT162b2 in healthy adults 18 to 55 years of age or 65 to 85 years of age. As in Study BNT162-01, healthy participants with preexisting stable disease were eligible, although individuals with certain medical conditions or situations that could affect participant safety or evaluation of vaccine safety or immunogenicity were excluded. These included individuals at high risk for severe COVID-19 (eg, those with hypertension, diabetes mellitus, chronic pulmonary, liver, or kidney disease); and individuals who were immunocompromised (including infection with HIV or receipt of systemic corticosteroids); and those with autoimmune disease, HCV, or HBV). Individuals with a SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention or a positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the

screening visit were excluded. A complete list of inclusion and exclusion criteria is available in the protocol (Module 5.3.5.1 C4591001 Protocol Section 5).

Study vaccine was administered using the same 2-dose regimen as in Study BNT162-01 (21 days apart). An internal review committee (IRC) reviewed safety data to allow dose escalation or changes to continuation of dosing in specified groups. Escalation between dose levels was based on IRC review of at least 7-day post–Dose 1 safety data in this study and/or the Phase 1 study conducted in Germany (BNT162-01).

Each vaccine and dose level was first evaluated in a group of participants 18-55 years of age (randomized 4:1, with 12 receiving active vaccine and 3 receiving placebo). A given vaccine and dose level was administered to groups of participants 65-85 years of age (12 receiving active vaccine and 3 receiving placebo) only after the IRC had reviewed safety data for the RNA platform at the same, or a higher, dose level in the 18- to 55-year age group and deemed them acceptable. Further details regarding controlled enrollment to ensure safety at each dose level, progression between dose levels, and stopping rules are provided in the protocol (Module 5.3.5.1 C4591001 Protocol Section 4.1).

The following vaccine candidates and dose levels were evaluated in Phase 1:

- BNT162b1: 10, 20, 30, and 100 µg
- BNT162b2: 10, 20, and 30 µg

The IRC recommended that a second dose of BNT162b1 at 100 µg not be administered due to reactogenicity after the first dose (see Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 9.8 and Section 12.1). Participants in this group instead received a second dose of BNT162b1 at the 10-µg dose level, and the 100-µg dose level was not administered to older adults receiving BNT162b1.

Blood for immunogenicity evaluations was collected immediately before Dose 1 and at visits taking place approximately 7 and 21 days after Dose 1; at 7, 14, and 28 days after Dose 2, and at 6, 12, and 24 months after Dose 2. Immune responses were evaluated using the SARS-CoV-2 neutralization assay and antigen specific (S1-binding or RBD-binding) IgG level assays. Refer to Section 2.7.3.1.3 for information on immunogenicity evaluation methods.

2.7.3.1.1.2.2. Phase 2/3 of Study C4591001

Study Population

Initially, participants enrolled in Phase 2/3 were to be 18 to 85 years of age, in 2 age strata: 18 to 55 years (“younger participants”) and 56 to 85 years (“older participants”). It was intended that a minimum of 40% of participants would be in the >55-years stratum.
The protocol was later amended to lower the minimum age of participants to 16 years and to remove the upper age limit (Protocol Amendment 6, 08 September 2020). Protocol Amendment 7 (06 October 2020) allowed for enrollment of adolescents 12 to 15 years of age as an additional age stratum. The 12- to 15-year stratum was expected to comprise up to approximately 2000 participants enrolled at selected investigational sites. Note that both of

these amendments were implemented after Phase 2 of the study had been fully enrolled (N=360 participants), and therefore the Phase 2 study population included only adults 18 to 85 years of age.

Enrollment criteria for Phase 2/3 were defined to ensure a broad study population representative of the "real-world" populations expected to receive the registered vaccine. Healthy participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, were eligible for the study. Individuals were to be, in the judgment of the investigator, at higher risk for acquiring COVID-19 (including, but not limited to, use of mass transportation, relevant demographics, and frontline essential workers). Individuals with medical conditions placing them at high risk of severe COVID-19 or in occupations with high risk of exposure to SARS-CoV-2 were eligible for the study. Also included were individuals with previous clinical or microbiological diagnosis of COVID-19 or with evidence of current or prior infection based on serology or nasal swab. Immunocompromised individuals were excluded, including those receiving immunosuppressive therapy or systemic corticosteroids (inhaled/nebulized corticosteroids were permitted). Initially, known infection with human immunodeficiency virus (HIV), hepatitis C virus (HCV), or hepatitis B virus (HBV) were exclusionary; however, Amendment 6 (08 September 2020) allowed enrollment of individuals with stable HIV, hepatitis B, or hepatitis C. Additional selection criteria are described in the protocol (Module 5.3.5.1 C4591001 Protocol Section 5).

Vaccine Administration

Based on review of safety and immunogenicity results through 1 week post-Dose 2 in both Study BNT162-01 and Study C4591001 Phase 1, as well as key results from non-human primate studies, the vaccine selected for efficacy evaluation in Phase 2/3 of Study C4591001 was BNT162b2 at the 30 µg dose level.

Participants were randomized in a 1:1 ratio to receive either:

- BNT162b2 (30 µg); or
- Placebo (normal saline).

Vaccines were administered by an unblinded administrator. Participants received a 2-dose regimen, administered approximately 21 days apart, at Visit 1 and at Visit 2, with Visit 2 intended to take place 19 to 23 days after Visit 1.

Scheduled Assessments

Blood samples were collected from all participants for immunogenicity assessments immediately before Dose 1 and 1 month after Dose 2 (Visit 3). Samples will also be collected at follow-up visits scheduled at 6 months, 12 months, and 24 months after Dose 2.

Nasal (midturbinate) swabs for detection of SARS-CoV-2 were performed at Visit 1 and at Visit 2.

The complete schedule of study activities, including all efficacy, immunogenicity, and safety evaluations is available in the protocol (Module 5.3.5.1 C4591001 Protocol Section 1.3).

Definition of Phase 2

Phase 2 of the study comprised the collection and evaluation of safety and immunogenicity data for 360 of the earliest enrollees into the Phase 2/3 portion of the study, selected for balance between the younger (18 to 55 years of age) and older (56 to 85 years of age) protocol-defined strata within each vaccine group (BNT162b2 or placebo). Immunogenicity data for the 360 Phase 2 participants through 1 month after Dose 2 are presented below in Section 2.7.3.2.2.2. These participants were also included in the efficacy evaluation of the Phase 3 portion of the study.

2.7.3.1.2. Methods for the Evaluation of Efficacy – Study C4591001, Phase 2/3

Efficacy against confirmed COVID-19 was evaluated in Phase 2/3 of Study C4591001 using a case-accrual design. Under the assumption of a true vaccine efficacy (VE) rate of ≥60% after the second dose of study intervention, a target of 164 first primary-endpoint cases of confirmed COVID-19 due to SARS-CoV-2 occurring at least 7 days after Dose 2 were sufficient to provide 90% power to conclude true VE >30% with high probability.

Assuming a COVID-19 attack rate of 1.3% per year in the placebo group, accrual of 164 first primary-endpoint cases within 6 months, an estimated 20% nonevaluable rate, and 1:1 randomization, the required sample size was expected to be approximately 17,600 *evaluable* participants per group or 21,999 BNT162b2 recipients randomized in a 1:1 ratio with placebo, for a total sample size of 43,998. This was the number of participants initially targeted for Phase 2/3 and could be adjusted based on advice from the data monitoring committee's analyses of case accumulation and the percentage of participants who are seropositive at baseline.

Ongoing surveillance for potential cases of COVID-19 required participants who experienced symptoms of COVID-19 (as specified in the protocol) to contact the site immediately for assessment and case confirmation based on protocol-specified criteria (see Section 2.7.3.1.2.2).

2.7.3.1.2.1. Objectives and Endpoints for Efficacy Against Confirmed COVID-19

The primary efficacy objectives of the Phase 2/3 portion of the study were:

- To evaluate the efficacy of BNT162b2 against confirmed COVID-19 occurring from **7 days** after the second dose
  - in participants without evidence of infection before and during vaccination regimen (first primary objective), and
  - in participants with or without evidence of infection before and during vaccination regimen (second primary objective).

Secondary efficacy objectives were:

- To evaluate the efficacy of BNT162b2 against confirmed COVID-19 occurring from **14 days** after the second dose
  - in participants without evidence of infection before and during vaccination regimen;
  - in participants with or without evidence of infection before and during vaccination regimen.
- To evaluate the efficacy of BNT162b2 against confirmed **severe** COVID-19 occurring from **7 days** and from **14 days** after the second dose
  - in participants without evidence of infection before and during vaccination regimen;
  - in participants with or without evidence of infection before and during vaccination regimen.
- To describe the efficacy of BNT162b2 against confirmed COVID-19 (according to the CDC-defined symptoms) occurring from **7 days** and from **14 days** after the second dose
  - in participants without evidence of infection before and during vaccination regimen;
  - in participants with or without evidence of infection before and during vaccination regimen.

In addition, post hoc analyses (not specified in the protocol) were performed to describe the efficacy of BNT162b2 against confirmed **severe** COVID-19 (according to the CDC-defined severe symptoms).

The endpoint for each analysis was the incidence of disease (confirmed COVID-19, confirmed severe COVID 19, or confirmed COVID-19 according to the CDC-defined symptoms) per 1000 person-years of follow-up based on a nasal (midturbinate) swab positive for SARS-CoV-2 as determined by nucleic acid amplification test (NAAT) (central laboratory or locally confirmed). Only first occurrences of COVID-19 with onset of symptoms at least 7 days or 14 days after Dose 2 were included in the analyses.

The analyses were performed for endpoints as shown in Table 1.

Table 1. Primary and Secondary Efficacy Analyses for Efficacy Against Confirmed COVID-19

Efficacy Against Confirmed:	Occurring From (Days after Dose 2)	Incidence in Participants With/Without Infection Before and During Vaccination Regimen
Primary Efficacy Endpoints		
COVID-19		
First primary endpoint	7 days	Without
Second primary endpoint		With or Without
Secondary Efficacy Endpoints		
COVID-19	14 days	Without
		With or Without
Severe COVID-19	7 days	Without
		With or Without
	14 days	Without
		With or Without
CDC-Defined COVID-19	7 days	Without
		With or Without
	14 days	Without
		With or Without

2.7.3.1.2.2. Surveillance/Definitions /Case Determination for Confirmed COVID-19

Participants who developed any of the potential COVID-19 symptoms listed in the protocol (Module 5.3.5.1 C4591001 Protocol Section 8.13) were to contact the site immediately and, if confirmed, participate in an in-person or telehealth visit as soon as possible, optimally within 3 days of symptom onset. At the visit, investigators were to collect clinical information and results from local standard-of-care tests sufficient to confirm a diagnosis of COVID-19.

Confirmation of Infection with SARS-CoV-2: Investigators were to obtain a nasal swab (mid-turbinate) to be tested at a central laboratory using a reverse transcription–polymerase chain reaction (RT-PCR) test (Cepheid; FDA approved under emergency use authorization) to detect SARS-CoV-2. If the evaluation was conducted by telehealth, the participant was to self-collect a nasal swab and ship for assessment at the central laboratory. The central laboratory nucleic acid amplification–based test (NAAT) result was to be used for the case definition, unless no result was available from the central laboratory, in which case a local NAAT result could be used if it was obtained using one of the following assays:

- Cepheid Xpert Xpress SARS-CoV-2
- Roche cobas SARS-CoV-2 real-time RT-PCR test (EUA200009/A001)

- Abbott Molecular/RealTime SARS-CoV-2 assay (EUA200023/A001).

Confirmed COVID-19 was defined (per FDA guidance)[4] as the presence of at least 1 of the following symptoms and a positive SARS-CoV-2 NAAT (determined by the central laboratory or at a local testing facility using an acceptable test) during, or within 4 days before or after, the symptomatic period:

> fever; new or increased cough; new or increased shortness of breath; chills; new or increased muscle pain; new loss of taste or smell; sore throat; diarrhea; vomiting.

Confirmed COVID-19 (according to the CDC-defined symptoms) was defined as above, adding the following to the list of symptoms:

> fatigue; headache; nasal congestion or runny nose; nausea.[5]

Confirmed severe COVID-19 was defined (per FDA guidance)[4] as confirmed COVID-19 and the presence of at least 1 of the following:

- Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, SpO2 ≤93% on room air at sea level, or PaO2/FiO2 <300 mm Hg);
- Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO);
- Evidence of shock (SBP <90 mm Hg, DBP <60 mm Hg, or requiring vasopressors);
- Significant acute renal, hepatic, or neurologic dysfunction*;
- Admission to an ICU;
- Death.

For post hoc analyses (not specified in the protocol), ***confirmed severe COVID-19 (according to the CDC-defined severe symptoms)*** was defined as COVID-19 illness events that resulted in hospitalization, admission to the ICU, intubation or mechanical ventilation, or death.[6]

2.7.3.1.2.3. Statistical Methods (Efficacy)

2.7.3.1.2.3.1. Efficacy Analysis Datasets

The efficacy evaluations were performed using data for the ***evaluable efficacy population***, which included all eligible randomized participants who received all vaccinations as randomized, with Dose 2 received within the predefined window (19-42 days after Dose 1), and had no other important protocol deviations as determined by the clinician on or before 7 days after Dose 2 (for 7-day post vaccination efficacy endpoints) or on or before 14 days after Dose 2 (for 14-day post vaccination efficacy endpoints).

Efficacy evaluations were also performed for the ***Dose 1 all-available efficacy population*** (all randomized participants who received at least 1 vaccination) and the ***Dose 2 all-available efficacy population*** (all randomized participants who received 2 vaccination doses).

Vaccine efficacy evaluations for the primary endpoints were also performed for subgroups of participants by age, race, ethnicity, sex, and country, as well as by risk status and by comorbidity status. In addition, in analyses of cases among participants with or without evidence of prior infection, efficacy evaluations for the primary endpoints were also performed for subgroups of participants by baseline SARS-CoV-2 infection status.

2.7.3.1.2.3.2. Statistical Analyses for Efficacy

Interim and Final Analyses

The assessment of efficacy against confirmed COVID-19 was event-driven. Initially, 4 interim analyses were planned to be performed by an unblinded statistical team supporting the data monitoring committee after accrual of 32, 62, 92, and 120 confirmed COVID-19 cases for the first primary endpoint, with the final analysis performed after accrual of at least 164 cases. For operational reasons, the first planned IA (after 32 cases) was not performed. Amendment 9 to the C4591001 protocol eliminated the planned interim analysis at 32 cases and provided for 3 interim analyses to be performed after accrual of *at least* 62, 92, and 120 cases for the first primary endpoint. At each of the IAs, vaccine efficacy with respect to the first primary efficacy endpoint was to be assessed. At the final analysis (at least 164 cases) vaccine efficacy with respect to all efficacy endpoints was to be assessed.

VE against confirmed COVID-19 was estimated by 100 × (1 – IRR), where IRR was the ratio of COVID-19 illness rate in the BNT162b2 group to the corresponding illness rate in the placebo group. The Bayesian 95% credible interval and the posterior probability for the true vaccine efficacy greater than 30% conditioning on the available data, ie, P[VE >30%|data], were calculated using a beta-binomial model and a pre-specified minimally informative beta distribution as prior. The calculation of posterior probability and 95% credible interval were adjusted for surveillance time. All efficacy endpoints were to be analyzed using the same Bayesian approach unless stated otherwise.

If the posterior probability of VE>30% were greater than 99.5% at any pre-planned interim analysis, or greater than 98.6% at the final analysis, the vaccine efficacy of BNT162b2 would be declared.

If the predicted posterior probability of demonstrating vaccine efficacy at the final analysis were less than 5.0% at the analyses after accrual of at least 62 and at least 92 cases, the study would stop for lack of benefit (futility).

For the subgroup analyses of the efficacy endpoints, and for the analyses of efficacy for COVID-19 cases determined according to the CDC-defined symptoms, VE and the 2-sided 95% CI for VE was derived based on the Clopper and Pearson method adjusted for surveillance time.

Updated Efficacy Analyses

Updated efficacy analyses were performed for COVID-19 cases accrued during blinded placebo-controlled follow-up, up to the data cutoff date (13 March 2021). Updated descriptive efficacy analyses were conducted for the primary efficacy endpoints, including subgroup analyses, and for secondary efficacy endpoints of severe disease and CDC-defined severe disease cases occurring ≥7 days after Dose 2. The analyses for cases of COVID-19 occurring ≥14 days after Dose 2 were not updated.

The point estimate of VE in the blinded follow-up period and associated 2-sided 95% CI was derived using the Clopper Pearson method adjusted for surveillance time, and the posterior probability (ie, P[VE >30%|data]) was provided for the primary endpoints and secondary endpoints of severe disease.

Additional details of the analysis methods are provided in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Appendix 16.1.9 SAP Section 5.1.1 and Section 6.

2.7.3.1.3. Methods for Evaluation of Immunogenicity

2.7.3.1.3.1. Measurement of the Immune Response

Serological Assays

Blood samples were collected for immunogenicity assessments at the visits specified in the protocols (Module 5.3.5.1 C4591001 Protocol Section 1.3; Module 5.3.5.1 BNT162-01 Protocol Section 1.3). In both studies BNT162-01 and C4591001, immune responses were evaluated using 3 serological assays: the SARS-CoV-2 neutralization assay, the S1-binding IgG level assay, and the RBD-binding IgG level assay.[7,8]

Details regarding the neutralization and binding assays are available in Module 2.7.1 Summary of Biopharmaceutic Studies and Associated Analytical Methods and Module 5.3.1.4 Reports of Bioanalytical and Analytical Methods for Human Studies.

Human Convalescent Sera Panel for Serology Comparisons

To facilitate interpretation of immunogenicity data generated in both studies, a human convalescent serum (HCS) panel was obtained from Sanguine Biosciences (Sherman Oaks, CA), MT Group (Van Nuys, CA), and Pfizer Occupational Health and Wellness (Pearl River, NY).[7,8] The 38 sera in the panel were collected from SARS-CoV-2 infected or COVID-19 diagnosed individuals 18 to 83 years of age ≥14 days after PCR-confirmed diagnosis at a time when they were asymptomatic. The serum donors had predominantly had symptomatic infections (35 of 38), including 1 who had been hospitalized. Data for SARS-CoV-2 serum neutralizing titers (geometric mean titers, GMTs) from the two clinical studies were compared with data for GMTs determined for the HCS panel.

CD4+ and CD8+ T Cell Responses

In addition, in Study BNT162-01, T cell mediated immune responses were evaluated using Enzyme-Linked Immuno-Spot (ELISpot) and intracellular cytokine staining (ICS) visualized

with fluorescence-activated cell sorting (FACS). Blood samples for evaluation of T cell responses were collected at baseline (before Dose 1) and at the visit that was to take place approximately 7 days after Dose 2 (~Day 29).

Cell mediated immune response data were also evaluated in post hoc analyses (not specified in the protocol) using blood collected for general research purposes on approximately Day 43 (21 days after Dose 2) Day 85 (63 days after Dose 2) and Day 184 (162 days after Dose 2). T cell responses were evaluated at these later time points for only a small number of participants who received BNT162b2 at doses of 10, 20, or 30 µg.

ELISpot

The ELISpot assay was used to measure the frequency of cytokine-secreting cells in samples of peripheral blood mononuclear cells (PBMCs) obtained from whole blood samples of vaccinated participants. Briefly, PBMCs enriched for CD4+ or CD8+ effector cells are placed in ELISpot plates pre-coated with antibodies specific for IFN-γ and are incubated overnight (≥18 hours) with peptides originating from the vaccine antigens (ie, from RBD or full-length S protein). IFN-γ secreted by CD4+ or CD8+ cells in response to stimulation by the peptides is bound to the plate by the coating antibody. After incubation, the plates are developed by addition of alkaline phosphatase conjugated secondary anti-IFN-γ antibody followed by enzyme substrate; each spot corresponds to the IFN-γ secreted by a single cell. Developed plates are read by an AID ELISpot Reader. Details of the ELISpot assay are available in the analytical interim report (Module 5.3.5.1 BNT162-01 Interim CSR Appendix 16.1.14 GA-RB-022-01A v3).

For benchmarking, the T cell responses (IFN-γ secretion) after stimulation by peptides derived from the vaccine antigens were compared to those after stimulation by recall antigens in the following assay peptide mixtures:

- **CEF**: MHC-class I restricted peptides originating from CMV, EBV, and Flu virus (cytomegalovirus, Epstein-Barr virus, and influenza virus), which are expected to stimulate IFN-γ production from CD8+ T cells in the majority of donors; the peptides included in this pool are short peptides which mainly stimulate CD8+ T cells.

- **CEFT**: MHC-class II restricted peptides originating from CMV, EBV, Flu (influenza) virus and Tetanus toxin, which are expected to stimulate IFN-γ production from CD4+ T cells in the majority of donors.

Intracellular Cytokine Staining with FACS

Intracellular cytokine staining (ICS) is a flow cytometry-based assay to detect the production and accumulation of cytokines intracellularly upon cell stimulation. PBMCs obtained from vaccinated participants were restimulated in a round-bottom 96-well plate with synthetic peptides covering the encoded antigens (RBD or full-length S protein). After stimulation of PBMCs, inhibitors of protein transport were added to retain the produced cytokines within the cells. In order to discriminate between antigen-specific CD4 and CD8 T cell responses, fluorescently labelled antibodies for CD4 and CD8 were used for staining of extracellular

surface markers. Next, PBMCs were fixed (with paraformaldehyde) and subsequently permeabilized for intracellular staining of CD4 and CD8, and of produced cytokines using fluorescently labelled, cytokine-specific antibodies (IFNγ, IL-2 and IL-4). After the staining procedure, cells were analyzed using FACS on a flow cytometer to visualize the proportions of vaccine antigen-specific Th1 and Th2 CD4+ T cells and cytotoxic CD8+ T cells producing each cytokine. For benchmarking, PBMCs from recovered COVID-19 patients were used. Details of the ICS/flow cytometry assay are available in the interim technical report, Module 5.3.5.1 BNT162-01 Interim CSR Appendix 16.1.14 – R-20-0235 v2.0 (for BNT162b1) and R-20-0241 v3.0 (for BNT162b2).

2.7.3.1.3.2. Immunogenicity Objectives and Endpoints

The methods described below apply to both Study BNT162-01 and Study C4591001, except as noted. The immunogenicity objectives and endpoints are listed for each study in Module 5.3.5.1 BNT162-01 Protocol Section 3 and in Module 5.3.5.1 C4591001 Protocol Section 3.

For the immunogenicity serological assay results (neutralizing titers, S1-binding IgG levels, and RBD-binding IgG levels), the estimands included:

- Geometric mean concentrations (GMCs) or geometric mean titers (GMTs) at protocol specified time points; (Note that GMT data were summarized for 50% neutralizing titers and for 90% neutralizing titers. The estimand of principal interest is the 50% neutralizing titer. The 90% neutralizing titer was primarily intended to assist in differentiation of the candidate vaccines in Phase 1, if needed, for the purpose of candidate selection. Results for 90% neutralizing titers are available in the CSR, but will not be discussed in this SCE.)

- Geometric mean fold-rise (GMFR) from before vaccination to subsequent protocol specified time points;

- Proportion of participants achieving ≥4-fold rise from before vaccination to subsequent protocol-specified time point after vaccination (Study BNT162-01 and Study C4591001 Phase 1 only).

2.7.3.1.3.3. Immunogenicity Analysis Sets

In Study BNT162-01, immunogenicity evaluations were performed for the immunogenicity set (IMM), defined as all participants who received at least one dose of study vaccine and had at least one post-baseline immunogenicity assessment.

In Study C4591001, immunogenicity analyses are primarily based on the Dose 1 and Dose 2 evaluable immunogenicity populations. Additional analyses were to be performed based on the all-available populations if there was a large enough difference in sample size between the all-available immunogenicity population and the evaluable immunogenicity population. The criteria for each population are shown below. Participants were analyzed according to the vaccine group to which they were randomized.

Dose 1 evaluable immunogenicity	For Phase 1 only, all eligible randomized participants who received the vaccine to which they are randomly assigned at the first dose, have at least 1 valid and determinate immunogenicity result from the blood collection within an appropriate window after Dose 1 (same as visit window, ie, within 19-23 days after Dose 1), and have no other important protocol deviations as determined by the clinician.
Dose 2 evaluable immunogenicity	All eligible randomized participants who receive 2 doses of the vaccine to which they are randomly assigned, with Dose 2 received within the predefined window (19-42 days after Dose 1), have at least 1 valid and determinate immunogenicity result from the blood collection within an appropriate window after Dose 2 (6-8 days after Dose 2 for Phase 1 and within 28-42 days after Dose 2 for Phase 2/3), and have no other important protocol deviations as determined by the clinician.
Dose 1 all-available immunogenicity	For Phase 1 only, all randomized participants who receive at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after Dose 1 but before Dose 2.
Dose 2 all-available immunogenicity	All randomized participants who receive at least 1 dose of the study intervention with at least 1 valid and determinate immunogenicity result after Dose 2.

2.7.3.1.3.4. Statistical Analyses for Immunogenicity

For immunogenicity results of SARS-CoV-2 neutralizing titers and S1- or RBD-binding IgG concentrations, the GMTs and GMCs were calculated as the mean of the assay results after making the logarithm transformation and then exponentiating the mean to express results on the original scale. Two-sided 95% CIs were obtained by taking log transforms of the titers, calculating the 95% CI with reference to Student's t-distribution, and then exponentiating the confidence limits.

GMFRs were defined as the post-vaccination assay result divided by the pre-vaccination result. GMFRs were calculated as the mean of the difference of logarithmically transformed neutralization titers or antibody levels (later result minus earlier result) and exponentiating the mean. The associated 2-sided 95% CIs were obtained by constructing CIs using Student's t-distribution for the mean difference on the natural log scale and exponentiating the confidence limits.

The exact 2-sided 95% CIs for binary endpoints were computed using the F distribution (Clopper-Pearson).[9]

Further details of the analyses are available in the SAPs (Module 5.3.5.1 C4591001 6-Month Update Interim CSR Appendix 16.1.9 SAP Section 5 and Section 6; and Module 5.3.5.1 BNT162-01 Interim CSR Appendix 16.1.9 SAP Section 6). Titers/concentrations below the lower limit of quantitation (LLOQ) or denoted as below the level of quantitation were set to 0.5 × LLOQ for analysis.

2.7.3.2. Summary of Results of Individual Studies

2.7.3.2.1. Efficacy Against Confirmed COVID-19 - Pivotal Study C4591001 (Phase 2/3)

The efficacy of BNT162b2 in preventing COVID-19 among participants without evidence of SARS-CoV-2 infection before and during vaccination regimen was demonstrated at the first interim analysis, which was conducted after accrual of at least 62 cases (cutoff date

04 November 2020). The results from this analysis, which evaluated the first primary efficacy endpoint only, are provided in Section 2.7.3.2.1.1

The final analysis of efficacy was conducted after accrual of at least 164 cases for the first primary efficacy endpoint (cutoff date, 14 November 2020). The results from these analyses are provided in Section 2.7.3.2.1.2.

Updated descriptive efficacy analyses were performed for COVID-19 cases accrued during blinded placebo-controlled follow-up, up to the cutoff date of 13 March 2021. The results from these analyses are provided in Section 2.7.3.2.1.3.

Details of results from the interim and final efficacy analyses are provided in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 11.1 and are summarized below. Details of results from the updated efficacy analyses are provided in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 11.1.2 and are summarized below.

2.7.3.2.1.1. Interim Analysis of Efficacy in Study C4591001

2.7.3.2.1.1.1. Efficacy Populations – Interim Analysis

For the first primary efficacy endpoint, VE for BNT162b2 against confirmed COVID-19 was evaluated in participants without evidence of prior SARS-CoV-2 infection before and during vaccination regimen. Participants with positive or unknown NAAT results at any illness visit prior to 7 days after Dose 2 were not included in this evaluation for VE. Cases were counted from 7 days after Dose 2.

In the interim analysis, the proportions of participants included in the evaluable efficacy population were similar in the BNT162b2 and placebo groups (Table 26). Most participants who were excluded from the evaluable efficacy population had not received all vaccinations as randomized or did not receive Dose 2 within the predefined window (ie, 19 to 42 days after Dose 1). There were 302 participants (1.4%) in the BNT162b2 group and 52 participants (0.2%) in the placebo group excluded for having important protocol deviations at or prior to 7 days after Dose 2.

Demographics of participants in the interim analysis evaluable efficacy population for participants without evidence of infection before and during the vaccination regimen were similar between the BNT162b2 and placebo groups (Table 27). This analysis population had generally similar demographics compared to the safety population. Demographic characteristics for the interim analysis Dose 2 all-available efficacy population were similar to those for the evaluable efficacy population.

2.7.3.2.1.1.2. Primary Efficacy Results – Interim Analysis

2.7.3.2.1.1.2.1. Vaccine Efficacy in Participants Without Prior Evidence of SARS-CoV-2 Infection – 7 Days After Dose 2 – Interim Analysis

Among participants included in the evaluable efficacy population, 32,279 participants overall (16,061 in the BNT162b2 group and 16,218 in the placebo groups) did not have evidence of prior infection with SARS-CoV-2 through 7 days after Dose 2 (Table 26).

As of the time of the interim analysis, there were 4 confirmed COVID-19 cases in the BNT162b2 group and 90 confirmed COVID-19 cases in the placebo group (Table 2). All evaluable cases were confirmed by tests conducted at the central laboratory.

VE for BNT162b2 against confirmed COVID-19 cases was evaluated in participants without evidence of prior SARS-CoV-2 infection before and during vaccination regimen with cases counted from 7 days after Dose 2.

VE of BNT162b2 was 95.5% with a 99.99% posterior probability for the true VE being >30% conditioning on available data, to overwhelmingly meet the prespecified interim analysis success criterion (>99.5%).

The 95% credible interval for the vaccine efficacy was 88.8% to 98.4%, indicating that given these observed data there was a 95% probability that the true VE lies in this interval. Also, note that the posterior probability that true VE >86.0% is 99.5% and VE >88.8% is 97.5%.

VE of BNT162b2 for the same primary efficacy endpoint based on the all-available efficacy population was 95.7%, with 4 cases in the BNT162b2 group and 93 cases in the placebo group (Table 28).

Table 2. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (7 Days) – Interim Analysis 1

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=16061)		Placebo (N[a]=16218)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	4	1.722 (15899)	90	1.732 (16010)	95.5	(88.8, 98.4)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.

Table 2. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (7 Days) – Interim Analysis 1

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=16061)		Placebo (N[a]=16218)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]

f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details. This probability must be at least 99.5% at the interim analysis in order to conclude that the vaccine is efficacious.
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(Cutoff Date: 04Nov2020, Snapshot Date: 04Nov2020) Output File: ./nda2_unblinded_ia/C4591001_IA_62/adc19ef_ve_cov_7pd2_wo_eval

2.7.3.2.1.1.2.2. Vaccine Efficacy by Subgroup – Interim Analysis

VE in participants without prior evidence of SARS-CoV-2 infection was further evaluated by subgroups based on age, sex, race/ethnicity, and country. VE was >90% in all subgroups (Table 3). Results for the Dose 2 all-available population were similar, demonstrating no clinically meaningful differences in VE on the basis of subgroup (Table 29).

Table 3. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (7 Days) – Interim Analysis 1

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=16061)		Placebo (N[a]=16218)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	4	1.722 (15899)	90	1.732 (16010)	95.5	(88.1, 98.8)
Age group (years)						
16 to 55	2	0.954 (8994)	67	0.959 (9040)	97.0	(88.7, 99.6)
>55	2	0.767 (6905)	23	0.773 (6970)	91.2	(64.6, 99.0)
Sex						
Male	2	0.874 (8115)	38	0.865 (8029)	94.8	(79.8, 99.4)
Female	2	0.848 (7784)	52	0.867 (7981)	96.1	(85.1, 99.5)
Race						
White	4	1.477 (13399)	85	1.491 (13530)	95.3	(87.4, 98.7)
Black or African American	0	0.124 (1263)	4	0.124 (1277)	100.0	(-51.8, 100.0)
All others[f]	0	0.121 (1237)	1	0.118 (1203)	100.0	(-3690.1, 100.0)
Ethnicity						
Hispanic/Latino	1	0.464 (4389)	34	0.459 (4342)	97.1	(82.7, 99.9)
Non-Hispanic/non-Latino	3	1.247 (11418)	56	1.262 (11570)	94.6	(83.3, 98.9)
Country						
Argentina	0	0.271 (2436)	28	0.266 (2402)	100.0	(86.2, 100.0)
Brazil	0	0.087 (878)	2	0.087 (879)	100.0	(-432.5, 100.0)
USA	4	1.360 (12384)	60	1.376 (12530)	93.3	(81.8, 98.2)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.
f. American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, not reported race categories are presented as “All others”.

Table 3. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (7 Days) – Interim Analysis 1

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=16061)		Placebo (N[a]=16218)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

PFIZER CONFIDENTIAL SDTM Creation: 05NOV2020 (20:53) Source Data: adc19ef Table Generation: 09NOV2020 (16:43)
(Cutoff Date: 04Nov2020, Snapshot Date: 04Nov2020) Output File: ./nda2_unblinded_ia/C4591001_IA_62/adc19ef_ve_cov_7pd2_wo_sg_eval

2.7.3.2.1.1.3. Additional Descriptive Efficacy Results – Interim Analysis

2.7.3.2.1.1.3.1. Vaccine Efficacy by Baseline SARS-CoV-2 Status – Interim Analysis

COVID-19 cases evaluable for efficacy after Dose 2 were further evaluated by participant SARS-CoV-2 status at baseline (ie, evidence of prior infection with SARS-CoV-2).

At the time of the interim analysis, there were 2 participants in the evaluable efficacy population who had evaluable COVID-19 and were baseline positive for prior SARS-CoV-2 infection: 1 participant in the BNT162b2 group and 1 participant in the placebo group (Table 30).

Results were similar for the Dose 2 all-available population (ie, 1 participant with COVID-19 in each group was baseline SARS-CoV-2 positive; all others were SARS-CoV-2 negative up to 7 days after Dose 2) (Table 31).

2.7.3.2.1.1.3.2. Vaccine Efficacy for Severe COVID-19 Cases – Interim Analysis

Severe cases of COVID-19 were evaluated from after Dose 1 onwards, and were reported for the Dose 1 all-available efficacy population (see efficacy analysis populations in (Section 2.7.3.2.1.1).

As of the time of the interim analysis efficacy, a total of 7 severe cases of COVID-19 were reported as occurring from Dose 1 onwards (Table 4). All of these severe cases were reported in the placebo group. Of these, 5 of 7 severe cases were reported as occurring after Dose 1 and prior to Dose 2; the remaining 2 cases were reported ≥7 days after Dose 2.

Of these 7 severe cases reported in the placebo group, all were confirmed as being SARS-CoV-2 negative at baseline.

Table 4. Severe COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population – Interim Analysis 1

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=21617)	Placebo (N[a]=21633)
Efficacy Endpoint	**n[b]**	**n[b]**
Severe COVID-19 occurrence after Dose 1	0	7

Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.
a. N = number of subjects in the specified group.
b. n = Number of subjects meeting the endpoint definition.
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(Cutoff Date: 04Nov2020, Snapshot Date: 04Nov2020) Output File:
./nda2 unblinded ia/C4591001 IA 62/adc19ef sev cov d1 aai

2.7.3.2.1.1.4. Efficacy Conclusions From the Interim Analysis – Study C4591001

The first primary efficacy objective met success criteria at the first interim analysis performed on an accrued 94 cases of COVID-19. BNT162b2 achieved VE of 95.5% with a 95% credible interval of 88.8% to 98.4% among participants without evidence of infection before and during vaccination regimen, and a >99.99% posterior probability for the true VE being >30%, conditioning on available data.

There were no clinically meaningful differences in VE for the first primary efficacy endpoint by participant subgroup, as VE was >90% across age groups, for both male and female participants, across race/ethnic groups, and on the basis of geographic location across study countries.

Evaluation of efficacy among participants who had COVID-19 based on prior SARS-CoV-2 infection status showed 2 participants with COVID-19 cases were SARS-CoV-2 positive at baseline, 1 in each group.

A total of 7 severe cases of COVID-19 were reported in the interim analysis of efficacy, with 5 cases reported after Dose 1 and prior to Dose 2 and the remaining 2 cases reported ≥7 days after Dose 2. All severe cases were reported in placebo recipients and none were reported in BNT162b2 recipients. None were baseline positive for SARS-CoV-2.

The interim analysis efficacy results suggest BNT162b2 at 30 µg provided protection against COVID-19 overall and across subgroups of participants who had no evidence of prior infection with SARS-CoV-2, with severe cases observed exclusively in the placebo group.

2.7.3.2.1.2. Final Analysis of Efficacy in Study C4591001

Efficacy data for the Phase 3 portion of Study C4591001 were analyzed for all enrolled participants who met the protocol-specified criteria for efficacy evaluation, with a final analysis cutoff date of 14 November 2020.

COVID-19 case evaluation for primary and secondary efficacy endpoints is discussed in Section 2.7.3.1.2.

2.7.3.2.1.2.1. Efficacy Populations – Final Analysis

The proportions of participants included in the final analysis efficacy populations was similar in the BNT162b2 and placebo groups (Table 32). Most participants who were excluded from the evaluable efficacy population had not received all vaccinations as randomized or did not receive Dose 2 within the predefined window (ie, 19 to 42 days after Dose 1). There were 311 participants in the BNT162b2 group and 60 participants in the placebo group excluded for having important protocol deviations on or prior to 7 days after Dose 2. In the BNT162b2 group, most of these deviations were related to improper administration of the investigational product (263 participants, as compared with 20 participants in the placebo group); among these, most exclusions in the BNT162b2 group were due to dosing/administration errors (105 participants) or administration of investigational product that was deemed not suitable for use by the contractor who distributed the vaccine to study sites (144 participants).

Demographics of participants in the final analysis evaluable efficacy population for participants without evidence of infection prior to 7 days after Dose 2 were similar between BNT162b2 and placebo groups (Table 33). This analysis population had generally similar demographics compared to the safety population. Demographic characteristics for the final analysis Dose 2 all-available efficacy population and the evaluable population without evidence of infection prior to 14 days after Dose 2 were similar to those for the Dose 2 evaluable efficacy (7 days) population.

2.7.3.2.1.2.2. Signs and Symptoms of COVID-19

The criteria for COVID-19 case determination are described in Section 2.7.3.1.2.2.

The signs and symptoms reported for cases contributing to the analysis for the first primary efficacy endpoint (8 cases in the BNT162b2 group and 162 cases in the placebo group) are summarized in Table 34. These include cases occurring at least 7 days after the second vaccination among participants in the evaluable efficacy population who had no evidence of SARS-CoV-2 infection before or during the vaccination regimen. Most of these participants reported new or increased cough, and other symptoms reported most frequently were new or increased muscle pain, fever, and sore throat. New or increased shortness of breath was reported for 25 participants (15.4%) in the placebo group and for no participants who received BNT162b2.

Table 35 summarizes the signs and symptoms for all cases of COVID-19 occurring at any time after Dose 1 (50 cases in the BNT162b2 group and 275 cases in the placebo group). These include cases occurring among participants in the Dose 1 all-available efficacy population, regardless of evidence of SARS-CoV-2 infection before or during the vaccination

regimen. Most participants reported 2 or more symptoms, and the most frequently reported symptoms were similar to those for the primary efficacy analysis population.

All participants with severe COVID-19 occurring at any time after Dose 1 (1 case in the BNT162b2 group and 9 cases in the placebo group) experienced clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, SpO2 ≤93% on room air at sea level, or PaO2/FiO2 <300 mm Hg); respiratory failure and admission to an ICU were each reported for 3 participants (33.3%) in the placebo group (Table 36).

Complete details of signs and symptoms for all efficacy populations and analyses are provided in the CSR.

2.7.3.2.1.2.3. Primary Efficacy Results – Final Analysis

For the first primary efficacy endpoint, VE for BNT162b2 against confirmed COVID-19 was evaluated in participants without evidence of prior SARS-CoV-2 infection before and during vaccination regimen. Cases were counted from 7 days after Dose 2. For the second primary efficacy endpoint, VE for BNT162b2 against confirmed COVID-19 was evaluated in participants with or without evidence of prior SARS-CoV-2 infection before and during vaccination regimen. Cases were counted from 7 days after Dose 2.

Secondary efficacy endpoints evaluated confirmed COVID-19 cases in participants either without or with or without evidence of prior SARS-CoV-2 infection before and during vaccination regimen. Cases were counted from 7 days after Dose 2 or from 14 days after Dose 2. Secondary efficacy endpoints are described in Section 2.7.3.1.2.1.

2.7.3.2.1.2.3.1. Vaccine Efficacy Without Prior Evidence of SARS-CoV-2 Infection – 7 Days After Dose 2 – Final Analysis

Among participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 95.0%, with 8 COVID-19 cases in the BNT162b2 group compared to 162 COVID-19 cases in the placebo group (Table 5). The 95% credible interval for the vaccine efficacy was 90.3% to 97.6%, indicating that the true VE is at least 90.3% with a 97.5% probability given the observed data.

The vaccine efficacy of BNT162b2 for the same primary efficacy endpoint based on the Dose 2 all-available efficacy population was 95.2%, with 8 and 165 cases in the BNT162b2 and placebo group, respectively (Table 37).

Table 5. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	8	2.214 (17411)	162	2.222 (17511)	95.0	(90.3, 97.6)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 7pd2 wo eval

2.7.3.2.1.2.3.2. Vaccine Efficacy With or Without Prior Evidence of SARS-CoV-2 Infection – 7 Days After Dose 2 – Final Analysis

For the second primary efficacy endpoint, VE for BNT162b2 against confirmed COVID-19 was evaluated in participants with or without evidence of prior SARS-CoV-2 infection through 7 days after Dose 2. Cases were counted from 7 days after Dose 2.

Among participants with or without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 94.6%, with 9 and 169 cases in the BNT162b2 and placebo groups respectively. The posterior probability of >99.99% for the true VE greater than 30% met the prespecified success criterion of >98.6% for this endpoint. The 95% credible interval for the vaccine efficacy was 89.9% to 97.3%, indicating that the true VE is at least 89.9% with a 97.5% probability given the available data (Table 6). Note that with a posterior probability of 98.6%, the true vaccine efficacy is at least 89.2% given the available data.

The vaccine efficacy of BNT162b2 for the same primary efficacy endpoint based on the Dose 2 all-available efficacy population was 94.8%, with 9 and 172 cases in the BNT162b2 and placebo group, respectively (Table 38).

Table 6. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20172)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	9	2.332 (18559)	169	2.345 (18708)	94.6	(89.9, 97.3)	>0.9999

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 7pd2 eval

2.7.3.2.1.2.3.3. Vaccine Efficacy for All Confirmed Cases of COVID-19 After Dose 1 – Dose 1 All-Available Population

A number of confirmed cases of COVID-19 are not captured in the analyses of the first primary endpoint for the evaluable efficacy population because they occurred less than 7 days after Dose 2, or because they occurred in participants who were excluded from the evaluable efficacy population or who had evidence of infection before or during the vaccination regimen.

All reports of COVID-19 with onset at any time after Dose 1 are accounted for in Table 7, which provides a summary of cases for all participants in the Dose 1 all-available efficacy (modified intention-to-treat) population, regardless of evidence of infection before or during the vaccination regimen. Among these participants, 50 cases of COVID-19 occurred after Dose 1 in the BNT162b2 group compared to 275 cases in the placebo group. Notably, in the BNT162b2 group, most cases occurred before Dose 2. The estimated VE against confirmed COVID-19 occurring after Dose 1 was 82% (2-sided 95% CI: 75.6 %, 86.9%), with an

estimated VE of 52.4% (2-sided 95% CI: 29.5%, 68.4%) against confirmed COVID-19 occurring after Dose 1 but before Dose 2.

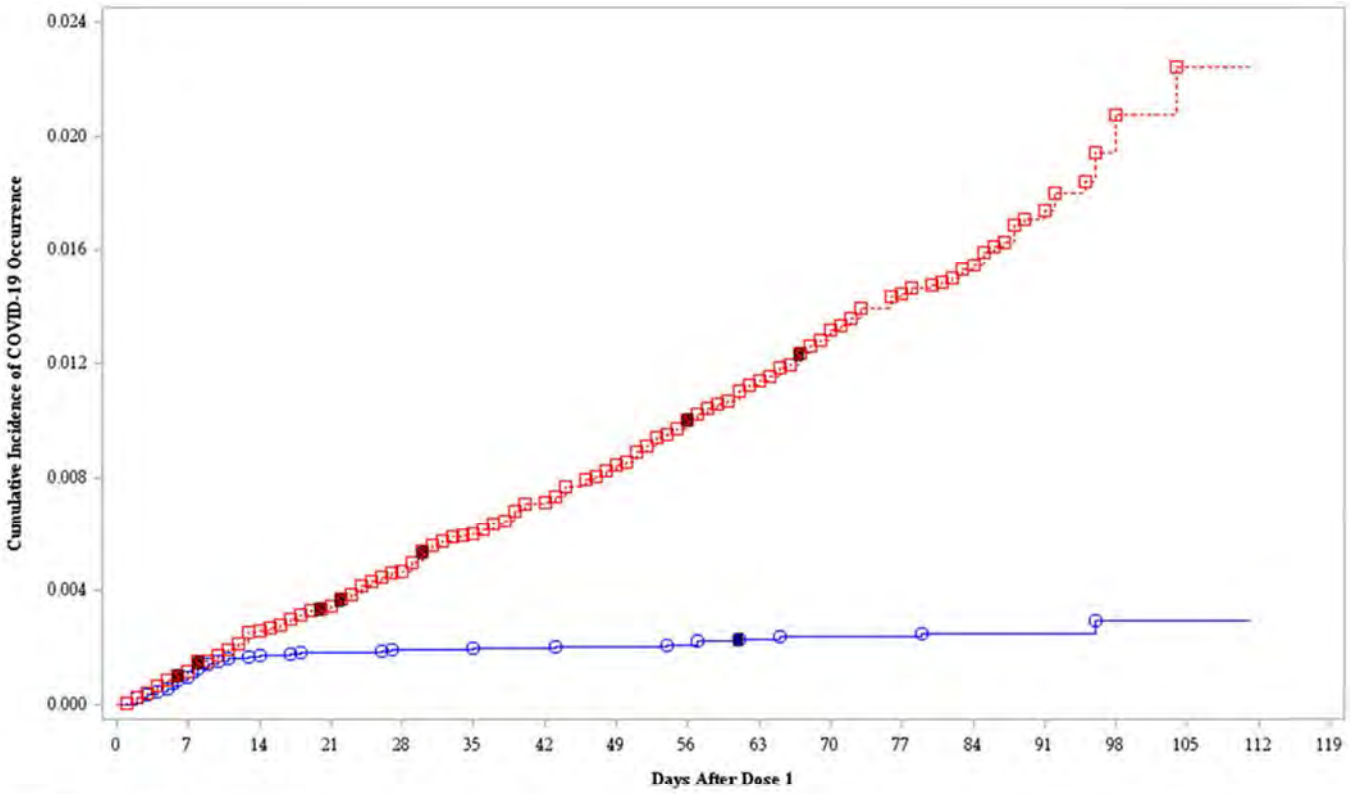
Table 7. Vaccine Efficacy – First COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=21669)		Placebo (N[a]=21686)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence after Dose 1	50	4.015 (21314)	275	3.982 (21258)	82.0	(75.6, 86.9)
After Dose 1 to before Dose 2	39		82		52.4	(29.5, 68.4)
Dose 2 to 7 days after Dose 2	2		21		90.5	(61.0, 98.9)
≥7 Days after Dose 2	9		172		94.8	(89.8, 97.6)

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method (adjusted for surveillance time for overall row).
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 18NOV2020 (17:06)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_cov_pd1_aai

The early onset of protection is readily apparent in Figure 1, which displays cumulative incidence for the first COVID-19 occurrence after Dose 1 among all vaccinated participants based on Dose 1 all-available efficacy (modified intention-to-treat) population. Disease onset appears to track together for BNT162b2 and placebo until approximately 14 days after Dose 1, at which point the curves diverge, with cases steadily accumulating in the placebo group, while remaining virtually flat in the BNT162b2 group. The darker-appearing symbols for both BNT162b2 (blue circles) and placebo (red squares) curves in Figure 1 have an "S" written inside the open symbol, which denotes severe cases. Severe COVID-19 cases reported in the final analysis are discussed further in Section 2.7.3.2.1.2.4.2.

Figure 1. Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population



Note: "S" indicates subjects with severe COVID-19 or COVID-19 leading to hospitalization.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adc19ef Table Generation: 17NOV2020 (21:40)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: /nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_f001_km_d1_aai

2.7.3.2.1.2.3.4. Vaccine Efficacy by Subgroup – Final Analysis

For both primary endpoints, VE was also evaluated for subgroups of participants by age, sex, race/ethnicity, and country for participants without evidence of prior infection and for participants with or without evidence of prior infection.

Among participants without prior evidence of SARS-CoV-2 infection before and during vaccination regimen, VE was >93% in all subgroups, with the exception of "all others" race group (89.3% VE) and Brazil (87.7% VE) (Table 8). VE for additional age subgroups and for all racial groups is provided in Table 39. Notably, in participants ≥65 years of age, VE was 94.7% (1 case in BNT162b2 group vs 19 cases in placebo group; 2-sided 95% CI: 66.7%, 99.9%) (Table 8), and VE in participants ≥75 years of age was 100% (0 cases in BNT162b2 group vs 5 cases in placebo group+; 2-sided 95% CI: -13.1%, 100.0%) (Table 39).

Among participants with or without prior evidence of SARS-CoV-2 infection before and during vaccination regimen, VE was >93% in all subgroups, with the exception of "all others" race group (78.2% VE), Brazil (75.4% VE), and positive prior SARS-CoV-2 infection at baseline (-7.1% VE, 1 case in each vaccine group) (Table 40).

Results for the all-available population were similar; no clinically meaningful differences were observed in VE on the basis of subgroup.

Post Hoc Subgroup Analyses by Risk Status

Post hoc analyses of efficacy by risk status were performed. For these analyses, at-risk participants were defined as those who had at least one Charlson Comorbidity Index condition or who were obese (defined as body mass index ≥30 kg/m^2). For a summary of Charlson comorbidities among all participants at study entry, see Table 41.

Among participants without prior evidence of SARS-CoV-2 infection before and during the vaccination regimen, VE for participants at risk was 95.3%, as compared with 94.7% for those not at risk (Table 9). VE for participants ≥65 years of age and at risk was 91.7%, as compared with 100% for those ≥65 years of age and not at risk. VE was similar in obese (95.4%) and non-obese (94.8%) participants. A summary of VE for groups of participants by specific co-morbidity is provided in Table 42.

Table 8. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint Subgroup	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**
First COVID-19 occurrence from 7 days after Dose 2						
Overall	8	2.214 (17411)	162	2.222 (17511)	95.0	(90.0, 97.9)
Age group (years)						
16 to 55	5	1.234 (9897)	114	1.239 (9955)	95.6	(89.4, 98.6)
>55	3	0.980 (7500)	48	0.983 (7543)	93.7	(80.6, 98.8)
≥65	1	0.508 (3848)	19	0.511 (3880)	94.7	(66.7, 99.9)
Sex						
Male	3	1.124 (8875)	81	1.108 (8762)	96.4	(88.9, 99.3)
Female	5	1.090 (8536)	81	1.114 (8749)	93.7	(84.7, 98.0)
Race						
White	7	1.889 (14504)	146	1.903 (14670)	95.2	(89.8, 98.1)
Black or African American	0	0.165 (1502)	7	0.164 (1486)	100.0	(31.2, 100.0)
All others[f]	1	0.160 (1405)	9	0.155 (1355)	89.3	(22.6, 99.8)
Ethnicity						
Hispanic/Latino	3	0.605 (4764)	53	0.600 (4746)	94.4	(82.7, 98.9)
Non-Hispanic/non-Latino	5	1.596 (12548)	109	1.608 (12661)	95.4	(88.9, 98.5)
Country						
Argentina	1	0.351 (2545)	35	0.346 (2521)	97.2	(83.3, 99.9)
Brazil	1	0.119 (1129)	8	0.117 (1121)	87.7	(8.1, 99.7)
USA	6	1.732 (13359)	119	1.747 (13506)	94.9	(88.6, 98.2)

Table 8. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.

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(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_cov_7pd2_wo_sg_eval

Table 9. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	8	2.214 (17411)	162	2.222 (17511)	95.0	(90.0, 97.9)
At risk[f]						
Yes	4	1.025 (8030)	86	1.025 (8029)	95.3	(87.7, 98.8)
No	4	1.189 (9381)	76	1.197 (9482)	94.7	(85.9, 98.6)
Age group (years) and at risk						
16-64 and not at risk	4	0.962 (7671)	69	0.964 (7701)	94.2	(84.4, 98.5)
16-64 and at risk	3	0.744 (5878)	74	0.746 (5917)	95.9	(87.6, 99.2)
≥65 and not at risk	0	0.227 (1701)	7	0.233 (1771)	100.0	(29.0, 100.0)
≥65 and at risk	1	0.281 (2147)	12	0.279 (2109)	91.7	(44.2, 99.8)
Obese[g]						
Yes	3	0.763 (6000)	67	0.782 (6103)	95.4	(86.0, 99.1)
No	5	1.451 (11406)	95	1.439 (11404)	94.8	(87.4, 98.3)
Age group (years) and obese						
16-64 and not obese	4	1.107 (8811)	83	1.101 (8825)	95.2	(87.3, 98.7)
16-64 and obese	3	0.598 (4734)	60	0.609 (4789)	94.9	(84.4, 99.0)
≥65 and not obese	1	0.343 (2582)	12	0.338 (2567)	91.8	(44.5, 99.8)
≥65 and obese	0	0.165 (1265)	7	0.173 (1313)	100.0	(27.1, 100.0)

Table 9. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. At risk is defined as having at least one of the Charlson Comorbidity Index (CMI) category or obesity (BMI ≥30 kg/m^2).
g. Obese is defined as BMI ≥30 kg/m^2.

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 24NOV2020 (17:41)
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2.7.3.2.1.2.4. Secondary Efficacy Results – Final Analysis

2.7.3.2.1.2.4.1. Vaccine Efficacy for COVID-19 (≥14 Days After Dose 2)

Participants Without Evidence of Infection Before and During Vaccination Regimen

For this efficacy endpoint, participants with positive or unknown NAAT results at any illness visit prior to 14 days after Dose 2 were not included in the evaluation for efficacy.

Among participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against confirmed COVID-19 occurring at least 14 days after Dose 2 was 94.2%, with 8 and 139 cases in the BNT162b2 and placebo groups respectively (Table 10). The posterior probability of >99.99% for the true VE greater than 30% met the prespecified success criterion of >98.6% for this endpoint. The 95% credible interval for the vaccine efficacy was 88.7% to 97.2%, indicating that the true VE is at least 88.7% with a 97.5% probability given the available data.

Table 10. Vaccine Efficacy – First COVID-19 Occurrence From 14 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=18175)		Placebo (N[a]=18261)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 14 days after Dose 2	8	1.887 (16612)	139	1.893 (16663)	94.2	(88.7, 97.2)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 14 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 14 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
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(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 14pd2 wo eval

Participants With or Without Evidence of Infection Before and During Vaccination Regimen

Among participants with or without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against confirmed COVID-19 occurring at least 14 days after Dose 2 was 94.4%, with 8 and 144 cases in the BNT162b2 and placebo groups respectively (Table 11). The posterior probability of >99.99% for the true VE greater than 30% met the prespecified success criterion of >98.6% for this endpoint. The 95% credible interval for the vaccine efficacy was 89.1% to 97.3%, indicating that the true VE is at least 89.1% with a 97.5% probability given the available data.

Table 11. Vaccine Efficacy – First COVID-19 Occurrence From 14 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20171)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 14 days after Dose 2	8	1.984 (17645)	144	1.995 (17746)	94.4	(89.1, 97.3)	>0.9999

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
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(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 14pd2 eval

2.7.3.2.1.2.4.2. Vaccine Efficacy for Severe COVID-19 Cases – Final Analysis

Efficacy Against Severe COVID-19 (≥7 Days After Dose 2)

Participants Without Evidence of Infection Before and During Vaccination Regimen

For this efficacy endpoint, participants with positive or unknown NAAT results at any illness visit prior to 7 days after Dose 2 were not included in the evaluation for efficacy.

Among participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, the estimated VE against severe COVID-19 occurring at least 7 days after Dose 2 was 66.4%, with 1 and 3 cases in the BNT162b2 and placebo groups respectively (Table 12). The posterior probability for the true vaccine efficacy greater than 30% is 74.29%, which did not meet the prespecified success criterion of >98.6% for this endpoint due to the small number of severe cases observed after Dose 2 in the study. Consequently, statistical testing of subsequent secondary endpoints (ie, the additional secondary endpoints related to severe disease with pre-specified control of overall type 1 error) ended. However, descriptive summaries for the additional endpoints are provided.

Table 12. Vaccine Efficacy – First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)				
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**	**Pr (VE >30% | data)[f]**
First severe COVID-19 occurrence from 7 days after Dose 2	1	2.215 (17411)	3	2.232 (17511)	66.4	(-124.8, 96.3)	0.7429

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
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./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve sev cov 7pd2 wo eval

Participants With or Without Evidence of Infection Before and During Vaccination Regimen

Among participants with or without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against severe COVID-19 occurring at least 7 days after Dose 2

was 66.3%, with 1 and 3 cases in the BNT162b2 and placebo groups respectively (Table 13). The posterior probability for the true vaccine efficacy greater than 30% is 74.19%.

Table 13. Vaccine Efficacy – First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20172)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First severe COVID-19 occurrence from 7 days after Dose 2	1	2.333 (18566)	3	2.358 (18733)	66.3	(-125.5, 96.3)	0.7419

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
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(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File:
./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve sev cov 7pd2 eval

All Confirmed Cases of Severe COVID-19 After Dose 1 – All-Available Population

Among participants in the Dose 1 all-available efficacy population, 1 case of severe COVID-19 occurred after Dose 1 in the BNT162b2 group compared to 9 cases in the placebo group (Table 14). The estimated VE against severe COVID-19 occurring after Dose 1 was 88.9% (2-sided 95% CI: 20.1%, 99.7%), with an estimated VE of 75.0% against severe COVID-19 occurring at least 7 days after Dose 2 (1 case in the BNT162b2 group and 4 cases in the placebo group).

In addition, a post hoc analysis was conducted for efficacy against severe cases of COVID-19 using the CDC definition of severe COVID-19 (hospitalization, admission to the intensive care unit (ICU), intubation or mechanical ventilation, or death).[6] In this analysis in the Dose 1 all-available efficacy population, 1 case of severe COVID-19 occurred after Dose 1 in the BNT162b2 group compared to 14 cases in the placebo group (Table 43). The estimated VE against severe COVID-19 occurring after Dose 1 was 92.9% (2-sided 95% CI:

53.2%, 99.8%), with an estimated VE of 100.0% against severe COVID-19 occurring at least 7 days after Dose 2 (no cases in the BNT162b2 group and 5 cases in the placebo group).

Table 14. Vaccine Efficacy – First Severe COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=21669)		Placebo (N[a]=21686)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First severe COVID-19 occurrence after Dose 1	1	4.021 (21314)	9	4.006 (21259)	88.9	(20.1, 99.7)
After Dose 1 to before Dose 2	0		4		100.0	(-51.5, 100.0)
Dose 2 to 7 days after Dose 2	0		1		100.0	(-3800.0, 100.0)
≥7 Days after Dose 2	1		4		75.0	(-152.6, 99.5)

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method (adjusted for surveillance time for overall row).
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Efficacy Against Severe COVID-19 (≥14 Days After Dose 2)

Participants Without Evidence of Infection Before and During Vaccination Regimen (14 Days) – Severe

For this efficacy endpoint, participants with positive or unknown NAAT results at any illness visit prior to 14 days after Dose 2 were not included in the evaluation for efficacy.

Among participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, the estimated VE against severe COVID-19 occurring at least 14 days after Dose 2 was 66.4%, with 1 and 3 cases in the BNT162b2 and placebo groups respectively (Table 15). The posterior probability for the true vaccine efficacy greater than 30% is 74.32%.

Table 15. Vaccine Efficacy – First Severe COVID-19 Occurrence From 14 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=18175)		Placebo (N[a]=18261)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First severe COVID-19 occurrence from 14 days after Dose 2	1	1.888 (16612)	3	1.901 (16663)	66.4	(-124.7, 96.3)	0.7432

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 14 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 14 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
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(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_sev_cov_14pd2_wo_eval

Participants With or Without Evidence of Infection Before and During Vaccination Regimen (14 Days) – Severe

Among participants with or without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against severe COVID-19 occurring at least 14 days after Dose 2 was 66.3%, with 1 and 3 cases in the BNT162b2 and placebo groups respectively (Table 16). The posterior probability for the true vaccine efficacy greater than 30% is 74.18%.

Table 16. Vaccine Efficacy – First Severe COVID-19 Occurrence From 14 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20171)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First severe COVID-19 occurrence from 14 days after Dose 2	1	1.985 (17652)	3	2.007 (17792)	66.3	(-125.6, 96.3)	0.7418

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
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2.7.3.2.1.2.4.3. Vaccine Efficacy for COVID-19 Cases per CDC Definition – Final Analysis

Efficacy Against COVID-19 Based on CDC-Defined Symptoms (≥7 Days After Dose 2)

Participants Without Evidence of Infection Before and During Vaccination Regimen – CDC Defined – 7 Days

For this efficacy endpoint, participants with positive or unknown NAAT results at any illness visit prior to 7 days after Dose 2 were not included in the evaluation for efficacy.

Among participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against CDC-defined COVID-19 occurring at least 7 days after Dose 2 was 95.1% (2-sided 95% CI: 90.2%, 97.9%), with 8 and 165 cases in the BNT162b2 and placebo groups, respectively (Table 44).

Participants With and Without Evidence of Infection Before and During Vaccination Regimen – CDC Defined – 7 Days

Among participants with and without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against CDC-defined COVID-19 occurring at least 7 days after

Dose 2 was 94.7% (2-sided 95% CI: 89.8%, 97.6%), with 9 and 172 cases in the BNT162b2 and placebo groups, respectively (Table 45).

Efficacy Against COVID-19 Based on CDC-Defined Symptoms (≥14 Days After Dose 2)

Among participants without and with or without evidence of SARS-CoV-2 infection before and during vaccination regimen, observed VE results against CDC-defined COVID-19 occurring at least 14 days after Dose 2 were similar to those occurring at least 7 days after Dose 2 (Table 46 and Table 47).

2.7.3.2.1.2.5. Efficacy Conclusions From the Final Analysis – Study C4591001

Evaluable Efficacy Population

In the final efficacy analysis, among participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 95.0%, with 8 COVID-19 cases in the BNT162b2 group compared to 162 COVID-19 cases in the placebo group. The 95% credible interval for the vaccine efficacy was 90.3% to 97.6%.

For the second primary endpoint, VE against confirmed COVID-19 occurring at least 7 days after Dose 2 in participants with or without evidence of SARS-CoV-2 infection before and during vaccination regimen was 94.6%, with 9 and 169 cases in the BNT162b2 and placebo groups respectively. The posterior probability of >99.99% for the true VE greater than 30% met the prespecified success criterion of >98.6% for this endpoint. The 95% credible interval for the vaccine efficacy was 89.9% to 97.3%.

Observed VE was very high for the first primary efficacy endpoint across subgroups of age, sex, race/ethnicity, and country, as VE was >93% in all subgroups, with the exception of “all others” race group (89.3% VE) and Brazil (87.7% VE).

For the secondary efficacy endpoints, observed VE against confirmed COVID-19 occurring at least 14 days after Dose 2 in participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, was 94.2%, with 8 and 139 cases in the BNT162b2 and placebo groups, respectively. The posterior probability of >99.99% for the true VE greater than 30% met the prespecified success criterion of >98.6% for this endpoint. The 95% credible interval for the vaccine efficacy was 88.7% to 97.2%.

Similarly, among participants with or without evidence of SARS-CoV-2 infection before and during vaccination regimen, VE against confirmed COVID-19 occurring at least 14 days after Dose 2 was 94.4%, with 8 and 144 cases in the BNT162b2 and placebo groups respectively. The posterior probability of >99.99% for the true VE greater than 30% met the prespecified success criterion of >98.6% for this endpoint. The 95% credible interval for the vaccine efficacy was 89.1% to 97.3%.

Among participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, observed VE of 66.3% against severe COVID-19 occurring at least 7 days after Dose 2 did not meet the prespecified success criterion of the posterior probability

>98.6%, due to the small number of severe cases (1 in the BNT162b2 group, 3 in the placebo group) observed within the prespecified timeframe of ≥7 Days after Dose 2 in the study.

The efficacy analyses using CDC defined symptoms to identify COVID-19 cases and severe COVID-19 cases gave similar efficacy results as the analyses using the protocol-defined symptoms.

All-Available Efficacy Population

The early onset of protection is readily apparent from cumulative incidence curves, which show that disease onset tracks conjointly for BNT162b2 and placebo until approximately 14 days after Dose 1, at which point the curves diverge, with cases steadily accumulating in the placebo group, while remaining virtually flat after BNT162b2.

Among all participants (regardless of evidence of infection before or during the vaccination regimen) 50 cases of COVID-19 occurred after Dose 1 in the BNT162b2 group compared with 275 cases in the placebo group, indicating an estimated VE of 82% (2-sided 95% CI: 75.6%, 86.9%) against confirmed COVID-19 occurring after Dose 1, with VE of 52.4% (95% CI: 29.5%, 68.4%) between Dose 1 and Dose 2.

Among the total of 10 severe COVID-19 cases observed after Dose 1, only 1 severe case was seen in BNT162b2 recipients compared to 9 severe COVID-19 cases in placebo recipients; these results, as well as case splits between Dose 1 and Dose 2 and after Dose 2, were consistent with overall efficacy seen against COVID-19.

In conclusion, the final efficacy results show that BNT162b2 at 30 µg provided protection against COVID-19 in participants who had no evidence of prior infection with SARS-CoV-2, including across demographic subgroups, with severe cases observed predominantly in the placebo group.

2.7.3.2.1.3. Updated Efficacy Analyses – Study C4591001

Updated descriptive efficacy analyses were performed using all cases accrued during the blinded placebo-controlled follow-up through the cutoff date of 13 March 2021. Updated efficacy analyses were conducted for the primary efficacy endpoints, including subgroup analyses, and for secondary efficacy endpoints of severe disease and CDC-defined severe disease.

2.7.3.2.1.3.1. Efficacy Populations – Updated Analysis

The proportions of participants included in the updated analysis efficacy populations were similar in the BNT162b2 and placebo groups (Table 48). Most participants who were excluded from the evaluable efficacy population had not received all vaccinations as randomized or did not receive Dose 2 within the predefined window (ie, 19 to 42 days after Dose 1). There were 240 participants in the BNT162b2 group and 60 participants in the placebo group excluded for having important protocol deviations on or prior to 7 days after Dose 2. In the BNT162b2 group, most of these deviations were related to improper administration of the investigational product (203 participants, as compared with 23 participants in the placebo group); among these, most exclusions in the BNT162b2 group

were due to dosing/administration errors (76 participants) or administration of investigational product that was deemed not suitable for use by the contractor who distributed the vaccine to study sites (110 participants) Table 49. These were administration errors that could not have applied to participants who received placebo: eg, errors in dilution of the vaccine or temperature excursions.

Demographic characteristics of participants in the updated analysis evaluable efficacy population for participants without evidence of infection prior to 7 days after Dose 2 were similar in the BNT162b2 and placebo groups (Table 50). This analysis population had generally similar demographic characteristics compared to the safety population.

2.7.3.2.1.3.2. Efficacy Results – Updated Analyses

As described above, based on results for the first primary efficacy endpoint, overwhelming efficacy was declared at the first (and only) interim analysis (Section 2.7.3.2.1.1.2.1) and was confirmed at the final analysis (Section 2.7.3.2.1.2.3.1). A descriptive update based on a total of 927 confirmed cases for the first primary endpoint accrued during blinded placebo-controlled follow-up, up to the data cutoff date of 13 March 2021, is summarized below.

The results presented are for the evaluable efficacy populations, except as noted.

2.7.3.2.1.3.2.1. Vaccine Efficacy Against Confirmed COVID-19 Occurring at Least 7 Days After Dose 2 – Evaluable Efficacy Population - Updated Analysis

Participants Without Evidence of SARS-CoV-2 Infection

Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 91.3%, with 77 COVID-19 cases in the BNT162b2 group compared to 850 cases in the placebo group (Table 17). The 2-sided 95% CI for vaccine efficacy was 89.0% to 93.2%. The posterior probability for the true VE being greater than 30%, given the available data, was >99.99%.

The estimated VE of BNT162b2 for the same efficacy endpoint based on the Dose 2 all-available efficacy population was 91.4% (2-sided 95% CI: 89.1%, 93.3%), with 78 and 866 cases in the BNT162b2 and placebo group, respectively (Table 51).

Table 17. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

Efficacy Endpoint	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	77	6.247 (20712)	850	6.003 (20713)	91.3	(89.0, 93.2)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (01:59)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_ve_cov_7pd2_wo_eval

Participants With or Without Evidence of SARS-CoV-2 Infection

Among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen, estimated VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 91.1%, with 81 and 873 cases in the BNT162b2 and placebo groups, respectively (Table 18). The 2-sided 95% CI for vaccine efficacy was 88.8% to 93.0%. The posterior probability for the true VE being greater than 30%, given the available data, was >99.99%.

The estimated VE of BNT162b2 for the same endpoint based on the Dose 2 all-available efficacy population was 91.2% (2-sided 95% CI: 88.9%, 93.0%), with 82 and 889 cases in the BNT162b2 and placebo group, respectively (Table 52).

Table 18. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	81	6.509 (21642)	873	6.274 (21689)	91.1	(88.8, 93.0)	>0.9999

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (01:59)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adc19ef ve cov 7pd2 eval

2.7.3.2.1.3.2.2. Vaccine Efficacy for All Confirmed Cases of COVID-19 After Dose 1 – Dose 1 All-Available Population – Updated Analysis

A number of confirmed cases of COVID-19 are not captured in the analyses of the primary endpoints for the evaluable efficacy population because they either occurred in participants who were excluded from the evaluable efficacy population, or occurred less than 7 days after Dose 2.

All reports of COVID-19 with onset at any time after Dose 1 are accounted for in Table 19, which provides a summary of VE for confirmed cases for all participants in the Dose 1 all-available efficacy (modified intention-to-treat) population adjusted for surveillance time, regardless of evidence of infection before or during the vaccination regimen. Among these participants, 131 cases of COVID-19 occurred after Dose 1 in the BNT162b2 group compared to 1034 cases in the placebo group. The estimated VE against confirmed COVID-19 occurring at any time after Dose 1 was 87.8% (2-sided 95% CI: 85.3%, 89.9%).

In this population, the estimated VE against all cases occurring ≥7 days after Dose 2 was 91.2%. The estimated VE was 91.7% for cases occurring from ≥11 days after Dose 1 to before Dose 2, 96.2% for cases occurring from ≥7 days after Dose 2 to <2 months after Dose 2, 90.1% for the period from ≥2 months to <4 months after Dose 2, and 83.7% for the period ≥4 months after Dose 2.

Table 19. Vaccine Efficacy – First COVID-19 Occurrence After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

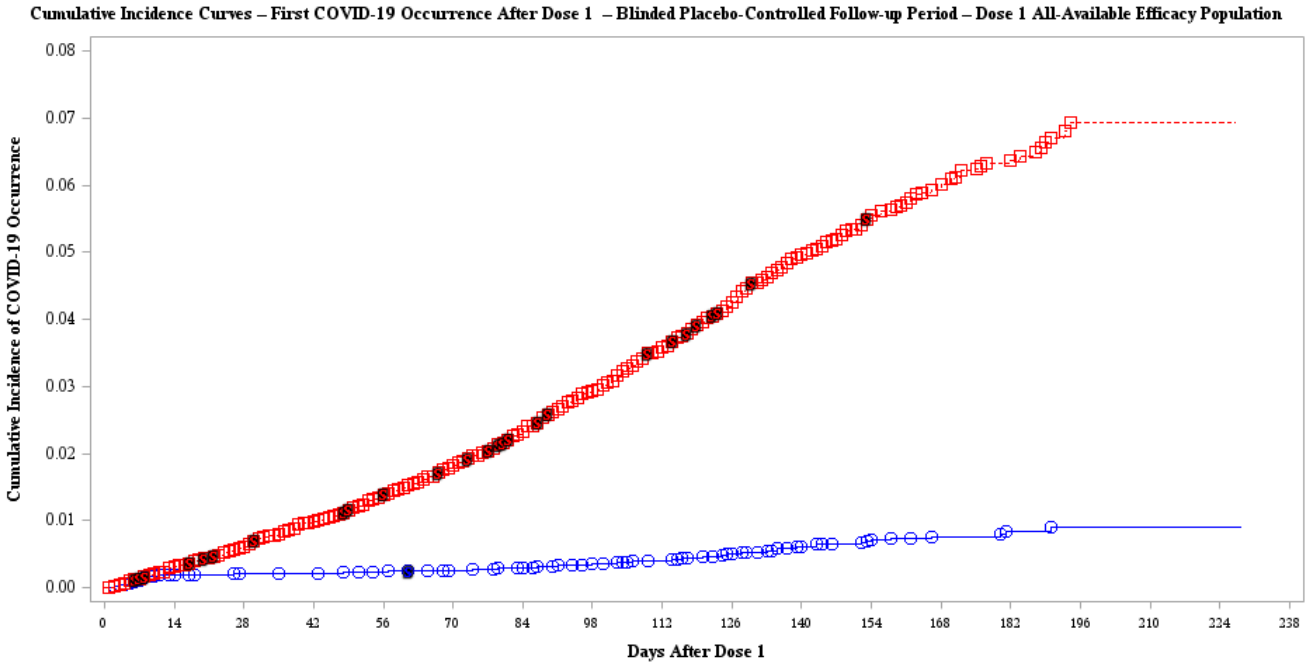
	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=23040)		Placebo (N[a]=23037)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence after Dose 1	131	8.412 (22505)	1034	8.124 (22434)	87.8	(85.3, 89.9)
After Dose 1 to before Dose 2	46	1.339 (22505)	110	1.331 (22434)	58.4	(40.8, 71.2)
After Dose 1 to <11 days after Dose 1	41	0.677 (22505)	50	0.675 (22434)	18.2	(-26.1, 47.3)
≥11 Days after Dose 1 to before Dose 2	5	0.662 (22399)	60	0.656 (22369)	91.7	(79.6, 97.4)
Dose 2 to 7 days after Dose 2	3	0.424 (22163)	35	0.422 (22057)	91.5	(72.9, 98.3)
≥7 Days after Dose 2	82	6.649 (22132)	889	6.371 (22001)	91.2	(88.9, 93.0)
≥7 days after Dose 2 to <2 Months after Dose 2	12	2.923 (22132)	312	2.884 (22001)	96.2	(93.3, 98.1)
≥2 Months after Dose 2 to <4 Months after Dose 2	46	2.696 (20814)	449	2.593 (20344)	90.1	(86.6, 92.9)
≥4 Months after Dose 2	24	1.030 (12670)	128	0.895 (11802)	83.7	(74.7, 89.9)

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 19APR2021 (17:34)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adc19ef ve cov pd1 aai

The early onset of protection is readily apparent in Figure 2, which displays cumulative incidence for the first COVID-19 occurrence after Dose 1 among all vaccinated participants based on Dose 1 all-available efficacy (modified intention-to-treat) population. Disease onset appears to track together for BNT162b2 and placebo until approximately 11 days after Dose 1 (consistent with the data shown in Table 19), at which point the curves diverge, with cases steadily accumulating in the placebo group, while remaining virtually flat in the BNT162b2 group.

The darker-appearing symbols for both BNT162b2 (blue circles) and placebo (red squares) curves in Figure 2 have an "S" written inside the open symbol, which denotes severe cases. Severe COVID-19 cases reported in the updated analysis are discussed further in Section 2.7.3.2.1.3.2.4.

Figure 2. Cumulative Incidence Curves for the First COVID-19 Occurrence After Dose 1– Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population



Note: "S" indicates subjects with severe COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adc19ef Table Generation: 27MAR2021 (11:38)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: /nda2_unblinded/C4591001_BLA/adc19ef_f001_km_d1_aai

2.7.3.2.1.3.2.3. Vaccine Efficacy by Subgroup – Updated Analysis

For both primary endpoints, VE was also evaluated for subgroups of participants by age, sex, race/ethnicity, and country, as well as for groups of subjects by risk status and comorbidities. Overall, the results show high rates of VE based on subgroup analyses.

Subgroups of Age, Sex, Race/Ethnicity, and Country

In the evaluable efficacy population, among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, estimated VE was ≥90% in most subgroups, similar to the 91.3% overall VE (Table 20). High VE was also observed across age groups, with an estimated VE of 100.0% in 12 to 15 year olds, 90.6% in 16 to 64 year olds, 94.5% in those ≥65 years, and 96.2% in those ≥75 years of age. Estimated VEs were 87.6% among Asian and 88.5% among Hispanic/Latino participants; the estimated VE was 92.6% in the United States, 86.5% in Argentina, 86.2% in Brazil, and 100.0% in South Africa, Germany, and Turkey.

Similar results were observed for subgroup analyses among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen (Table 53). In analyses for the Dose 1 all-available efficacy population, which included all confirmed cases occurring at any time after Dose 1, no clinically meaningful differences among the subgroups were identified (Table 54).

Subgroup analyses included evaluation of VE by prior SARS-CoV-2 status at baseline. The number of participants with positive prior SARS-CoV-2 status at baseline was relatively small, and the 95% CIs for the estimated VEs in these subgroup analyses were very wide; therefore, the data must be interpreted with caution. However, the results may provide some information regarding the benefits of vaccination for individuals with prior SARS-CoV-2 infection.

Participants with positive prior SARS-CoV-2 status at baseline were defined as those with positive N-binding antibody or NAAT results at Visit 1 or a medical history of COVID-19. In the evaluable efficacy analysis for this subgroup, the estimated VE against cases occurring ≥7 days after Dose 2 was 46.9% (3 cases BNT162b2; 6 cases placebo) (Table 53), and in the all-available efficacy analysis the estimated VE against cases occurring at any time after Dose 1 was 19.2% (13 cases BNT162b2, 17 cases placebo) (Table 54).

It is important to note that the subgroup defined above includes participants with both past infections (positive N-binding antibody) and current infections (NAAT positive). Since it is reasonable to expect that vaccination may be less effective in participants currently infected with SARS-CoV-2 at Visit 1, it may be relevant to examine VE specifically in participants who were positive for N-binding only (and were not NAAT-positive) at Visit 1. In the evaluable efficacy analysis for these participants, the estimated VE against cases occurring ≥7 days after Dose 2 was 58.9% (2 cases BNT162b2; 5 cases placebo) (Table 53), and in the all-available efficacy analysis the estimated VE against cases occurring at any time after Dose 1 was 70.5% (2 cases BNT162b2, 7 cases placebo) (Table 54). Therefore, estimates of VE are considerably higher in participants who were positive for N-binding antibody only,

suggesting that vaccination provides a benefit for individuals with previous SARS-CoV-infection.

Table 20. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	77	6.247 (20712)	850	6.003 (20713)	91.3	(89.0, 93.2)
Age group (years)						
12 to 15	0	0.154 (1001)	16	0.147 (972)	100.0	(75.3, 100.0)
16 to 55	52	3.593 (11517)	568	3.439 (11533)	91.2	(88.3, 93.5)
>55	25	2.499 (8194)	266	2.417 (8208)	90.9	(86.3, 94.2)
≥65	7	1.233 (4192)	124	1.202 (4226)	94.5	(88.3, 97.8)
16 to 17	0	0.061 (342)	10	0.057 (331)	100.0	(58.2, 100.0)
16 to 25	8	0.482 (1629)	80	0.466 (1622)	90.3	(80.0, 96.0)
16 to 64	70	4.859 (15519)	710	4.654 (15515)	90.6	(87.9, 92.7)
18 to 64	70	4.798 (15177)	700	4.597 (15184)	90.4	(87.7, 92.6)
55 to 64	21	1.399 (4426)	157	1.334 (4388)	87.3	(79.8, 92.3)
65 to 74	6	0.994 (3350)	98	0.966 (3379)	94.1	(86.6, 97.9)
≥75	1	0.239 (842)	26	0.237 (847)	96.2	(76.9, 99.9)
75 to 85	1	0.238 (837)	25	0.235 (841)	96.0	(75.9, 99.9)
>85	0	0.001 (5)	1	0.001 (6)	100.0	(-4055.9, 100.0)
Sex						
Male	42	3.246 (10637)	399	3.047 (10433)	90.1	(86.4, 93.0)
Female	35	3.001 (10075)	451	2.956 (10280)	92.4	(89.2, 94.7)
Race						
White	67	5.208 (17186)	747	5.026 (17256)	91.3	(88.9, 93.4)
Black or African American	4	0.545 (1737)	48	0.527 (1737)	91.9	(78.0, 97.9)
American Indian or Alaska Native	0	0.041 (186)	3	0.037 (176)	100.0	(-119.0, 100.0)
Asian	3	0.260 (946)	23	0.248 (934)	87.6	(58.9, 97.6)
Native Hawaiian or other Pacific Islander	0	0.015 (54)	1	0.008 (30)	100.0	(-1961.2, 100.0)
Multiracial	3	0.151 (518)	22	0.128 (476)	88.5	(61.6, 97.8)
Not reported	0	0.026 (85)	6	0.030 (104)	100.0	(2.8, 100.0)

Table 20. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
All others[f]	6	0.494 (1789)	55	0.451 (1720)	90.0	(76.9, 96.5)
Ethnicity						
Hispanic/Latino	29	1.786 (5161)	241	1.711 (5120)	88.5	(83.0, 92.4)
Non-Hispanic/non-Latino	47	4.429 (15449)	609	4.259 (15484)	92.6	(90.0, 94.6)
Not reported	1	0.032 (102)	0	0.033 (109)	-∞	(NA, NA)
Country						
Argentina	15	1.012 (2600)	108	0.986 (2586)	86.5	(76.7, 92.7)
Brazil	12	0.406 (1311)	80	0.374 (1293)	86.2	(74.5, 93.1)
Germany	0	0.047 (236)	1	0.048 (242)	100.0	(-3874.2, 100.0)
South Africa	0	0.080 (291)	9	0.074 (276)	100.0	(53.5, 100.0)
Turkey	0	0.027 (228)	5	0.025 (222)	100.0	(-0.1, 100.0)
USA	50	4.674 (16046)	647	4.497 (16094)	92.6	(90.1, 94.5)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
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(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adc19ef ve cov 7pd2 wo sg eval

Subgroup Analyses by Risk Status and Comorbidities

Analyses of efficacy by risk status were performed. For these analyses, at-risk participants were defined as those who had at least one Charlson Comorbidity Index condition or who were obese (defined as body mass index ≥30 kg/m2). For a summary of Charlson comorbidities among all participants ≥16 years of age at study entry, see Table 55.

Among participants without evidence of SARS-CoV-2 infection before and during vaccination regimen, estimated VE was similar for participants at risk (91.6%) and participants not at risk (91.0%) (Table 21). The estimated VE for participants ≥65 years of age and at risk was 91.8%, as compared with 98.1% for those ≥65 years of age and not at risk. Estimated VE was similar in obese (91.6%) and non-obese (91.1%) participants. When evaluated by type of comorbidity, estimated VE was >85% for participants with each comorbidity evaluated, including any malignancy, cardiovascular disease, chronic pulmonary disease, diabetes, obesity, and hypertension (Table 56).

Table 21. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	77	6.247 (20712)	850	6.003 (20713)	91.3	(89.0, 93.2)
At risk[f]						
Yes	35	2.797 (9167)	401	2.681 (9136)	91.6	(88.2, 94.3)
No	42	3.450 (11545)	449	3.322 (11577)	91.0	(87.6, 93.6)
Age group (years) and at risk						
12-15 and not at risk	0	0.121 (788)	11	0.116 (769)	100.0	(61.9, 100.0)
12-15 and at risk	0	0.034 (213)	5	0.032 (203)	100.0	(-2.0, 100.0)
16-64 and not at risk	41	2.776 (8887)	385	2.661 (8886)	89.8	(85.9, 92.8)
16-64 and at risk	29	2.083 (6632)	325	1.993 (6629)	91.5	(87.5, 94.4)
≥65 and not at risk	1	0.553 (1870)	53	0.546 (1922)	98.1	(89.2, 100.0)
≥65 and at risk	6	0.680 (2322)	71	0.656 (2304)	91.8	(81.4, 97.1)
Obese[g]						
Yes	27	2.103 (6796)	314	2.050 (6875)	91.6	(87.6, 94.6)
No	50	4.143 (13911)	536	3.952 (13833)	91.1	(88.1, 93.5)
Age group (years) and obese						
12-15 and not obese	0	0.135 (878)	13	0.131 (867)	100.0	(68.3, 100.0)
12-15 and obese	0	0.019 (123)	3	0.016 (105)	100.0	(-104.8, 100.0)
16-64 and not obese	46	3.178 (10212)	444	3.028 (10166)	90.1	(86.6, 92.9)
16-64 and obese	24	1.680 (5303)	266	1.624 (5344)	91.3	(86.7, 94.5)
≥65 and not obese	4	0.829 (2821)	79	0.793 (2800)	95.2	(87.1, 98.7)
≥65 and obese	3	0.404 (1370)	45	0.410 (1426)	93.2	(78.9, 98.7)

Table 21. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Risk Status – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Includes subjects who had at least one of the Charlson Comorbidity Index (CMI) category or obesity (BMI ≥30 kg/m^2 [≥16 Years of age] or BMI ≥95th percentile [12-15 Years of age]).
g. Subjects (≥16 Years of age) who had BMI ≥30 kg/m^2. For 12 through 15 years age group, obesity is defined as a BMI at or above the 95th percentile. Refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev htm.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 30MAR2021 (22:35)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adc19ef ve cov 7pd2 wo rg eval

2.7.3.2.1.3.2.4. Vaccine Efficacy for Severe COVID-19 Cases – Updated Analysis

Efficacy Against Severe COVID-19 (≥7 Days After Dose 2)

Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against severe COVID-19 as defined by FDA occurring at least 7 days after Dose 2 was 95.3% (2-sided 95% CI: 71.0%, 99.9%), with 1 and 21 cases in the BNT162b2 and placebo groups, respectively (Table 22). The posterior probability for the true vaccine efficacy being greater than 30%, given the available data, was >99.99%.

The same number of severe cases were reported among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen (1 case in the BNT162 group and 21 cases in the placebo group), and the estimated VE was the same (95.3%) (Table 57).

Table 22. Vaccine Efficacy – First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First severe COVID-19 occurrence from 7 days after Dose 2	1	6.257 (20712)	21	6.120 (20713)	95.3	(71.0, 99.9)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (02:26)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_ve_sev_cov_7pd2_wo_eval

All Confirmed Cases of Severe COVID-19 (As Defined by FDA) After Dose 1 – All-Available Efficacy Population

Among participants in the Dose 1 all-available efficacy (modified intention-to-treat) population, 1 case of severe COVID-19 as defined by FDA occurred after Dose 1 in the BNT162b2 group compared to 30 cases in the placebo group (Table 23). The estimated VE against severe COVID-19 occurring after Dose 1 was 96.7% (2-sided 95% CI: 80.3%, 99.9%).

Table 23. Vaccine Efficacy – First Severe COVID-19 Occurrence After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=23040)		Placebo (N[a]=23037)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First severe COVID-19 occurrence after Dose 1	1	8.439 (22505)	30	8.288 (22435)	96.7	(80.3, 99.9)
After Dose 1 to before Dose 2	0	1.351 (22505)	6	1.360 (22435)	100.0	(14.5, 100.0)
Dose 2 to 7 days after Dose 2	0	0.425 (22170)	1	0.423 (22070)	100.0	(-3783.5, 100.0)
≥7 Days after Dose 2	1	6.663 (22142)	23	6.505 (22048)	95.8	(73.9, 99.9)

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 19APR2021 (18:26)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adc19ef ve sev cov pd1 aai

2.7.3.2.1.3.2.5. Vaccine Efficacy for Severe COVID-19 Cases per CDC Definition – Updated Analysis

In addition, a supportive analysis was conducted for efficacy against severe cases of COVID-19 using the CDC definition of severe COVID-19 (hospitalization, admission to the intensive care unit (ICU), intubation or mechanical ventilation, or death).[6]

Among efficacy evaluable participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against CDC-defined severe COVID-19 occurring at least 7 days after Dose 2 was 100.0% (2-sided 95% CI: 88.1%, 100.0%), with 0 and 32 cases in the BNT162b2 and placebo groups, respectively (Table 24).

The same number of CDC-defined severe cases were reported among efficacy evaluable participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen (Table 58).

Table 24. Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC-Definition From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First severe COVID-19 occurrence based on CDC-definition from 7 days after Dose 2	0	6.250 (20688)	32	6.108 (20680)	100.0	(88.1, 100.0)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (02:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_ve_sev_7pd2_cdc_wo_eval

All Confirmed Cases of CDC-Defined Severe COVID-19 After Dose 1 – All-Available Efficacy Population

Among participants in the Dose 1 all-available efficacy population, 1 case of CDC-defined severe COVID-19 occurred after Dose 1 (but before Dose 2) in the BNT162b2 group compared to 45 cases in the placebo group (Table 25). The estimated VE against severe CDC-defined COVID-19 occurring after Dose 1 was 97.8% (2-sided 95% CI: 87.2%, 99.9%).

Table 25. Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC-Definition After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=23040)		Placebo (N[a]=23037)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First Severe COVID-19 occurrence based on CDC-definition after Dose 1	1	8.427 (22473)	45	8.269 (22394)	97.8	(87.2, 99.9)
After Dose 1 to before Dose 2	1	1.348 (22473)	11	1.355 (22394)	90.9	(37.1, 99.8)
Dose 2 to 7 days after Dose 2	0	0.424 (22141)	1	0.422 (22030)	100.0	(-3781.6, 100.0)
≥7 Days after Dose 2	0	6.654 (22113)	33	6.491 (22008)	100.0	(88.5, 100.0)

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 19APR2021 (18:26)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adc19ef ve sev cdc pd1 aai

2.7.3.2.1.3.3. Signs and Symptoms of COVID-19

The signs and symptoms reported for cases contributing to the analysis for the first primary efficacy endpoint (77 cases in the BNT162b2 group and 850 cases in the placebo group) are summarized in Table 59. These include cases occurring at least 7 days after the second vaccination among participants in the evaluable efficacy population who had no evidence of SARS-CoV-2 infection before or during the vaccination regimen. In this analysis, the proportions of participants reporting only 1 symptom were 36.4% in the BNT162b2 group, compared with 20.9% in the placebo group; and 15.6% of participants in the BNT162b2 group reported 4 or more symptoms, compared with 30.8% of participants in the placebo group. Most participants reported new or increased cough (63.9% of symptomatic cases overall), and other symptoms reported most frequently were new or increased muscle pain (45.2%), sore throat (38.6%), new loss of taste or smell (36.0%), and fever (35.9%).

Table 60 summarizes the signs and symptoms for all cases of COVID-19 occurring at any time after Dose 1 (131 cases in the BNT162b2 group and 1034 cases in the placebo group). These include cases occurring among participants in the Dose 1 all-available efficacy population, regardless of evidence of SARS-CoV-2 infection before or during the vaccination regimen. The proportions of participants reporting 4 or more symptoms were 19.1% in the BNT162b2 group compared with 30.0% of participants in the placebo group. The most

frequently reported symptoms were similar to those for the analysis of the first primary efficacy endpoint.

The signs and symptoms reported for all confirmed cases of FDA-defined severe COVID-19 reported at any time after Dose 1 (in the all-available population) (1 case in the BNT162b2 group and 30 cases in the placebo group) are summarized in Table 61. The participant who was diagnosed with severe COVID-19 after receiving BNT162b2 had one symptom, SpO2 ≤93%. Among the 30 severe cases in the placebo group, 63.3% had clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, SpO2 ≤93% on room air at sea level, or PaO2/FiO2 <300 mm Hg); 46.7% had respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO), and 26.7% were admitted to an ICU.

2.7.3.2.1.3.4. Efficacy Conclusions From the Updated Analyses – Study C4591001

Updated Analysis – Efficacy Against Confirmed COVID-19

- In the updated descriptive efficacy analysis (cutoff date 13 March 2021), among participants in the evaluable efficacy population without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 91.3% (95% CI: 89.0%. 93.2%), with 77 cases in the BNT162b2 group and 850 cases in the placebo group. Among participants with or without evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was 91.1% (95% CI: 88.8%, 93.0%), with 81 and 873 cases in the BNT162b2 and placebo groups, respectively.

- All cases of confirmed COVID-19 are accounted for in the analyses of VE in the all-available (modified intention-to-treat) population (regardless of evidence of infection before or during the vaccination regimen). In this analysis, estimated VE against all cases occurring at any time after Dose 1 was 87.8% (2-sided 95% CI: 85.3%, 89.9%), with 131 cases in the BNT162b2 group and 1034 cases in the placebo group.

- In the all-available (modified intention-to-treat) population, the estimated VE against all cases occurring ≥7 days after Dose 2 was 91.2%. The estimated VE was 91.7% for cases occurring from ≥11 days after Dose 1 to before Dose 2, 96.2% for cases occurring from ≥7 days after Dose 2 to <2 months after Dose 2, 90.1% for the period from ≥2 months to <4 months after Dose 2, and 83.7% for the period ≥4 months after Dose 2.

Efficacy Against Severe Cases of COVID-19

- Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen (evaluable efficacy population), the estimated VE against FDA defined severe COVID-19 (protocol definition) occurring at least 7 days after Dose 2 was 95.3% (2-sided 95% CI: 71.0%, 99.9%), with 1 and 21 cases in the BNT162b2 and placebo groups, respectively. Similarly, the estimated VE was also 95.3% (2-sided 95% CI: 70.9%, 99.9%) among participants with or without evidence of SARS-CoV-2 infection, also with 1 and 21 cases in the BNT162b2 and placebo groups, respectively.

- Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen (evaluable efficacy population), the estimated VE against CDC-defined severe COVID-19 occurring at least 7 days after Dose 2 was 100.0% (2-sided 95% CI: 88.1%, 100.0%), with 0 and 32 cases in the BNT162b2 and placebo groups, respectively. Similarly, the estimated VE was also 100.0% (2-sided 95% CI: 88.0%, 100.0%) among participants with or without evidence of SARS-CoV-2 infection, also with 0 and 32 cases in the BNT162b2 and placebo groups, respectively
- Among participants in the Dose 1 all-available efficacy population (regardless of evidence of infection before or during the vaccination regimen), estimated VE against severe cases of COVID-19 (as defined by FDA) occurring at any time after Dose 1 was 96.7% (2-sided 95% CI: 80.3%, 99.9%), with 1 case of severe COVID-19 in the BNT162b2 group compared to 30 cases in the placebo group.

Efficacy in Demographic and Risk Subgroups

Among participants without evidence of SARS-CoV-2 infection before and during the vaccination regimen (efficacy evaluable population) VE against COVID-19 occurring at least 7 days after Dose 2 was evaluated, with results as follows:

- Estimated VE was ≥90% in most subgroups, similar to the 91.3% overall estimated VE.
- High VE was observed across age subgroups, with an estimated VE of 100.0% in 12 to 15 year olds, 90.6% in 16 to 64 year olds, 94.5% in those ≥65 years, and 96.2% in those ≥75 years of age.
- The estimated VE was 86.5% in Argentina, 86.2% in Brazil, 92.6% in the United States, and 100.0% in South Africa, Germany, and Turkey.
- The estimated VE was similar for participants at risk (91.6%) and participants not at risk (91.0%). Estimated VE for participants ≥65 years of age and at risk was 91.8%, as compared with 98.1% for those ≥65 years of age and not at risk. Estimated VE was similar in obese (91.6%) and non-obese (91.1%) participants. When evaluated by type of comorbidity, estimated VE was >85% for participants with each comorbidity evaluated, including any malignancy, cardiovascular disease, chronic pulmonary disease, diabetes, obesity, and hypertension.

2.7.3.2.2. Immunogenicity Evaluations

In this section, immunogenicity results are first summarized for Phase 1 data from Study BNT162-01 (Section 2.7.3.2.2.1.1) and Study C4591001 (Section 2.7.3.2.2.1.2), including discussion of the rationale for the selection of the vaccine candidate and dose level to take forward into Phase 2/3 of Study C4591001 (Section 2.7.3.2.2.1.3). Subsequently, results from Study C4591001 are presented for the analyses of immunogenicity data for the 360 participants in Phase 2 (Section 2.7.3.2.2.2).

2.7.3.2.2.1. Phase 1 Immunogenicity Results – Candidate and Dose Selection

2.7.3.2.2.1.1. Study BNT162-01 – Phase 1

Study BNT162-01 is currently ongoing, and immunogenicity results reported here are for interim data.

This submission includes serology results (SARS-CoV-2 neutralizing titers and antigen-specific binding IgG levels) through the cutoff date of 23 October 2020. For participants 18 to 55 years of age (younger age group), serology data are available up to Day 43 (21 days after Dose 2) for BNT162b1 recipients and up to Day 85 (63 days after Dose 2) for BNT162b2 recipients. Serology data are also available up to Day 29 (7 days after Dose 2) for individuals 56 to 85 years of age (older age group) who received BNT162b2 at the 20 µg dose level.

This submission also includes T cell response data with cutoff dates as follows:

- ELISpot data: 02 March 2021;
- ICS data: 17 November 2020 for BNT162b1 and 02 March 2021 for BNT162b2.

T cell response data are available for all participants with evaluable data at Day 29 (7 days after Dose 2) and up to Day 184 for a subset of participants who received BNT162b2 at 10, 20, or 30 µg.

2.7.3.2.2.1.1.1. Disposition and Demographics - Study BNT162-01

BNT162b1 – Younger Participants 18 to 55 Years of Age

A total of 84 participants in the 18 to 55 years age group received Dose 1 of BNT162b1, 12 in each of the 7 dose level groups (1, 3, 10, 20, 30, 50, 60 µg), and 69 of these participants received Dose 2 of BNT162b1. Based on the Safety Review Committee's determination, none of the 12 participants in the 60 µg group received the second dose, due to reactogenicity; however, these participants continued in the study. Three participants were withdrawn from the study before the administration of Dose 2 (1 in the 10 µg group due to an adverse event of malaise considered not related to study vaccine by the investigator; 1 in the 20 µg group due to withdrawal by participant; and 1 in the 50 µg group due to private reasons). One additional participant in the 20 µg group was withdrawn from the study after Dose 2 due to private reasons.

Among the 84 younger participants who received at least 1 dose of study vaccine, the mean age was approximately 38 years (range, 19 to 55 years); 52% of participants were male, 96% were white, and 98% were non-Hispanic.

BNT162b1 – Older Participants 56 to 85 Years of Age

A total of 36 participants in the older age group (56 to 85 years of age) received Dose 1 of BNT162b1 (12 at each dose level: 10, 20, and 30 µg). At the time of data cutoff, all of these participants had received Dose 2, except for 1 participant in the 20 µg group, who was continuing in the study. Among the 36 older participants who received at least 1 dose of BNT162b1, the mean age was approximately 66 years (range, 56 to 76); 64% were female, and all were white and non-Hispanic.

BNT162b2 – Younger Participants 18 to 55 Years of Age

A total of 60 younger participants (18 to 55 years of age) received Dose 1 of BNT162b2, 12 in each of the 5 dose level groups (1, 3, 10, 20, 30 µg). All of these participants also received Dose 2 of BNT162b2, except for 2 participants who were withdrawn from the study (one participant in the 1 µg group due to withdrawal by participant, and one participant in the 10 µg group due to an adverse event of nasopharyngitis, considered not related to study vaccine by the investigator).

Among the 60 younger participants who received at least 1 dose of BNT162b2, the mean age was approximately 40 years (range, 19 to 55); 57% of participants were female, and all were white and non-Hispanic.

BNT162b2 – Older Participants 56 to 85 Years of Age

A total of 36 older participants (56 to 85 years of age) received both doses of BNT162b2, 12 in each of the 3 dose level groups (10, 20, and 30 µg). At the time of data cutoff none of these participants had been prematurely discontinued from the study. Among these participants, the mean age was approximately 65 years (range, 56 to 84); 54% were female; and all were white and non-Hispanic.

2.7.3.2.2.1.1.2. T Cell Response Data – Study BNT162-01

T cell mediated immune responses were evaluated using Enzyme-Linked Immuno-Spot (ELISpot) and intracellular cytokine staining (ICS) visualized with fluorescence-activated cell sorting (FACS). Blood samples for evaluation of T cell responses were collected per protocol at baseline (before Dose 1) and at the visit that was to take place approximately 7 days after Dose 2 (Day 29). Cell mediated immune response data were also evaluated in post hoc analyses (not specified in the protocol) using blood collected for general research purposes on approximately Day 43 (21 days after Dose 2) Day 85 (63 days after Dose 2) and Day 184 (162 days after Dose 2). T cell responses were evaluated at these later time points for only a small number of participants who received BNT162b2 at doses of 10, 20, or 30 µg.

Based on the ELISpot and intracellular cytokine staining assay results described below, BNT162b1 and BNT162b2 induced poly-functional and pro-inflammatory CD4+/CD8+

T cell responses in most participants in both the older and younger age groups. Re-stimulation of PBMCs with peptide pools representing the encoded antigens (RBD or full-length S protein) demonstrated a helper response characterized by a robust IFNγ/IL-2 response and only minor IL-4 production. This cytokine profile indicates a favorable Th1 response and only a minimal Th2 immune response.

SARS-CoV-2 specific CD4+ and CD8+ T cell responses - ELISpot

At the ELISpot data cutoff date, evaluable ELISpot data were available for 97 participants who received BNT162b1: 70 in the younger age group (at 1, 3, 10, 20, 30, 50, 60 µg) and 27 in the older age group (at 10, 20, 30 µg). For BNT162b2, ELISpot data were available for 76 participants who received BNT162b2: 47 younger participants (at 1, 3, 10, 20, 30 µg), and 29 older participants (at 10, 20, 30 µg).

Overall, for both BNT162b1 and BNT162b2, based on data for Day 29, the T cell response rate and the magnitude of the responses as measured by ELISpot were similar across dose levels of 10 µg and higher and were similar between younger and older participants. Results are shown in Figure 3 (a) for the BNT162b2 group.

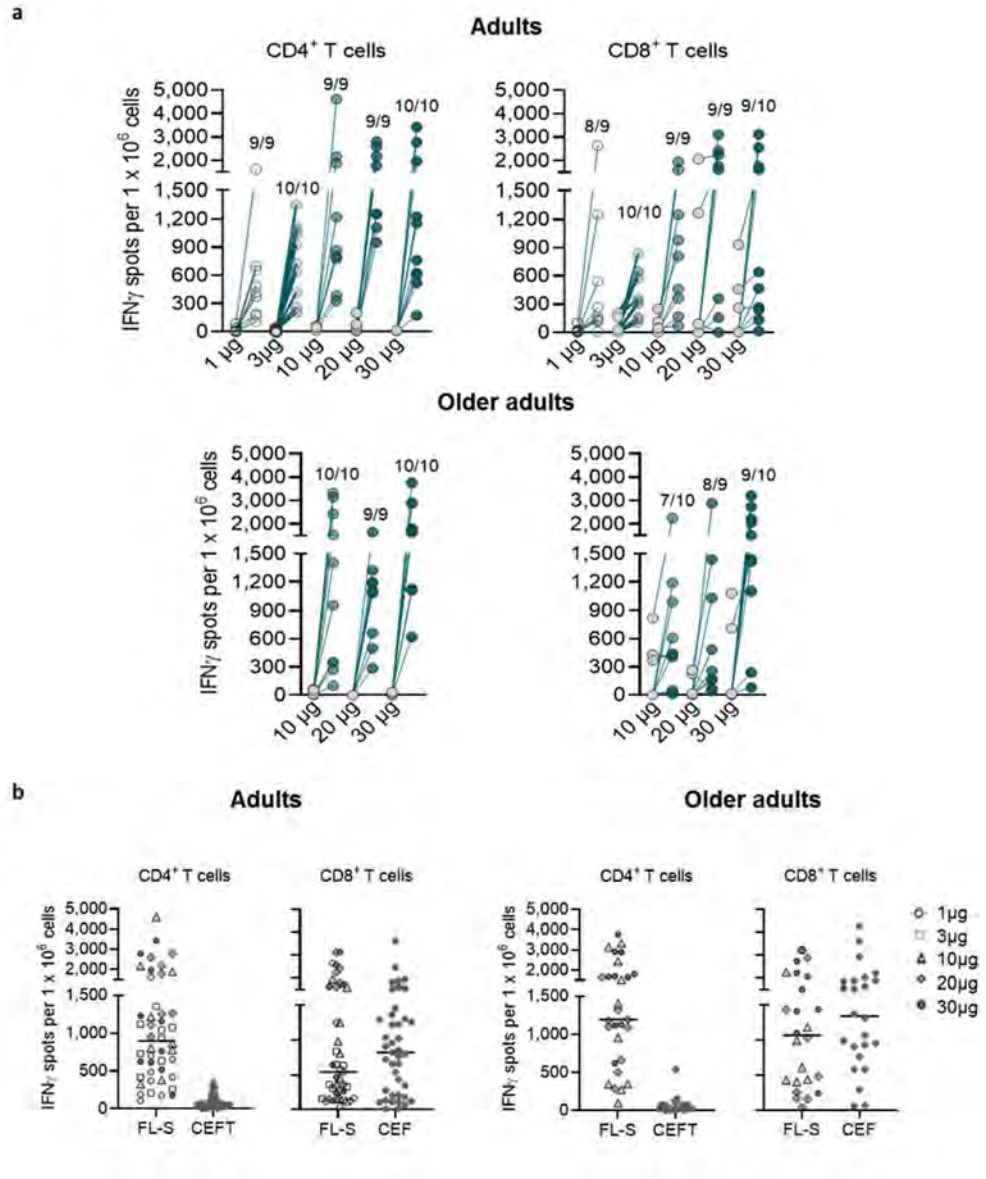
Among participants who received both Dose 1 and Dose 2, BNT162b1 induced strong SARS-CoV-2 RBD-specific $CD4^+$ T cell responses in 96.7% (59/61) of younger participants and in 100% (27/27) of older participants; $CD8^+$ responses were induced in 77.0% (47/61) of younger participants and in 77.8% (21/27) of older participants. In contrast, T cell responses were detected less often and were lower in magnitude in 9 younger participants who received only Dose 1 in the 60 µg dose group (55.6% for $CD4^+$ and 66.7% for $CD8^+$), indicating the importance of a booster dose.

BNT162b2 induced strong SARS-CoV-2 S protein-specific CD4+ T cell responses in all participants in both the younger (47/47) and older (29/29) age groups. CD8+ T cell responses were induced in 95.7% (45/47) of younger participants and 82.8% (24/29) of older participants. Despite the slightly lower CD8+ immunogenicity rate in older participants, the magnitude of the BNT162b2-induced responses was comparable to those induced in younger participants receiving 30 µg of BNT162b2. These T cell responses were directed against different parts of the antigen, including non-RBD sequences, indicating the induction of multi-epitopic responses by BNT162b2 in both age groups.

For both BNT162b1 and BNT162b2, while the magnitude of the responses varied among individuals, in participants with the strongest responses, post-vaccination $CD4^+$ T cell responses to pools of S protein peptides were more than 10-fold the memory responses to peptides of CMV, EBV, influenza virus and tetanus toxoid observed in the same participants, and $CD8^+$ T cell responses were comparable with memory responses against the viral antigen peptides in the same participants. Results for BNT162b2 are shown in Figure 3 (b).

Complete results for the ELISpot data are presented in Module 5.3.5.1 BNT162-01 Interim CSR Appendix 16.1.14 Report R-20-0244 v3.0 and Report GA-RB-022-01A v3.0.

Figure 3. Frequency and Magnitude of BNT162b2-Induced CD4+ and CD8+ T cell Responses Against Full-length S protein

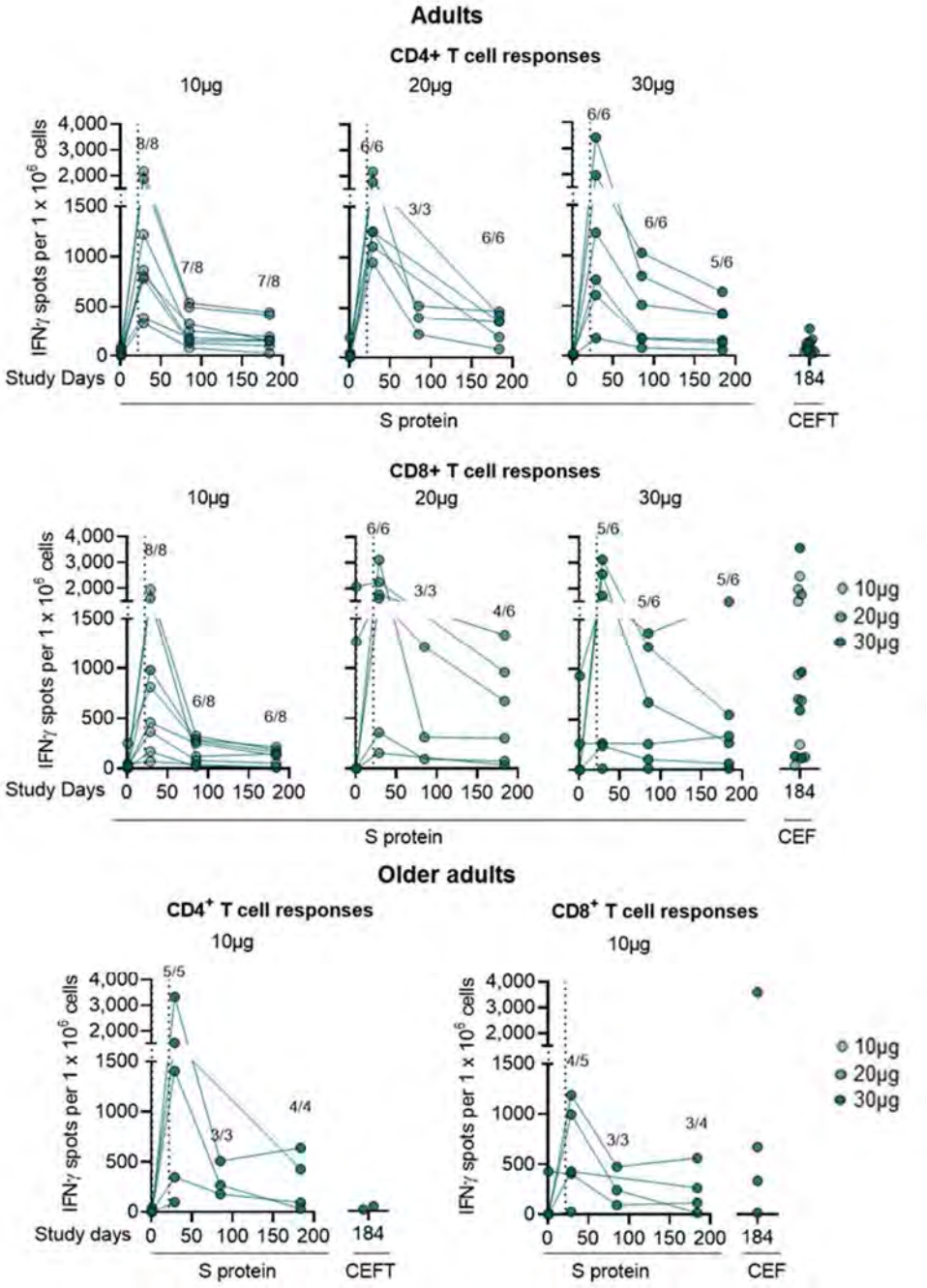


PBMCs obtained on Day 1 (pre-Dose 1) and on Day 29 (7 days post-Dose 2) were analyzed in *ex vivo* IFNγ ELISpot (for details see GA-RB-022-01A). Common pathogen T cell epitope pools CEF (CMV, EBV, and influenza virus HLA class I epitopes) and CEFT (CMV, EBV, influenza virus, and tetanus toxoid HLA class II epitopes) served to assess general T cell reactivity, cell culture medium served as negative control. Each dot represents the sum of normalized mean spot count from duplicate wells stimulated with two peptide pools corresponding to the full-length wt S protein for one study subject, after subtraction of the medium-only control. a, Ratios above post-vaccination data points are the number of subjects with detectable $CD4^+$ or $CD8^+$ T cell responses within the total number of tested subjects per dose group. b, S protein-specific $CD4^+$ and $CD8^+$ T cell responses in all subjects with a positive response to S protein (n=46 adults, 29 older adults for $CD4^+$ and n=43 adults, 24 older adults for $CD8^+$ T cell responses) and their baseline CEFT- and CEF-specific T cell responses. Note: CD4 data from 1 adult subject from the 20 µg group and CD8 data from two adult subjects from the 20 µg group could not be normalized and hence have not been included in the plots. Horizontal lines represent the median of each group. Source: Report R-20-0244 v3.0

Durability of BNT162b2-Induced CD4+ and CD8+ T Cell Responses - ELISpot

Figure 4 illustrates the durability of the CD4+ and CD8+ T cell responses induced by BNT162b2 among younger participants (N = 20) at doses of 10, 20, and 30 µg and among older participants (N=4) receiving 10 µg. T cell responses decreased from Day 29 to Day 85 (63 days after Dose 2), but on Day 184 (162 days after Dose 2) both CD4+ and CD8+ T cell responses were still detectable in the majority of participants at levels higher than, or in the range of, recall antigen memory responses (CEF and CEFT in the figure) (Figure 4).

Figure 4. Durability of BNT162b2-Induced T Cell Responses



PBMCs obtained on Day 1 (before Dose 1), Day 29, Day 85, and Day 184 (7, 63, and 162 days post-Dose 2, respectively), were analyzed in *ex vivo* IFNγ ELISpot (for details see GA-RB-022-01A). Common pathogen T cell epitope pools CEF (CMV, EBV, and influenza virus HLA class I epitopes) and CEFT (CMV, EBV, influenza virus, and tetanus toxoid HLA class II epitopes) served to assess general T cell reactivity, cell culture medium served as negative control. Each dot represents the sum of normalized mean spot count from duplicate wells stimulated with two peptide pools corresponding to the full-length wild-type S protein for one study participant, after subtraction of the medium-only control. Ratios above post-vaccination data points are the number of participants with detectable $CD4^+$ or $CD8^+$ T cell responses within the total number of tested participants per dose group and time point. Source: Report R-20-0244 v3.0.

Functional and Pro-inflammatory CD4+/CD8+ T cell Responses – ICS

BNT162b1

ICS/FACS data are available for 95 participants who received any dose level of BNT162b1:

- 68 younger participants (18-55 years): 1 µg (n=10), 3 µg (n=10), 10 µg (n=10), 20 µg (n=6), 30 µg (n=12), 50 µg (n=9), 60 µg (n=11).
- 27 older participants (56-85 years): 10 µg (n=8), 20 µg (n=8), 30 µg (n=11).

Two doses of BNT162b1 (dose range 1 to 50 µg) induced CD4 and CD8 vaccine-specific T cell responses. RBD-specific CD4+ T cell responses had a type 1 helper T (Th1) cell cytokine profile secreting IFNγ, or IL-2, or both. For 81 of the 84 analyzed participants who received both BNT162b1 doses, no production of Th2 cytokine IL-4 in response to RBD peptide pool stimulation was detected. Similarly, RBD-specific CD8+ T cells secreted IFNγ in 54 of the analyzed 84 participants who received both BNT162b1 doses; however, lower levels of IL-2-secreting CD8+ T cells compared to CD4+ T cells were detected.

In the 30 µg dose groups, the fractions of RBD-specific IFNγ+ CD8+ T cells reached up to 0.49% (younger participants) and 1.58% (older participants) of total peripheral blood CD8+ T cells. In the 50 µg dose group with younger participants, fractions of up to 3.87% were detected. The mean fraction of both CD4+ and CD8+ cytokine-producing T cells in the BNT162b1 dosed participants (1 to 50 µg) was substantially higher (eg, for participants dosed at 30 µg, 11-fold higher) than that observed in 15 patients who recovered from COVID-19. In the 60 µg group, treated with Dose 1 only, mean fractions of cytokine-producing T cells were lower compared to the other dose level groups, indicating the importance of the booster vaccination. Importantly, the cytokine responses elicited after dosing with BNT162b1 in older participants were similar in response pattern and intensity with those of younger participants.

Complete results of the ICS/FACS analyses for BNT162b1 are provided in Module 5.3.5.1 BNT162-01 Interim CSR Appendix 16.1.14 Report R-20-0235 v2.0.

BNT162b2

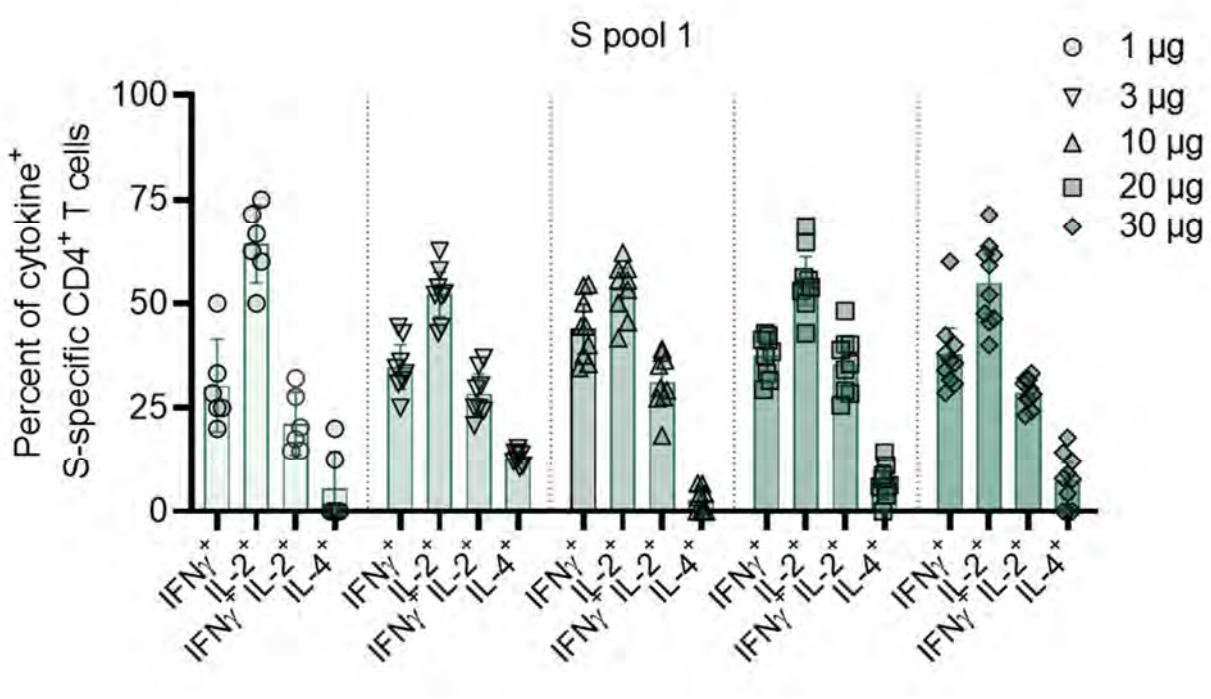
Data are available for 79 participants who received any dose level of BNT162b2:

- 50 younger participants (18-55 years): 1 µg (n=8), 3 µg (n=9), 10 µg (n=11), 20 µg (n=11), 30 µg (n=11).
- 29 older participants (56-85 years): 10 µg (n=11), 20 µg (n=9), 30 µg (n=9).

As evaluated at Day 29, two doses of BNT162b2 (dose range 1 to 30 µg) induced vaccine-specific T cell responses in both age groups analyzed (Figure 5 and Figure 6). Testing for SARS-CoV-2 S protein-specific T cell responses was performed with two different peptide pools – S pool 1 comprising overlapping peptides from the N-terminal region of the S protein (which is not equivalent to structural domains) and S pool 2 comprising C-terminal regions

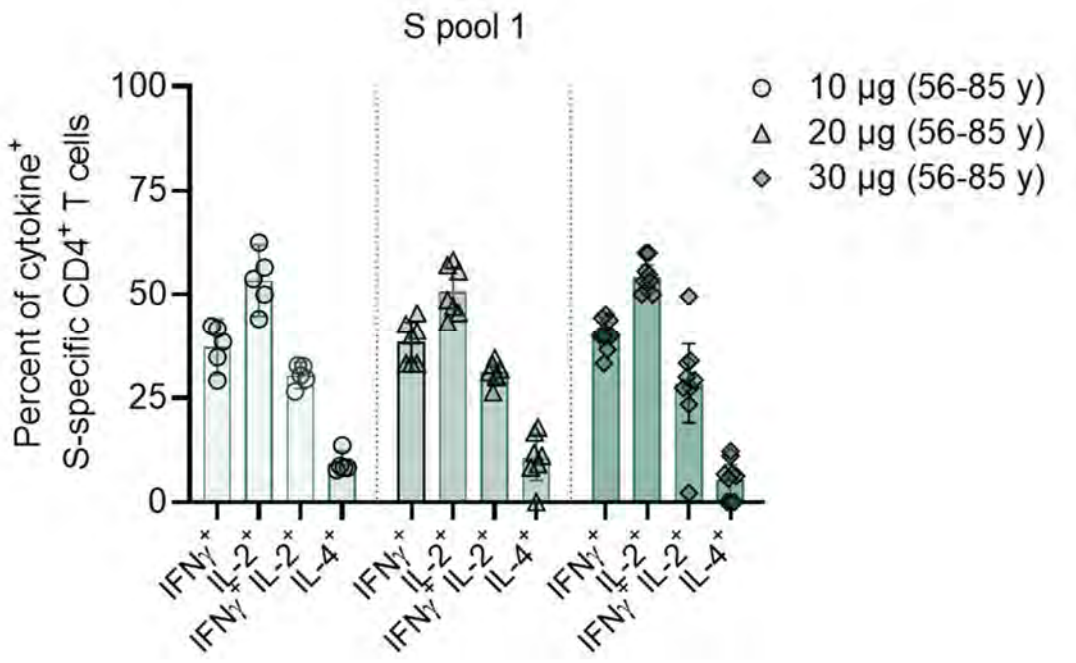
of the S protein. S-specific CD4+ T cell responses analyzed in 79 participants dosed with BNT162b2 are characterized by a Th1 cytokine profile secreting IFNγ, or IL-2, or both.

Figure 5. S-specific CD4+ T Cells Producing the Indicated Cytokines in Response to S Protein Pool 1 as a Fraction of Total Cytokine-Producing S-Specific CD4+ T Cells – BNT162b2, Adults 18-55 Years of Age



Bar charts show arithmetic means with 95% confidence interval at Day 29 (7 days after Dose 2). Cytokine production was calculated by summing up the fractions of all $CD4^+$ T cells positive for either IFNγ, IL-2, or IL-4, setting this sum to 100% and calculating the fraction of each specific cytokine-producing subset thereof. Two participants from the 1 µg dose group, 1 participant from the 3 µg dose group, and 1 participant from the 10 µg dose group were excluded from this analysis (frequency of total cytokine-producing $CD4^+$ T cells <0.03%).
Source: Report R-20-0241 v3.0.

Figure 6. S-specific CD4+ T Cells Producing the Indicated Cytokines in Response to S Protein Pool 1 as a Fraction of Total Cytokine-Producing S-Specific CD4+ T Cells (10 to 30 µg BNT162b2 Older Participant Dose Groups)



Bar charts show arithmetic means with 95% CI at Day 29 (7 days after Dose 2). Cytokine production was calculated by summing up the fractions of all $CD4^+$ T cells positive for either IFNγ, IL-2, or IL-4, setting this sum to 100%, and calculating the fraction of each specific cytokine-producing subset thereof. Four participants from the 10 µg dose group and 1 participant from the 20 µg dose group were excluded from this analysis (frequency of total cytokine-producing $CD4^+$ T cells <0.03%).
Source: Report R-20-0241 v3.0.

Almost no Th2 cytokine IL-4 secreting T cells were detectable in response to S peptide sub-pool stimulations (mean fractions: 0.01% and 0.02% of antigen-specific circulating CD4+ T cells in younger participants in the 20 and 30 µg dose level groups, respectively; separate stimulation with S protein sub-pool 1 and sub-pool 2). At Day 29, S-specific CD8+ T cells secreted IFNγ in 65 of the 79 analyzed participants (43/50 younger participants; 22/29 older participants), and IL-2 secreting CD8+ T cells were also detectable. Fractions of S-specific IFNγ+ CD8+ T cells targeting the N-terminal domain of the S protein reached up to 1.24% of total peripheral blood CD8+ T cells in the 20 and 30 µg younger participant dose groups and up to 1.57% in the 30 µg older participant dose group. Pre-existing CD8+ T cell responses against the C-terminal region of the S protein were detected in 17 of 79 dosed participants (range: 0.07 to 5.59% IFNγ-producing CD8+ T cells). In 5 of 17 participants, these preexisting responses were slightly amplified upon BNT162b2 dosing.

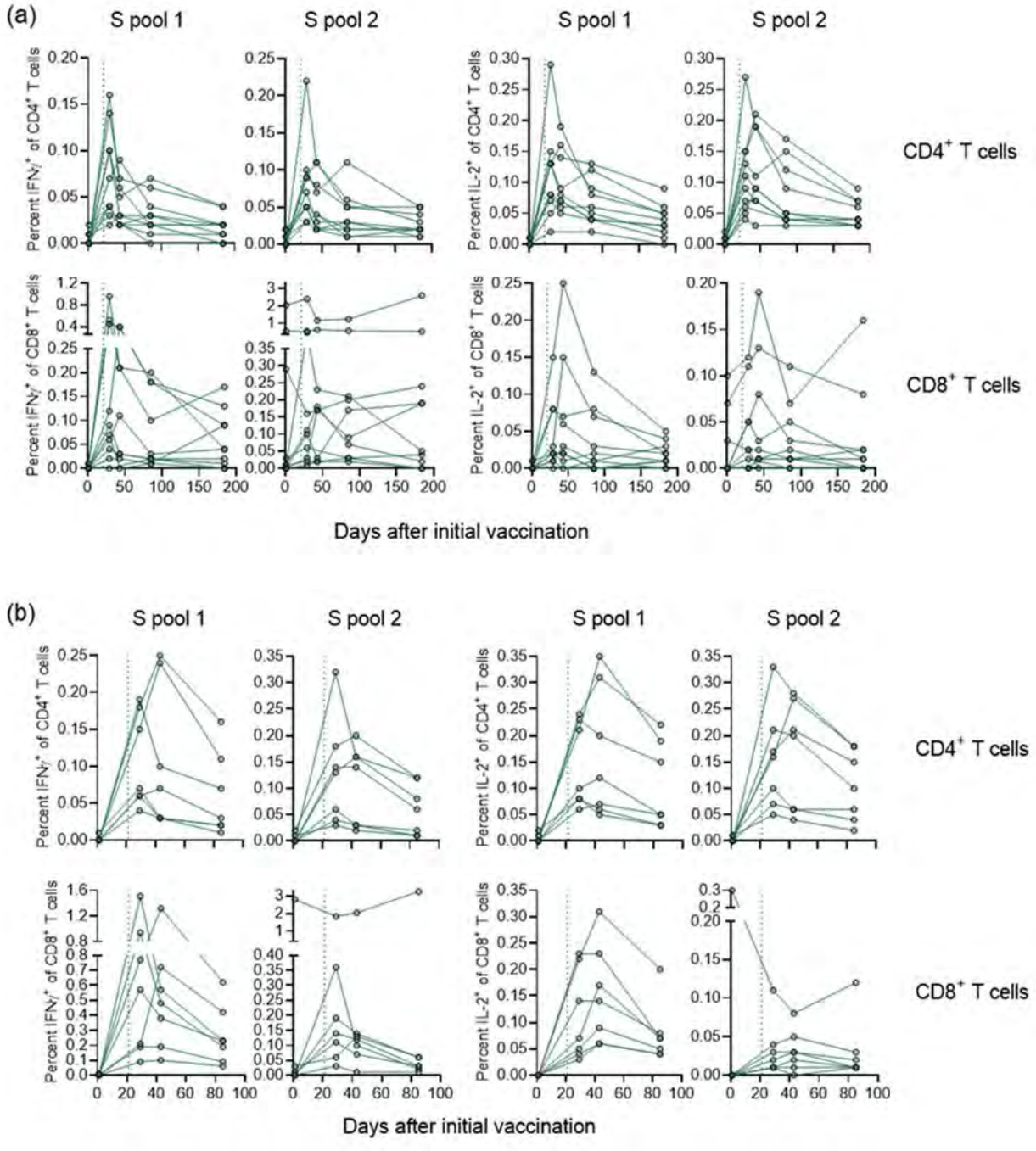
BNT162b2-induced T cell responses, especially for CD8+ T cells, were not limited to the RBD, and pronounced and strong T cell recognition of non-RBD regions of the S protein were observed.

Overall, at Day 29, the mean fractions of S-specific CD4+ and CD8+ T cells were substantially higher (eg, the S protein pool 1 IFNγ CD8+ response of 30 µg dosed participants was 12.5-fold higher) than that observed in 18 patients who recovered from COVID-19. Importantly, for the clinically targeted 30 µg dose group, the cytokine responses elicited after vaccination with BNT162b2 in older participants was mostly identical in response pattern and intensity with that of the younger participants.

Persistence of BNT162b2-Induced S-specific CD4+ and CD8+ T Cells - ICS

For the majority of participants, the strong S-specific IFNγ+ and IL-2+ CD8+ and Th1 CD4+ T cell responses contracted by Day 43 (3 weeks after Dose 2) and plateaued at a lower level towards Day 85 (9 weeks after Dose 2). This observation held true for all dose level groups analyzed, with varying response magnitudes among individuals. Among the younger participants, the cell-mediated immune responses remained detectable until Day 184 (23 weeks after Dose 2). Day 184 PBMC material from the older adult participants was not yet available at the time of this interim report. Figure 7 shows the data for the 30 µg BNT162b2 dose group in younger (a, N=10) and older (b, N=7) participants and is considered representative of what is seen for other dose groups.

Figure 7. Persistence of S-specific CD4+ and CD8+ T Cells Producing the Indicated Cytokines (IFNγ and IL-2) as a Fraction of Total Circulating CD4+ and CD8+ T cells – 30 µg BNT162b2 Dose Group in Younger (a) and Older (b) Participants



Cytokine data are plotted for participants from (a) the 30 µg dose group in younger participants (aged 18 to 55 yrs, n=10) and (b) 30 µg dose group in older participants (aged 56 to 85 yrs, n=7) from Day 1 (before Dose 1), Day 29 (7 d post-Dose 2), Day 43 (3 wks post-Dose 2), Day 85 (9 wks post-Dose 2) and Day 184 (23 wks post-Dose 2, (a) only) after Dose 1. Green dotted lines indicate the time point of Dose 2 (Day 21).
Source: Interim report R-20-0241 v 3.0.

In summary, BNT162b2 induced poly-functional and pro-inflammatory CD4+/CD8+ T cell responses in almost all participants. The responses persisted in the majority of participants for up to 6 months after Dose 2. The Th1 polarization of the helper T cell response was characterized by a robust IFNγ/IL-2 and only minor IL-4 production upon antigen-specific (wild-type SARS-CoV-2 S protein peptide pools) re-stimulation, which was still observed, although with a reduced magnitude, at later time points.

Complete results of the ICS/FACS analyses for BNT162b2 are provided in Module 5.3.5.1 BNT162-01 Interim CSR Appendix 16.1.14 Report R-20-0241 v3.0.

Conclusion – T Cell Response Data

In conclusion, as analyzed using ELISpot and ICS/FACS, the cytokine responses elicited by both BNT162b1 and BNT162b2 showed no clear dose dependency, and the response pattern and intensity in the older age group were mostly identical to those in the younger age group.

BNT162b1 and BNT162b2 induced poly-functional and pro-inflammatory CD4+/CD8+ T cell responses in almost all participants, with a Th1 polarization of the helper response. The detection of robust IFNγ and IL-2 production but only minor IL-4 production indicates a favorable Th1 profile and the absence of a potentially deleterious Th2 immune response.

2.7.3.2.2.1.1.3. Serological Response Data – Study BNT162-01

At the time of data cutoff for serology, results for serum neutralizing titers and binding antibody concentrations were available for participants in the immunogenicity sets as follows.

BNT162b1:

Younger age group (18-55): 60 participants (12 in each dose level group: 1, 10, 30, 50, and 60 µg); up to Day 43 for all dose level groups.

BNT162b2:

Younger age group (18-55): 60 participants (12 in each dose level group: 1, 3, 10, 20, 30 µg); up to Day 50 for 1 µg and 3 µg groups, up to Day 85 for 10, 20, 30 µg groups.

Older age group (56-85): 12 participants in the 20 µg group; up to Day 29.

Complete data supporting the graphs in the following sections are available in the technical report Module 5.3.5.1 BNT162-01 Interim CSR Appendix 16.1.14 Report R-20-0253 v2.0.

2.7.3.2.2.1.1.3.1. SARS-CoV-2 Serum 50% Neutralizing Titers – Study BNT162-01

For both BNT162b1 and BNT162b2, data for SARS-CoV-2 serum 50% neutralizing titers demonstrated the importance of receiving 2 doses of investigational vaccine. Only modest immune responses were apparent by 21 days after Dose 1, while Dose 2 elicited rapid increases in neutralizing titers, with maximal response levels achieved by 7 days after Dose 2 (Day 29). In the younger age group, results for SARS-CoV-2 serum 50% neutralizing titer

GMTs and GMFRs for the 10 µg and 30 µg dose level groups were similar between BNT162b1 and BNT162b2.

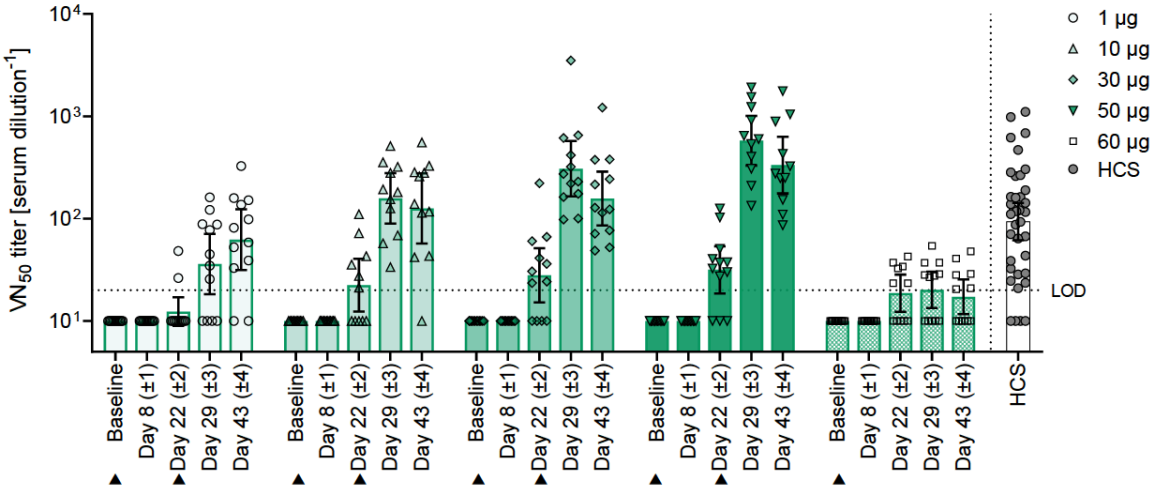
Geometric Mean Titers

For benchmarking, GMTs of the dose level groups were compared with those of a panel of human convalescent sera (HCS) comprising samples obtained from 38 individuals 18 to 85 years of age at least 14 days after confirmed diagnosis of COVID-19.

BNT162b1

Participants in the younger age group who received BNT162b1 showed a strong dose-dependent neutralizing antibody response (Figure 8 and Report R-20-0253 v2.0 Appendix Table 3). At 21 days after Dose 1 (Day 22), virus neutralizing antibody GMTs (neutralizing GMTs) had increased in a dose-dependent manner for the 1, 10, 30, and 50 µg dose groups. At 7 days after Dose 2 (Day 29), neutralizing GMTs showed a strong, dose level dependent booster response. In the 60 µg dose group, which received Dose 1 but not Dose 2, neutralizing GMTs remained at a lower level, indicating that a booster dose is necessary to increase functional antibody titers. At 21 days after Dose 2 (Day 43), neutralizing GMTs decreased (with exception of the 1 µg dose level). Day 43 virus neutralizing GMTs were 0.7-fold (1 µg) to 3.6-fold (50 µg) those of the COVID-19 HCS panel.

Figure 8. BNT162b1 – Functional 50% SARS-CoV-2 Neutralizing Antibody Titers (VN_{50}) – IMM – Adults 18 to 55 Years of Age



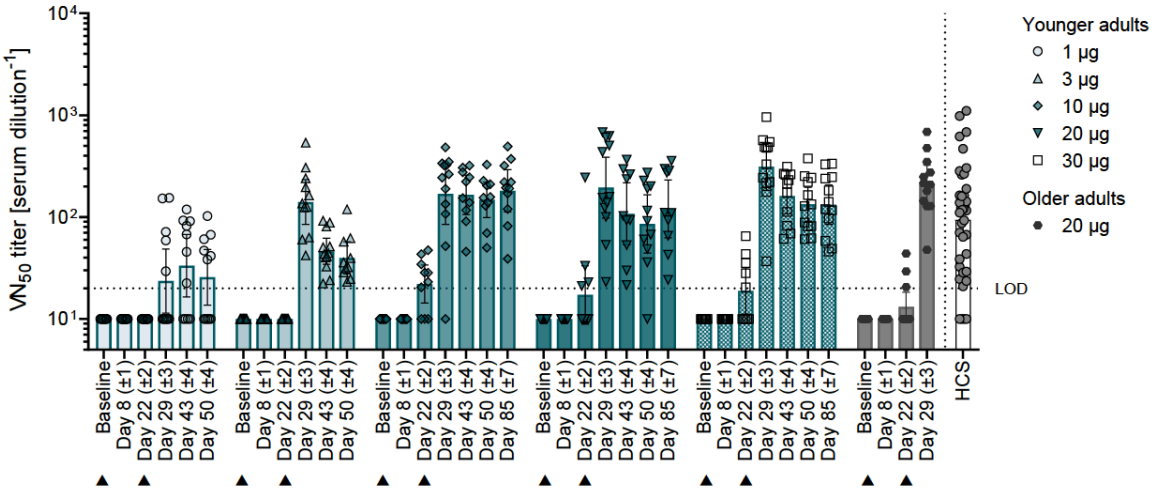
VN_{50} titers with 95% confidence intervals are shown for younger participants (aged 18 to 55 years) immunized with 1, 10, 30, 50, or 60 µg BNT162b1. Values smaller than the limit of detection (LOD) are plotted as 0.5*LOD. Arrowheads indicate baseline (pre-Dose 1, Day 1) and Dose 2 (Day 22). Dose 2 was not performed in the 60 µg dose group. The dotted horizontal line represents the LOD.
IMM = Immunogenicity set; VN_{50} = 50% SARS-CoV-2 neutralizing antibody titers; HCS = human COVID-19 convalescent serum.
Source: Report R-20-0253.

BNT162b2

Participants who received BNT162b2 showed a strong antibody response (Figure 9 and Report R-20-0253 v2.0 Appendix Table 6). Virus neutralizing GMTs were detected at 21 days after Dose 1 (Day 22), and by 7 days after Dose 2 (Day 29), GMTs had increased substantially in younger participants who received ≥3 µg BNT162b2 and in older participants who received 20 µg BNT162b2. Day 29 virus neutralizing GMTs were comparable between the younger and older adult 20 µg dose level groups.

At 21 days after Dose 2 (Day 43), virus neutralizing GMTs in the younger age group decreased for the 3, 20, and 30 µg dose levels. Thereafter, neutralizing GMTs remained stable up to 63 days after Dose 2 (Day 85) for younger adult dose groups 10, 20, and 30 µg and were 1.3-fold to 1.9-fold those of a COVID-19 HCS panel.

Figure 9. BNT162b2 - Functional 50% SARS-CoV-2 Neutralizing Antibody Titers (VN_{50}) - IMM - Adults 18 to 55 Years of Age and 56 to 85 Years of Age



VN_{50} titers with 95% confidence intervals are shown for younger adults (aged 18 to 55 years) immunized with 1, 3, 10, 20, or 30 µg BNT162b2, and older adults (aged 56 to 85 yrs) immunized with 20 µg BNT162b2. Values smaller than the limit of detection (LOD) are plotted as 0.5*LOD. Arrowheads indicate baseline (pre-Dose 1, Day 1) and Dose 2 (Day 22). The dotted horizontal line represents the LOD.

IMM = Immunogenicity set; VN_{50} = 50% SARS-CoV-2 neutralizing antibody titers; HCS = human COVID-19 convalescent serum.

Source: Report R-20-0253.

Geometric Mean Fold-Rise and Seroconversion

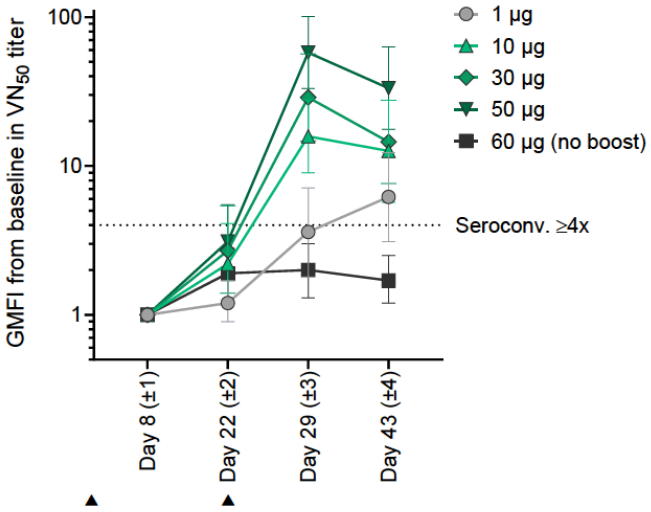
Results for GMFRs in SARS-CoV-2 50% neutralizing titers are consistent with the data described above for GMTs. In the younger age groups, for both vaccines at doses ≥3 µg, GMFRs from before vaccination to 7 days after Dose 2 (Day 29) were substantially higher compared to the respective GMFRs 21 days after Dose 1, and GMFRs declined slightly by Day 43 (Figure 10 and Figure 11; Report R-20-0253 v2.0 Appendix Table 4 and Appendix Table 7).

For BNT162b1 in the younger age group, GMFRs 7 days after Dose 2 were dose dependent, with an observed 15.8 fold-rise after 10 µg, 28.9 fold-rise after 30 µg, and 57.8 fold-rise after

the 50 µg dose. For BNT162b2, in the younger age group, GMFRs 7 days after Dose 2 indicated a 16.9 fold-rise after 10 µg, 19.5 fold-rise after 20 µg, and 29.2 fold-rise after the 30 µg dose. For the 30 µg dose of BNT162b2, GMFRs were 15.1 at Day 43, 12.0 at Day 50, and 12.2 at Day 85 (63 days after Dose 2). For the older age group, the GMFR after 20 µg BNT162b2 indicated a 21.7 fold-rise at Day 29.

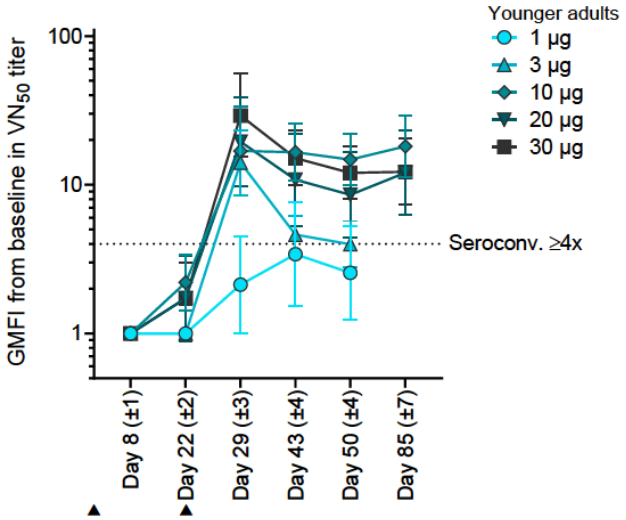
Seroconversion is defined as a ≥4-fold increase in functional antibody titer as compared to baseline. All participants who received the 30 µg or 50 µg dose levels of BNT162b1 were seropositive at 7 days and 21 days after Dose 2 (Day 29 and Day 43) (Report R-20-0253 v2.0 Appendix Table 5). For the BNT162b2 30 µg dose group in the younger age group, the seroconversion rate was 90.0% at Day 29 and 100% on Days 43, 50, and 85; for the older age group the seroconversion rate after 20 µg BNT162b2 was 100% at Day 29 (Report R-20-0253 v2.0 Appendix Table 8).

Figure 10. BNT162b1 – Fold Increase From Baseline in Functional 50% SARS-CoV-2 Neutralizing Antibody Titers (VN_{50}) – IMM – Adults 18 to 55 Years of Age



Geometric means fold increase (GMFI) from baseline in VN50 titer with 95% confidence intervals are shown. Arrowheads indicate baseline (pre-Dose 1, Day 1) and Dose 2 (Day 22). Dose 2 was not performed in the 60 µg dose group. The dotted horizontal line represents the threshold for seroconversion (fold increase ≥4).
IMM = Immunogenicity set; VN_{50} = 50% SARS-CoV-2 neutralizing antibody titers.
Source: Report R-20-0253 v2.0.

Figure 11. BNT162b2 – Fold Increase from Baseline in Functional 50% SARS-CoV-2 Neutralizing Antibody Titers (VN_{50}) – IMM – Adults 18 to 55 Years of Age



Geometric means fold increase (GMFI) from baseline in VN_{50} titer with 95% confidence intervals are shown. Arrowheads indicate baseline (pre-Dose 1, Day 1) and Dose 2 (Day 22). The dotted horizontal line represents the threshold for seroconversion (fold increase ≥4). IMM = Immunogenicity set; VN_{50} = 50% SARS-CoV-2 neutralizing antibody titers. Source: Report R-20-0253 v2.0.

2.7.3.2.2.1.1.3.2. SARS-CoV-2 Antigen-Specific Binding Antibody Concentrations

As measured by S1- and RBD-binding IgG GMCs, both BNT162b1 and BNT162b2 elicited strong antibody responses. Results for S1- and RBD-binding IgG responses are available in the CSR (Module 5.3.5.1 BNT162-01 Interim CSR Section 11.2 and Appendix 16.1.14 Report R-20-0253 v2.0 Section 5.1.2 and Section 5.2.2).

2.7.3.2.2.1.1.4. Immunogenicity Conclusions – Study BNT162-01

- **T Cell Responses**

– Based on the ELISpot and ICS assay results, BNT162b1 and BNT162b2 induced poly-functional and pro-inflammatory CD4+/CD8+ T cell responses in most participants. The cytokine responses in older participants were mostly identical in response pattern and intensity with those in younger participants.

– Re-stimulation of PBMCs with peptide pools representing the encoded antigens (RBD or full-length S protein) demonstrated a helper response characterized by a robust IFNγ/IL-2 response and only minor IL-4 production. This cytokine profile indicates a favorable Th1 response and only a minimal Th2 immune response.

– BNT162b2-induced CD4+ and CD8+ T cell responses showed a decrease on Day 85 (63 days after Dose 2), but remained detectable on Day 184 (162 days after Dose 2) in almost all participants vaccinated with >10 µg at levels higher than or in range of recall antigen memory responses.

- **Serological Responses**

– For both BNT162b1 and BNT162b2, only modest immune responses were apparent by 21 days after Dose 1, while Dose 2 elicited rapid increases in neutralizing titers, with maximal response levels achieved by 7 days after Dose 2 (Day 29). These results demonstrate the importance of receiving 2 doses of investigational vaccine.

– Results for SARS-CoV-2 serum 50% neutralizing titer GMTs and GMFRs for the 10 µg and 30 µg dose level groups (younger age group) were similar between BNT162b1 and BNT162b2.

– Results for serum neutralizing titers indicated comparable immune responses between the younger and older age groups receiving the 20 µg dose level of BNT162b2 at 7 days after Dose 2 (Day 29).

– In the younger age group, after Dose 2 of BNT162b2, GMTs decreased from Day 29 to Day 43 (21 days after Dose 2) and then remained stable up to Day 85 (63 days after Dose 2), when GMTs for the 10, 20, and 30 µg groups were 1.3-fold to 1.9-fold those of a COVID-19 HCS panel.

2.7.3.2.2.1.2. Study C4591001 – Phase 1

Phase 1 immunogenicity data from Study C4591001 were summarized through 1 month after Dose 2 for all dose levels for both vaccine candidates (BNT162b1 and BNT162b2) (data cutoff date 24 August 2020); these data are reported in full in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 11.2.1 and are summarized briefly in this SCE, Section 2.7.3.2.2.1.2.2.

Immunogenicity results are also available for the 6-month post Dose 2 time point for participants who received BNT162b2 30 µg (data cutoff date 13 March 2021); these results are reported in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 11.2.1 and in this SCE, Section 2.7.3.2.2.1.2.3.

All immunogenicity results for C4591001 presented in the SCE are for the evaluable immunogenicity populations; results for the all-available immunogenicity populations are available in the CSRs.

2.7.3.2.2.1.2.1. Disposition, Data Sets Analyzed, and Demographics - Study C4591001, Phase 1

Disposition – Phase 1

A total of 195 participants were randomized in 2 age groups (18-55 or 65-85 years of age) to receive 2 doses of BNT162b1 or placebo (N=105) or BNT162b2 or placebo (N=90).

In each age group, 15 participants were randomized at each successive dose level (eg, 10 µg, 20 µg, 30 µg) to receive either active vaccine (N=12) or placebo (N=3). In both the younger and older age groups, all participants randomized to the BNT162b1 and BNT162b2 10-µg, 20-µg, and 30-µg dose groups and the corresponding placebo groups received both doses of active vaccine or placebo.

In the BNT162b1 100-µg dose group, all 12 participants in the younger age group who were randomized received Dose 1. However, based on observed reactogenicity after Dose 1, the IRC recommended that a second dose of 100-ug BNT162b1 not be administered. Because dosing of 100 µg BNT162b1 could not be completed, results for this group and the corresponding placebo group will not be discussed further in this SCE, but are available in the C4591001 Final Analysis CSR.

Data Sets Analyzed – Phase 1

Exclusions from the evaluable immunogenicity populations are detailed in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 10.4.1.

Demographics Phase 1

BNT162b1

Overall, in the Dose 1 evaluable immunogenicity population, most participants were white in both the younger age group (82.2%) and older age group (93.2%). Median age was 35.0

years in the younger age group and 68.5 years in the older age group. In the younger age group, 62.2% of participants were male; and in the older age group, 70.5% were female.

BNT162b2

Overall, in the Dose 1 evaluable immunogenicity population, most participants were white in the younger age group (85.7%), and all participants were white in the older age group (100%). Median age was 36.0 years in the younger age group and 68.0 years in the older age group. In the younger age group, 61.9% of participants were female, and in the older age group, 61.4% were female.

2.7.3.2.2.1.2.2. Immunogenicity Results Through 1 Month After Dose 2

2.7.3.2.2.1.2.2.1. SARS-CoV-2 Neutralizing Titers – Study C4591001, Phase 1

Overall, both BNT162b1 and BNT162b2 elicited robust SARS-CoV-2 neutralization responses 7 days after Dose 2 in both younger and older adults, based on GMTs, GMFRs, and proportions of participants achieving a ≥4-fold rise in neutralizing titers, and high response levels were maintained through 1 month after Dose 2. In general, SARS-CoV-2 neutralization responses in older participants (65-85 years of age) tended to be lower than those in younger participants (18-55 years of age).

Geometric Mean Titers

For both BNT162b1 and BNT162b2 recipients in both age groups, SARS-CoV-2 50% neutralizing GMTs modestly increased by Day 21 after Dose 1 and were substantially increased 7 days after Dose 2. At most time points, for both BNT162b1 and BNT162b2 recipients, GMTs in the older age group tended to be lower than GMTs in the younger age group at the same dose level.

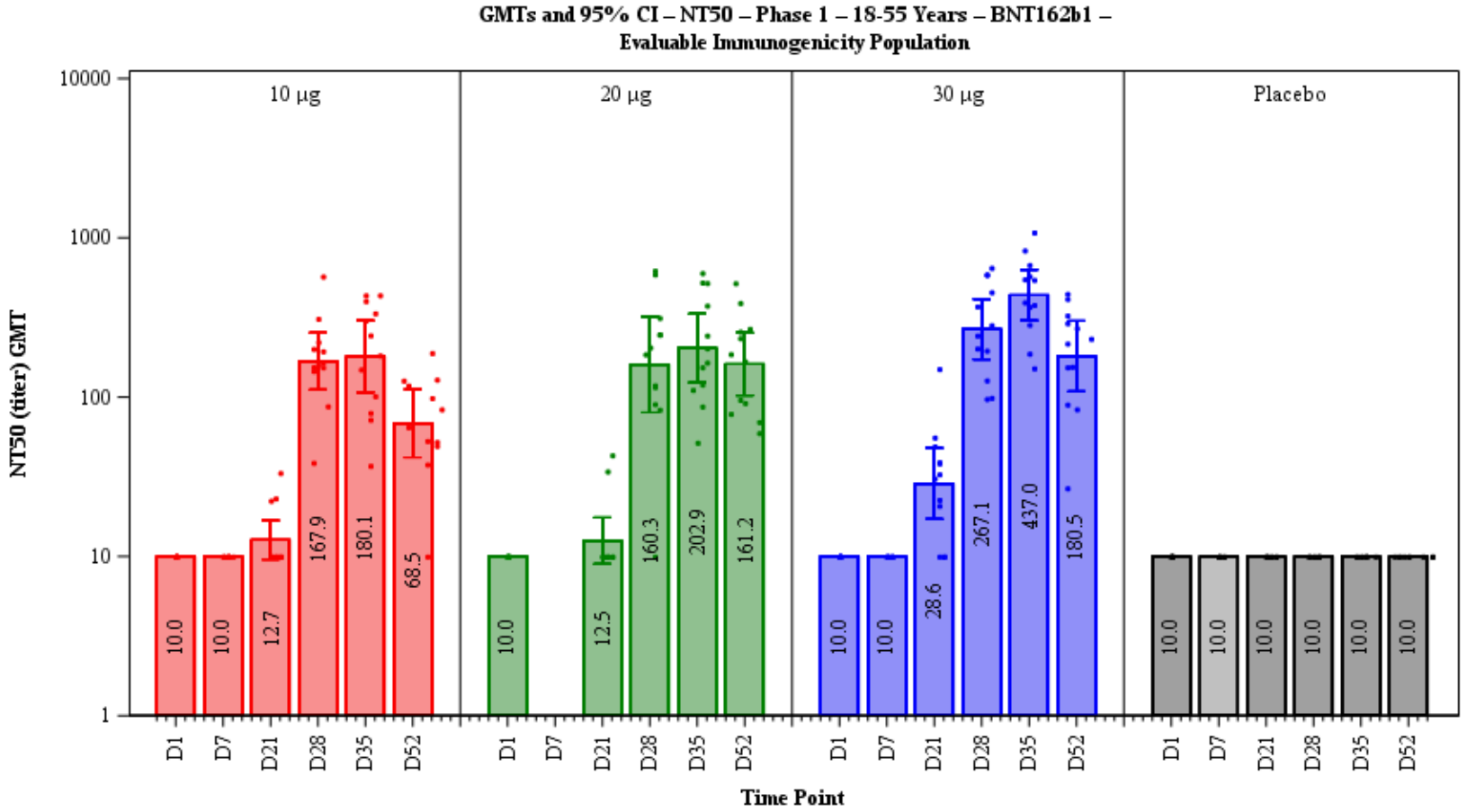
BNT162b1

In the younger age group, SARS-CoV-2 50% neutralizing GMTs modestly increased by Day 21 after Dose 1 of BNT162b1 and were substantially increased 7 days after Dose 2 (Day 28), with higher GMTs observed in the 30-µg dose group compared to the 10-µg and 20-µg dose groups (Figure 12). For all dose groups, GMTs increased further at 14 days after Dose 2 (Day 35) and then decreased at 1 month after Dose 2 (Day 52); however, the Day 52 GMTs remained substantially higher than those at Day 21 after Dose 1.

In the older age group, generally similar trends were observed, in that substantial SARS-CoV-2 50% neutralizing responses (GMTs) were observed by 7 days after Dose 2 (Day 28) and at later time points in the 20-µg and 30-µg dose groups (Figure 13). However, only modest responses were observed at any time point in the 10-µg dose group.

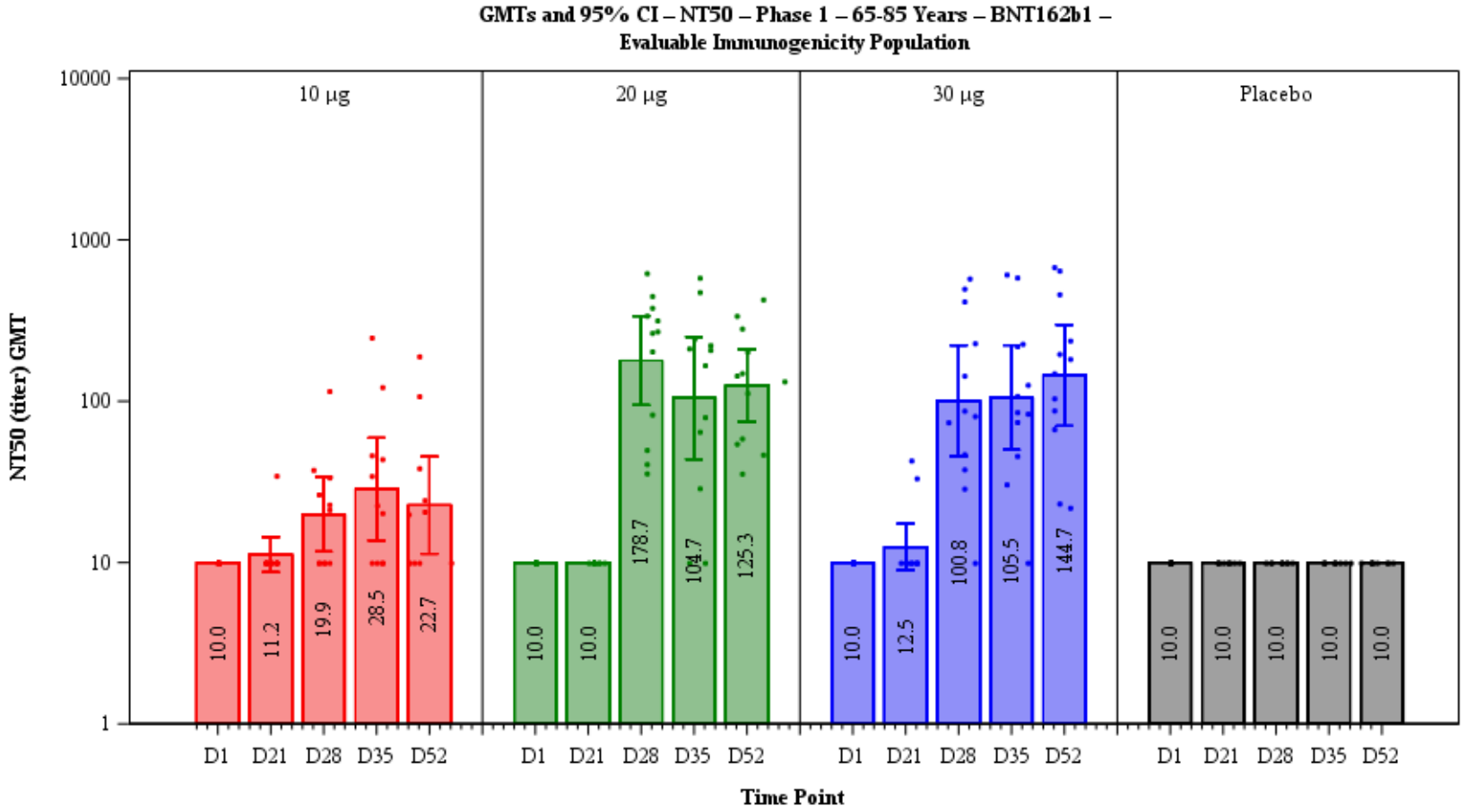
SARS-CoV-2 50% neutralizing GMTs were generally lower in the older age group than in the younger age group at the same dose level.

Figure 12. Geometric Mean Titers and 95% CI: SARS-CoV-2 Neutralization Assay - NT50 – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Evaluable Immunogenicity Population



Abbreviations: GMT = geometric mean titer; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_sars_50_18_b1_p1

Figure 13. Geometric Mean Titers and 95% CI: SARS-CoV-2 Neutralization Assay - NT50 – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b1 – Evaluable Immunogenicity Population



Abbreviations: GMT = geometric mean titer; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
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(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_sars_50_65_b1_p1

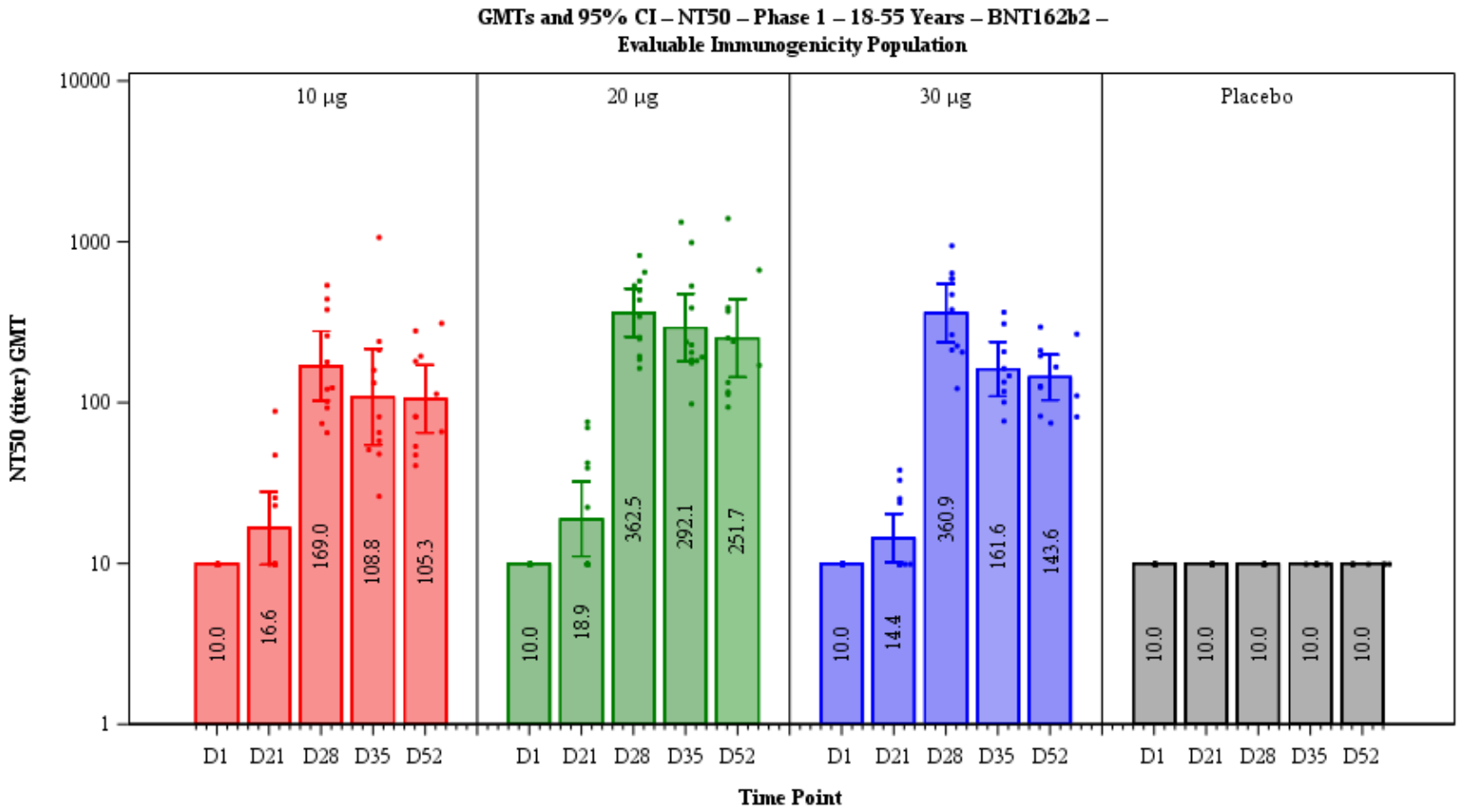
BNT162b2

***In the younger age group*,** SARS-CoV-2 50% neutralizing GMTs modestly increased by Day 21 after Dose 1 of BNT162b2 and were substantially increased 7 days after Dose 2 (Day 28), with higher GMTs observed in the 20-µg and 30-µg dose groups compared to the 10-µg dose group (Figure 14). The GMTs decreased at 14 days after Dose 2 (Day 35) and 1 month after Dose 2 (Day 52) of BNT162b2; however, the GMTs remained substantially higher than those at 21 days after Dose 1.

In the older age group, SARS-CoV-2 50% neutralizing GMTs were substantially increased 7 days after Dose 2 (Day 28) and were similar in the 10-µg and 20-µg dose groups and higher in the 30-µg dose group (Figure 15). At 1 month after Dose 2 (Day 52), GMTs had decreased in all dose groups; however, the Day 52 GMTs remained higher than those at 21 days after Dose 1.

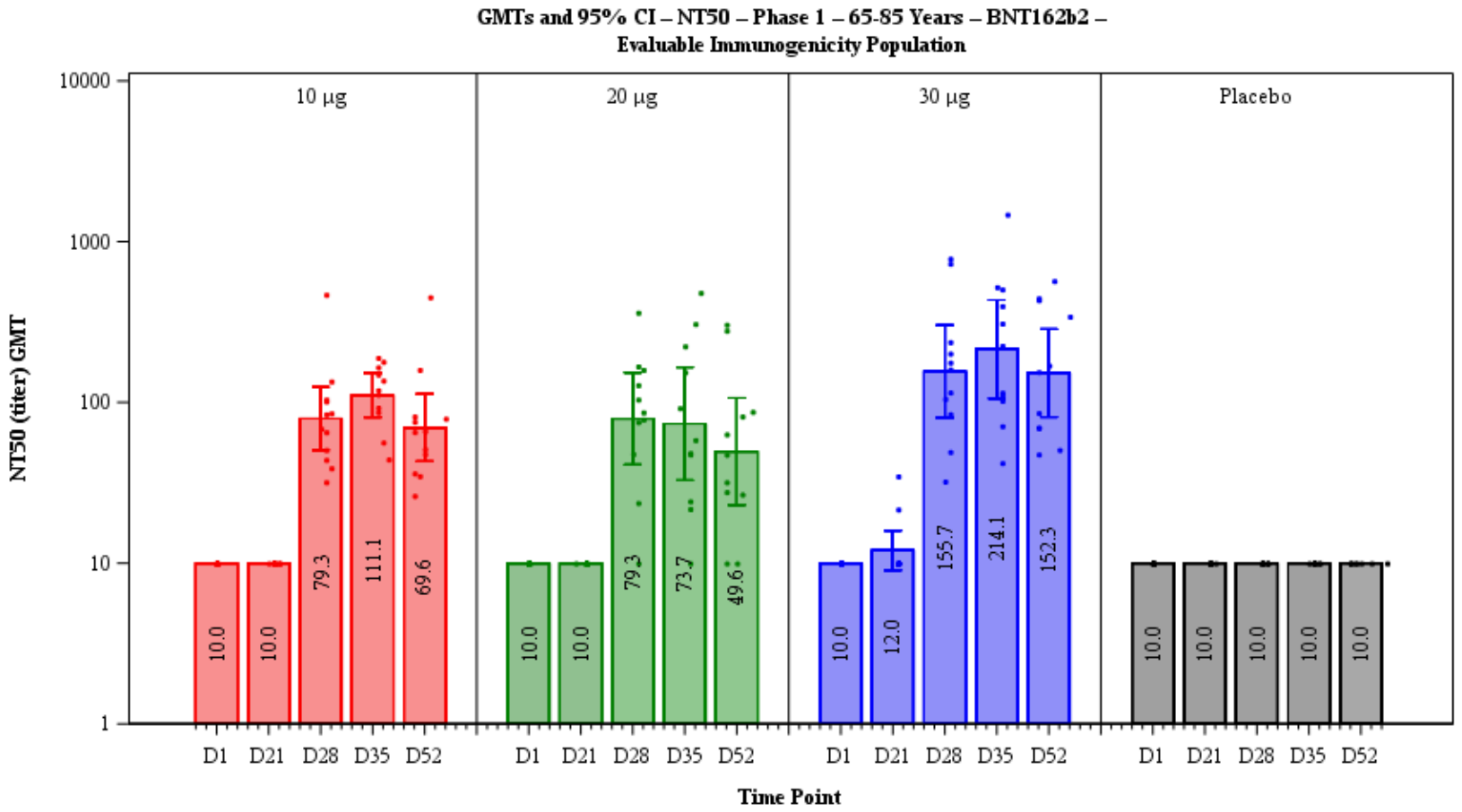
Among participants who received 20 µg BNT162b2, SARS-CoV-2 50% neutralizing GMTs were substantially lower in the older age group than in the younger age group; however, among those receiving 30 µg BNT162b2, GMTs were similar or higher in the older age group than in the younger age group at 14 days and 1 month after Dose 2 (Days 35 and 52).

Figure 14. Geometric Mean Titers and 95% CI: SARS-CoV-2 Neutralization Assay - NT50 – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Evaluable Immunogenicity Population



Abbreviations: GMT = geometric mean titer; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_sars_50_18_b2_p1

Figure 15. Geometric Mean Titers and 95% CI: SARS-CoV-2 Neutralization Assay - NT50 – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Evaluable Immunogenicity Population



Abbreviations: GMT = geometric mean titer; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_sars_50_65_b2_p1

Geometric Mean Fold-Rise (GMFR)

For the BNT162b1 and the BNT162b2 recipients, across dose level groups and in both age groups, GMFRs of SARS-CoV-2 50% neutralizing titers from before vaccination to 7 days after Dose 2 (Day 28) were substantially higher compared to GMFRs 21 days after Dose 1. Among both BNT162b1 and BNT162b2 recipients, GMFRs in the older age group were generally lower than those in the younger age group at the same dose level. Results for GMFR are available in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 11.2.1.1.2.

Proportion of Participants Achieving ≥4-Fold Rise

Overall, for both BNT162b1 and BNT162b2 recipients, across dose level groups and in both age groups, most participants achieved a ≥4-fold rise in SARS-CoV-2 50% neutralizing titers from before vaccination to 7 days after Dose 2, except for participants in the older age group receiving the 10-µg BNT162b1 dose. Results for the proportion of participants achieving a ≥4-fold rise are available in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 11.2.1.1.3.

2.7.3.2.2.1.2.2.2. SARS-CoV-2 Antigen-Specific Binding IgG Levels – Study C4591001, Phase 1

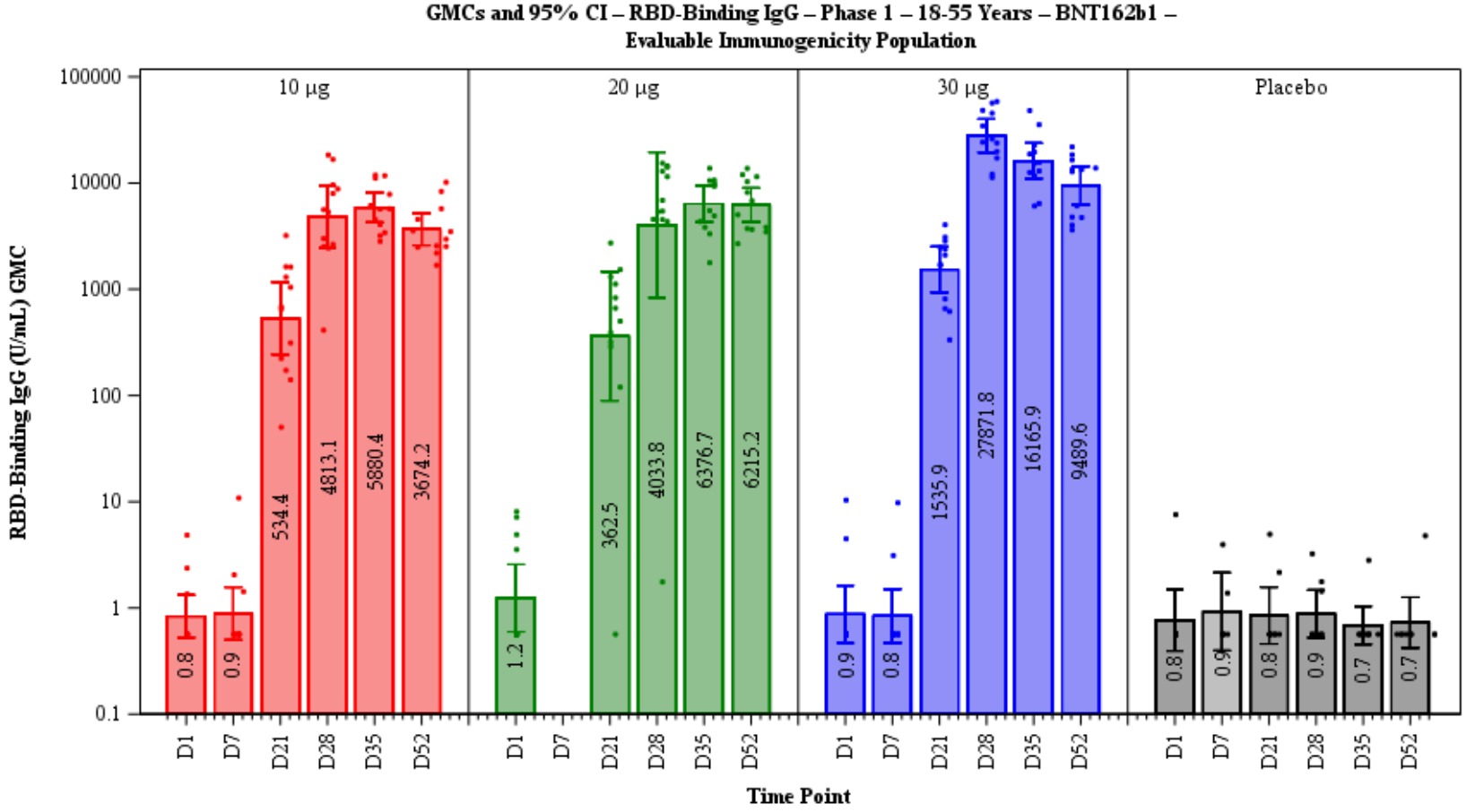
Vaccine candidate BNT162b1 encodes the RBD of SARS-CoV-2, and BNT162b2 encodes the P2 S. In this section, RBD-binding IgG responses are described for BNT162b1, and S1-binding IgG responses are described for BNT162b2.

Both BNT162b1 and BNT162b2 elicited substantial rises in antigen binding IgG levels 7 days after Dose 2, based on GMCs, GMFRs, and proportions of participants achieving a ≥4-fold rise in IgG-antigen specific binding. Responses were maintained through Day 52.

Geometric Mean Concentrations

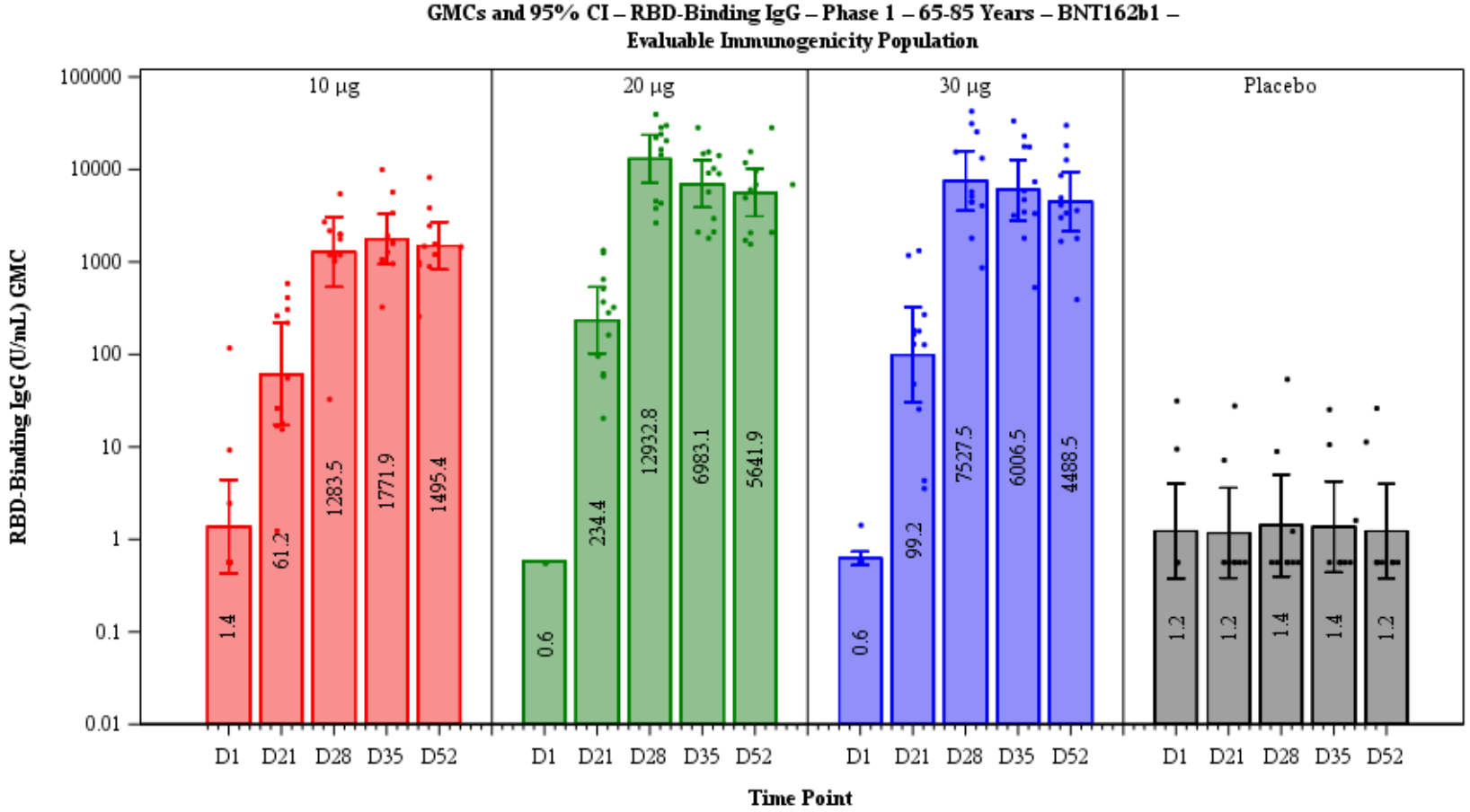
Overall, for both BNT162b1 and BNT162b2 recipients, and in both age groups, RBD- and S1-binding GMCs increased substantially by Day 21 after Dose 1 and were further increased 7 days after Dose 2 (see Figure 16 through Figure 19). At 1 month after Dose 2 (Day 52), the GMCs remained higher than at Day 21 after Dose 1. GMCs in the older age group were generally lower than the GMCs in the younger age group at the same dose level.

Figure 16. Geometric Mean Concentrations and 95% CI: SARS-CoV-2 RBD-binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b1 – Evaluable Immunogenicity Population



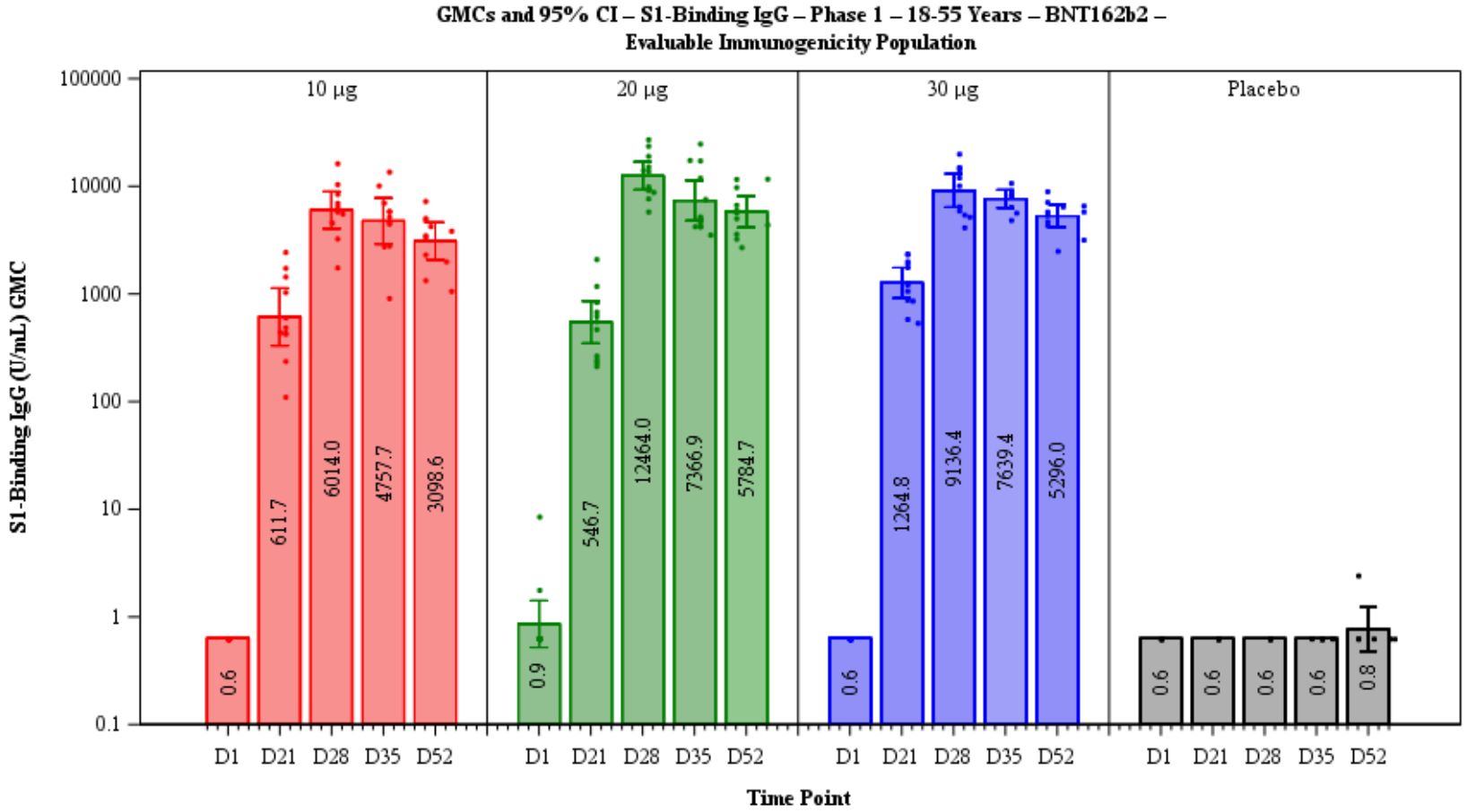
Abbreviations: GMC = geometric mean concentration; IgG = immunoglobulin G; RBD = receptor-binding domain.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_rbd_18_b1_p1

Figure 17. Geometric Mean Concentrations and 95% CI: SARS-CoV-2 RBD-binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age, BNT162b1 – Evaluable Immunogenicity Population



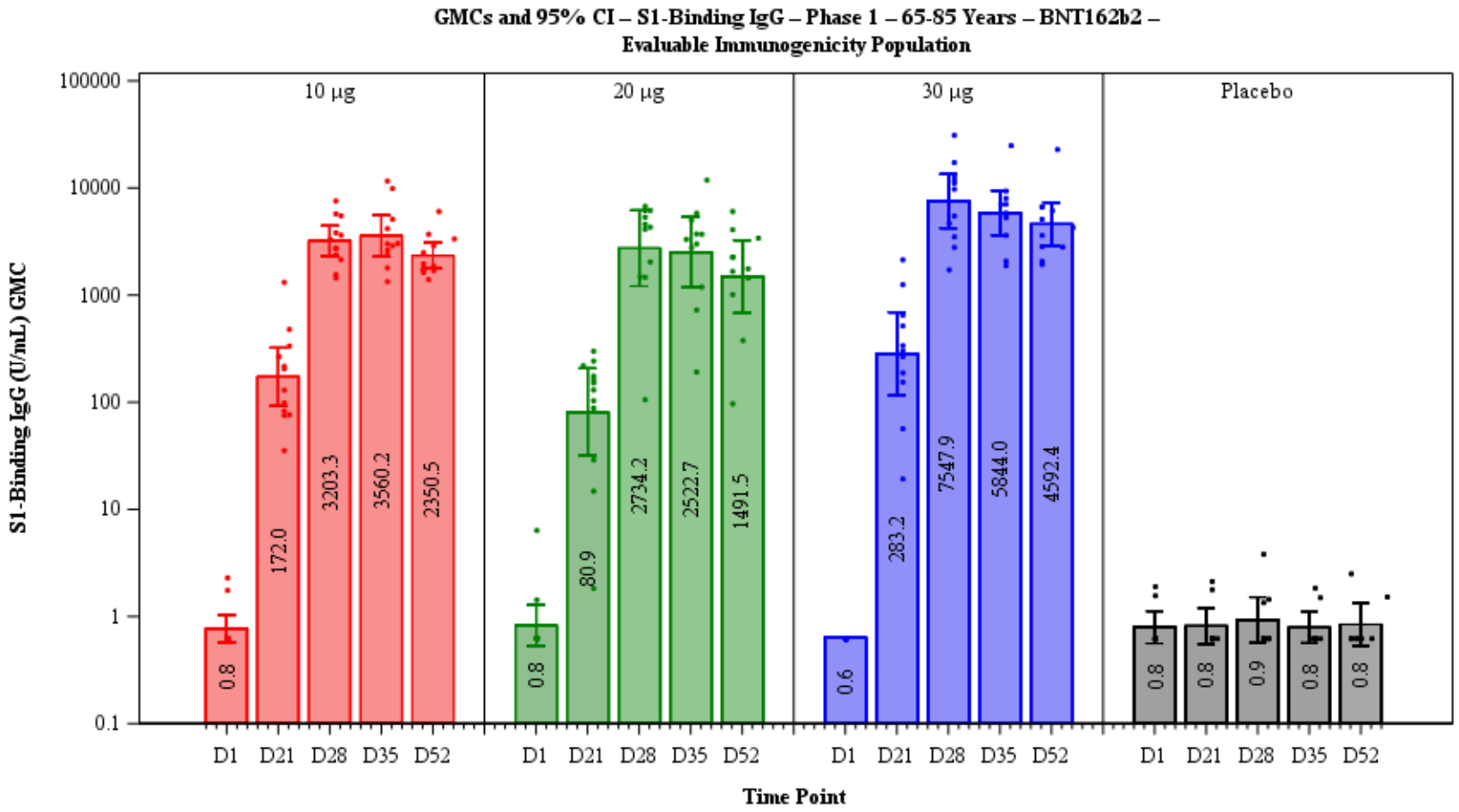
Abbreviations: GMC = geometric mean concentration; IgG = immunoglobulin G; RBD = receptor-binding domain.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_rbd_65_b1_p1

Figure 18. Geometric Mean Concentrations and 95% CI: SARS-CoV-2 S1-binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 18-55 Years of Age – BNT162b2 – Evaluable Immunogenicity Population



Abbreviations: GMC = geometric mean concentration; IgG = immunoglobulin G; S1 = spike protein S1 subunit.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_s1_18_b2_p1

Figure 19. Geometric Mean Concentrations and 95% CI: SARS-CoV-2 S1-binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – 65-85 Years of Age – BNT162b2 – Evaluable Immunogenicity Population



Abbreviations: GMC = geometric mean concentration; IgG = immunoglobulin G; S1 = spike protein S1 subunit.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 17SEP2020 (22:01) Source Data: adva Table Generation: 17SEP2020 (23:29)
(Cutoff Date: 24AUG2020, Snapshot Date: 17SEP2020) Output File: ./nda3/C4591001_IA_P1_Serology/adva_f002_s1_65_b2_p1

Geometric Mean Fold-Rise (GMFR)

For BNT162b1 and BNT162b2 recipients, and in both age groups, GMFRs of SARS-CoV-2 antigen-specific binding IgG were substantially higher 7 days after Dose 2 (Day 28) than 21 days after Dose 1. GMFRs peaked by 7 days or 14 days after Dose 2, and although decreased by 1 month after Dose 2, GMFRs at this time point were still substantially higher than at Day 21 after Dose 1. Results for GMFR are available in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 11.2.1.2.2.

Proportion of Participants Achieving a ≥4-Fold Rise

BNT162b1

In both age groups, 100% of participants in each dose level group achieved a ≥4-fold rise in RBD-binding IgG levels at all time points after Dose 2 of BNT162b1, except for the 20-µg dose group at Day 7 after Dose 2 (91.7% in the younger age group).

BNT162b2

In both age groups, 100% of participants in each dose level group achieved a ≥4-fold rise in S1-binding IgG levels at all time points after Dose 2 of BNT162b2.

Results for the proportion of participants achieving a ≥4-fold rise are available in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 11.2.1.2.3.

2.7.3.2.2.1.2.3. Persistence of the Immune Response Through 6 Months After Dose 2 of 30 µg BNT162b2 – Study C4591001, Phase 1

For participants who received the 30 µg dose level of BNT162b2 (and corresponding placebo), blood samples collected approximately 6 months after Dose 2 were assayed for SARS-CoV-2 neutralizing activity and for S1-binding IgG concentrations. Blood samples from some earlier time points for these participants were re-analyzed with the 6-month post Dose 2 samples to assure assay comparability between time points.

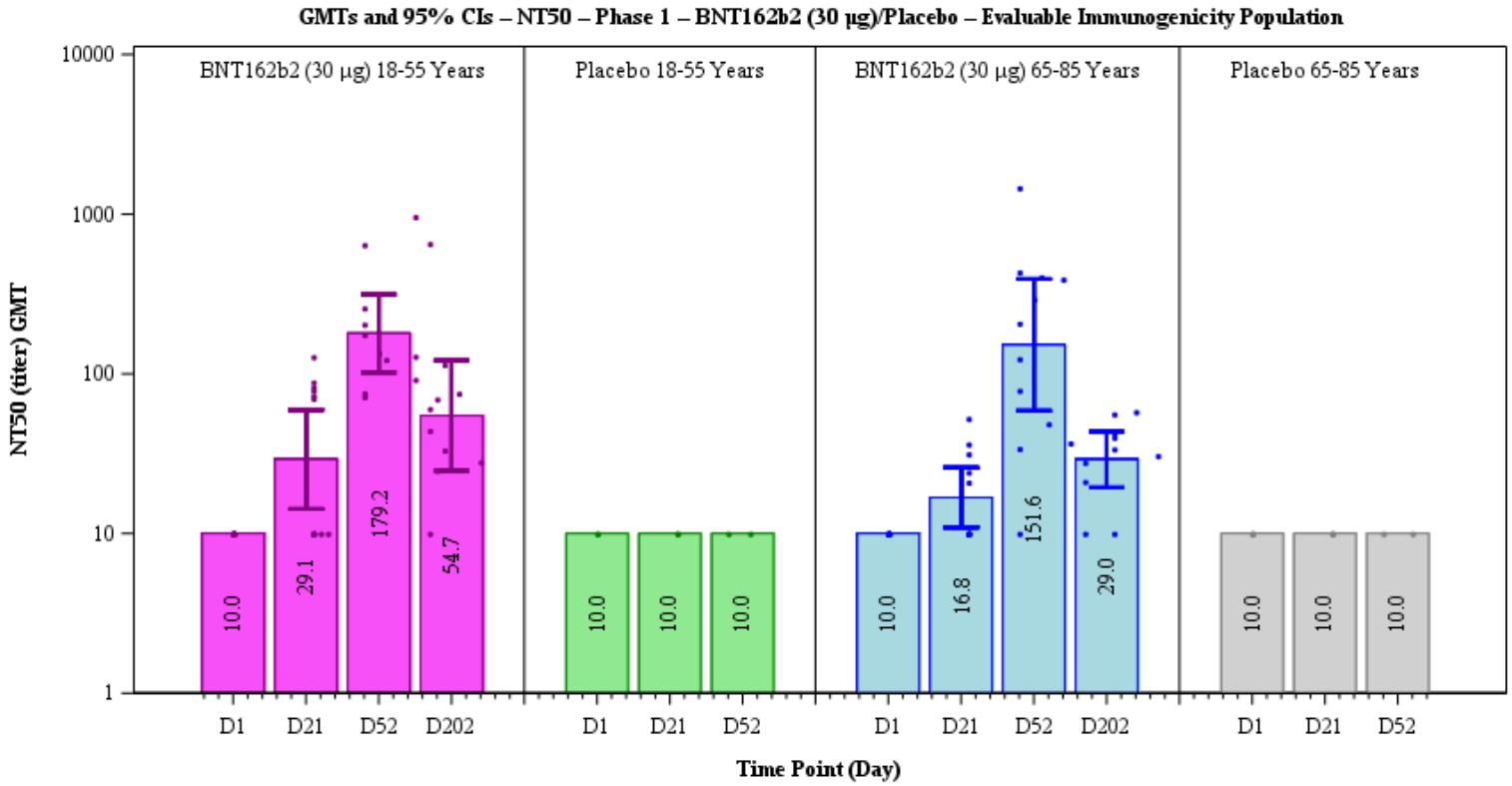
GMTs, GMCs, and GMFRs

Among participants who received the 30 µg dose level of BNT162b2, in both age groups, the observed SARS-CoV-2 serum 50% neutralizing GMTs declined from 1 month after Dose 2 (Day 52) to 6 months after Dose 2 (Day 202). In the younger age group, GMTs were 179.2 at 1 month after Dose 2 and 54.7 at 6 months after Dose 2; in the older age group GMTs declined from 151.6 to 29.0 (Figure 20 and Table 62). While GMTs at 6 months after Dose 2 of BNT162b2 were lower than those at 1 month after Dose 2, they were numerically higher than those observed before vaccination. Observed S1-binding IgG GMCs demonstrated similar trends (Figure 21 and Table 62).

In the younger and older age groups, respectively, GMFRs of SARS-CoV-2 serum 50% neutralizing titers from before BNT162b2 to each subsequent time point were 2.9 and 1.7 at Day 21 (immediately before Dose 2), 17.9 and 15.2 at 1 month after Dose 2; and 5.5 and

2.9 at 6 months after Dose 2. Results for GMFRs of S1-binding IgG concentrations reflected similar trends (Table 63).

Figure 20. **Geometric Mean Titers and 95% CIs: SARS-CoV-2 Neutralization Assay – NT50 – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – Evaluable Immunogenicity Population**



Abbreviations: D = day; GMT = geometric mean titer; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

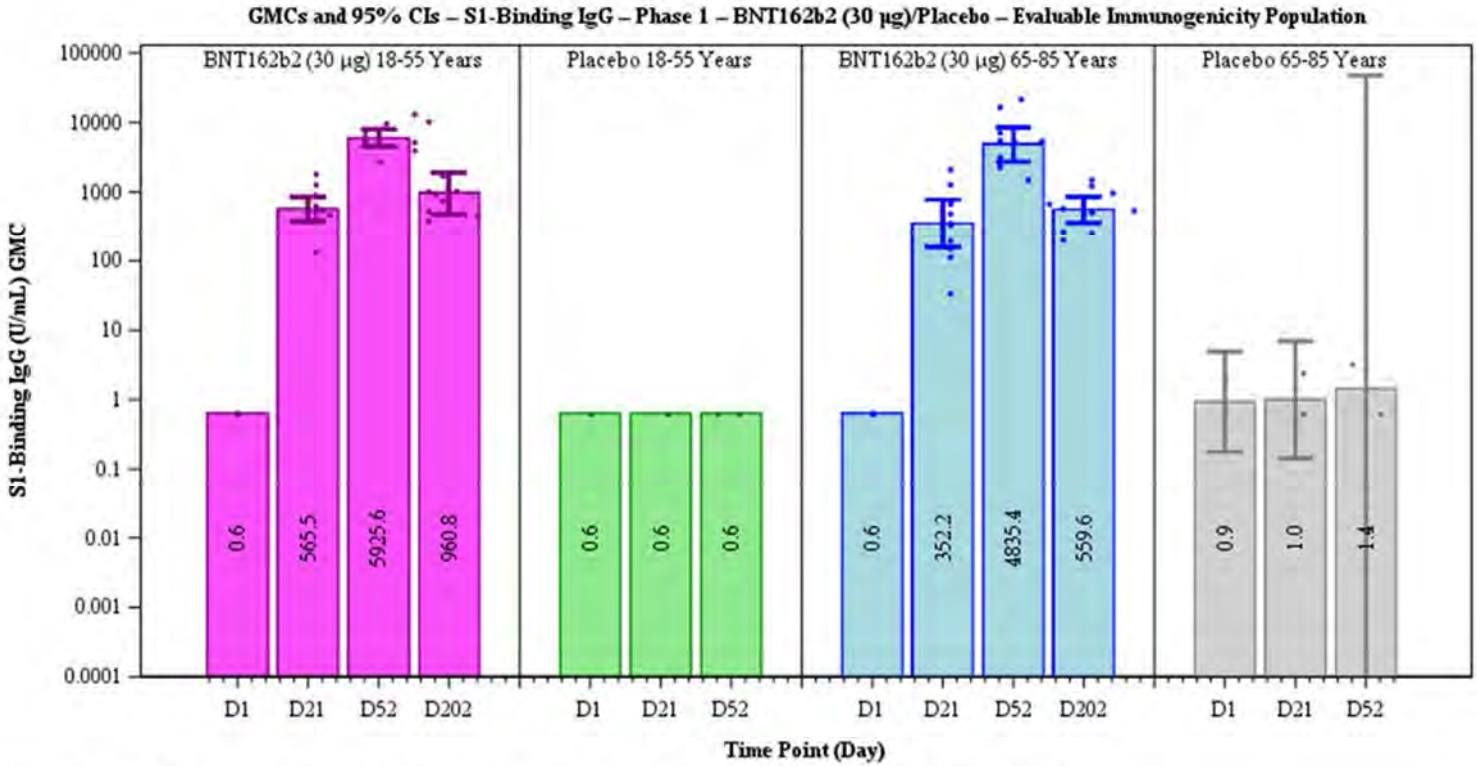
Note: Blood samples from the Day 7 and Day 14 post–Dose 2 visits are not included since these samples were not retested with the 6-month post–Dose 2 samples.

Note: Dots represent individual antibody levels.

Note: Number within each bar denotes geometric mean titer.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 01APR2021 (02:17) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA1/adva_f002_sars_50_b2_p1

Figure 21. Geometric Mean Concentrations and 95% CIs: S1-Binding IgG Level Assay – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – Evaluable Immunogenicity Population



Abbreviations: D = day; GMC = geometric mean concentration; IgG = immunoglobulin G; S1 = spike protein S1 subunit.

Note: Blood samples from the Day 7 and Day 14 post–Dose 2 visits are not included since these samples were not retested with the 6-month post–Dose 2 samples.

Note: Dots represent individual antibody levels.

Note: Number within each bar denotes geometric mean titer.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 01APR2021 (02:19) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: /nda2_unblinded/C4591001_BLA1/adva_f002_s1_b2_p1

Proportion of Participants Achieving ≥4-Fold Rise

In the younger age group receiving BNT162b2, the proportions of participants who achieved a ≥4-fold increase in SARS-CoV-2 50% neutralizing titers from before vaccination to each time point were: 50.0% (6/12) at Day 21; 100.0% (11/11) at 1 month after Dose 2; and 60.0% (6/10) at 6 months after Dose 2. In the older age group receiving BNT162b2, these proportions were 9.1% (1/11) at Day 21; 81.8% (9/11) at 1 month after Dose 2; and 27.3% (3/11) at 6 months after Dose 2 (Table 64). With respect to S1-binding IgG concentrations, 100% of participants in both age groups had a ≥4-fold increase from baseline at each of these time points.

2.7.3.2.2.1.2.4. Immunogenicity Conclusions – Study C4591001 Phase 1

- Both BNT162b1 and BNT162b2 elicited robust SARS-CoV-2 neutralizing titers. GMTs were modestly increased by Day 21 after the first dose and were substantially increased by 7 days after the second dose, with high response levels maintained through 1 month after Dose 2.

- Antigen binding IgG levels increased substantially by Day 21 after the first dose and were further increased by 7 days after the second dose, with high response levels maintained through 1 month after Dose 2.

- GMTs and GMCs in the older age group were generally lower than in the younger age group at the same dose level.

- For Phase 1 participants who received BNT162b2 30 µg, SARS-CoV-2 serum neutralizing titers and serum S1-binding IgG concentrations at 6 months after dose 2 had decreased relative to those observed at 1 month after Dose 2 but remained higher than values observed before vaccination.

2.7.3.2.2.1.3. Phase 1 Conclusions – Rationale for Candidate and Dose Level Selection

The Phase 1 immunogenicity data from both Studies C4591001 and BNT162-01 collectively showed robust immunogenicity elicited by both candidate vaccines. Overall, the immunogenicity responses were similar between the 2 candidates. When selecting the dose level for Phase 2/3, the major driver was maximizing SARS-CoV-2 neutralizing antibody responses in the older age group, who are at highest risk of severe disease. A robust immune response was elicited in both younger and older adults by BNT162b2 at the 30 µg dose level, which was ultimately selected to proceed to Phase 2/3 development.

- In Phase 1 of Study C4591001, both BNT162b1 and BNT162b2 elicited robust SARS-CoV-2 neutralization and antigen-specific IgG binding in younger and older adults as shown by GMTs/GMCs, GMFRs, and proportions of participants achieving a ≥4-fold rise in neutralizing titers and antigen-binding IgG levels.

- Both BNT162b1 and BNT162b2 vaccine candidates demonstrated robust SARS-CoV-2 neutralization and substantial rises in IgG-antigen binding levels following the second dose across dose levels and age groups.

- In older adults, who are at higher risk of severe COVID-19 disease, the neutralizing response to BNT162b2 was highest at the 30 µg dose level compared to the 20 µg dose level, favoring the 30 µg dose level for Phase 2/3 development.

- Study BNT162-01 provides evidence for robust T cell-mediated immunity, with both BNT162b1 and BNT162 inducing poly-functional and pro-inflammatory CD4+/CD8+ T cell responses in almost all participants. The detection of robust IFNγ and IL-2 production but only minimal IL-4 production indicates a favorable Th1 profile and the absence of a potentially deleterious Th2 immune response.

- Immunogenicity data from Study BNT162-01 were generally concordant with results in pivotal Study C4591001, showing robust SARS CoV-2 neutralization and substantial rises in IgG-antigen binding levels following the second dose, and complimentary T cell immune response data.

2.7.3.2.2.2. Phase 2 Immunogenicity Results – Study C4591001

2.7.3.2.2.2.1. Disposition, Data Sets Analyzed, and Demographics – Study C4591001 Phase 2

Disposition

The 360 participants enrolled as part of Phase 2 were randomized equally to the BNT162b2 (30 µg) and placebo groups (180 participants each). Among participants randomized to the BNT162b2 group, 88 participants were in the younger age group (18 to 55 years of age) and 92 participants were in the older age group (56 to 85 years of age) (Table 65).

All 360 participants received both doses of study vaccine, except for 1 participant in the younger age group who was withdrawn from the study after Dose 1 of BNT162b2 but before Dose 2 because of an SAE of gastric adenocarcinoma 23 days after receiving Dose 1.

Data Sets Analyzed

Immunogenicity results are currently available for the prevaccination and 1 month post Dose 2 time point; results for later time points will be reported when available.

A total of 7 participants (3 in the BNT162b2 group and 4 in the placebo group) were excluded from the Dose 2 all-available immunogenicity population because they did not have at least 1 valid and determinate immunogenicity result after Dose 2. The Dose 2 evaluable immunogenicity population included 93.9% of participants who received BNT162b2 and 92.8% of participants who received placebo. The reasons for data exclusion are shown in Table 65. Serology data at 1 month after Dose 2 from 2 participants who had a postbaseline positive SARS-CoV-2 test result were excluded in the analysis based on the Dose 2 evaluable immunogenicity populations, following the study protocol and SAP.

Demographics

In the Dose 2 evaluable immunogenicity population, 52.1% of participants were male; 84.8% were White and 10.1% were Black or African American; 10.7% were Hispanic; and the median age was 56 years (range 18 to 85) (Table 66).

2.7.3.2.2.2.2. SARS-CoV-2 Neutralizing Titers and S1-Binding IgG Concentrations – Study C4591001, Phase 2

Results of immunogenicity analyses reported here are those for the Dose 2 evaluable immunogenicity population; note that baseline positive participants (by SARS-CoV-2 N-binding antibody or positive NAAT at Visit 1) were not excluded from these analyses. Immunogenicity results for the Dose 2 all-available immunogenicity population were similar to those for the evaluable population.

Geometric Mean Titers/Concentrations (GMTs/GMCs)

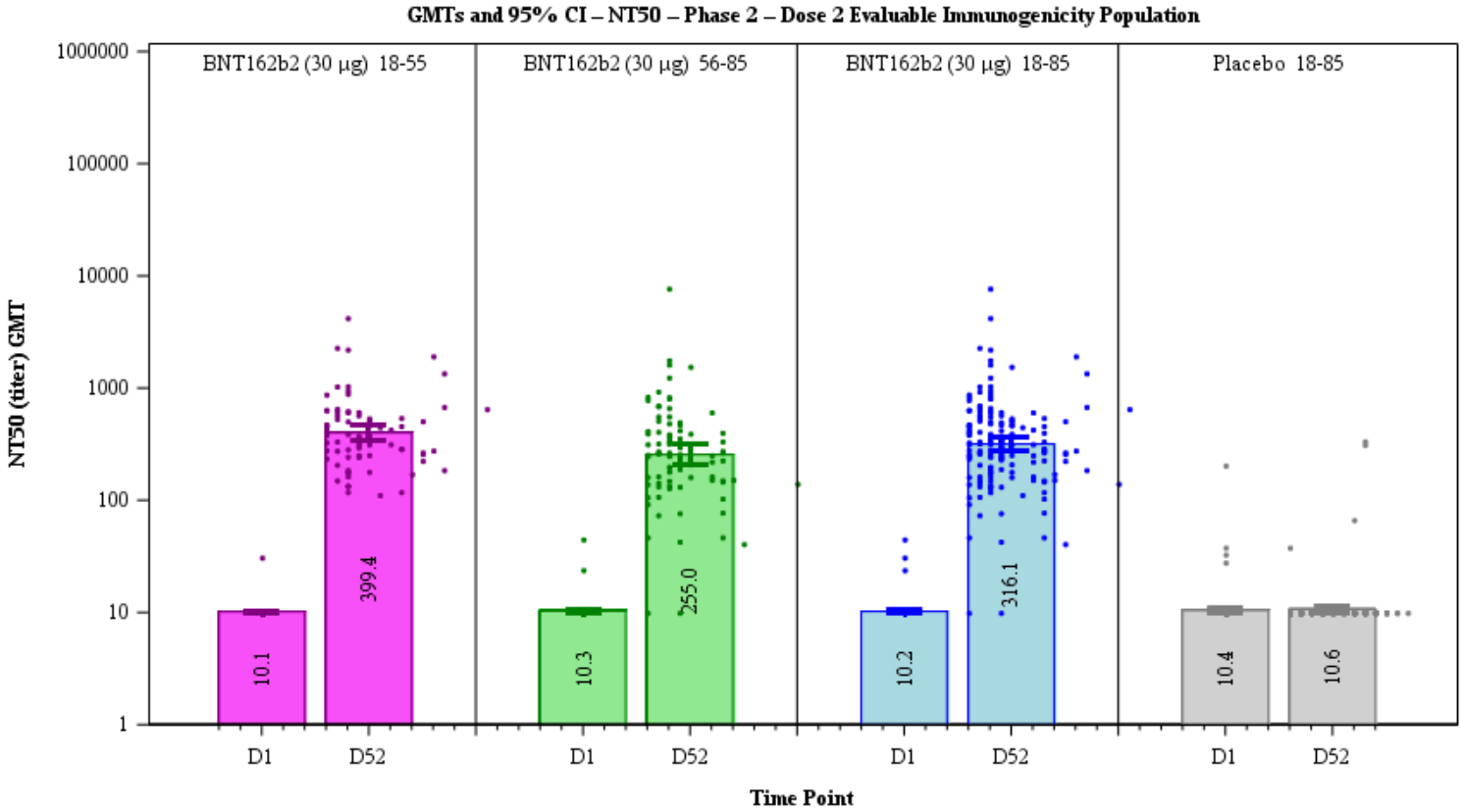
BNT162b2 elicited robust SARS-CoV-2 immune responses at 1 month after Dose 2 as measured by both SARS-CoV-2 50% neutralizing titers (GMTs) (Figure 22) and S1-binding IgG concentrations (GMCs) (Figure 23). GMTs and GMCs were higher in younger participants (18-55 years of age) than in older participants (56-85 years of age) (Table 67).

Of note, 50% neutralizing GMTs at 1-month post Dose 2 for both younger (GMT = 399.4) and older participants (GMT = 255.0) in the evaluable immunogenicity population were similar to the GMTs of a comparative panel of HCS (GMT = 319).[8] The HCS is the same panel described in Section 2.7.3.1.3.4 except that 5 sera from the N=38 serum panel had been depleted.

Geometric Mean Fold-Rise (GMFR) in Titers/Concentrations

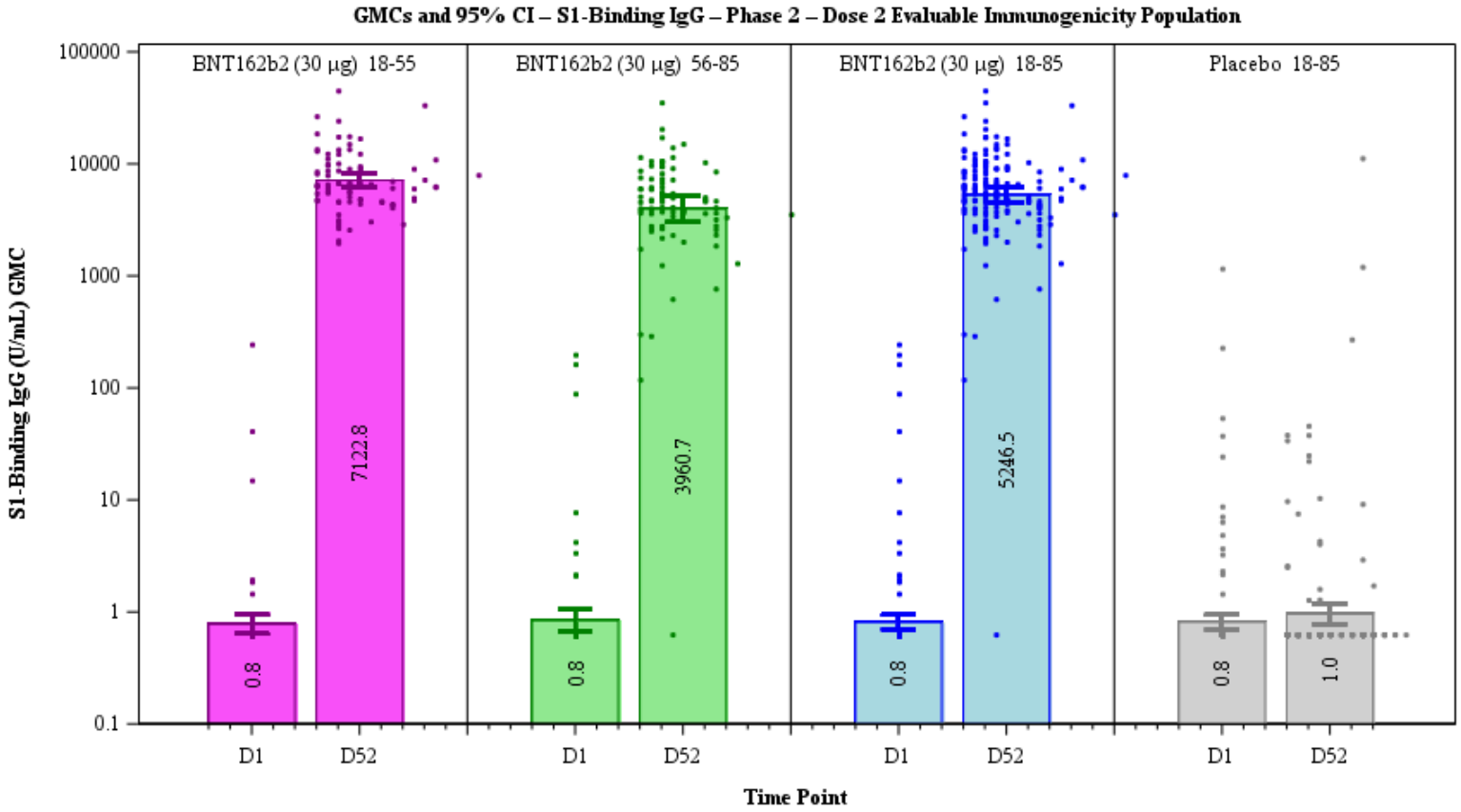
Results for GMFRs in SARS-CoV-2 50% neutralizing titers and S1-binding IgG concentrations were robust at 1 month after Dose 2 of BNT162b2, with higher GMFRs observed in younger participants than in older participants (Table 68).

Figure 22. **Geometric Mean Titers: SARS-CoV-2 Neutralization Assay - NT50 – Evaluable Immunogenicity Population (Study C4591001, Phase 2)**



Abbreviations: GMT = geometric mean titer; NT50 = 50% neutralizing titer; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adva_f002_sars_50_p2

Figure 23. Geometric Mean Concentrations: SARS-CoV-2 S1-binding IgG Level Assay – Evaluable Immunogenicity Population (Study C4591001, Phase 2)



Abbreviations: GMC = geometric mean concentration; IgG = immunoglobulin G; S1 = spike protein S1 subunit.
Note: Dots present individual antibody levels.
Note: Number within each bar denotes geometric mean.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adva_f002_s1_p2

2.7.3.2.2.2.3. SARS-CoV-2 Neutralizing Titers and S1-Binding IgG Concentrations by Baseline SARS-CoV-2 Status – Study C4591001, Phase 2

Immunogenicity results were summarized by baseline SARS-CoV-2 status (positive or negative; ie, participants with or without serological or virological evidence of SARS-CoV-2 infection before vaccination). Positive baseline SARS-CoV-2 status was defined as positive by N-binding antibody at Visit 1, or positive NAAT at Visit 1, or a medical history of COVID-19; negative baseline SARS-CoV-2 status was defined as negative by N-binding antibody and negative NAAT at Visit 1.

Geometric Mean Titers/Concentrations (GMTs/GMCs)

A few participants in the Dose 2 evaluable immunogenicity population had a positive baseline SARS-CoV-2 status: a total of 9 participants with immunogenicity data at the pre-vaccination time point (5 who received BNT162b2 and 4 who received placebo) and 7 participants (3 who received BNT162b2 and 4 who received placebo) with immunogenicity data at the 1 month post Dose 2 time point. These SARS-CoV-2 status positive participants were analyzed separately from the baseline negative participants. In general, at 1 month post Dose 2 among BNT162b2 recipients, observed SARS-CoV-2 50% neutralizing GMTs and S1-binding IgG GMCs were numerically higher in participants with a positive baseline SARS-CoV-2 status (n=3) than in those with a negative baseline SARS-CoV-2 status (n=163) (Table 69).

Geometric Mean Fold-Rise (GMFR) in Titers/Concentrations

When analyzing GMFRs stratified by SARS-CoV-2 status at 1 month post Dose 2, among BNT162b2 recipients (Table 70), the GMFRs for SARS-CoV-2 50% neutralizing titers and S1-binding IgG were similar to those in the combined baseline positive and negative participant group (Table 68).

2.7.3.2.2.2.4. Phase 2 Immunogenicity Conclusions – Study C4591001

Immunogenicity results from 360 participants in Phase 2 of Study C4591001 demonstrated that BNT162b2 at 30 µg elicited robust SARS-CoV-2 neutralization and S1-binding IgG antibody responses at 1 month after Dose 2 similar to those previously observed in Phase 1 of the study. Notably, SARS-CoV-2 neutralizing titers were higher in the younger age group compared to the older age group. Of note, GMTs for younger and older participants at 1 month after Dose 2 were similar to the GMTs of a comparative panel of HCS.[8] S1-binding GMCs were generally higher in the younger age group compared to the older age group, again concordant with observations in the Phase 1 portion of the study.

2.7.3.2.2.3. Immunogenicity Conclusions for BNT162b2

- Two doses of BNT162b2 (30 µg) administered 21 days apart elicited robust SARS-CoV-2 neutralization responses and substantial rises in SARS-CoV-2 antigen-specific binding IgG levels in younger (18-55 years) and older (56-85 years) adults.

- SARS-CoV-2 50% neutralizing titers were modestly increased from baseline by 21 days after Dose 1, with substantial increases observed by 7 Days after Dose 2.

- S1-binding GMCs increased substantially from baseline by Day 21 after Dose 1 and were further increased 7 days after Dose 2.

- High response levels were maintained through 1 month after Dose 2 as measured by both SARS-CoV-2 neutralizing titers and S1-binding IgG.

- In Phase 1 of Study C4591001, at 6 months after Dose 2 of BNT162b2 30 µg, neutralizing titers and S1-binding IgG concentrations had decreased relative to levels observed at 1 month after Dose 2 but were above prevaccination levels.

- SARS-CoV-2 neutralizing GMTs and S1-binding GMCs were generally higher in the younger participants than older participants.

- Of note, SARS-CoV-2 neutralizing GMTs for younger and older participants were similar to or greater than the GMTs for a comparative panel of human convalescent sera.

- Participants who had evidence of prior SARS-CoV-2 infection had modestly elevated GMTs and GMCs detected at study baseline compared with baseline negative participants. Both baseline SARS-CoV-2 positive and negative participants had substantial increases in GMTs and GMCs from baseline to 1 month after Dose 2. The increases were more pronounced for those who were baseline positive, which suggests that immune responses from prior infection were further boosted by BNT162b2 immunization.

- BNT162 induces poly-functional and pro-inflammatory CD4+/CD8+ T cell responses in almost all participants. The detection of robust IFNγ and IL-2 production but only minimal IL-4 production indicates a favorable Th1 profile and the absence of a potentially deleterious Th2 immune response.

2.7.3.3. Comparison and Analyses of Results Across Studies

Not applicable.

2.7.3.4. Analysis of Clinical Information Relevant to Dosing Recommendations

The immunogenicity data supporting the selection of the SARS-CoV-2 mRNA vaccine candidate, regimen, and dose level are from Study BNT162-01 and Phase 1 of Study C4591001, which are described in Section 2.7.3.2.2.1.

2.7.3.5. Persistence of Efficacy and/or Tolerance Effects

Following demonstration of VE of ≥95% in the prespecified interim and final efficacy analyses (data cutoff dates of 04 November 2020 and 14 November 2020, respectively), updated analyses were conducted for COVID-19 cases accrued over a longer period during blinded placebo-controlled follow-up after Dose 2 (updated analysis data cutoff date: 13 March 2021).

In the updated analyses in the evaluable efficacy populations, both among participants without, and among those with and without, evidence of SARS-CoV-2 infection before and during the vaccination regimen, the estimated VE against confirmed COVID-19 occurring at least 7 days after Dose 2 was approximately 91% and the estimated VE against FDA-defined severe COVID-19 (as defined by FDA) occurring at least 7 days after Dose 2 was approximately 95%. In the all-available efficacy population, estimated VE against severe COVID-19 occurring at any time after Dose 1 was 96.7%. The total duration of protection BNT162b2 provides against symptomatic COVID-19 is not yet known.

Phase 1 immunogenicity data indicate that the functional antibody and T cell responses induced by 30 µg BNT162b2 persist for at least 6 months after Dose 2. SARS-CoV-2 serum neutralizing titers and serum S1-binding IgG concentrations at 6 months after dose 2 had decreased relative to those observed at 1 month after Dose 2 but remained higher than values observed before vaccination. The total duration of antibody persistence is not yet known. Results for antibody persistence at 6 months after Dose 2 are not yet available for participants vaccinated in Phase 2. Those results, as well as data for 12 and 24 months after Dose 2 in both Phase 1 and Phase 2, will be provided in future submissions.

Despite the decrease in SARS-CoV-2 serum neutralizing titers and serum S1-binding IgG concentrations from 1 month to 6 months after dose 2 that was observed in Phase 1 participants who received 30 µg BNT162b2, VE remained high (>90%) in updated efficacy analyses for Phase 2/3 participants. Data are insufficient to allow estimation of an immunological correlate of protection.

REFERENCES

1 Vogel AB, Lambert L, Kinnear E, et al. Self-amplifying RNA vaccines give equivalent protection against influenza to mRNA vaccines but at much lower doses. Mol Ther 2018;26(2):446-55.

2 Moyo N, Vogel AB, Buus S, et al. Efficient induction of T cells against conserved HIV-1 regions by mosaic vaccines delivered as self-amplifying mRNA. Mol Ther Methods 2019;12:32-46.

3 Pardi N, Hogan MJ, Pelc RS, et al. Zika virus protection by a single low-dose nucleoside-modified mRNA vaccination. Nature 2017;543(7644):248-51.

4 US Food and Drug Administration. Development and Licensure of Vaccines to Prevent COVID-19. Guidance for Industry. June 2020. Available at: https://www.fda.gov/media/139638/download (Accessed 26 April 2021)

5 Centers for Disease Control and Prevention. COVID-19 website: Symptoms of COVID-19. https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html (Accessed 16 April 2021)

6 Centers for Disease Control and Prevention. COVID-19 website: People with Certain Medical Conditions. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html (Accessed 18 February 2021).

7 Mulligan MJ, Lyke KE, Kitchin N, et al. Phase I/II study of COVID-19 RNA vaccine BNT162b1 in adults. Nature 2020;586(7830):589-93.

8 Walsh EE, Frenck RW Jr, Falsey AR, et al. Safety and immunogenicity of two RNA-Based COVID-19 vaccine candidates. N Engl J Med 2020;383(25):2439-50.

9 Agresti A. Introduction: distributions and inference for categorical data. In: Agresti A, ed. Categorical data analysis. 2nd ed. Hoboken, NJ: John Wiley & Sons; 2002:1-35.

2.7.3.6. Appendix

Study C4591001 – Efficacy – Interim Analysis

Table 26. Efficacy Populations – Interim Analysis 1

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Randomized[b]	21653 (100.0)	21672 (100.0)	43325 (100.0)
Dose 1 all-available efficacy population	21617 (99.8)	21633 (99.8)	43250 (99.8)
Subjects without evidence of infection before Dose 1	17237 (79.6)	17221 (79.5)	34458 (79.5)
Subjects excluded from Dose 1 all-available efficacy population	36 (0.2)	39 (0.2)	75 (0.2)
Reason for exclusion[c]			
Did not receive at least 1 vaccination	35 (0.2)	39 (0.2)	74 (0.2)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Dose 2 all-available efficacy population	18868 (87.1)	18877 (87.1)	37745 (87.1)
Subjects without evidence of infection prior to 7 days after Dose 2	16463 (76.0)	16426 (75.8)	32889 (75.9)
Subjects excluded from Dose 2 all-available efficacy population	2785 (12.9)	2795 (12.9)	5580 (12.9)
Reason for exclusion[c]			
Did not complete 2 vaccination doses	2784 (12.9)	2795 (12.9)	5579 (12.9)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Evaluable efficacy population (7 Days)	18380 (84.9)	18618 (85.9)	36998 (85.4)
Subjects without evidence of infection prior to 7 days after Dose 2	16061 (74.2)	16218 (74.8)	32279 (74.5)
Subjects excluded from evaluable efficacy population (7 Days)	3273 (15.1)	3054 (14.1)	6327 (14.6)
Reason for exclusion[c]			
Randomized but did not meet all eligibility criteria	15 (0.1)	16 (0.1)	31 (0.1)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Did not receive all vaccination(s) as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)	3038 (14.0)	3035 (14.0)	6073 (14.0)
Had other important protocol deviations on or prior to 7 days after Dose 2	302 (1.4)	52 (0.2)	354 (0.8)

Table 26. Efficacy Populations – Interim Analysis 1

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)

Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.
a. n = Number of subjects with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. Subjects may have been excluded for more than 1 reason.
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Table 27. Demographic Characteristics – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (7 Days) – Interim Analysis 1

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=16061) n[b] (%)	Placebo (N[a]=16218) n[b] (%)	Total (N[a]=32279) n[b] (%)
Sex			
Male	8197 (51.0)	8144 (50.2)	16341 (50.6)
Female	7864 (49.0)	8074 (49.8)	15938 (49.4)
Race			
White	13502 (84.1)	13692 (84.4)	27194 (84.2)
Black or African American	1298 (8.1)	1303 (8.0)	2601 (8.1)
American Indian or Alaska native	88 (0.5)	82 (0.5)	170 (0.5)
Asian	712 (4.4)	716 (4.4)	1428 (4.4)
Native Hawaiian or other Pacific Islander	40 (0.2)	26 (0.2)	66 (0.2)
Multiracial	341 (2.1)	297 (1.8)	638 (2.0)
Not reported	80 (0.5)	102 (0.6)	182 (0.6)
Ethnicity			
Hispanic/Latino	4415 (27.5)	4383 (27.0)	8798 (27.3)
Non-Hispanic/non-Latino	11553 (71.9)	11736 (72.4)	23289 (72.1)
Not reported	93 (0.6)	99 (0.6)	192 (0.6)
Country			
Argentina	2445 (15.2)	2415 (14.9)	4860 (15.1)
Brazil	889 (5.5)	889 (5.5)	1778 (5.5)
South Africa	215 (1.3)	218 (1.3)	433 (1.3)
USA	12512 (77.9)	12696 (78.3)	25208 (78.1)
Age group			
16-55 Years	9093 (56.6)	9172 (56.6)	18265 (56.6)
>55 Years	6968 (43.4)	7046 (43.4)	14014 (43.4)
Age at vaccination (years)			

Table 27. Demographic Characteristics – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy Population (7 Days) – Interim Analysis 1

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=16061) n[b] (%)	**Placebo (N[a]=16218) n[b] (%)**	**Total (N[a]=32279) n[b] (%)**
Mean (SD)	50.9 (15.58)	50.7 (15.68)	50.8 (15.63)
Median	52.0	52.0	52.0
Min, max	(16, 89)	(16, 91)	(16, 91)

Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
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Table 28. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population – Interim Analysis 1

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=16463)		Placebo (N[a]=16426)				
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])	Pr (VE >30% | data)[f]
First COVID-19 occurrence from 7 days after Dose 2	4	1.761 (16298)	93	1.748 (16213)	95.7	(89.3, 98.5)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.

a. N = number of subjects in the specified group.

b. n1 = Number of subjects meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of subjects at risk for the endpoint.

e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.

f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102,1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details. This probability must be at least 99.5% at the interim analysis in order to conclude that the vaccine is efficacious.

PFIZER CONFIDENTIAL SDTM Creation: 05NOV2020 (20:48) Source Data: adc19ef Table Generation: 09NOV2020 (16:43)
(Cutoff Date: 04Nov2020, Snapshot Date: 04Nov2020) Output File: ./nda2_unblinded_ia/C4591001_IA_62/adc19ef_ve_cov_7pd2_wo_aai

Table 29. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population – Interim Analysis 1

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=16463)		Placebo (N[a]=16426)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	4	1.761 (16298)	93	1.748 (16213)	95.7	(88.7, 98.9)
Age group (years)						
16 to 55	2	0.975 (9217)	70	0.968 (9156)	97.2	(89.4, 99.7)
>55	2	0.785 (7081)	23	0.780 (7057)	91.4	(65.0, 99.0)
Sex						
Male	2	0.893 (8320)	41	0.874 (8138)	95.2	(81.6, 99.4)
Female	2	0.867 (7978)	52	0.874 (8075)	96.1	(85.3, 99.5)
Race						
White	4	1.513 (13771)	88	1.505 (13708)	95.5	(88.0, 98.8)
Black or African American	0	0.125 (1281)	4	0.125 (1285)	100.0	(-50.8, 100.0)
All others[f]	0	0.122 (1246)	1	0.119 (1220)	100.0	(-3708.9, 100.0)
Ethnicity						
Hispanic/Latino	1	0.471 (4499)	35	0.464 (4437)	97.2	(83.3, 99.9)
Non-Hispanic/non-Latino	3	1.279 (11702)	58	1.274 (11678)	94.8	(84.2, 99.0)
Country						
Argentina	0	0.275 (2516)	29	0.269 (2477)	100.0	(86.7, 100.0)
Brazil	0	0.087 (878)	2	0.087 (881)	100.0	(-433.0, 100.0)
USA	4	1.395 (12702)	62	1.389 (12656)	93.6	(82.7, 98.3)

Table 29. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population – Interim Analysis 1

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=16463)		Placebo (N[a]=16426)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein-binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
Note: Data from subjects who are not confirmed 7 days post dose 2 cases are included in the analysis to comprehensively show all data reported and/or contribute to the total surveillance time calculation but may be subject to change with additional follow-up.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.
f. American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, not reported race categories are presented as “All others”.
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(Cutoff Date: 04Nov2020, Snapshot Date: 04Nov2020) Output File: ./nda2 unblinded ia/C4591001 IA 62/adc19ef ve cov 7pd2 wo sg aai

Table 30. COVID-19 Occurrence From 7 Days After Dose 2, by Prior SARS-CoV-2 Status – Evaluable Efficacy Population (7 Days) – Interim Analysis 1

Efficacy Endpoint Subgroup	Vaccine Group (as Randomized) BNT162b2 (30 µg) (N[a]=18380) n[b]	Vaccine Group (as Randomized) Placebo (N[a]=18618) n[b]
COVID-19 occurrence from 7 days after Dose 2		
Prior SARS-CoV-2 Status		
Positive at baseline[c]	1	1
Negative at baseline but positive on or prior to 7 days after Dose 2[d]	0	0
Negative prior to 7 days after Dose 2[e]	4	90

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose prior SARS-CoV-2 status cannot be determined due to missing N-binding antibody or NAAT at Visit 1 or Visit 2 were not included in the analysis.
a. N = number of subjects in the specified group.
b. n = Number of subjects meeting the endpoint definition.
c. Positive N-binding antibody at Visit 1, or positive NAAT at Visit 1, or had medical history of COVID-19.
d. Negative N-binding antibody at Visit 1 and negative NAAT at Visit 1, positive NAAT at Visit 2 or at unscheduled visit, if any, prior to 7 days after Dose 2.
e. Negative N-binding antibody at Visit 1, negative NAAT at Visit 1 and Visit 2, and negative at unscheduled visit, if any, prior to 7 days after Dose 2.
PFIZER CONFIDENTIAL SDTM Creation: 05NOV2020 (20:48) Source Data: adc19ef Table Generation: 06NOV2020 (16:32)
(Cutoff Date: 04Nov2020, Snapshot Date: 04Nov2020) Output File: ./nda2 unblinded ia/C4591001 IA 62/adc19ef cov bl 7dpd2 eval

Table 31. COVID-19 Occurrence From 7 Days After Dose 2, by Prior SARS-CoV-2 Status – Dose 2 All-Available Efficacy Population – Interim Analysis 1

Efficacy Endpoint Subgroup	Vaccine Group (as Randomized) BNT162b2 (30 µg) (N[a]=18868) n[b]	Vaccine Group (as Randomized) Placebo (N[a]=18877) n[b]
COVID-19 occurrence from 7 days after Dose 2		
Prior SARS-CoV-2 Status		
Positive at baseline[c]	1	1
Negative at baseline but positive on or prior to 7 days after Dose 2[d]	0	0
Negative prior to 7 days after Dose 2[e]	4	93

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose prior SARS-CoV-2 status cannot be determined due to missing N-binding antibody or NAAT at Visit 1 or Visit 2 were not included in the analysis.
a. N = number of subjects in the specified group.
b. n = Number of subjects meeting the endpoint definition.
c. Positive N-binding antibody at Visit 1, or positive NAAT at Visit 1, or had medical history of COVID-19.
d. Negative N-binding antibody at Visit 1 and negative NAAT at Visit 1, positive NAAT at Visit 2 or at unscheduled visit, if any, prior to 7 days after Dose 2.
e. Negative N-binding antibody at Visit 1, negative NAAT at Visit 1 and Visit 2, and negative at unscheduled visit, if any, prior to 7 days after Dose 2.
PFIZER CONFIDENTIAL SDTM Creation: 05NOV2020 (20:48) Source Data: adc19ef Table Generation: 06NOV2020 (16:32)
(Cutoff Date: 04Nov2020, Snapshot Date: 04Nov2020) Output File: ./nda2 unblinded ia/C4591001 IA 62/adc19ef cov bl 7dpd2 aai

Study C4591001 – Efficacy – Final Analysis

Table 32. Efficacy Populations

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Randomized[b]	21823 (100.0)	21828 (100.0)	43651 (100.0)
Dose 1 all-available efficacy population	21768 (99.7)	21783 (99.8)	43551 (99.8)
Subjects without evidence of infection before Dose 1	20314 (93.1)	20296 (93.0)	40610 (93.0)
Subjects excluded from Dose 1 all-available efficacy population	55 (0.3)	45 (0.2)	100 (0.2)
Reason for exclusion[c]			
Did not receive at least 1 vaccination	54 (0.2)	45 (0.2)	99 (0.2)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Dose 2 all-available efficacy population	20566 (94.2)	20536 (94.1)	41102 (94.2)
Subjects without evidence of infection prior to 7 days after Dose 2	18701 (85.7)	18627 (85.3)	37328 (85.5)
Subjects without evidence of infection prior to 14 days after Dose 2	18678 (85.6)	18563 (85.0)	37241 (85.3)
Subjects excluded from Dose 2 all-available efficacy population	1257 (5.8)	1292 (5.9)	2549 (5.8)
Reason for exclusion[c]			
Did not receive 2 vaccinations	1256 (5.8)	1292 (5.9)	2548 (5.8)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Evaluable efficacy (7 days) population	20033 (91.8)	20244 (92.7)	40277 (92.3)
Subjects without evidence of infection prior to 7 days after Dose 2	18242 (83.6)	18379 (84.2)	36621 (83.9)
Evaluable efficacy (14 days) population	20033 (91.8)	20243 (92.7)	40276 (92.3)
Subjects without evidence of infection prior to 14 days after Dose 2	18219 (83.5)	18315 (83.9)	36534 (83.7)
Subjects excluded from evaluable efficacy (7 days) population	1790 (8.2)	1584 (7.3)	3374 (7.7)
Subjects excluded from evaluable efficacy (14 days) population	1790 (8.2)	1585 (7.3)	3375 (7.7)
Reason for exclusion[c]			
Randomized but did not meet all eligibility criteria	36 (0.2)	26 (0.1)	62 (0.1)
Did not provide informed consent	1 (0.0)	0	1 (0.0)
Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)	1550 (7.1)	1561 (7.2)	3111 (7.1)

Table 32. Efficacy Populations

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Had other important protocol deviations on or prior to 7 days after Dose 2	311 (1.4)	60 (0.3)	371 (0.8)
Had other important protocol deviations on or prior to 14 days after Dose 2	311 (1.4)	61 (0.3)	372 (0.9)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. n = Number of subjects with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. Subjects may have been excluded for more than 1 reason.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (18:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsl_eff_pop

Table 33. Demographic Characteristics – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=18242) n[b] (%)	Placebo (N[a]=18379) n[b] (%)	Total (N[a]=36621) n[b] (%)
Sex			
Male	9318 (51.1)	9225 (50.2)	18543 (50.6)
Female	8924 (48.9)	9154 (49.8)	18078 (49.4)
Race			
White	15110 (82.8)	15301 (83.3)	30411 (83.0)
Black or African American	1617 (8.9)	1617 (8.8)	3234 (8.8)
American Indian or Alaska native	118 (0.6)	106 (0.6)	224 (0.6)
Asian	815 (4.5)	810 (4.4)	1625 (4.4)
Native Hawaiian or other Pacific Islander	48 (0.3)	29 (0.2)	77 (0.2)
Multiracial	448 (2.5)	402 (2.2)	850 (2.3)
Not reported	86 (0.5)	114 (0.6)	200 (0.5)
Ethnicity			
Hispanic/Latino	4886 (26.8)	4857 (26.4)	9743 (26.6)
Non-Hispanic/non-Latino	13253 (72.7)	13412 (73.0)	26665 (72.8)
Not reported	103 (0.6)	110 (0.6)	213 (0.6)
Country			
Argentina	2561 (14.0)	2539 (13.8)	5100 (13.9)
Brazil	1232 (6.8)	1223 (6.7)	2455 (6.7)
Germany	121 (0.7)	126 (0.7)	247 (0.7)
South Africa	287 (1.6)	279 (1.5)	566 (1.5)
USA	14041 (77.0)	14212 (77.3)	28253 (77.1)
Age group			
12-15 Years	46 (0.3)	42 (0.2)	88 (0.2)
16-55 Years	10428 (57.2)	10507 (57.2)	20935 (57.2)

Table 33. Demographic Characteristics – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=18242) n[b] (%)	Placebo (N[a]=18379) n[b] (%)	Total (N[a]=36621) n[b] (%)
>55 Years	7768 (42.6)	7830 (42.6)	15598 (42.6)
≥65 Years	3980 (21.8)	4038 (22.0)	8018 (21.9)
Age at vaccination (years)			
Mean (SD)	50.6 (15.70)	50.4 (15.81)	50.5 (15.76)
Median	52.0	52.0	52.0
Min, max	(12, 89)	(12, 91)	(12, 91)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:49) Source Data: adsl Table Generation: 17NOV2020 (18:29)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2 unblinded/C4591001 Efficacy FA 164/adsl demo 7d eval eff

Table 34. Summary of Signs and Symptoms for COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=8)	Placebo (N[a]=162)	Total (N[a]=170)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	2 (25.0)	76 (46.9)	78 (45.9)
New or increased cough	3 (37.5)	114 (70.4)	117 (68.8)
New or increased shortness of breath	0 (0.0)	25 (15.4)	25 (14.7)
Chills	2 (25.0)	57 (35.2)	59 (34.7)
New or increased muscle pain	1 (12.5)	81 (50.0)	82 (48.2)
New loss of taste or smell	5 (62.5)	43 (26.5)	48 (28.2)
Sore throat	3 (37.5)	68 (42.0)	71 (41.8)
Diarrhea	1 (12.5)	18 (11.1)	19 (11.2)
Vomiting	2 (25.0)	6 (3.7)	8 (4.7)
Subjects with specific number of signs and symptoms			
1	1 (12.5)	24 (14.8)	25 (14.7)
2	3 (37.5)	46 (28.4)	49 (28.8)
3	4 (50.0)	34 (21.0)	38 (22.4)
4	0 (0.0)	33 (20.4)	33 (19.4)
5	0 (0.0)	16 (9.9)	16 (9.4)
>5	0 (0.0)	9 (5.6)	9 (5.3)

Table 34. Summary of Signs and Symptoms for COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=8)	Placebo (N^a=162)	Total (N^a=170)
Signs and Symptoms	**n^b(%)**	**n^b(%)**	**n^b(%)**

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects with COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:47)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_cov_7d2_wo_eval

Table 35. Summary of Signs and Symptoms for COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=50)	Placebo (N[a]=275)	Total (N[a]=325)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	20 (40.0)	122 (44.4)	142 (43.7)
New or increased cough	22 (44.0)	186 (67.6)	208 (64.0)
New or increased shortness of breath	4 (8.0)	44 (16.0)	48 (14.8)
Chills	10 (20.0)	86 (31.3)	96 (29.5)
New or increased muscle pain	12 (24.0)	121 (44.0)	133 (40.9)
New loss of taste or smell	24 (48.0)	91 (33.1)	115 (35.4)
Sore throat	18 (36.0)	111 (40.4)	129 (39.7)
Diarrhea	4 (8.0)	35 (12.7)	39 (12.0)
Vomiting	5 (10.0)	11 (4.0)	16 (4.9)
Subjects with specific number of signs and symptoms			
1	16 (32.0)	44 (16.0)	60 (18.5)
2	14 (28.0)	82 (29.8)	96 (29.5)
3	11 (22.0)	63 (22.9)	74 (22.8)
4	5 (10.0)	40 (14.5)	45 (13.8)
5	2 (4.0)	31 (11.3)	33 (10.2)
>5	2 (4.0)	15 (5.5)	17 (5.2)

a. N = number of subjects with COVID-19 occurrence after dose 1 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:47)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_cov_d1_aai

Table 36. Summary of Signs and Symptoms for Severe COVID-19 Occurrence After Dose 1 – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=1)	Placebo (N[a]=9)	Total (N[a]=10)
Signs and Symptoms	**n[b](%)**	**n[b](%)**	**n[b](%)**
Subjects with specific signs and symptoms of severe COVID-19			
Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, SpO_2 ≤93% on room air at sea level, or PaO_2/FiO_2 <300 mm Hg)	1 (100.0)	9 (100.0)	10 (100.0)
Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO)	0 (0.0)	3 (33.3)	3 (30.0)
Significant acute renal, hepatic, or neurologic dysfunction	0 (0.0)	1 (11.1)	1 (10.0)
Admission to an ICU	0 (0.0)	3 (33.3)	3 (30.0)
Subjects with specific number of signs and symptoms			
1	1 (100.0)	5 (55.6)	6 (60.0)
2	0 (0.0)	2 (22.2)	2 (20.0)
3	0 (0.0)	1 (11.1)	1 (10.0)
5	0 (0.0)	1 (11.1)	1 (10.0)

Abbreviations: DBP = diastolic blood pressure; ECMO = extracorporeal membrane oxygenation; FiO_2 = fraction of inspired oxygen; HR = heart rate; ICU = intensive care unit; PaO_2 = partial pressure of oxygen, arterial; RR = respiratory rate; SBP = systolic blood pressure; SpO_2 = oxygen saturation as measured by pulse oximetry.
a. N = number of subjects with severe COVID-19 occurrence after dose 1 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 17NOV2020 (16:49)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adsympt_symp_sev_cov_d1_aai

Table 37. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=18650)		Placebo (N[a]=18570)				
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**	**Pr (VE >30% | data)[f]**
First COVID-19 occurrence from 7 days after Dose 2	8	2.266 (17852)	165	2.244 (17746)	95.2	(90.6, 97.7)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.

a. N = number of subjects in the specified group.

b. n1 = Number of subjects meeting the endpoint definition.

c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.

d. n2 = Number of subjects at risk for the endpoint.

e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.

f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102,1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_cov_7pd2_wo_aai

Table 38. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=20488)		Placebo (N[a]=20459)				
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**	**Pr (VE >30% | data)[f]**
First COVID-19 occurrence from 7 days after Dose 2	9	2.389 (19049)	172	2.370 (18971)	94.8	(90.2, 97.4)	>0.9999

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 17NOV2020 (16:46)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_cov_7pd2_aai

Table 39. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Requested Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	8	2.214 (17411)	162	2.222 (17511)	95.0	(90.0, 97.9)
Age group (years)						
12 to 15	0	0.000 (14)	0	0.000 (13)	NE	(NE, NE)
16 to 17	0	0.002 (52)	0	0.003 (55)	NE	(NE, NE)
18 to 64	7	1.703 (13497)	143	1.708 (13563)	95.1	(89.6, 98.1)
65 to 74	1	0.406 (3074)	14	0.406 (3095)	92.9	(53.1, 99.8)
≥75	0	0.102 (774)	5	0.106 (785)	100.0	(-13.1, 100.0)
Race						
White	7	1.889 (14504)	146	1.903 (14670)	95.2	(89.8, 98.1)
Black or African American	0	0.165 (1502)	7	0.164 (1486)	100.0	(31.2, 100.0)
American Indian or Alaska native	0	0.011 (100)	1	0.010 (96)	100.0	(-3429.0, 100.0)
Asian	1	0.092 (764)	4	0.093 (769)	74.6	(-156.6, 99.5)
Native Hawaiian or other Pacific Islander	0	0.006 (46)	1	0.003 (29)	100.0	(-2266.9, 100.0)
Multiracial	0	0.042 (414)	1	0.036 (359)	100.0	(-3231.3, 100.0)
Not reported	0	0.010 (81)	2	0.012 (102)	100.0	(-563.3, 100.0)

Table 39. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Requested Subgroup – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint Subgroup	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 23NOV2020 (16:38)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2 unblinded/C4591001 EUA FAEF RR/adc19ef ve cov 7pd2 worq sg eval

Table 40. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20172)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	9	2.332 (18559)	169	2.345 (18708)	94.6	(89.6, 97.6)
Age group (years)						
16 to 55	6	1.309 (10653)	120	1.317 (10738)	95.0	(88.7, 98.2)
>55	3	1.022 (7892)	49	1.028 (7956)	93.8	(80.9, 98.8)
≥65	1	0.530 (4044)	19	0.532 (4067)	94.7	(66.8, 99.9)
Sex						
Male	4	1.183 (9457)	85	1.170 (9342)	95.3	(87.6, 98.8)
Female	5	1.149 (9102)	84	1.176 (9366)	93.9	(85.2, 98.1)
Race						
White	7	1.975 (15294)	153	1.990 (15473)	95.4	(90.3, 98.2)
Black or African American	0	0.187 (1758)	7	0.188 (1758)	100.0	(30.4, 100.0)
All others[f]	2	0.170 (1507)	9	0.167 (1477)	78.2	(-5.4, 97.7)
Ethnicity						
Hispanic/Latino	3	0.637 (5074)	55	0.638 (5090)	94.5	(83.2, 98.9)
Non-Hispanic/non-Latino	6	1.681 (13380)	114	1.693 (13509)	94.7	(88.1, 98.1)
Country						
Argentina	1	0.366 (2664)	36	0.367 (2684)	97.2	(83.5, 99.9)
Brazil	2	0.134 (1274)	8	0.132 (1257)	75.4	(-23.5, 97.5)
USA	6	1.816 (14141)	124	1.830 (14287)	95.1	(89.1, 98.2)
South Africa	0	0.015 (362)	1	0.015 (363)	100.0	(-3818.9, 100.0)

Table 40. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20172)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Prior SARS-CoV-2 Status						
Positive at baseline[g]	1	0.056 (526)	1	0.060 (567)	-7.1	(-8309.9, 98.6)
Negative at baseline but positive prior to 7 days after Dose 2[h]	0	0.003 (27)	1	0.004 (34)	100.0	(-6004.9, 100.0)
Negative prior to 7 days after Dose 2[i]	8	2.214 (17411)	162	2.222 (17511)	95.0	(90.0, 97.9)
Unknown	0	0.059 (595)	5	0.060 (596)	100.0	(-9.6, 100.0)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.

a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
g. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
h. Negative N-binding antibody result and negative NAAT result at Visit 1, positive NAAT result at Visit 2 or at unscheduled visit, if any, prior to 7 days after Dose 2.
i. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1 and Visit 2, and negative NAAT result at unscheduled visit, if any, prior to 7 days after Dose 2.

PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 18NOV2020 (15:55)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_cov_7pd2_sg_eval

Table 41. Baseline Charlson Comorbidities – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)		
Charlson Comorbidity Index Category	BNT162b2 (30 µg) (N[a]=21720) n[b] (%)	Placebo (N[a]=21728) n[b] (%)	Total (N[a]=43448) n[b] (%)
Subjects with any Charlson comorbidity	4559 (21.0)	4419 (20.3)	8978 (20.7)
AIDS/HIV	99 (0.5)	98 (0.5)	197 (0.5)
Any Malignancy	808 (3.7)	753 (3.5)	1561 (3.6)
Cerebrovascular Disease	227 (1.0)	194 (0.9)	421 (1.0)
Chronic Pulmonary Disease	1730 (8.0)	1713 (7.9)	3443 (7.9)
Congestive Heart Failure	108 (0.5)	97 (0.4)	205 (0.5)
Dementia	7 (0.0)	11 (0.1)	18 (0.0)
Diabetes With Chronic Complication	112 (0.5)	125 (0.6)	237 (0.5)
Diabetes Without Chronic Complication	1692 (7.8)	1676 (7.7)	3368 (7.8)
Hemiplegia or Paraplegia	15 (0.1)	22 (0.1)	37 (0.1)
Leukemia	14 (0.1)	10 (0.0)	24 (0.1)
Lymphoma	25 (0.1)	36 (0.2)	61 (0.1)
Metastatic Solid Tumor	4 (0.0)	3 (0.0)	7 (0.0)
Mild Liver Disease	145 (0.7)	112 (0.5)	257 (0.6)
Moderate or Severe Liver Disease	1 (0.0)	2 (0.0)	3 (0.0)
Myocardial Infarction	220 (1.0)	216 (1.0)	436 (1.0)
Peptic Ulcer Disease	62 (0.3)	81 (0.4)	143 (0.3)
Peripheral Vascular Disease	144 (0.7)	132 (0.6)	276 (0.6)
Renal Disease	139 (0.6)	145 (0.7)	284 (0.7)
Rheumatic Disease	75 (0.3)	65 (0.3)	140 (0.3)

Table 41. Baseline Charlson Comorbidities – Phase 2/3 (All Subjects) – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=21720)	Placebo (N[a]=21728)	Total (N[a]=43448)
Charlson Comorbidity Index Category	**n[b] (%)**	**n[b] (%)**	**n[b] (%)**

Note: MedDRA (v23.1) coding dictionary applied.
Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
Note: Data for subjects randomized on or after 10OCT2020 are included to comprehensively show all data reported but are subject to change with additional follow-up.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic. Subjects with multiple occurrences within each category are counted only once. For 'Subjects with any Charlson comorbidity', n = number of subjects reporting at least 1 occurrence of any Charlson comorbidity.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (10:04) Source Data: admh Table Generation: 17NOV2020 (16:25)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P3_2MPD2/admh_s002_risk_all_p3_saf

Table 42. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Comorbidity Status – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint Subgroup	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**
First COVID-19 occurrence from 7 days after Dose 2						
Overall	8	2.214 (17411)	162	2.222 (17511)	95.0	(90.0, 97.9)
Comorbidity						
No comorbidity	4	1.189 (9381)	76	1.197 (9482)	94.7	(85.9, 98.6)
Any comorbidity[f]	4	1.025 (8030)	86	1.025 (8029)	95.3	(87.7, 98.8)
Any malignancy	1	0.092 (704)	4	0.090 (681)	75.7	(-145.8, 99.5)
Cardiovascular	0	0.067 (534)	5	0.062 (492)	100.0	(-0.8, 100.0)
Chronic pulmonary disease	1	0.175 (1374)	14	0.171 (1358)	93.0	(54.1, 99.8)
Diabetes	1	0.176 (1372)	19	0.176 (1374)	94.7	(66.8, 99.9)
Obese (≥30.0 kg/m^2)	3	0.763 (6000)	67	0.782 (6103)	95.4	(86.0, 99.1)
Hypertension	2	0.567 (4413)	44	0.567 (4437)	95.4	(82.6, 99.5)
Diabetes (including gestational diabetes)	1	0.177 (1381)	20	0.178 (1384)	95.0	(68.7, 99.9)

Table 42. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Comorbidity Status – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint Subgroup	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Subject who had 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥30 kg/m^2.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:54) Source Data: adc19ef Table Generation: 29NOV2020 (21:33)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_EUA_FAEF_RR/adc19ef_ve_cov_7pd2_wo_cg_eval

Table 43. Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC-Definition After Dose 1 – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=21669)		Placebo (N[a]=21686)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First Severe COVID-19 occurrence based on CDC-definition after Dose 1	1	4.018 (21299)	14	4.001 (21238)	92.9	(53.2, 99.8)
After Dose 1 to before Dose 2	1		8		87.5	(6.8, 99.7)
Dose 2 to 7 days after Dose 2	0		1		100.0	(-3800.0, 100.0)
≥7 Days after Dose 2	0		5		100.0	(-9.1, 100.0)

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method (adjusted for surveillance time for overall row).
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 03DEC2020 (22:53)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2 unblinded/C4591001 VRBPAC/adc19ef ve sev cdc pd1 aai

Table 44. Vaccine Efficacy – First COVID-19 Occurrence Based on CDC-Defined Symptoms From 7 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18198)		Placebo (N[a]=18325)			
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**
First COVID-19 occurrence based on CDC-defined symptoms from 7 days after Dose 2	8	2.213 (17399)	165	2.220 (17495)	95.1	(90.2, 97.9)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 18NOV2020 (07:39)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2_unblinded/C4591001_Efficacy_FA_164/adc19ef_ve_cov_7pd2_wo_cdc_eval

Table 45. Vaccine Efficacy – First COVID-19 Occurrence Based on CDC-Defined Symptoms From 7 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20172)			
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**
First COVID-19 occurrence based on CDC-defined symptoms from 7 days after Dose 2	9	2.330 (18544)	172	2.343 (18690)	94.7	(89.8, 97.6)

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 18NOV2020 (07:39)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 7pd2 cdc eval

Table 46. Vaccine Efficacy – First COVID-19 Occurrence Based on CDC-Defined Symptoms From 14 Days After Dose 2 – Subjects Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=18175)		Placebo (N[a]=18261)			
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**
First COVID-19 occurrence based on CDC-defined symptoms from 14 days after Dose 2	8	1.886 (16600)	141	1.891 (16647)	94.3	(88.5, 97.6)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 14 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 14 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 18NOV2020 (07:39)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 14pd2 wo cdc eval

Table 47. Vaccine Efficacy – First COVID-19 Occurrence Based on CDC-Defined Symptoms From 14 Days After Dose 2 – Subjects With or Without Evidence of Infection Prior to 14 Days After Dose 2 – Evaluable Efficacy (14 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=19965)		Placebo (N[a]=20171)			
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**
First COVID-19 occurrence based on CDC-defined symptoms from 14 days after Dose 2	8	1.983 (17630)	146	1.993 (17727)	94.5	(88.9, 97.7)

Abbreviations: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 14 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 17NOV2020 (09:48) Source Data: adc19ef Table Generation: 18NOV2020 (07:39)
(Cutoff Date: 14NOV2020, Snapshot Date: 16NOV2020) Output File: ./nda2 unblinded/C4591001 Efficacy FA 164/adc19ef ve cov 14pd2 cdc eval

Study C4591001 – Efficacy – Updated Analysis

Table 48. Efficacy Populations – Blinded Placebo-Controlled Follow-up Period

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Randomized[b]	23219 (100.0)	23210 (100.0)	46429 (100.0)
Dose 1 all-available efficacy population	23140 (99.7)	23137 (99.7)	46277 (99.7)
Subjects without evidence of infection before Dose 1	22200 (95.6)	22191 (95.6)	44391 (95.6)
Subjects excluded from Dose 1 all-available efficacy population	79 (0.3)	73 (0.3)	152 (0.3)
Reason for exclusion[c]			
Did not receive at least 1 vaccination	58 (0.2)	51 (0.2)	109 (0.2)
Data considered potentially unreliable due to lack of PI oversight identified as significant quality event	21 (0.1)	22 (0.1)	43 (0.1)
Dose 2 all-available efficacy population	22771 (98.1)	22741 (98.0)	45512 (98.0)
Subjects without evidence of infection prior to 7 days after Dose 2	21544 (92.8)	21470 (92.5)	43014 (92.6)
Subjects excluded from Dose 2 all-available efficacy population	448 (1.9)	469 (2.0)	917 (2.0)
Reason for exclusion[c]			
Did not receive 2 vaccinations	384 (1.7)	443 (1.9)	827 (1.8)
Data considered potentially unreliable due to lack of PI oversight identified as significant quality event	21 (0.1)	22 (0.1)	43 (0.1)
Unblinded prior to 7 days after Dose 2	45 (0.2)	11 (0.0)	56 (0.1)
Evaluable efficacy (7 days) population	22255 (95.8)	22410 (96.6)	44665 (96.2)
Subjects without evidence of infection prior to 7 days after Dose 2	21069 (90.7)	21175 (91.2)	42244 (91.0)
Subjects excluded from evaluable efficacy (7 days) population	964 (4.2)	800 (3.4)	1764 (3.8)
Reason for exclusion[c]			
Randomized but did not meet all eligibility criteria	33 (0.1)	30 (0.1)	63 (0.1)
Data considered potentially unreliable due to lack of PI oversight identified as significant quality event	21 (0.1)	22 (0.1)	43 (0.1)

Table 48. Efficacy Populations – Blinded Placebo-Controlled Follow-up Period

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) n[a] (%)	Placebo n[a] (%)	Total n[a] (%)
Did not receive all vaccinations as randomized or did not receive Dose 2 within the predefined window (19-42 days after Dose 1)	732 (3.2)	748 (3.2)	1480 (3.2)
Unblinded prior to 7 days after Dose 2	45 (0.2)	11 (0.0)	56 (0.1)
Had other important protocol deviations on or prior to 7 days after Dose 2	240 (1.0)	60 (0.3)	300 (0.6)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. n = Number of subjects with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. Subjects may have been excluded for more than 1 reason.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (02:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adsl eff pop

Table 49. Subjects Excluded From Evaluable Efficacy Population Due to Important Protocol Deviations on or Prior to 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N^a=240)	Placebo (N^a=60)
	n^b (%)	n^b (%)
Concomitant Medications	3 (1.3)	7 (11.7)
Receipt of any other nonstudy coronavirus vaccine at any time prior to or during the study.	0 (0.0)	1 (1.7)
Subject received chronic systemic treatment with known immunosuppressant medication, or radiotherapy, within 60 days before enrollment through conclusion of the study.	1 (0.4)	1 (1.7)
Subject received systemic corticosteroids (>=20mg/day of prednisone or equivalent) for >=14 days is prohibited from 28 days prior to enrollment to specified visits/cohorts per protocol.	2 (0.8)	5 (8.3)
Inclusion/Exclusion	16 (6.7)	15 (25.0)
Participant failed to meet inclusion criterion #01 (Male or female participants between the ages of 18 and 55 years, inclusive, 65 and 85 years, inclusive, or 18 and 85 years, inclusive, at randomization (dependent upon study phase).	1 (0.4)	0 (0.0)
Participant failed to meet inclusion criterion #03 (Healthy participants who are determined by medical history, physical examination and clinical judgement of the investigator to be eligible for inclusion in the study)	1 (0.4)	5 (8.3)
Participant met exclusion criterion #01 (participant having other medical or psychiatric condition)	0 (0.0)	2 (3.3)
Participant met exclusion criterion #02 (participant having known infection with HIV, HCV or HBV)	4 (1.7)	3 (5.0)
Participant met exclusion criterion #11 (women who are pregnant or breastfeeding)	4 (1.7)	3 (5.0)
Participant met exclusion criterion #13 (participant receiving treatment with immunosuppressive therapy as specified in protocol)	4 (1.7)	1 (1.7)
Participant met exclusion criterion #16 (Participation in other studies involving study intervention within 28 days prior to study entry and/or during study participation)	0 (0.0)	1 (1.7)
Participant met exclusion criterion #22 (investigator site staff or Pfizer employees directly involved in the conduct of the study, site staff otherwise supervised by the investigator, and their respective family members)	2 (0.8)	0 (0.0)
Investigational Product	203 (84.6)	23 (38.3)
Dosing/administration error, subject did not receive correct dose of vaccine	76 (31.7)	3 (5.0)
IP administered that was deemed not suitable for use by Almac	110 (45.8)	0 (0.0)

Table 49. Subjects Excluded From Evaluable Efficacy Population Due to Important Protocol Deviations on or Prior to 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N^a=240)	Placebo (N^a=60)
	n^b (%)	n^b (%)
Incorrect IP assigned to subject due to IRT not being utilized	1 (0.4)	0 (0.0)
Incorrect vaccine allocation/assigned to subject	5 (2.1)	5 (8.3)
Other IP deviation	9 (3.8)	11 (18.3)
Subject was vaccinated despite being ineligible	1 (0.4)	2 (3.3)
Subject was vaccinated despite meeting temporary delay criterion #4 (receiving short-term (	2 (0.8)	2 (3.3)
Laboratory	2 (0.8)	1 (1.7)
Nasal swab can't be analyzed due to incorrect shipping procedure	2 (0.8)	1 (1.7)
Other	19 (7.9)	15 (25.0)
Efficacy data considered potentially unreliable due to lack of PI oversight identified as significant quality event	15 (6.3)	13 (21.7)
Safety and efficacy data considered potentially unreliable due to lack of PI oversight identified as significant quality event.	4 (1.7)	2 (3.3)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects excluded from evaluable efficacy population due to important protocol deviations in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (15:56)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_eff_pop_dev

Table 50. Demographic Characteristics – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=21069) n[b] (%)	Placebo (N[a]=21175) n[b] (%)	Total (N[a]=42244) n[b] (%)
Sex			
Male	10824 (51.4)	10689 (50.5)	21513 (50.9)
Female	10245 (48.6)	10486 (49.5)	20731 (49.1)
Race			
White	17458 (82.9)	17604 (83.1)	35062 (83.0)
Black or African American	1799 (8.5)	1812 (8.6)	3611 (8.5)
American Indian or Alaska Native	188 (0.9)	182 (0.9)	370 (0.9)
Asian	959 (4.6)	949 (4.5)	1908 (4.5)
Native Hawaiian or other Pacific Islander	55 (0.3)	31 (0.1)	86 (0.2)
Multiracial	522 (2.5)	489 (2.3)	1011 (2.4)
Not reported	88 (0.4)	108 (0.5)	196 (0.5)
All others[c]	1812 (8.6)	1759 (8.3)	3571 (8.5)
Racial Designation			
Japanese	78 (0.4)	74 (0.3)	152 (0.4)
Ethnicity			
Hispanic/Latino	5241 (24.9)	5217 (24.6)	10458 (24.8)
Non-Hispanic/non-Latino	15725 (74.6)	15846 (74.8)	31571 (74.7)
Not reported	103 (0.5)	112 (0.5)	215 (0.5)
Country			
Argentina	2624 (12.5)	2617 (12.4)	5241 (12.4)
Brazil	1326 (6.3)	1314 (6.2)	2640 (6.2)
Germany	238 (1.1)	242 (1.1)	480 (1.1)
South Africa	307 (1.5)	297 (1.4)	604 (1.4)
Turkey	231 (1.1)	226 (1.1)	457 (1.1)

Table 50. Demographic Characteristics – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=21069) n[b] (%)	Placebo (N[a]=21175) n[b] (%)	Total (N[a]=42244) n[b] (%)
USA	16343 (77.6)	16479 (77.8)	32822 (77.7)
Age group (years)			
12 to 15	1005 (4.8)	978 (4.6)	1983 (4.7)
16 to 55	11753 (55.8)	11824 (55.8)	23577 (55.8)
>55	8311 (39.4)	8373 (39.5)	16684 (39.5)
≥65	4245 (20.1)	4296 (20.3)	8541 (20.2)
16 to 17	344 (1.6)	334 (1.6)	678 (1.6)
16 to 25	1657 (7.9)	1668 (7.9)	3325 (7.9)
16 to 64	15819 (75.1)	15901 (75.1)	31720 (75.1)
18 to 64	15475 (73.4)	15567 (73.5)	31042 (73.5)
55 to 64	4499 (21.4)	4493 (21.2)	8992 (21.3)
65 to 74	3392 (16.1)	3442 (16.3)	6834 (16.2)
≥75	853 (4.0)	854 (4.0)	1707 (4.0)
75 to 85	848 (4.0)	848 (4.0)	1696 (4.0)
>85	5 (0.0)	6 (0.0)	11 (0.0)
Comorbidities[d]			
Yes	9390 (44.6)	9411 (44.4)	18801 (44.5)
No	11679 (55.4)	11764 (55.6)	23443 (55.5)
Age at vaccination (years)			
Mean (SD)	48.3 (17.41)	48.2 (17.41)	48.3 (17.41)
Median	50.0	50.0	50.0
Min, max	(12, 89)	(12, 91)	(12, 91)

Table 50. Demographic Characteristics – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=21069) n[b] (%)	Placebo (N[a]=21175) n[b] (%)	Total (N[a]=42244) n[b] (%)

Note: HIV-positive subjects are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
d. Number of subjects who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥30 kg/m^2 (≥16 Years of age) or BMI ≥95th percentile (12-15 Years of age).
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 19APR2021 (17:13)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adsl demo 7d eval eff

Table 51. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=21467)		Placebo (N[a]=21387)				
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**	**Pr (VE >30% | data)[f]**
First COVID-19 occurrence from 7 days after Dose 2	78	6.380 (21177)	866	6.094 (20999)	91.4	(89.1, 93.3)	>0.9999

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102,1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (01:59)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adc19ef ve cov 7pd2 wo aai

Table 52. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Dose 2 All-Available Efficacy Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=22675)		Placebo (N[a]=22645)				
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**	**Pr (VE >30% | data)[f]**
First COVID-19 occurrence from 7 days after Dose 2	82	6.649 (22132)	889	6.371 (22001)	91.2	(88.9, 93.0)	>0.9999

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (02:26)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adc19ef ve cov 7pd2 aai

Table 53. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	81	6.509 (21642)	873	6.274 (21689)	91.1	(88.8, 93.0)
Age group (years)						
12 to 15	0	0.170 (1109)	18	0.163 (1094)	100.0	(78.1, 100.0)
16 to 55	56	3.766 (12088)	584	3.619 (12142)	90.8	(87.9, 93.1)
>55	25	2.573 (8445)	271	2.491 (8453)	91.1	(86.5, 94.3)
≥65	7	1.267 (4315)	128	1.232 (4326)	94.7	(88.7, 97.9)
16 to 17	0	0.065 (365)	11	0.061 (355)	100.0	(62.4, 100.0)
16 to 25	10	0.511 (1734)	84	0.498 (1740)	88.4	(77.6, 94.6)
16 to 64	74	5.073 (16218)	727	4.879 (16269)	90.2	(87.6, 92.4)
18 to 64	74	5.008 (15853)	716	4.817 (15914)	90.1	(87.4, 92.3)
55 to 64	21	1.442 (4563)	159	1.386 (4559)	87.3	(79.9, 92.4)
65 to 74	6	1.021 (3450)	102	0.992 (3468)	94.3	(87.1, 98.0)
≥75	1	0.246 (865)	26	0.240 (858)	96.2	(77.2, 99.9)
75 to 85	1	0.244 (860)	25	0.238 (852)	96.1	(76.2, 99.9)
>85	0	0.001 (5)	1	0.001 (6)	100.0	(-4055.9, 100.0)
Sex						
Male	44	3.376 (11103)	411	3.181 (10920)	89.9	(86.2, 92.8)
Female	37	3.133 (10539)	462	3.093 (10769)	92.1	(88.9, 94.5)
Race						

Table 53. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
White	69	5.379 (17801)	768	5.191 (17880)	91.3	(88.9, 93.3)
Black or African American	4	0.611 (1958)	49	0.601 (1985)	92.0	(78.1, 97.9)
American Indian or Alaska Native	0	0.044 (200)	3	0.039 (182)	100.0	(-114.5, 100.0)
Asian	3	0.268 (976)	24	0.257 (967)	88.0	(60.5, 97.7)
Native Hawaiian or other Pacific Islander	0	0.016 (57)	1	0.008 (31)	100.0	(-1896.2, 100.0)
Multiracial	5	0.164 (561)	22	0.145 (532)	79.9	(45.7, 94.1)
Not reported	0	0.028 (89)	6	0.033 (112)	100.0	(-0.0, 100.0)
All others[f]	8	0.519 (1883)	56	0.481 (1824)	86.8	(72.1, 94.5)
Ethnicity						
Hispanic/Latino	32	1.862 (5408)	245	1.794 (5391)	87.4	(81.8, 91.6)
Non-Hispanic/non-Latino	48	4.615 (16128)	628	4.445 (16186)	92.6	(90.1, 94.6)
Not reported	1	0.033 (106)	0	0.034 (112)	-∞	(NA, NA)
Country						
Argentina	16	1.033 (2655)	110	1.017 (2670)	85.7	(75.7, 92.1)
Brazil	14	0.441 (1419)	82	0.408 (1401)	84.2	(71.9, 91.7)
Germany	0	0.047 (237)	1	0.048 (243)	100.0	(-3868.6, 100.0)
South Africa	0	0.099 (358)	10	0.096 (358)	100.0	(56.6, 100.0)
Turkey	0	0.029 (238)	6	0.026 (232)	100.0	(22.2, 100.0)
USA	51	4.861 (16735)	664	4.678 (16785)	92.6	(90.2, 94.6)
Prior SARS-CoV-2 Status						
Positive at baseline[g]	3	0.190 (639)	6	0.201 (689)	46.9	(-148.7, 91.4)

Table 53. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Positive N-binding only	2	0.147 (494)	5	0.151 (516)	58.9	(-151.3, 96.1)
Positive NAAT only	0	0.014 (50)	1	0.015 (58)	100.0	(-3996.1, 100.0)
Positive NAAT and N-binding	1	0.028 (95)	0	0.035 (114)	-∞	(NA, NA)
Negative at baseline but positive prior to 7 days after Dose 2[h]	0	0.011 (43)	3	0.014 (60)	100.0	(-211.3, 100.0)
Negative prior to 7 days after Dose 2[i]	77	6.247 (20712)	850	6.003 (20712)	91.3	(89.0, 93.2)
Unknown	1	0.062 (248)	14	0.055 (228)	93.7	(58.3, 99.9)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
g. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
h. Negative N-binding antibody result and negative NAAT result at Visit 1, positive NAAT result at Visit 2 or at unscheduled visit, if any, prior to 7 days after Dose 2.
i. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1 and Visit 2, and negative NAAT result at unscheduled visit, if any, prior to 7 days after Dose 2.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 30MAR2021 (22:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_ve_cov_7pd2_sg_eval

Table 54. Vaccine Efficacy – First COVID-19 Occurrence After Dose 1, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=23040)		Placebo (N[a]=23037)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence after Dose 1						
Overall	131	8.412 (22505)	1034	8.124 (22434)	87.8	(85.3, 89.9)
Age group (years)						
12 to 15	3	0.257 (1120)	35	0.250 (1119)	91.6	(73.5, 98.4)
16 to 55	95	4.845 (12645)	693	4.669 (12626)	86.8	(83.6, 89.5)
>55	33	3.310 (8740)	306	3.204 (8689)	89.6	(85.0, 92.9)
≥65	12	1.645 (4455)	138	1.596 (4437)	91.6	(84.8, 95.7)
16 to 17	3	0.094 (373)	19	0.090 (370)	84.8	(48.4, 97.1)
16 to 25	18	0.661 (1811)	114	0.651 (1836)	84.4	(74.3, 91.1)
16 to 64	116	6.511 (16930)	861	6.278 (16878)	87.0	(84.2, 89.4)
18 to 64	113	6.417 (16557)	842	6.188 (16508)	87.1	(84.2, 89.5)
55 to 64	25	1.840 (4738)	185	1.772 (4697)	87.0	(80.2, 91.8)
65 to 74	10	1.319 (3550)	112	1.285 (3560)	91.3	(83.4, 95.9)
≥75	2	0.326 (905)	26	0.310 (877)	92.7	(70.7, 99.2)
75 to 85	2	0.324 (899)	25	0.309 (871)	92.4	(69.4, 99.1)
>85	0	0.002 (6)	1	0.002 (6)	100.0	(-3408.8, 100.0)
Sex						
Male	70	4.355 (11560)	500	4.115 (11312)	86.8	(83.0, 89.9)
Female	61	4.057 (10945)	534	4.009 (11122)	88.7	(85.3, 91.5)
Race						

Table 54. Vaccine Efficacy – First COVID-19 Occurrence After Dose 1, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=23040)		Placebo (N[a]=23037)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
White	115	6.957 (18538)	916	6.719 (18479)	87.9	(85.3, 90.1)
Black or African American	6	0.783 (2042)	53	0.770 (2063)	88.9	(74.1, 96.1)
American Indian or Alaska Native	1	0.061 (216)	7	0.055 (209)	86.9	(-1.6, 99.7)
Asian	4	0.348 (995)	26	0.337 (990)	85.1	(57.0, 96.2)
Native Hawaiian or other Pacific Islander	0	0.021 (58)	1	0.011 (32)	100.0	(-2000.0, 100.0)
Multiracial	5	0.208 (565)	25	0.190 (546)	81.8	(51.6, 94.6)
Not reported	0	0.035 (91)	6	0.042 (115)	100.0	(-0.7, 100.0)
All others[f]	10	0.672 (1925)	65	0.635 (1892)	85.5	(71.5, 93.3)
Ethnicity						
Hispanic/Latino	52	2.351 (5701)	302	2.282 (5673)	83.3	(77.5, 87.8)
Non-Hispanic/non-Latino	78	6.018 (16692)	730	5.799 (16647)	89.7	(87.0, 92.0)
Not reported	1	0.043 (112)	2	0.043 (114)	49.4	(-872.9, 99.1)
Country						
Argentina	32	1.282 (2846)	146	1.269 (2840)	78.3	(68.0, 85.7)
Brazil	14	0.554 (1430)	95	0.520 (1420)	86.1	(75.6, 92.7)
Germany	2	0.067 (246)	1	0.069 (250)	-104.5	(-11965.9, 89.4)
South Africa	0	0.128 (367)	11	0.125 (365)	100.0	(61.1, 100.0)
Turkey	3	0.048 (246)	12	0.045 (244)	76.4	(12.4, 95.7)
USA	80	6.333 (17370)	769	6.095 (17315)	90.0	(87.4, 92.1)
Baseline SARS-CoV-2 status						
Positive[g]	13	0.250 (692)	17	0.265 (736)	19.2	(-76.6, 63.9)
Positive N-binding only	2	0.192 (521)	7	0.198 (542)	70.5	(-54.7, 97.0)
Positive NAAT only	10	0.020 (66)	9	0.020 (69)	-10.5	(-207.3, 59.7)

Table 54. Vaccine Efficacy – First COVID-19 Occurrence After Dose 1, by Subgroup – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=23040)		Placebo (N[a]=23037)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Positive NAAT and N-binding	1	0.038 (105)	1	0.046 (124)	-20.5	(-9359.2, 98.5)
Negative[h]	116	8.101 (21615)	1015	7.804 (21521)	89.0	(86.6, 91.0)
Unknown	2	0.061 (198)	2	0.055 (177)	9.7	(-1145.4, 93.5)

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. All others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
g. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
h. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 30MAR2021 (22:32)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_ve_cov_pd1_sg_aai

Table 55. Baseline Charlson Comorbidities – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
Charlson Comorbidity Index Category	**BNT162b2 (30 µg) (N[a]=22026) n[b] (%)**	**Placebo (N[a]=22021) n[b] (%)**	**Total (N[a]=44047) n[b] (%)**
Subjects with any Charlson comorbidity	4628 (21.0)	4511 (20.5)	9139 (20.7)
AIDS/HIV	100 (0.5)	100 (0.5)	200 (0.5)
Any malignancy	812 (3.7)	757 (3.4)	1569 (3.6)
Cerebrovascular disease	227 (1.0)	198 (0.9)	425 (1.0)
Chronic pulmonary disease	1783 (8.1)	1775 (8.1)	3558 (8.1)
Congestive heart failure	109 (0.5)	102 (0.5)	211 (0.5)
Dementia	7 (0.0)	11 (0.0)	18 (0.0)
Diabetes with chronic complication	116 (0.5)	130 (0.6)	246 (0.6)
Diabetes without chronic complication	1700 (7.7)	1699 (7.7)	3399 (7.7)
Hemiplegia or paraplegia	15 (0.1)	25 (0.1)	40 (0.1)
Leukemia	14 (0.1)	11 (0.0)	25 (0.1)
Lymphoma	26 (0.1)	36 (0.2)	62 (0.1)
Metastatic solid tumor	4 (0.0)	3 (0.0)	7 (0.0)
Mild liver disease	152 (0.7)	115 (0.5)	267 (0.6)
Moderate or severe liver disease	2 (0.0)	3 (0.0)	5 (0.0)
Myocardial infarction	225 (1.0)	218 (1.0)	443 (1.0)
Peptic ulcer disease	63 (0.3)	84 (0.4)	147 (0.3)
Peripheral vascular disease	144 (0.7)	139 (0.6)	283 (0.6)
Renal disease	140 (0.6)	153 (0.7)	293 (0.7)
Rheumatic disease	75 (0.3)	71 (0.3)	146 (0.3)

Table 55. Baseline Charlson Comorbidities – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=22026)	Placebo (N[a]=22021)	Total (N[a]=44047)
Charlson Comorbidity Index Category	**n[b] (%)**	**n[b] (%)**	**n[b] (%)**

Abbreviation: AIDS = acquired immunodeficiency syndrome.
Note: MedDRA (v23.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic. Subjects with multiple occurrences within each category are counted only once. For "Subjects with any Charlson comorbidity," n = number of subjects reporting at least 1 occurrence of any Charlson comorbidity.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:25) Source Data: admh Table Generation: 27MAR2021 (01:28)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/admh_s002_risk_all_p3_saf

Table 56. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Comorbidity Status – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after Dose 2						
Overall	77	6.247 (20712)	850	6.003 (20713)	91.3	(89.0, 93.2)
Comorbidity						
No comorbidity	42	3.450 (11545)	449	3.322 (11577)	91.0	(87.6, 93.6)
Any comorbidity[f]	35	2.797 (9167)	401	2.681 (9136)	91.6	(88.2, 94.3)
Any malignancy	3	0.228 (770)	27	0.214 (748)	89.6	(66.2, 98.0)
Cardiovascular	3	0.172 (584)	23	0.159 (555)	88.0	(60.2, 97.7)
Chronic pulmonary disease	8	0.490 (1684)	69	0.460 (1671)	89.1	(77.3, 95.5)
Diabetes	9	0.465 (1529)	61	0.444 (1517)	85.9	(71.4, 93.8)
Obese (≥30.0 kg/m^2 [≥16 Years of age])	27	2.083 (6673)	311	2.034 (6770)	91.5	(87.4, 94.5)
Obese (≥95th percentile [12-15 Years of age])	0	0.019 (123)	3	0.016 (105)	100.0	(-104.8, 100.0)
Hypertension	15	1.481 (4900)	191	1.427 (4896)	92.4	(87.2, 95.8)
Diabetes (including gestational diabetes)	9	0.468 (1538)	63	0.447 (1531)	86.3	(72.4, 94.0)

Table 56. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Dose 2, by Comorbidity Status – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=20998)		Placebo (N[a]=21096)			
Efficacy Endpoint Subgroup	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; VE = vaccine efficacy.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Subject who had 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as subjects who had at least one of the Charlson comorbidity index category or BMI ≥30 kg/m^2 (≥16 Years of age) or BMI ≥95^{th} percentile (12-15 Years of age).
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 30MAR2021 (22:39)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adc19ef ve cov 7pd2 wo cg eval

Table 57. Vaccine Efficacy – First Severe COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)						
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)				
Efficacy Endpoint	**n1[b]**	**Surveillance Time[c] (n2[d])**	**n1[b]**	**Surveillance Time[c] (n2[d])**	**VE (%)**	**(95% CI[e])**	**Pr (VE >30% | data)[f]**
First severe COVID-19 occurrence from 7 days after Dose 2	1	6.522 (21649)	21	6.404 (21730)	95.3	(70.9, 99.9)	>0.9999

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Posterior probability (Pr) was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. Refer to the statistical analysis plan, Appendix 2, for more details.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (02:26)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_ve_sev_cov_7pd2_eval

Table 58. Vaccine Efficacy – First Severe COVID-19 Occurrence Based on CDC-Definition From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects With or Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)					
	BNT162b2 (30 µg) (N[a]=22166)		Placebo (N[a]=22320)			
Efficacy Endpoint	n1[b]	Surveillance Time[c] (n2[d])	n1[b]	Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First severe COVID-19 occurrence based on CDC-definition from 7 days after Dose 2	0	6.514 (21620)	32	6.391 (21693)	100.0	(88.0, 100.0)

Abbreviation: VE = vaccine efficacy.
a. N = number of subjects in the specified group.
b. n1 = Number of subjects meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after Dose 2 to the end of the surveillance period.
d. n2 = Number of subjects at risk for the endpoint.
e. Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:19) Source Data: adc19ef Table Generation: 27MAR2021 (02:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adc19ef_ve_sev_7pd2_cdc_eval

Table 59. Summary of Signs and Symptoms for First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
Signs and Symptoms	**BNT162b2 (30 µg) (N^a=77) n^b(%)**	**Placebo (N^a=850) n^b(%)**	**Total (N^a=927) n^b(%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	14 (18.2)	319 (37.5)	333 (35.9)
New or increased cough	36 (46.8)	556 (65.4)	592 (63.9)
New or increased shortness of breath	8 (10.4)	121 (14.2)	129 (13.9)
Chills	15 (19.5)	262 (30.8)	277 (29.9)
New or increased muscle pain	24 (31.2)	395 (46.5)	419 (45.2)
New loss of taste or smell	37 (48.1)	297 (34.9)	334 (36.0)
Sore throat	29 (37.7)	329 (38.7)	358 (38.6)
Diarrhea	11 (14.3)	136 (16.0)	147 (15.9)
Vomiting	3 (3.9)	32 (3.8)	35 (3.8)
Subjects with specific number of signs and symptoms			
1	28 (36.4)	178 (20.9)	206 (22.2)
2	22 (28.6)	233 (27.4)	255 (27.5)
3	15 (19.5)	177 (20.8)	192 (20.7)
4	6 (7.8)	132 (15.5)	138 (14.9)
5	2 (2.6)	70 (8.2)	72 (7.8)
>5	4 (5.2)	60 (7.1)	64 (6.9)

Table 59. Summary of Signs and Symptoms for First COVID-19 Occurrence From 7 Days After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Subjects Without Evidence of Infection Prior to 7 Days After Dose 2 – Evaluable Efficacy (7 Days) Population

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N^a=77)	Placebo (N^a=850)	Total (N^a=927)
Signs and Symptoms	**n^b(%)**	**n^b(%)**	**n^b(%)**

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-COV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days after Dose 2 were included in the analysis.
a. N = number of subjects with first COVID-19 occurrence from 7 days after dose 2 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 27MAR2021 (02:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adsympt symp cov 7d2 wo eval

Table 60. Summary of Signs and Symptoms for First COVID-19 Occurrence After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
Signs and Symptoms	**BNT162b2 (30 µg) (N^a=131) n^b(%)**	**Placebo (N^a=1034) n^b(%)**	**Total (N^a=1165) n^b(%)**
Subjects with specific signs and symptoms of COVID-19			
Fever	33 (25.2)	393 (38.0)	426 (36.6)
New or increased cough	61 (46.6)	668 (64.6)	729 (62.6)
New or increased shortness of breath	15 (11.5)	150 (14.5)	165 (14.2)
Chills	25 (19.1)	311 (30.1)	336 (28.8)
New or increased muscle pain	42 (32.1)	468 (45.3)	510 (43.8)
New loss of taste or smell	58 (44.3)	370 (35.8)	428 (36.7)
Sore throat	50 (38.2)	403 (39.0)	453 (38.9)
Diarrhea	16 (12.2)	157 (15.2)	173 (14.8)
Vomiting	7 (5.3)	38 (3.7)	45 (3.9)
Subjects with specific number of signs and symptoms			
1	47 (35.9)	215 (20.8)	262 (22.5)
2	36 (27.5)	288 (27.9)	324 (27.8)
3	23 (17.6)	221 (21.4)	244 (20.9)
4	14 (10.7)	149 (14.4)	163 (14.0)
5	5 (3.8)	93 (9.0)	98 (8.4)
>5	6 (4.6)	68 (6.6)	74 (6.4)

a. N = number of subjects with first COVID-19 occurrence after dose 1 in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 27MAR2021 (02:27)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adsympt symp cov d1 aai

Table 61. Summary of Signs and Symptoms for First Severe COVID-19 Occurrence After Dose 1 – Blinded Placebo-Controlled Follow-up Period – Dose 1 All-Available Efficacy Population

	Vaccine Group (as Randomized)		
Signs and Symptoms	**BNT162b2 (30 µg) (N^a=1) n^b(%)**	**Placebo (N^a=30) n^b(%)**	**Total (N^a=31) n^b(%)**
Subjects with specific signs and symptoms of severe COVID-19			
Clinical signs at rest indicative of severe systemic illness (RR ≥30 breaths per minute, HR ≥125 beats per minute, SpO_2 ≤93% on room air at sea level, or PaO_2/FiO_2 <300 mm Hg)	1 (100.0)	19 (63.3)	20 (64.5)
Respiratory failure (defined as needing high-flow oxygen, noninvasive ventilation, mechanical ventilation, or ECMO)	0 (0.0)	14 (46.7)	14 (45.2)
Evidence of shock (SBP <90 mm Hg, DBP <60 mm Hg, or requiring vasopressors)	0 (0.0)	3 (10.0)	3 (9.7)
Significant acute renal, hepatic, or neurologic dysfunction	0 (0.0)	2 (6.7)	2 (6.5)
Admission to an ICU	0 (0.0)	8 (26.7)	8 (25.8)
Subjects with specific number of signs and symptoms			
1	1 (100.0)	20 (66.7)	21 (67.7)
2	0 (0.0)	4 (13.3)	4 (12.9)
3	0 (0.0)	5 (16.7)	5 (16.1)
5	0 (0.0)	1 (3.3)	1 (3.2)

Abbreviations: DBP = diastolic blood pressure; ECMO = extracorporeal membrane oxygenation; FiO_2 = fraction of inspired oxygen; HR = heart rate; ICU = intensive care unit; PaO_2 = partial pressure of oxygen, arterial; RR = respiratory rate; SBP = systolic blood pressure; SpO_2 = oxygen saturation as measured by pulse oximetry.

a. N = number of subjects with first severe COVID-19 occurrence after dose 1 in the specified group. This value is used as the denominator for the percentage calculations.

b. n = Number of subjects with the specific criteria meeting the definition. A subject can have more than 1 symptom.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adc19ef Table Generation: 27MAR2021 (20:27) (Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adsympt symp sev cov d1 aai

Study C4591001 – Phase 1 Immunogenicity

Table 62. Summary of Geometric Mean Titers/Concentrations – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		18-55 Years of Age				65-85 Years of Age			
		BNT162b2 (30 µg)		Placebo		BNT162b2 (30 µg)		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	12	10.0 (10.0, 10.0)	2	10.0 (10.0, 10.0)	11	10.0 (10.0, 10.0)	3	10.0 (10.0, 10.0)
	1/Day 21	12	29.1 (14.2, 59.6)	2	10.0 (10.0, 10.0)	11	16.8 (10.9, 25.8)	3	10.0 (10.0, 10.0)
	2/1 Month	11	179.2 (102.3, 313.8)	2	10.0 (10.0, 10.0)	11	151.6 (58.6, 392.1)	2	10.0 (10.0, 10.0)
	2/6 Months	10	54.7 (24.7, 121.1)	0	NE (NE, NE)	11	29.0 (19.4, 43.5)	0	NE (NE, NE)
S1-binding IgG level assay (U/mL)	1/Prevax	12	0.6 (0.6, 0.6)	2	0.6 (0.6, 0.6)	11	0.6 (0.6, 0.6)	3	0.9 (0.2, 4.9)
	1/Day 21	12	565.5 (372.5, 858.5)	2	0.6 (0.6, 0.6)	11	352.2 (160.1, 775.2)	3	1.0 (0.1, 6.9)
	2/1 Month	11	5925.6 (4457.2, 7877.7)	2	0.6 (0.6, 0.6)	11	4835.4 (2756.1, 8483.3)	2	1.4 (0.0, 47501.5)
	2/6 Months	10	960.8 (483.8, 1908.1)	0	NE (NE, NE)	11	559.6 (363.0, 862.8)	0	NE (NE, NE)

Table 62. Summary of Geometric Mean Titers/Concentrations – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		18-55 Years of Age				65-85 Years of Age			
		BNT162b2 (30 µg)		Placebo		BNT162b2 (30 µg)		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NE = not estimable; NT50 = 50% neutralizing titer; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: The Dose 1 evaluable population was used for time points after Dose 1 and before Dose 2 and the Dose 2 evaluable population was used for time points after Dose 2.
Note: Blood samples from the Day 7 and Day 14 post–Dose 2 visits are not included since these samples were not retested with the 6-month post–Dose 2 samples.
a. Protocol-specified timing for blood sample collection.
b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentrations and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:57)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adva_s001_gm_b2_eval_p1

Table 63. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		18-55 Years of Age				65-85 Years of Age			
		BNT162b2 (30 µg)		Placebo		BNT162b2 (30 µg)		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Day 21	12	2.9 (1.4, 6.0)	2	1.0 (1.0, 1.0)	11	1.7 (1.1, 2.6)	3	1.0 (1.0, 1.0)
	2/1 Month	11	17.9 (10.2, 31.4)	2	1.0 (1.0, 1.0)	11	15.2 (5.9, 39.2)	2	1.0 (1.0, 1.0)
	2/6 Months	10	5.5 (2.5, 12.1)	0	NE (NE, NE)	11	2.9 (1.9, 4.3)	0	NE (NE, NE)
S1-binding IgG level assay (U/mL)	1/Day 21	12	893.0 (588.2, 1355.7)	2	1.0 (1.0, 1.0)	11	556.3 (252.7, 1224.2)	3	1.1 (0.8, 1.4)
	2/1 Month	11	9357.4 (7038.6, 12440.1)	2	1.0 (1.0, 1.0)	11	7635.8 (4352.3, 13396.5)	2	1.3 (0.1, 26.9)
	2/6 Months	10	1517.2 (764.0, 3013.2)	0	NE (NE, NE)	11	883.7 (573.2, 1362.5)	0	NE (NE, NE)

Table 63. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		18-55 Years of Age				65-85 Years of Age			
		BNT162b2 (30 µg)		Placebo		BNT162b2 (30 µg)		Placebo	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NE = not estimable; NT50 = 50% neutralizing titer; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: The Dose 1 evaluable population was used for time points after Dose 1 and before Dose 2 and the Dose 2 evaluable population was used for time points after Dose 2.

Note: Blood samples from the Day 7 and Day 14 post–Dose 2 visits are not included since these samples were not retested with the 6-month post–Dose 2 samples.

a. Protocol-specified timing for blood sample collection.

b. n = Number of subjects with valid and determinate assay results for the specified assay both before vaccination and at the given dose/sampling time point.

c. GMFRs and the corresponding 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.

PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:57)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adva_s002_gmfr_b2_eval_p1

Table 64. Number (%) of Subjects Achieving a ⩾4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		18-55 Years of Age				65-85 Years of Age			
		BNT162b2 (30 µg)		Placebo		BNT162b2 (30 µg)		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Day 21	12	6 (50.0) (21.1, 78.9)	2	0 (0.0) (0.0, 84.2)	11	1 (9.1) (0.2, 41.3)	3	0 (0.0) (0.0, 70.8)
	2/1 Month	11	11 (100.0) (71.5, 100.0)	2	0 (0.0) (0.0, 84.2)	11	9 (81.8) (48.2, 97.7)	2	0 (0.0) (0.0, 84.2)
	2/6 Months	10	6 (60.0) (26.2, 87.8)	0	0 (NE) (NE, NE)	11	3 (27.3) (6.0, 61.0)	0	0 (NE) (NE, NE)
S1-binding IgG level assay (U/mL)	1/Day 21	12	12 (100.0) (73.5, 100.0)	2	0 (0.0) (0.0, 84.2)	11	11 (100.0) (71.5, 100.0)	3	0 (0.0) (0.0, 70.8)
	2/1 Month	11	11 (100.0) (71.5, 100.0)	2	0 (0.0) (0.0, 84.2)	11	11 (100.0) (71.5, 100.0)	2	0 (0.0) (0.0, 84.2)
	2/6 Months	10	10 (100.0) (69.2, 100.0)	0	0 (NE) (NE, NE)	11	11 (100.0) (71.5, 100.0)	0	0 (NE) (NE, NE)

Table 64. Number (%) of Subjects Achieving a ⩾4-Fold Rise From Before Vaccination to Each Subsequent Time Point – Phase 1, 2 Doses, 21 Days Apart – BNT162b2 (30 µg)/Placebo – Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		18-55 Years of Age				65-85 Years of Age			
		BNT162b2 (30 µg)		Placebo		BNT162b2 (30 µg)		Placebo	
Assay	Dose/ Sampling Time Point[a]	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])	N[b]	n[c] (%) (95% CI[d])

Abbreviations: IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NE = not estimable; NT50 = 50% neutralizing titer;
S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.
Note: The Dose 1 evaluable population was used for time points after Dose 1 and before Dose 2 and the Dose 2 evaluable population was used for time points after Dose 2.
Note: Blood samples from the Day 7 and Day 14 post–Dose 2 visits are not included since these samples were not retested with the 6-month post–Dose 2 samples.
a. Protocol-specified timing for blood sample collection.
b. N = number of subjects with valid and determinate assay results for the specified assay both before vaccination and at the given dose/sampling time point. These values are the denominators for the percentage calculations.
c. n = Number of subjects with ≥4-fold rise from before vaccination for the given assay at the given dose/sampling time point.
d. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:25) Source Data: adva Table Generation: 27MAR2021 (04:57)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2 unblinded/C4591001 BLA/adva s003 fr4 b2 eval p1

Study C4591001 – Phase 2 Immunogenicity

Table 65. Immunogenicity Populations – Phase 2

	Vaccine Group (as Randomized)				
	BNT162b2 (30 µg)			Placebo	
	18-55 Years n[a] (%)	56-85 Years n[a] (%)	18-85 Years n[a] (%)	18-85 Years n[a] (%)	Total n[a] (%)
Randomized[b]	88 (100.0)	92 (100.0)	180 (100.0)	180 (100.0)	360 (100.0)
Dose 2 all-available immunogenicity population	85 (96.6)	91 (98.9)	176 (97.8)	176 (97.8)	352 (97.8)
Subjects excluded from Dose 2 all-available immunogenicity population	3 (3.4)	1 (1.1)	4 (2.2)	4 (2.2)	8 (2.2)
Reason for exclusion					
Did not receive Dose 2	1 (1.1)	0	1 (0.6)	0	1 (0.3)
Did not have at least 1 valid and determinate immunogenicity result after Dose 2	2 (2.3)	1 (1.1)	3 (1.7)	4 (2.2)	7 (1.9)
Dose 2 evaluable immunogenicity population	80 (90.9)	89 (96.7)	169 (93.9)	167 (92.8)	336 (93.3)
Subjects excluded from Dose 2 evaluable immunogenicity population	8 (9.1)	3 (3.3)	11 (6.1)	13 (7.2)	24 (6.7)
Reason for exclusion[c]					
Did not receive 2 doses of the vaccine to which they are randomly assigned	1 (1.1)	0	1 (0.6)	0	1 (0.3)
Did not receive Dose 2 within 19-42 days after Dose 1	0	1 (1.1)	1 (0.6)	4 (2.2)	5 (1.4)
Did not have at least 1 valid and determinate immunogenicity result after Dose 2	2 (2.3)	1 (1.1)	3 (1.7)	4 (2.2)	7 (1.9)
Did not have blood collection within 28-42 days after Dose 2	5 (5.7)	2 (2.2)	7 (3.9)	7 (3.9)	14 (3.9)
Had important protocol deviation(s) as determined by the clinician	0	0	0	1 (0.6)	1 (0.3)

a. n = Number of subjects with the specified characteristic, or the total sample.
b. These values are the denominators for the percentage calculations.
c. Subjects may have been excluded for more than 1 reason.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adsl Table Generation: 12NOV2020 (02:19)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adva_s008_imm_pop_p2

Table 66. Demographic Characteristics – Phase 2 – Dose 2 Evaluable Immunogenicity Population

	Vaccine Group (as Randomized)				
	BNT162b2 (30 µg)			Placebo	
	18-55 Years (N[a]=80) n[b] (%)	56-85 Years (N[a]=89) n[b] (%)	18-85 Years (N[a]=169) n[b] (%)	18-85 Years (N[a]=167) n[b] (%)	Total (N[a]=336) n[b] (%)
Sex					
Male	41 (51.3)	49 (55.1)	90 (53.3)	85 (50.9)	175 (52.1)
Female	39 (48.8)	40 (44.9)	79 (46.7)	82 (49.1)	161 (47.9)
Race					
White	64 (80.0)	83 (93.3)	147 (87.0)	138 (82.6)	285 (84.8)
Black or African American	9 (11.3)	3 (3.4)	12 (7.1)	22 (13.2)	34 (10.1)
American Indian or Alaska native	0	1 (1.1)	1 (0.6)	1 (0.6)	2 (0.6)
Asian	5 (6.3)	0	5 (3.0)	4 (2.4)	9 (2.7)
Multiracial	1 (1.3)	1 (1.1)	2 (1.2)	1 (0.6)	3 (0.9)
Not reported	1 (1.3)	1 (1.1)	2 (1.2)	1 (0.6)	3 (0.9)
Ethnicity					
Hispanic/Latino	13 (16.3)	3 (3.4)	16 (9.5)	20 (12.0)	36 (10.7)
Non-Hispanic/non-Latino	66 (82.5)	85 (95.5)	151 (89.3)	145 (86.8)	296 (88.1)
Not reported	1 (1.3)	1 (1.1)	2 (1.2)	2 (1.2)	4 (1.2)
Age at vaccination (years)					
Mean (SD)	41.0 (10.47)	65.9 (6.64)	54.1 (15.18)	51.6 (15.92)	52.8 (15.58)
Median	43.5	65.0	56.0	56.0	56.0
Min, max	(18, 55)	(56, 85)	(18, 85)	(20, 83)	(18, 85)

a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adsl Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adsl_s005_demo_p2_d2_eval

Table 67. Summary of Geometric Mean Titers/Concentrations – Phase 2 – Dose 2 Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)						Placebo	
		18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])	n[b]	GMT/GMC[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	80	10.1 (9.9, 10.4)	88	10.3 (9.9, 10.7)	168	10.2 (10.0, 10.5)	167	10.4 (10.0, 10.9)
	2/1 Month	80	399.4 (342.1, 466.2)	87	255.0 (205.7, 316.0)	167	316.1 (275.6, 362.6)	167	10.6 (10.0, 11.3)
S1-binding IgG level assay (U/mL)	1/Prevax	80	0.8 (0.6, 0.9)	88	0.8 (0.7, 1.1)	168	0.8 (0.7, 0.9)	167	0.8 (0.7, 0.9)
	2/1 Month	80	7122.8 (6217.4, 8160.2)	87	3960.7 (3007.2, 5216.6)	167	5246.5 (4460.3, 6171.4)	167	1.0 (0.8, 1.2)

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

a. Protocol-specified timing for blood sample collection.

b. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.

c. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentrations and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.

PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adva_s001_gm_p2_eval

Table 68. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point – Phase 2 – Dose 2 Evaluable Immunogenicity Population

		Vaccine Group (as Randomized)							
		BNT162b2 (30 µg)						Placebo	
		18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])	n[b]	GMFR[c] (95% CI[c])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	80	39.4 (34.0, 45.6)	86	24.9 (20.2, 30.9)	166	31.1 (27.2, 35.5)	167	1.0 (1.0, 1.1)
S1-binding IgG level assay (U/mL)	2/1 Month	80	9167.2 (7452.8, 11276.0)	86	4975.5 (3655.9, 6771.4)	166	6679.4 (5511.6, 8094.7)	167	1.2 (1.0, 1.4)

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NT50 = 50% neutralizing titer; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

a. Protocol-specified timing for blood sample collection.

b. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.

c. GMFRs and the corresponding 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.

PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (00:12)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adva_s001_gmfr_p2_eval

Table 69. Summary of Geometric Mean Titers/Concentrations by Baseline SARS-CoV-2 Status – Phase 2 – Dose 2 Evaluable Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)						Placebo	
			18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	1/Prevax	POS	1	31.0 (NE, NE)	4	18.1 (5.6, 58.2)	5	20.2 (8.7, 46.9)	4	38.4 (5.2, 282.5)
		NEG	79	10.0 (10.0, 10.0)	83	10.0 (10.0, 10.0)	162	10.0 (10.0, 10.0)	162	10.1 (9.9, 10.2)
	2/1 Month	POS	1	4233.0 (NE, NE)	2	3469.9 (0.1, 9.247E7)	3	3707.6 (495.5, 27743.3)	4	53.2 (5.5, 515.3)
		NEG	79	387.6 (335.4, 448.0)	84	237.7 (194.4, 290.7)	163	301.3 (264.7, 342.9)	162	10.2 (9.8, 10.7)
S1-binding IgG level assay (U/mL)	1/Prevax	POS	1	246.1 (NE, NE)	4	36.9 (0.5, 2848.7)	5	53.9 (2.4, 1222.0)	4	153.0 (12.7, 1844.4)
		NEG	79	0.7 (0.6, 0.8)	83	0.7 (0.6, 0.8)	162	0.7 (0.7, 0.8)	162	0.7 (0.7, 0.8)
	2/1 Month	POS	1	45474.1 (NE, NE)	2	23255.3 (106.2, 5.092E6)	3	29080.6 (6983.3, 121100.2)	4	144.4 (9.5, 2189.7)
		NEG	79	6957.6 (6113.5, 7918.3)	84	3759.2 (2847.3, 4963.2)	163	5066.1 (4308.9, 5956.5)	162	0.8 (0.7, 1.0)

Table 69. Summary of Geometric Mean Titers/Concentrations by Baseline SARS-CoV-2 Status – Phase 2 – Dose 2 Evaluable Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)						Placebo	
			18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])	n[c]	GMT/GMC[d] (95% CI[d])

Abbreviations: GMC = geometric mean concentration; GMT = geometric mean titer; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; NE = not estimable; NEG = negative; NT50 = 50% neutralizing titer; POS = positive;
S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Subjects whose baseline SARS-CoV-2 status cannot be determined due to missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
a. Protocol-specified timing for blood sample collection.
b. Positive = Positive N-binding antibody at Visit 1, or positive NAAT at Visit 1, or had medical history of COVID-19. Negative = Negative N-binding antibody at Visit 1 and negative NAAT at Visit 1.
c. n = Number of subjects with valid and determinate assay results for the specified assay at the given dose/sampling time point.
d. GMTs, GMCs, and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of the titers or concentration and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ.
PFIZER CONFIDENTIAL SDTM Creation: 02NOV2020 (19:23) Source Data: adva Table Generation: 12NOV2020 (04:18)
(Cutoff Date: 12OCT2020, Snapshot Date: 02NOV2020) Output File: ./nda2_unblinded/C4591001_IA_P2_Serology/adva_s001_gm_lt_p2_eval

Table 70. Summary of Geometric Mean Fold Rises From Before Vaccination to Each Subsequent Time Point by Baseline SARS-CoV-2 Status – Phase 2 – Dose 2 Evaluable Immunogenicity Population

			Vaccine Group (as Randomized)							
			BNT162b2 (30 µg)						Placebo	
			18-55 Years		56-85 Years		18-85 Years		18-85 Years	
Assay	Dose/ Sampling Time Point[a]	Baseline SARS-CoV-2 Status[b]	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])	n[c]	GMFR[d] (95% CI[d])
SARS-CoV-2 neutralization assay - NT50 (titer)	2/1 Month	POS	1	136.5 (NE, NE)	2	163.6 (0.0, 6.156E10)	3	154.0 (3.2, 7377.7)	4	1.4 (0.9, 2.0)
		NEG	79	38.8 (33.5, 44.8)	83	23.6 (19.3, 29.0)	162	30.1 (26.4, 34.3)	162	1.0 (1.0, 1.1)
S1-binding IgG level assay (U/mL)	2/1 Month	POS	1	184.7 (NE, NE)	2	191.8 (0.0, 1.993E6)	3	189.4 (31.0, 1156.2)	4	0.9 (0.6, 1.5)
		NEG	79	9631.6 (8008.6, 11583.6)	83	5312.3 (3946.8, 7150.4)	162	7100.7 (5925.1, 8509.7)	162	1.2 (1.0, 1.4)

Abbreviations: GMFR = geometric mean fold rise; IgG = immunoglobulin G; LLOQ = lower limit of quantitation; NAAT = nucleic acid amplification test; NE = not estimable; NEG = negative; NT50 = 50% neutralizing titer; POS = positive; S1 = spike protein S1 subunit; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Subjects whose baseline SARS-CoV-2 status cannot be determined due to missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.

a. Protocol-specified timing for blood sample collection.

b. Positive = Positive N-binding antibody at Visit 1, or positive NAAT at Visit 1, or had medical history of COVID-19. Negative = Negative N-binding antibody at Visit 1 and negative NAAT at Visit 1.

c. n = Number of subjects with valid and determinate assay results for the specified assay at both prevaccination and the given dose/sampling time point.

d. GMFRs and 2-sided 95% CIs were calculated by exponentiating the mean logarithm of fold rises and the corresponding CIs (based on the Student t distribution). Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.

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2.7.4 SUMMARY OF CLINICAL SAFETY

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ABBREVIATIONS

Abbreviation	Definition
ADR	adverse drug reaction
AE	adverse event
AESI	adverse events of special interest
ALT	alanine aminotransferase
AST	aspartate aminotransferase
BLA	Biologics License Application
BMI	body mass index
BUN	blood urea nitrogen
C4591001 Efficacy Final Analysis Interim CSR	Study C4591001 interim clinical study report including prespecified final analysis of efficacy and available immunogenicity and safety data up to data cutoff date of 14 November 2020
C4591001 6-Month Update Interim CSR	Study C4591001 interim clinical study report including updated efficacy, immunogenicity, and safety up to 6 months after Dose 2 up to data cutoff date of 13 March 2021
CBER	(US Food and Drug Administration) Center for Biologics Evaluation and Research
CDC	(US) Centers for Disease Control and Prevention
CDS	Core Data Sheet
CI	confidence interval
CO	Clinical Overview
COVID-19	Coronavirus Disease 2019
CRF	case report form
CRP	c-reactive protein
CSR	Clinical Study Report
CTA	Clinical Trial Application
DART	Developmental and Reproductive Toxicology
DMC	(US Study C4591001) Data Monitoring Committee
ECG	electrocardiogram
EoS	end of study
FDA	(US) Food and Drug Administration
FIH	first-in-human
FU	follow-up
HBV	hepatitis B virus

Abbreviation	Definition
HBc Abs	hepatitis B core antibodies
HBsAg	hepatitis B surface antigen
HCV	hepatitis C virus
HCV Abs	hepatitis C virus antibodies
HIV	human immunodeficiency virus
HLT	high level term
ICD	informed consent document
IgG	immunoglobulin G
IgM	immunoglobulin M
IM	intramuscular(ly)
IND	Investigational New Drug
IR	incidence rate
IRC	(US Study C4591001) Internal Review Committee
IRT	interactive response technology
IV	intravenous
IWR	interactive Web-based response
LLN	lower limit of normal
MedDRA	Medical Dictionary for Regulatory Activities
MIS-C	multisystem inflammatory syndrome in children
NAAT	nucleic acid amplification testing
NHP	non-human primate
P/B	prime/boost: dosing regimen of a priming immunization and a booster immunization
PCR	polymerase chain reaction
PT	Preferred Term
PY	person-years
RNA	ribonucleic acid
SAF	Safety Set
SAP	statistical analysis plan
SAE	serious adverse event
SARS-CoV-2	SARS Coronavirus-2; virus causing the disease COVID-19
SCE	Summary of Clinical Efficacy
SCS	Summary of Clinical Safety

Abbreviation	Definition
SIRVA	shoulder injury related to vaccine administration
SMQ	Standardised MedDRA Queries
SoA	schedule of activities
SOC	System Organ Class
SRC	Safety Review Committee
US	United States
VOC	variant of concern
TEAE	treatment-emergent adverse events

2.7.4. SUMMARY OF CLINICAL SAFETY

This SCS presents the safety and tolerability data for BNT162b2. BNT162b2 (BioNTech code number BNT162, Pfizer code number PF-07302048) is an investigational vaccine developed by BioNTech and Pfizer intended to prevent COVID-19, which is caused by SARS-CoV-2. The data are derived from the pivotal registration study, Phase 1/2/3 Study C4591001 (BNT162-02), conducted under IND 19736. Supporting data are presented from the FIH, dose level-finding, Phase 1/2 Study BNT162-01 conducted in Germany (which is not being conducted under the IND, but under a CTA).

The proposed indication and dosing administration for BNT162b2 (30 µg) is:

- Proposed indication: Active immunization against COVID-19 disease caused by SARS-CoV-2 virus in individuals ≥16 years of age.

- Proposed dosing administration: single 0.3 mL intramuscular (IM) dose followed by a second 0.3 mL dose 21 days later.

Nonclinical studies in this development program are summarized in the CO (Module 2.5 Section 2.5.1.2.3.1).

Phase 1 of Study C4591001 evaluated 2 vaccine candidates, BNT162b1 and BNT162b2. These 2 candidates were selected based on safety and immunogenicity data from Study BNT162-01 (which is evaluating four vaccine candidates). Phase 1 of Study C4591001 comprised of dose-level finding evaluations of the 2 selected vaccine candidates; multiple dose levels were evaluated, including some that corresponded to those evaluated in Study BNT162-01 (BNT162b1 and BNT162b2 at 10 µg, 20 µg, and 30 µg). Study vaccine was administered using the same 2-dose regimen as in Study BNT162-01 (21 days apart). Dose levels were administered first to an 18 to 55 years of age cohort, then to a 65 to 85 years of age cohort.

Evaluation of Phase 1 safety and immunogenicity results led to the selection of a single candidate. Both constructs were safe and well tolerated (except for BNT162b1 at 100 µg). Given that the reactogenicity profile for BNT162b2 was more favorable than BNT162b1 in both younger and older adults with similar immunogenicity results, and with non-human primate (NHP) challenge studies showing that BNT162b2 led to earlier virus clearance and no evidence of virus in the lung, BNT162b2 at the 30 µg dose level was selected and advanced into the Phase 2/3 expanded cohort and efficacy evaluation.

Phase 2 of the study (for which enrollment has completed) comprised the evaluation of safety and immunogenicity data for the first 360 participants (180 from active vaccine group and 180 from placebo group) that entered the study after completion of Phase 1.

The Phase 3 part of the study is ongoing, and participants (including the first 360 participants from Phase 2) are continuing to be evaluated at the time of this SCS. The minimum age for inclusion in Phase 3 was lowered from 18 to 16 years of age after the approval of Study C4591001 protocol amendment 6 and from 16 to 12 years of age after the approval of

Study C4591001 protocol amendment 7. As such, Phase 3 has completed enrollment of adolescents ≥12 years of age (stratified as 12-15, 16-55, or >55 years of age).

C4591001 protocol amendment 10 allowed participants ≥16 years of age who originally received placebo the opportunity to receive BNT162b2 following local or national recommendations, or following completion of the active safety surveillance period. On 14 December 2020, the process of disclosing vaccine assignments for all trial participants ≥16 years of age began. Hence, for each trial participant, there are 2 periods in the study: enrollment into the observer-blind phase until the date of vaccine disclosure and the time in the study after disclosure. Participants who originally were randomized to BNT162b2, are continuing to be followed for safety as specified in the protocol. The safety data for participants who originally were randomized to and received placebo prior to disclosure of vaccine assignment are standard blinded data that contribute to controlled assessment of safety compared to individuals who randomly assigned to BNT162b2. After vaccine treatment disclosure and the administration of BNT162b2, the placebo participants can no longer be used for direct comparison with those who originally were randomized to BNT162b2. Given that individuals were unblinded on different days after 14 December 2020, the analysis of the observer-blinded, placebo-controlled portion of the study as well as the open-label portion displays rates of AEs adjusted for exposure time.

Safety data for Phase 3 of Study C4591001, based on the data cutoff date of 13 March 2021, presented in this SCS include:

- Blinded placebo-controlled period: Dose 1 to 1 month after Dose 2 and to unblinding date:
    - Phase 1 participants randomized to BNT162b2 30 μg (up to ~6 months after Dose 2)
    - Phase 2/3 ≥16 years of age participants including HIV+ subset (up to ~6 months after Dose 2)
- Open-label observational period: from time of unblinding to data cutoff date:
    - Phase 2/3 participants ≥16 years of age originally randomized to BNT162b2
    - Phase 2/3 participants ≥16 years of age originally randomized to placebo who then received BNT162b2
- Cumulative follow-up from Dose 1 to 6 months after Dose 2: Phase 2/3 participants originally randomized to BNT162b2 (inclusive of blinded data and open-label data) comprised of at least 3000 in each age group (16 to 55 years of age, >55 years of age)

Overall, this SCS summarizes the safety data obtained from Study C4591001 (Phases 1 to 3) and Study BNT162-01 (Phase 1) to support registration of BNT162b2. The following data are presented in this document by study and phase:

- The overall safety evaluation plans for each study (including objectives, endpoints, methods, and criteria for narratives) are presented in Section 2.7.4.1.1.
- Data regarding exposure, disposition, and study population characteristics are presented in Section 2.7.4.1.2.
- The results of safety evaluations are presented in Section 2.7.4.2. These evaluations include:
    - Reactogenicity (local reactions and systemic events)
    - AEs (by SOC, related, immediate, severe, deaths, SAEs, and withdrawals due to AEs)
    - Other safety assessments
    - Narratives
- Safety in special groups and situations is presented in Section 2.7.4.3.
- Post-Authorization Data in Section 2.7.4.4.
- Overall conclusions are stated in Section 2.7.4.5.

The safety results presented in this SCS demonstrate that BNT162b2 is both safe and well-tolerated when administered on a 2-dose schedule (21 days apart) in individuals ≥16 years of age. The cutoff dates for safety data presented in this SCS are shown in Table 1.

Table 1. Cutoff Dates for Safety Data Presented in Summary of Clinical Safety

Phase/Study	Safety Data Available (Through)	N (number randomized)	Age (years of age)	Data Cutoff Date
Study BNT162-01	Reactogenicity: up to 7 days after each dose AEs: 1 month post-dose 2	216	Younger: 18 to 55 Older: 56 to 85	23 Oct 2020
Phase 1 (Study C4591001)	Reactogenicity: up to 7 days after each dose AEs: 1 month post-dose 2 SAEs: through the data cutoff date Laboratory Data: 7 days post-dose 2 BNT162b1 100 µg dose level (younger age group): 3 weeks post-dose 1 or to before Dose 2 (based on the data cutoff date)	195	Younger: 18 to 55 Older: 65 to 85	24 Aug 2020
	Long-term follow-up for AEs & SAEs for BNT162b2 30 µg group only: • From 1 month post-dose 2 to unblinding date (approximately 6 months post-dose 2)	30		13 Mar 2021
Phase 2 (Study C4591001)	Reactogenicity: up to 7 days after each dose AEs/SAEs: 7 days post-dose 2[a]	360[b]	18 to 85 • Younger: 18 to 55 • Older: 56 to 85	02 Sep 2020

Table 1. Cutoff Dates for Safety Data Presented in Summary of Clinical Safety

Phase/Study	Safety Data Available (Through)	N (number randomized)	Age (years of age)	Data Cutoff Date
Phase 3 (Study C4591001)	Reactogenicity: up to 7 days after each dose	9839[c]	Younger: 16 to 55 Older: >55	13 Mar 2021
	Blinded AEs/SAEs: • 1 month post-dose 2 (including HIV positive subset) • up to unblinding date (including HIV positive subset)[d]	43,847		
	Open-label AEs/SAEs (participants originally randomized to BNT162b2): • Date of unblinding to data cutoff	20,309		
	Blinded and open-label AEs/SAEs • BNT162b2 participants with at least 6 months follow-up post-dose 2	12,006		
	Open-label AEs/SAEs (participants originally randomized to placebo but were vaccinated with BNT162b2 after treatment disclosure): • Date of BNT162b2 vaccination (after treatment disclosure) to data cutoff	19,525		

a. Adverse event results beyond 7 days after Dose 2, as defined in the protocol objectives, are included in Phase 3 analyses.
b. The 360 Phase 2 participants are included in the Phase 3 analyses.
c. This subset of 9839 participants (which includes Phase 2 participants) completed the e-diary for reporting local reactions and systemic events.
d. Up to ~6 months after Dose 2

2.7.4.1. Exposure to BNT162b2

2.7.4.1.1. Overall Safety Evaluation Plan and Narratives of Safety Studies

The overall safety evaluation plan for Study BNT162-01 is presented in Section 2.7.4.1.1.1.

The overall safety evaluation plan for Study C4591001 is presented in Section 2.7.4.1.1.2.

Study BNT162-01 and Study C4591001 use different designs and safety data collection methods and definitions. For these reasons, safety data from Study BNT162-01 and Study C4591001 will not be pooled for analysis. As BNT162b1 and BNT162b2 were the 2 vaccine candidates evaluated in Phase 1 of the C4591001 study, only these 2 constructs will be discussed in the SCS as it relates to how the final candidate and dose level was determined.

2.7.4.1.1.1. Phase 1/2 Study BNT162-01

Safety and immunogenicity data from Study BNT162-01 are summarized in this BLA in support of the larger dataset from Phase 1/2/3 registration Study C4591001.

2.7.4.1.1.1.1. Safety Objectives and Endpoints (Study BNT162-01)

The safety objectives and endpoints for Study BNT162-01 are presented in Table 2.

Table 2. Safety Objectives and Endpoints for Study BNT162-01[a]

Objective	Endpoint
Primary:	

To describe the safety and tolerability profiles of prophylactic BNT162 vaccines in healthy adults after single dose (prime only) or P/B immunization.	• Solicited local reactions at the injection site (pain, tenderness, erythema/redness, induration/swelling) recorded up to 7±1 day after each immunization.
	• Solicited systemic reactions (nausea, vomiting, diarrhea, headache, fatigue, myalgia, arthralgia, chills, loss of appetite, malaise, and fever) recorded up to 7±1 day after each immunization.
	• The proportion of subjects with at least 1 unsolicited TEAE:
	  • For BNT162a1, BNT162b1, BNT162b2, and BNT162c2 (P/B): occurring up to 21±2 d after the prime immunization and 28±4 d after the boost immunization.
	  • For BNT162c2 (single dose): The proportion of subjects with at least 1 unsolicited TEAE occurring up to 28±4 days after the immunization.

a. Only BNT162b1 and BNT162b2 are discussed in this SCS.

2.7.4.1.1.1.2. Overall Design (Study BNT162-01)

Details regarding the study design of Study BNT162-01 are presented in the study protocol (Module 5.3.5.1 BNT162-01 Protocol Section 4).

German Study BNT162-01 is the ongoing, FIH, Phase 1/2 dose level-finding study, in which healthy adults aged 18 to 55 or 56 to 85 all receive active vaccine (open-label and non-randomized). Four vaccine candidates from 3 different RNA platforms are being tested. The trial has two parts: a dose-finding part (Part A) and a part dedicated to recruiting expansion cohorts with dose levels which were selected from data generated in Part A (Part B). The study schema for Part A is presented in Appendix A (Section 2.7.4.6.1).

BNT162b1 and BNT162b2 were administered in a prime/boost two-dose regimen separated by approximately 21 days:

- BNT162b1 (dose levels: 1, 3, 10, 20, 30, 50, 60 µg)
- BNT162b2 (dose levels: 1, 3, 10, 20, 30 µg).

The safety review committee (SRC) recommended that a second dose of BNT162b1 at the 60 µg dose level not be administered due to the reactogenicity after the first dose.

Subject safety was to be monitored from Visit 0 (screening) until approximately 6 months after the last immunization.

The following data are summarized and presented in this SCS as primary endpoints:

- Local reactions and systemic event data (acquired through the subject paper diaries) through Visit 5 (up to 7 days post-dose 2)
- TEAEs through Visit 7 (1-month follow-up visit post-dose 2)

Complete details regarding planned time points for all safety assessments during Phase 2/3 are provided in the SoA in Appendix A (Section 2.7.4.6.1).

2.7.4.1.1.1.3. Study Population (Study BNT162-01)

The full eligibility criteria for Study BNT162-01 can be found in the protocol (Module 5.3.5.1 BNT162-01 Protocol Section 5.1.1 and 5.2.1).

The study enrolled healthy adults 18 to 85 years of age. Healthy participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks prior to enrollment, were eligible for the study. Individuals with certain medical conditions that could affect participant safety or evaluation of vaccine safety or immunogenicity were excluded. A complete list of inclusion and exclusion criteria is available in the protocol (Module 5.3.5.1 BNT162-01 Protocol Section 5).

2.7.4.1.1.1.4. Analysis Sets (Study BNT162-01)

Populations from Study BNT162-01 discussed in this SCS include the following:

Population	Description
Screened Set	The screened set is defined as all subjects who signed informed consent
Safety Set (SAF)	The safety set is defined as all subjects who received at least one dose of study intervention

2.7.4.1.1.1.5. Safety Assessments (Study BNT162-01)

Details regarding safety assessments for Study BNT162-01 are found in Module 5.3.5.1 BNT162-01 Protocol Section 8.2.

Safety assessments were collected at planned time points as described in the Schedule of Activities (Appendix A, Section 2.7.4.6.1.2). Key Safety Assessments included:

- Physical examinations, Vital Signs, ECGs
- Clinical laboratory tests were performed at the times defined in the SoA and the specific tests are presented in Module 5.3.5.1 BNT162-01 Protocol Section 10.2. The classification of laboratory tests is presented in Module 5.3.5.1 BNT162-01 Statistical Analysis Plan Section 6.7.2.
- Local reactions after IM immunization were assessed by the investigator at the times given in the SoA (Appendix A, Section 2.7.4.6.1.2). In the 7 days after administration of the study intervention, participants used subject diaries to record any reactions between visits: solicited local reactions at the injection site and solicited systemic reactions (see Appendix A [Section 2.7.4.6.1.3.2] for further details). Grading scales used in this study to assess local reactions and systemic events are derived from the FDA CBER guidelines on toxicity grading scales for healthy adult volunteers enrolled in preventive vaccine clinical trials.[1]
- SARS-CoV-2 testing (PCR-based and antibody-based). This includes PCR-based testing for SARS-CoV-2 as an eligibility criterion and blood draws for anti-SARS-CoV-2 antibody testing as baseline reference for immunogenicity analysis. If required, this reference will allow the discrimination between vaccinated and infected subjects.
- AEs and SAEs were collected, recorded, and reported as defined in Module 5.3.5.1 BNT162-01 Protocol Section 8.3 and further discussed in Appendix A (Section 2.7.4.6.1.3.3).
- AESI were considered to be enhanced respiratory disease or flu-like symptomatology that did not resolve after 7 days or with symptom kinetics that are inconsistent with a relationship to RNA immunization.

2.7.4.1.1.1.6. Statistical Methods (Study BNT162-01)

There is no hypothesis testing in Study BNT162-01. Statistical methods are described in the study protocol (Module 5.3.5.1 BNT162-01 Protocol Section 9.4) and in the SAP (Module 5.3.5.1 BNT162-01 SAP).

In general, data will be summarized by groups and groups may be combined as appropriate. Part A and Part B will be analyzed separately and may be combined as appropriate.

All AEs will be coded using MedDRA terms. TEAEs will be summarized using the safety set (SAF). In general, AEs will be analyzed by group (ie, by type and dose level) and for each immunization. Additionally, AEs will be summarized for all dose levels combined for each type. For each analysis, the number and percentage of subjects reporting at least one AE will be summarized by PT nested within SOC for each AE type. The number and percentage of subjects with any AE will be summarized by worst grade by PT nested within SOC.

For each immunization, the number and percentage of subjects reporting at least one local reaction or systemic reaction (ie, solicited data collected using subject diaries) will be summarized for any local reactions or systemic reactions and for Grade ≥3 local reactions or systemic reactions in the SAF.

The analysis of local and systemic reactions will be repeated with a reduced set of terms (called the "comparability analysis"), to facilitate like-for-like comparisons between different trials in the clinical development program for BNT162 vaccines. The number and percentage of subjects reporting at least one local reaction will be summarized by worst grade using the SAF.

Safety data other than AEs that will be summarized includes clinical laboratory parameters, vital signs, and ECGs. All safety analyses will be based on the safety set and will be summarized descriptively by group unless otherwise stated.

Clinical laboratory parameters at each timepoint and change from baseline to each post-baseline time point will be summarized using descriptive summary statistics for each parameter by group.

The occurrence of clinically significant abnormal laboratory results within a study subject will be analyzed using descriptive summary statistics for each parameter and visit by group.

Abnormal laboratory results will be graded using criteria based on the guidance given in the FDA CBER guidelines on toxicity grading scales for healthy adult volunteers enrolled in preventive vaccine clinical trials.[1]

2.7.4.1.1.2. Pivotal Phase 1/2/3 Safety, Immunogenicity, and Efficacy Study C4591001

2.7.4.1.1.2.1. Safety Objectives, Estimands, Endpoints (Study C4591001)

Safety objectives, estimands, and endpoints for Study C4591001 are presented in Table 3.

Table 3. Safety Objectives, Estimands, and Endpoints for Study C4591001

Objectives[a]	Estimands	Endpoints	Reference
Primary:	**Primary:**	**Primary:**	
PHASE 1			
To describe the safety and tolerability profiles of prophylactic BNT162 vaccines in healthy adults after 1 or 2 doses	In participants receiving at least 1 dose of study intervention, the percentage of participants reporting: • Local reactions for up to 7 days following each dose • Systemic events for up to 7 days following each dose • AEs from Dose 1 to 1 month after the last dose • SAEs from Dose 1 to 6 months after the last dose	• Local reactions (pain at the injection site, redness, and swelling) • Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) • AEs • SAEs	Interim data for local reactions and systemic events reported up to 7 days after each dose, and AEs and SAEs are reported from Dose 1 to 1 month after the last dose for all groups evaluated, and to the cutoff date after Dose 2 for the BNT162b2 30 µg group only in final analysis interim CSR dated 03 December 2020. AEs and SAEs from Dose 1 to the unblinding date for the BNT162b2 30 µg group only are reported in this CSR.
	In addition, the percentage of participants with: • Abnormal hematology and chemistry laboratory values 1 and 7 days after Dose 1; and 7 days after Dose 2 • Grading shifts in hematology and chemistry laboratory assessments between baseline and 1 and 7 days after Dose 1; and before Dose 2 and 7 days after Dose 2	Hematology and chemistry laboratory parameters detailed in Module 5.3.5.1 C4591001 Protocol Section 10.2.	Interim data are reported in final analysis interim CSR dated 03 December 2020.
Exploratory			
To describe the safety profile of a third dose of prophylactic BNT162b2 administered to healthy adults 6 to 12 months after the second dose of either BNT162b1 or BNT162b2	In participants receiving a third dose of BNT162b2, the percentage of participants reporting: • Local reactions for up to 7 days after Dose 3 • Systemic events for up to 7 days after Dose 3 • AEs and SAEs from Dose 3 to 1 month after Dose 3	• Local reactions (pain at the injection site, redness, and swelling) • Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) • AEs • SAEs	Data will be reported at a later time.

Table 3. Safety Objectives, Estimands, and Endpoints for Study C4591001

Objectives[a]	Estimands	Endpoints	Reference
PHASE 2/3			
Primary Safety			
To define the safety profile of prophylactic BNT162b2 in the first 360 participants randomized (Phase 2)	In participants receiving at least 1 dose of study intervention, the percentage of participants reporting: • Local reactions for up to 7 days following each dose • Systemic events for up to 7 days following each dose • AEs from Dose 1 to 7 days after the second dose • SAEs from Dose 1 to 7 days after the second dose	• Local reactions (pain at the injection site, redness, and swelling) • Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) • AEs • SAEs	Interim data are reported in final analysis interim CSR dated 03 December 2020.
To define the safety profile of prophylactic BNT162b2 in all participants randomized in Phase 2/3	In participants receiving at least 1 dose of study intervention, the percentage of participants reporting: • Local reactions for up to 7 days following each dose • Systemic events for up to 7 days following each dose • AEs from Dose 1 to 1 month after the second dose • SAEs from Dose 1 to 6 months after the second dose	• AEs • SAEs • In a subset of at least 6000 participants: o Local reactions (pain at the injection site, redness, and swelling) o Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain)	Interim data are reported up to 1 month after Dose 2 and to the data cutoff date (14 November 2020) in final analysis interim CSR dated 03 December 2020. Cumulative interim data up to cutoff date are reported in this CSR.
To define the safety profile of prophylactic BNT162b2 in participants 12 to 15 years of age in Phase 3	In participants receiving at least 1 dose of study intervention, the percentage of participants reporting: • Local reactions for up to 7 days following each dose • Systemic events for up to 7 days following each dose • AEs from Dose 1 to 1 month after the second dose • SAEs from Dose 1 to 6 months after the second dose	• Local reactions (pain at the injection site, redness, and swelling) • Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) • AEs • SAEs	Data will be reported separately.

Table 3. Safety Objectives, Estimands, and Endpoints for Study C4591001

Objectives[a]	Estimands	Endpoints	Reference
To describe the safety and tolerability profile of BNT162b2$_{SA}$ given as 1 or 2 doses to BNT162b2-experienced participants, or as 2 doses to BNT162b2-naïve participants To describe the safety and tolerability profile of BNT162b2 given as a third dose to BNT162b2-experienced participants	In participants receiving at least 1 dose of study intervention, the percentage of participants reporting: • Local reactions for up to 7 days following each dose • Systemic events for up to 7 days following each dose • AEs from Dose 1 to 1 month after the second dose • SAEs from Dose 1 to 5 or 6 months after the second dose	• Local reactions (pain at the injection site, redness, and swelling) • Systemic events (fever, fatigue, headache, chills, vomiting, diarrhea, new or worsened muscle pain, and new or worsened joint pain) • AEs • SAEs	Data will be reported at a later time.
Exploratory			
To describe the safety, immunogenicity, and efficacy of prophylactic BNT162b2 in individuals with confirmed stable HIV disease		All safety, immunogenicity, and efficacy endpoints described above	Safety data only in participants with confirmed stable HIV disease are reported in this CSR.
To describe the safety and immunogenicity of prophylactic BNT162b2 in individuals 16 to 55 years of age vaccinated with study intervention produced by manufacturing "Process 1" or "Process 2"[b]		• AEs • SAEs • SARS-CoV-2 neutralizing titers	Data will be reported at a later time.

a. HIV-positive participants in Phase 3 will not be included in analyses of the objectives, with the exception of the specific exploratory objective.
b. See Module 5.3.5.1 C4591001 Protocol Section 6.1.1 for a description of the manufacturing process. The safety results for individuals 16 to 55 years of age vaccinated with study intervention produced by manufacturing "Process 1" or "Process 2" will be summarized descriptively when data become available.

2.7.4.1.1.2.2. Overall Design (Study C4591001)

US Study C4591001 is the ongoing, randomized, placebo-controlled, observer-blind, Phase 1/2/3 pivotal registration study. The study consists of 2 parts:

1. Phase 1: to identify preferred vaccine candidate(s) and dose level(s);

2. Phase 2/3: an expanded cohort and efficacy part.

These parts, and the progression between them, are detailed in the schema presented in Appendix B (Section 2.7.4.6.2.1).

Study C4591001 was conducted at sites in the US, Brazil, Argentina, Turkey, South Africa, and Germany

Phase 1

In Phase 1, 13 groups were studied, corresponding to a total of 195 participants. Each group (vaccine candidate/dose level/age group) was comprised of 15 participants randomized 4:1 to receive active vaccine or placebo (12 participants randomized to active vaccine and 3 to placebo, such that the placebo participants across the groups would produce a roughly comparably-sized cohort). Study intervention was to be administered intramuscularly into the deltoid muscle, preferably of the nondominant arm to 2 age cohorts (18 to 55 and 65 to 85 years of age,) in a two-dose regimen separated by 21 days at the following dose levels:

- **BNT162b1** (dose levels: 10, 20, 30, 100 µg)
- **BNT162b2** (dose levels: 10, 20, 30 µg).

The Internal Review Committee (IRC) recommended that a second dose of BNT162b1 at 100 µg not be administered due to reactogenicity after the first dose in the younger age group. Participants in this group of younger adults instead received a second dose of BNT162b1 at the 10 µg dose level.

Participants received active vaccine or placebo at Visit 1, with next day and 1-week follow-up visits (Visits 2 and 3) post-dose 1. Participants received dose 2 at Visit 4 (19 to 23 days after Visit 1). Follow-up visits were scheduled at 1-week, 2-weeks, 1-month, 6-months, 12-months- and 24-months.

Participants who originally received placebo may have become eligible for receipt of BNT162b2 or another COVID-19 vaccine.

Phase 1 participants who originally received BNT162b1 or BNT162b2 at dose levels of 10, 20, or 30 µg at Doses 1 and 2 were offered an additional dose of BNT162b2 at 30 µg approximately 6 to 12 months after their second dose of BNT162. This would provide an early assessment of the safety of a third dose of BNT162, as well as its immunogenicity. The booster analyses will be reported at a later time.

Participants were expected to participate for up to a maximum of approximately 26 months.

All participants in Phase 1 recorded local reactions, systemic events, and antipyretic/pain medication usage for 7 days, each evening following administration of study intervention using an e-diary. This allowed recording of these assessments only within a fixed time window, thus providing the accurate representation of the participant's experience at that time.

The following data are summarized and presented in this SCS as Phase 1 safety endpoints:

- Local reactions and systemic event data (acquired through the e-diaries) for up to 7 days after Dose 1 and Dose 2
- AEs through Visit 7 (1-month follow-up visit post-dose 2) and SAEs through the data cutoff date of 24 August 2020 (safety results for BNT162b1 at the 100 µg dose level in the younger age group are presented up to 3 weeks after Dose 1 or to before Dose 2 based on the data cutoff date).
- Long-term follow-up (approximately 6 months after Dose 2 [as of cutoff date 13 March 2021]) of AEs and SAEs for Phase 1 participants who were randomized to receive BNT162b2 30 µg or control.
- Abnormal hematology and chemistry laboratory values, as well as grading shifts in hematology and chemistry laboratory assessments, through Visit 5 (7 days post-dose 2).

Complete details regarding planned time points for all safety assessments during Phase 1 are provided in the SoA in Appendix B (Section 2.7.4.6.2.2.1). The investigator may have scheduled visits (unplanned visits) in addition to those listed in the SoA table in order to conduct evaluations or assessments required to protect the well-being of the participant.

Safety assessments for Study C4591001 are detailed in Section 2.7.4.1.1.2.5 and 2.7.4.6.2.3.

The Sponsor/agent study team was not blinded in this part of the study. Participants enrolled in Phase 1 were followed for cases of COVID-19 but did not contribute to the overall efficacy assessment. Details regarding efficacy and immunogenicity methods, results, and conclusions are presented in the SCE (Module 2.7.3).

Based upon review of safety and immunogenicity from the Phase 1 part of the study, a final candidate and dose level of 30 µg BNT162b2 was selected.

Phase 2/3

BNT162b2 at the 30 µg dose level was the vaccine candidate chosen by Pfizer/BioNTech to proceed into Phase 2/3. Participants ≥12 years of age (stratified as 12-15, 16-55 or >55 years of age, with the intention that a minimum of 40% of participants would be in the >55-year stratum) were randomized 1:1 to receive vaccine or placebo. The Phase 2 part of the study evaluated safety and immunogenicity for the first 360 participants enrolled (180 to active vaccine and 180 to placebo) in order to confirm the safety profile of BNT162b2 as seen in Phase 1. Participants enrolled into Phase 2 contributed to the overall efficacy assessment.

It was planned for the Phase 2/3 part of the study to comprise of approximately 21,999 vaccine recipients per group, for a total sample size of 43,998. The 12- to 15-year stratum will be comprised of up to approximately 2000 participants (1000 vaccine recipients) enrolled at selected investigational sites.

Participants received active vaccine or placebo at Visit 1 (dose 1) and Visit 2 (dose 2, 19 to 23 days after Visit 1). Follow-up visits were scheduled at 1-month, 6-months, 12-months- and 24-months (as described in the SoA, Appendix B, Section 2.7.4.6.2.2.2).

Participants ≥16 years of age who originally received placebo and became eligible for receipt of BNT162b2 according to recommendations detailed separately, had the opportunity to receive BNT162b2 in a phased manner as part of the study (no later than 6 months after Vaccination 2 [at the time of the originally planned Visit 4]). The investigator ensured that the participant met at least 1 of the recommendation criteria. Any participant ≥16 years of age who originally received placebo but then went on to receive BNT162b2 moved to a new visit schedule (2.7.4.6.2.2.3) and received 1 dose of BNT162b2 at each additional vaccination visit (Visits 101 and 102, receiving Dose 3 and Dose 4, respectively).

The following data are summarized and presented in this SCS as Phase 2/3 safety endpoints:

- For Phase 2 (first 360 participants), reactogenicity results for up to 7 days after Dose 1 and Dose 2, AEs and SAEs through the data cutoff date (2 September 2020), which includes up to 7 days follow-up after Dose 2.

- For Phase 3, reactogenicity results for up to 7 days after Dose 1 and Dose 2, AEs and SAEs through the data cutoff date (13 March 2021), which includes up to 6 months follow-up after Dose 2 (see Section 2.7.4.2.4.2 for more details).

Complete details regarding planned time points for all safety assessments during Phase 2/3 are provided in the SoA in Appendix B (Section 2.7.4.6.2.2.2). An unplanned potential COVID-19 illness visit and unplanned potential COVID-19 convalescent visit were required at any time between Visit 1 and Visit 6 (24-month follow-up visit) that potential COVID-19 symptoms were reported, including MIS-C.

Prior infection with SARS-CoV-2 was assessed at baseline and evaluated per serological samples over 24 months to explore efficacy against asymptomatic SARS-CoV-2 infections and to ensure safety in both sero-negative and sero-positive participants. Safety assessments for Study C4591001 are detailed in Section 2.7.4.1.1.2.5 and 2.7.4.6.2.3.

Planned Analyses

The following analyses are not included in this report and will be reported at a later time:

- For evaluation of boostability, a subset of Phase 3 participants 18 to 55 years of age will receive a third dose of BNT162b2 or a third and potentially a fourth dose of prototype BNT162b2$_{VOC}$ (based upon the South African variant and hereafter referred to as BNT162b2$_{SA}$). The third dose of BNT162b2 or BNT162b2$_{SA}$ will be administered approximately 5 to 7 months after their second dose of BNT162 (at

Visit 301) and a subset of those participants who received the third dose of BNT162b2$_{SA}$ will receive a further dose of BNT162b2$_{SA}$ one month after Dose 1 of BNT162b2$_{SA}$ (at Visit 303).

- To further describe potential homologous and heterologous protection against emerging SARS-CoV-2 VOCs, a new cohort of participants will be enrolled who are COVID-19 vaccine-naïve (ie, BNT162b2-naïve) and have not experienced COVID-19. They will receive BNT162b2$_{SA}$ given as a 2-dose series, separated by 21 days.

2.7.4.1.1.2.3. Study Population (Study C4591001)

The full eligibility criteria for Study C4591001 can be found in the protocol (Module 5.3.5.1 C4591001 Protocol Section 5).

The following eligibility criteria were designed to select participants for whom participation in the study was considered appropriate.

Key inclusion criteria:

Participants were eligible to be included in the study only if all of the following criteria apply:

- Male or female participants in the following age groups:
    - Phase 1: Between the ages of 18 and 55 years, inclusive, and between 65 and 85 years, inclusive, at randomization
    - Phase 2/3: ≥12 years, at randomization
- Healthy participants as determined by medical history, physical examination (if required), and clinical judgment of the investigator to be eligible for inclusion in the study

  Note: Healthy participants with preexisting stable disease, defined as disease not requiring significant change in therapy or hospitalization for worsening disease during the 6 weeks before enrollment, could be included. Specific criteria for Phase 3 participants with known stable infection with HIV, HCV, or HBV can be found in Module 5.3.5.1 C4591001 Protocol Section 10.8.
- Phase 2/3 only: Participants who, in the judgment of the investigator, were at higher risk for acquiring COVID-19 (including, but not limited to, use of mass transportation, relevant demographics, and frontline essential workers).

Key exclusion criteria:

Participants were excluded from the study if any of the following criteria applied:

- Other medical or psychiatric condition including recent (within the past year) or active suicidal ideation/behavior or laboratory abnormality that may increase the risk of study participation or, in the investigator's judgment, make the participant inappropriate for the study.
- Phases 1 and 2 only: Known infection with HIV, HCV, or HBV.
- History of severe adverse reaction associated with a vaccine and/or severe allergic reaction (eg, anaphylaxis) to any component of the study intervention(s).
- Receipt of medications intended to prevent COVID 19.
- Previous clinical (based on COVID-19 symptoms/signs alone, if a SARS-CoV-2 NAAT result was not available) or microbiological (based on COVID-19 symptoms/signs and a positive SARS-CoV-2 NAAT result) diagnosis of COVID 19.
- **Phase 1 only:** Individuals at high risk for severe COVID-19, including those with any of the following risk factors:
  - Hypertension
  - Diabetes mellitus
  - Chronic pulmonary disease
  - Asthma
  - Current vaping or smoking
  - History of chronic smoking within the prior year
  - Chronic liver disease
  - Stage 3 or worse chronic kidney disease (glomerular filtration rate <60 mL/min/1.73 m^2)
  - Resident in a long-term facility
  - BMI >30 kg/m^2
  - Anticipating the need for immunosuppressive treatment within the next 6 months
- **Phase 1 only:** Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (eg, healthcare worker, emergency response personnel).
- Immunocompromised individuals with known or suspected immunodeficiency, as determined by history and/or laboratory/physical examination.

- **Phase 1 only:** Individuals with a history of autoimmune disease or an active autoimmune disease requiring therapeutic intervention, including but not limited to: systemic or cutaneous lupus erythematosus, autoimmune arthritis/rheumatoid arthritis, Guillain-Barré syndrome, multiple sclerosis, Sjögren's syndrome, idiopathic thrombocytopenia purpura, glomerulonephritis, autoimmune thyroiditis, giant cell arteritis (temporal arteritis), psoriasis, and insulin-dependent diabetes mellitus (type 1).

- Bleeding diathesis or condition associated with prolonged bleeding that would, in the opinion of the investigator, contraindicate intramuscular injection.

- Women who are pregnant or breastfeeding.

- Previous vaccination with any coronavirus vaccine.

- Individuals who receive treatment with immunosuppressive therapy.

- **Phase 1 only:** Regular receipt of inhaled/nebulized corticosteroids.

- Receipt of blood/plasma products or immunoglobulin, from 60 days before study intervention administration or planned receipt throughout the study.

- Participation in other studies involving study intervention within 28 days prior to study entry through and including 6 months after the last dose of study intervention, with the exception of interventional studies for prevention of COVID 19, which are prohibited throughout study participation.

- Previous participation in other studies involving study intervention containing lipid nanoparticles.

- For Phase 1 only:

    - Positive serological test for SARS-CoV-2 IgM and/or IgG antibodies at the screening visit.
    - Any screening hematology and/or blood chemistry laboratory value that meets the definition of a ≥ Grade 1 abnormality.

    - Positive test for HIV, HBsAg, HBc Abs, or HCV Abs at the screening visit.

    - SARS-CoV-2 NAAT-positive nasal swab within 24 hours before receipt of study intervention.

2.7.4.1.1.2.4. Analysis Sets (Study C4591001)

Populations discussed in this SCS include the following:

Population	Description
Enrolled	All participants who had a signed ICD
Randomized	All participants who were assigned a randomization number in the IWR system
Safety	All randomized participants who received at least 1 dose of the study intervention. Analyses of reactogenicity endpoints will be based on a subset of the safety population that includes participants with any e-diary data reported after vaccination.

2.7.4.1.1.2.5. Safety Assessments (Study C4591001)

Safety assessments were collected at planned time points as described in Appendix B (Section 2.7.4.6.2). Key safety assessments included:

- A clinical assessment, including medical history, was performed on all participants at his/her first visit to establish a baseline. Significant medical history and observations from any physical examination, if performed, were documented in the CRF.

- The safety parameters included reactogenicity e-diary reports of local reactions and systemic events, fever, and use of antipyretic medication that occurred in the 7 days after administration of the study intervention in a subset of participants (see Appendix B [Section 2.7.4.6.2.3.1] for further details). Grading scales used in this study to assess local reactions and systemic events were derived from the FDA CBER guidelines on toxicity grading scales for healthy adult volunteers enrolled in preventive vaccine clinical trials.[1]

- AEs and SAEs were collected, recorded, and reported as defined in Module 5.3.5.1 C4591001 Protocol Section 8.3 and further discussed below in Appendix B (Section 2.7.4.6.2.3.2).

- Acute reactions within the first 4 hours after administration of the study intervention (for the first 5 participants vaccinated in each Phase 1 group), and within the first 30 minutes (for the remainder of participants), were assessed and documented in the AE CRF.

- Safety subgroup analyses by age, country, ethnicity, sex, and race were performed.

- Targeted medical events of potential clinical interest by PT, HLT, or SMQ (full scope, including broad and narrow) were monitored.

- Participants in all phases of the study were surveilled for potential COVID-19 illness from Visit 1 onwards. Further details are in Appendix B (Section 2.7.4.6.2.3.4). Note

that while this was monitored throughout the study, analyses were only planned for Phase 2/3 as efficacy endpoints.

- For Phase 1, safety laboratory tests were performed at the times defined in the SoA (Appendix B [Section 2.7.4.6.2.2.1]). The specific tests are presented in the Statistical Analysis Plan (Module 5.3.5.1 C4591001 Statistical Analysis Plan Section 3.1.1.6) and further described in Module 5.3.5.1 C4591001 Protocol Section 8.2.1. The primary criterion for abnormality followed the Pfizer safety rule book.

- For Phase 1, a physical examination was performed. It evaluated any clinically significant abnormalities within the following body systems: general appearance; skin; head, eyes, ears, nose, and throat; heart; lungs; abdomen; musculoskeletal; extremities; neurological; and lymph nodes. Clinically significant abnormal results were recorded in the CRF.

No adverse events of special interest were defined for Study C4591001; however, targeted medical events were monitored throughout the study.

2.7.4.1.1.2.6. Statistical Methods (Study C4591001)

Statistical methods are described in the study protocol (Module 5.3.5.1 C4591001 Protocol Section 9.4) and in the statistical analysis plan (Module 5.3.5.1 C4591001 Statistical Analysis Plan)

Safety objectives were evaluated by descriptive summary statistics for local reactions and systemic events, AEs/SAEs, and abnormal hematology and chemistry laboratory parameters (Phase 1 only) for each vaccine group. A 3-tier approach was used to summarize AEs in Phase 2/3. Under this approach, AEs were classified into 1 of 3 tiers:

Tier 1 events: prespecified events of clinical importance, identified in the product's safety review plan; there are no Tier 1 AEs identified for this program.

Tier 2 events: those that are not Tier 1 but are considered "relatively common"; a MedDRA preferred term is defined as a Tier 2 event if there are at least 1% of participants in at least 1 vaccine group reporting the event; and

Tier 3 events: those that are neither Tier 1 nor Tier 2 events.

For Tier 2 events, 2-sided 95% CIs for the difference between the vaccine and placebo groups in the percentage of participants reporting the events based on the Miettinen and Nurminen method will be provided.[2] For Tier 3 events, counts and percentages for each vaccine group will be provided. The safety analyses are based on the safety population. Analyses of reactogenicity endpoints are based on a subset of the safety population that includes participants with any e-diary data reported after vaccination. Participants will be summarized by vaccine group according to the study interventions they actually received. Missing reactogenicity e-diary data will not be imputed; missing AE dates will be handled according to the Pfizer safety rules.

AEs and SAEs reported during the open-label follow-up period will be summarized separately for participants who were unblinded at the time of being eligible for receipt of BNT162b2 according to recommendations detailed separately, and available in the electronic study reference portal, or no later than at approximately Visit 4.

AE analyses of participants who had different durations of follow-up time due to unblinding in the study (per protocol) were summarized as incidence rates (IR) adjusted for exposure time. This was calculated as: (number of participants reporting event) / (total exposure time across all participants in the specified group). This accounts for variable exposure since unblinding began for individual participants. Two-sided 95% CIs for the IRs were provided based on Poisson distribution.

Planned Analyses

For Phase 3 participants enrolled for assessment of boostability and protection against emerging VOCs, descriptive summary statistics will be provided at a later time.

2.7.4.1.1.3. Narratives

Narrative summaries were written for the following participants in Study BNT162-01:

- Participants who died;
- Participants who experienced SAEs assessed as related to study intervention by the investigator;
- Participants with any AEs leading to withdrawal from the study
- Participants with COVID-19

These participant narratives are available in Module 5.3.5.1 BNT162-01 CSR Section 12.6.

Narrative summaries were written for the following participants in Study C4591001:

- Deaths, vaccine-related SAEs, all other SAEs, safety-related withdrawals
- AEs of interest requested by FDA: anaphylaxis, Bell's palsy, lymphadenopathy, appendicitis, and pregnancy exposures and outcomes
- AESIs with a numerical imbalance with a higher frequency (or incidence rate) in the vaccine group vs placebo group that led to withdrawal, were related, or had biological plausibility
- COVID-19 cases (participants with severe and/or multiple episodes).

These participant narratives are available in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 14 Subject Narratives (for data available as of the

14 November 2020 cutoff date) or Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 14 Subject Narratives (for data available as of the 13 March 2021 cutoff date)

2.7.4.1.2. Overall Extent of Exposure, Disposition, and Study Population Characteristics

2.7.4.1.2.1. Study BNT162-01

Study results presented below are for Part A through the data cutoff date of 23 October 2020 and may not be representative of the final data. The full interim CSR for Study BNT162-01 is provided in Module 5.3.5.1 BNT162-01 CSR.

2.7.4.1.2.1.1. Disposition (Phase 1, Study BNT162-01)

In the BNT162b1 younger age group, a total of 84 participants were enrolled, with 12 participants in each dose group (1 µg, 3 µg, 10 µg, 20, µg, 30 µg, 50 µg, and 60 µg dose groups) (note: 60 µg group received only Dose 1 per SRC decision due to Dose 1 reactogenicity). In the BNT162b1 older age group, a total of 36 participants were enrolled, with 12 participants in each dose group (10 µg, 20, µg, 30 µg dose groups) (note: 10 µg group had data to 1 month after Dose 2; 20 and 30 µg groups had available data to 7 days after Dose 2). 80/84 younger and 11/36 older participants in the BNT162b1 group completed the study (ie, through the end of treatment visit), and 4 premature discontinuations have occurred (none in the 30 µg dose group or the older participant age group).

In the BNT162b2 younger age group, a total of 60 participants were enrolled, with 12 participants in each dose group (1 µg, 3 µg, 10 µg, 20, µg, and 30 µg groups). In the BNT162b2 older age group, a total of 36 participants were enrolled, with 12 participants in each dose group (10 µg, 20, µg, 30 µg dose groups). 53/60 younger and 30/36 older participants in the BNT162b2 group completed the study (ie, through end of treatment visit). Two premature discontinuations have occurred (none in the 30 µg dose group or the older participant age group).

2.7.4.1.2.1.2. Exposure (Phase 1, Study BNT162-01)

For BNT162b1, dosing of participants in the younger age group with the second 60 µg BNT162b1 dose was not performed. After 12 participants had received Dose 1, the SRC decided not to administer Dose 2 to these participants. 95.8% (69/72) of participants in all other dose levels received Dose 2. In the BNT162b1 older age group, 97.2% (35/36) of participants in all dose levels received Dose 2.

For the BNT162b2 group, 96.7% (58/60) and 100% (36/36) of participants in the younger and older age groups, respectively (in all dose levels) received Dose 2.

2.7.4.1.2.1.3. Safety Data Sets Analyzed (Phase 1, Study BNT162-01)

For BNT162b1 and BNT162b2, all participants randomized to receive study intervention in the younger and older age groups were included in the SAF.

2.7.4.1.2.1.4. Demographic and Other Characteristics of Study Population (Phase 1, Study BNT162-01)

In the BNT162b1 younger age group, BNT162b1 was administered to 84 participants, among whom 52% were male and 48% were female, 96% were White and 2% were Hispanic/Latino, with a median 36 years of age. In the BNT162b1 older age group (56 to 85 years of age), BNT162b1 was administered to 36 participants, among whom 36% were male and 64% were female, all were White and none were Hispanic/Latino, with a median 67 years of age.

In the BNT162b2 younger age group, BNT162b2 was administered to 60 participants, among whom 43% were male and 57% were female, 100% were White, none were Hispanic/Latino, with a median 42 years of age. In the BNT62b2 older age group, BNT162b2 was administered to 36 participants, among whom 50% were male and 50% were female, 100% were White, none were Hispanic/Latino, with a median 65 years of age.

Baseline Medical History

Participants in both the BNT162b1 and BNT162b1 groups were healthy with a medical history profile consistent with that of a healthy general population in the younger age group.

2.7.4.1.2.1.5. Diary Compliance (Phase 1, Study BNT162-01)

For BNT162b1 and BNT162b2, the participant's diary compliance for reporting reactogenicity was ≥99% 0 to 6 days after Dose 1. The participant's diary compliance for reporting reactogenicity was ≥64% and ≥92% from 0 to 6 days after Dose 2 for BNT162b1 and BNT162b2, respectively.

Overall, lower percentages postdose 2 were due to the ongoing nature of the study. These results are as of the data cutoff date and may not be representative of the final data.

2.7.4.1.2.2. Phase 1 (Study C4591001)

Results for healthy adults 18 to 85 years of age (younger age group: 18 to 55; older age group: 65 to 85) in the Phase 1 portion of Study C4591001 are presented through the data cutoff date of 24 August 2020. Updated disposition is provided through the cutoff date of 13 March 2021. For the BNT162b1 100 µg dose group in the younger age group, results are only presented after Dose 1 but before Dose 2.

Full details and outputs regarding disposition, exposure, data sets, demographics, and diary compliance for Phase 1 of Study C4591001 through the data cutoff date of 24 August 2020 (to 1 month after Dose 2) are in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 10.1.1, Section 10.3.1, Section 10.4.1, Section 10.5.1, and Section 10.6.2.1, respectively. Full details and outputs regarding disposition through the data cutoff date of 13 March 2021 for the BNT162b2 (30 µg) group are in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 10.1.1.

2.7.4.1.2.2.1. Disposition (Phase 1, Study C4591001)

Overall, 195 participants were randomized. No participants have been withdrawn due to an AE as of the data cutoff date (24 August 2020).

In the BNT162b1 younger age group, 12 participants were randomized to each of the 3 dose groups (10 µg, 20 µg, and 30 µg dose groups) and 9 participants to the placebo group (in the 100 µg dose group, 12 participants were randomized to vaccine and 3 participants were randomized to placebo). In the BNT162b1 older age group, 12 participants were randomized to each of the 3 dose groups and 9 participants were randomized to the placebo group.

In the BNT162b2 group, both the younger and older age groups, 12 participants were randomized to each of the 3 dose groups and 9 participants were randomized to placebo.

To the Data Cutoff Date of 13 March 2021 for BNT162b2 (30 µg)

All participants in each age group randomized to receive BNT162b2 30 µg completed the visit at 6 months after Dose 2, with most of these 6-month visits occurring during the open-label follow-up period. All participants in each age group randomized to the placebo group received both doses of BNT162b2 (Dose 3 and Dose 4 in the study) during the open-label period and completed the visit at 1 month after Dose 4, as of the data cutoff date of 13 March 2021. No participants were withdrawn from the study up to the data cutoff date.

2.7.4.1.2.2.2. Exposure (Phase 1, Study C4591001)

In the BNT162b1 younger age group, all participants randomized to the 10 µg, 20 µg, and 30 µg dose groups received both doses of BNT162b1 or placebo, and all participants randomized to the 100 µg dose group (from younger age group only) received Dose 1 of BNT162b1 or placebo. The IRC determined not to administer the second dose of 100 µg due to reactogenicity (these participants received BNT162b1 at 10 µg as their second dose). All participants in the BNT162b1 older age group randomized to each dose group received both doses of BNT162b1 or placebo. (No participants in the older age group received BNT162b1 100 µg.) All participants in the BNT162b1 group received Dose 2 within the protocol specified time.

In the BNT162b2 group, all participants randomized to each dose group in the younger and older age groups received both doses of study intervention, and all participants received Dose 2 within the protocol-specified time.

2.7.4.1.2.2.3. Safety Data Sets Analyzed (Phase 1, Study C4591001)

For BNT162b1 and BNT162b2, all participants randomized to receive study intervention in the younger and older age groups were included in the safety population.

2.7.4.1.2.2.4. Demographic and Other Characteristics of Study Population (Phase 1, Study C4591001)

Demographic characteristics were similar across the vaccine groups within each age group for participants who received BNT162b1.

Most participants in the BNT162b1 group were White in both the younger age group and older age group. Median age for this group was 35.0 years in the younger age group and 69.0 years in the older age group. In the BNT162b1 younger age group (up to 30 µg), 17 (37.8%) were female and 28 (62.2%) were male (9 [60%] female and 6 [40%] male in the 100 µg dose group); in the older age group, 32 (71.1%) were female and 13 (28.9%) were male.

Most participants in the BNT162b2 group were White in the younger age group, and all participants were White in the older age group. Median age in this group was 37.0 years in the younger age group and 68.0 years in the older age group. In the BNT162b2 younger age group, 26 (57.8%) were female and 19 (42.2%) were male; in the older age group, 28 (62.2%) were female and 17 (37.8%) were male.

Baseline Medical History

The study population of the BNT162b1 and BNT162b2 groups were healthy with medical history profiles consistent with those of the healthy general population in each age group.

2.7.4.1.2.2.5. E-Diary Compliance (Phase 1, Study C4591001)

Transmission of e-diary data after either dose of BNT162b1 or placebo was ≥77.8% for each day during the 7 days following any vaccination in the younger age group and older age group, and transmission rates were similar across dose groups in both age groups. Transmission of e-diary data after either dose of BNT162b2 or placebo was ≥75.0% for each day during the 7 days following any vaccination in the younger and older age groups, and transmission rates were similar across dose groups in both age groups.

2.7.4.1.2.3. Phase 2 (Study C4591001)

Results for participants in the younger (18 to 55 years) and older (56 to 85 years) age groups in the Phase 2 portion of Study C4591001 are presented through the data cutoff date of 02 September 2020.

Full details and outputs regarding disposition, exposure, data sets, demographics, and diary compliance for Phase 2 of Study C4591001 are in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 10.1.2, Section 10.3.2, Section 10.4.2, Section 10.5.2, and Section 10.6.2.2, respectively.

2.7.4.1.2.3.1. Disposition (Phase 2, Study C4591001)

The first 360 participants enrolled as part of Phase 2 were randomized equally (180 participants each) to the BNT162b2 and placebo groups. Among participants randomized to the BNT162b2 group, 88 participants were in the younger age group and 92 participants were in the older age group.

2.7.4.1.2.3.2. Exposure (Phase 2, Study C4591001)

Except for 1 participant in the BNT162b2 younger age group who was withdrawn after Dose 1 but before Dose 2 and 1 participant in the placebo group (who had not yet received Dose 2 at the time of data cutoff [02 September 2020]), all other participants received both doses of study intervention. The participant in the BNT162b2 younger group was withdrawn

from the study 23 days after receiving Dose 1 (after Dose 1 but before Dose 2 because of an SAE of gastric adenocarcinoma (Section 2.7.4.2.3.4.2). All other participants received both doses of vaccine. No participants received the incorrect study intervention. The majority of participants received Dose 2 between 19 to 23 days after Dose 1 in the BNT162b2 (97.2%) and placebo (96.7%) groups.

2.7.4.1.2.3.3. Safety Data Sets Analyzed (Phase 2, Study C4591001)

At the time of the data cutoff (02 September 2020), the proportions of participants in the safety population were the same in the BNT162b2 group and the placebo group (180 participants each). Within the BNT162b2 group, 88 participants were in the younger age group and 92 were in the older age group.

2.7.4.1.2.3.4. Demographic and Other Characteristics of Study Population (Phase 2, Study C4591001)

Demographic characteristics for Phase 2 were similar in the BNT162b2 group and the placebo group for the safety population. For the BNT162b2 younger age group, 42 (47.7%) were female and 46 (52.3%) were male. In the BNT162b2 older age group, 42 (45.7%) were female and 50 (54.3%) were male. Most participants were White (85.8%), followed by Black or African American (9.2%). The proportions of Hispanic/Latino participants were similar in the BNT162b2 and placebo groups. The median age was 56.0 years across participants ages 18 to 85 (44.0 years for the younger age group and 65.0 years for the older age group).

Baseline Medical History

The 360 participants in Phase 2 had a diverse medical history profile consistent with individuals of the same age group in the general population. In the BNT162b2 group, conditions in the surgical and medical procedures, immune system disorders, and metabolism and nutrition disorders SOCs were most frequently reported.

2.7.4.1.2.3.5. E-Diary Compliance (Phase 2, Study C4591001)

Overall, transmission of e-diary data was ≥91.7% for each day during the 7 days after Dose 1 of BNT162b2. After Dose 2 of BNT162b2, transmission of e-diary data was 80.6% on Day 1 and ranged from 88.9% to 91.7% for each day during Day 2 through Day 7. Transmission rates were similar in the BNT162b2 group and the placebo group.

2.7.4.1.2.4. Phase 3 (Study C4591001)

Results for participants (≥16 years of age) in the Phase 3 portion of Study C4591001 are presented through the data cutoff date of 13 March 2021.

Study population details and outputs (including subpopulation analyses) for Phase 3 of Study C4591001 are presented fully in the C4591001 6-Month Update Interim CSR:

- Disposition: Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 10.1.2
- Protocol deviations: Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 10.2

- Exposure: Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 10.3.2
- Safety Data sets: Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 10.4.2
- Demographics and Other Characteristics: Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 10.5.2
- Diary compliance: Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 10.6.2.2

Note: Phase 3 tables and figures are titled as "Phase 2/3" to capture the fact that the 360 Phase 2 participants are included in the overall phase 3 analyses.

2.7.4.1.2.4.1. Disposition (Phase 3, Study C4591001)

The disposition of all Phase 2/3 participants randomized is presented for the blinded placebo controlled and open-label follow-up periods in Table 31 (Appendix D).

In this ongoing study, tables summarizing participant withdrawals may include some participants who were reported as withdrawn but remain in the study and are continuing to be evaluated. These participants are documented in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Errata.

2.7.4.1.2.4.1.1. Blinded Placebo-Controlled Follow-Up Period

During the blinded placebo-controlled follow-up period, most participants randomized received Dose 1 (99.8%) and Dose 2 (98.1%). There were 352 (1.6%) participants in the BNT162b2 group and 528 (2.4%) participants in the placebo group who discontinued from the vaccination period (Dose 1 to 1 month after Dose 2) (Table 31). Most participants completed the 1 month post-Dose 2 visit 2 (≥96.4%). Few participants in the BNT162b2 and placebo groups were withdrawn from the study (1.6% and 2.2%, respectively), and most were due to withdrawals by the participant, or they were lost to follow-up.

There were 7 participants with special data issues: 8 participant identification numbers from 4 participants who enrolled into the study more than once and 3 participants whose vaccine assignment was not confirmed in IRT at the time of data cutoff.

- Three participants who were randomized and vaccinated, but actual vaccine assignment was not confirmed in IRT at the time of data cutoff. Participants were vaccinated as per CRF, but due to the inability to confirm consistency between the data in the CRF and IRT, these participants were not assigned to any actual dosing group. Safety data from these 3 participants were excluded from safety summary tables but their safety data are listed separately (Table 34).
- During the conduct of this study, 4 participants were each randomized twice with different participant identification numbers at 2 different sites. Because the significant misconduct of these participants compromised the integrity of the study data, results from these participants were excluded from all efficacy and safety analyses, including

disposition and demographic tabulations. These participants who were discontinued from vaccination and/or from the study are listed separately.

2.7.4.1.2.4.1.2. Open-Label Follow-Up Period

Individuals ≥16 years of age have been unblinded as they became locally eligible and wished to know their treatment assignment to confirm prior vaccination with BNT162b2 (if randomized to this group), or to receive BNT162b2 (if randomized to placebo). Unblinded recipients originally randomized to BNT162b2 continue to be followed in an open-label manner. Unblinded recipients originally randomized to placebo are offered BNT162b2 vaccination (Doses 3 and 4 [first and second dose of BNT162b2 30 µg, respectively]) and thereafter followed in an open-label manner.

Most participants in the BNT162b2 (96.8%) and placebo (96.4%) groups completed the 1 month post-Dose 2 visit before unblinding (Table 31).

A total of 87 (0.4%) Phase 2/3 original BNT162b2 participants received Dose 1 of BNT162b2 during the blinded placebo-controlled follow-up period and then received Dose 2 of BNT162b2 30 µg during the open-label follow-up period (when they were unblinded). There were 105 (0.5%) participants withdrawn from the study, and most were due to withdrawals by the participant, or they had a protocol deviation.

During the open-label follow-up period, most participants originally randomized in the placebo group received Doses 3 and 4 (88.8% and 72.4%, respectively) of BNT162b2. There were few participants in this group (0.1%) who were withdrawn from the study, and most were due to withdrawals by the participant.

The disposition of HIV-positive participants is included in this summary but summarized separately in safety analyses.

Disposition of all participants ≥16 years of age randomized was similar by age group.

There were no clinically meaningful differences in disposition by age group, baseline SARS-CoV-2 status, ethnicity, race, or sex.

2.7.4.1.2.4.2. Exposure (Phase 3, Study C4591001)

Almost all participants were administered study intervention as randomized; 99.7% received Dose 1 and 98.5% received Dose 2 of BNT162b2 in the BNT162b2 group, and 99.8% received Dose 1 and 98.0% received Dose 2 of placebo in the placebo group (Table 32 in Appendix D).

For Dose 1, 4 participants randomized to the placebo group received BNT162b2, and 2 participants randomized to the BNT162b2 group received placebo. Two participants randomized to the BNT162b2 group and 1 participant randomized to the placebo group received an indeterminate vaccine for Dose 1.

For Dose 2, 5 participants randomized to the placebo group received BNT162b2, and 3 participants randomized to the BNT162b2 group received placebo.

After unblinding, 88.8% of original placebo participants received Dose 3 (first dose of BNT162b2 30 µg) and 72.4% received Dose 4 (second dose of BNT162b2 30 µg) at the time of the data cutoff date.

The majority of participants received Dose 2 between 21 to 27 days after Dose 1 in the BNT162b2 (62.6%) and placebo (62.7%) groups (Table 33 in Appendix D). After unblinding, most original placebo participants received Dose 4 (second dose of BNT162b2 30 µg) between 14 to 20 (22.6%) and 21 to 27 (48.1%) days after Dose 3.

2.7.4.1.2.4.3. Safety Data Sets Analyzed (Phase 3, Study C4591001)

The safety population included a total of 44,050 participants: 22,026 participants in the BNT162b2 group and 22,021 participants in the placebo group (Table 34 in Appendix D). Most of the total 115 (0.3%) participants excluded from the safety population were excluded because those participants did not receive study vaccine.

There were no clinically meaningful differences in the safety population by age group, baseline SARS-CoV-2 status, ethnicity, race, or sex.

During the blinded placebo-controlled follow-up period, 51.1% of participants in the BNT162b2 group and 51.4% of participants in the placebo group had follow-up time between ≥4 months to <6 months after Dose 2 (Table 35 in Appendix D). From Dose 2 to the cutoff date, 54.5% of participants in the BNT162b2 group had a total follow-up time of ≥6 months.

In the younger age group, 48.5% of participants in the BNT162b2 group and 48.3% of participants in the placebo group had follow-up time between ≥4 months to <6 months after Dose 2 during the blinded placebo-controlled follow up period. From Dose 2 to the cutoff date, 51.0% of participants in the BNT162b2 group had a total follow-up time of ≥6 months.

In the older age group, 54.8% of participants in the BNT162b2 group and 55.9% of participants in the placebo group had follow-up time between ≥4 months to <6 months after Dose 2 during the blinded placebo-controlled follow-up period. From Dose 2 to the cutoff date, 59.6% of participants in the BNT162b2 group had a total follow-up time of ≥6 months.

During the open-label follow-up period, 47.5% of original placebo participants had follow-up time between ≥1 month to <2 months after Dose 1 of BNT162b2.

2.7.4.1.2.4.4. Demographic and Other Characteristics of Study Population (Phase 3, Study C4591001)

2.7.4.1.2.4.4.1. Overall – Participants ≥16 Years of Age (Phase 3, Study C4591001, Demographic and Other Characteristics of Study Population)

Demographic characteristics for all Phase 3 participants ≥16 years of age were similar in the BNT162b2 and placebo groups (Table 4). Overall, most participants were White (82.0%), with 9.6% Black or African American participants and 4.3% Asian participants, and all other racial groups were ≤2.5%. There were 25.9% Hispanic/Latino participants. Median age was

51.0 years and 50.9% of participants were male. Obesity was reported in 34.4% of participants in this safety population.

Baseline SARS-CoV-2 status was positive (defined as a positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19) in 3.1% of participants in the BNT162b2 group and 3.3% of participants in the placebo group.

Demographic data including participants 12 through 15 years of age enrolled in this study are summarized in Section 2.7.4.1.2.4.4.4. Safety data for participants 12 through 15 years of age will be reported separately.

Table 4. Demographic Characteristics – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Placebo (N[a]=22021) n[b] (%)	Total (N[a]=44047) n[b] (%)
Sex			
Male	11322 (51.4)	11098 (50.4)	22420 (50.9)
Female	10704 (48.6)	10923 (49.6)	21627 (49.1)
Race			
White	18056 (82.0)	18064 (82.0)	36120 (82.0)
Black or African American	2098 (9.5)	2118 (9.6)	4216 (9.6)
American Indian or Alaska Native	221 (1.0)	217 (1.0)	438 (1.0)
Asian	952 (4.3)	942 (4.3)	1894 (4.3)
Native Hawaiian or other Pacific Islander	58 (0.3)	32 (0.1)	90 (0.2)
Multiracial	550 (2.5)	533 (2.4)	1083 (2.5)
Not reported	91 (0.4)	115 (0.5)	206 (0.5)
Racial designation			
Japanese	78 (0.4)	78 (0.4)	156 (0.4)
Ethnicity			
Hispanic/Latino	5704 (25.9)	5695 (25.9)	11399 (25.9)
Non-Hispanic/non-Latino	16211 (73.6)	16212 (73.6)	32423 (73.6)
Not reported	111 (0.5)	114 (0.5)	225 (0.5)
Country			
Argentina	2883 (13.1)	2881 (13.1)	5764 (13.1)
Brazil	1452 (6.6)	1448 (6.6)	2900 (6.6)
Germany	249 (1.1)	250 (1.1)	499 (1.1)
South Africa	401 (1.8)	399 (1.8)	800 (1.8)
Turkey	249 (1.1)	249 (1.1)	498 (1.1)
USA	16792 (76.2)	16794 (76.3)	33586 (76.3)
Age group (at vaccination)			
16-55 Years	13069 (59.3)	13095 (59.5)	26164 (59.4)
>55 Years	8957 (40.7)	8926 (40.5)	17883 (40.6)
Age at vaccination (years)			
Mean (SD)	49.7 (15.99)	49.6 (16.05)	49.7 (16.02)
Median	51.0	51.0	51.0
Min, max	(16, 89)	(16, 91)	(16, 91)
Baseline SARS-CoV-2 status			
Positive[c]	689 (3.1)	716 (3.3)	1405 (3.2)
Negative[d]	21185 (96.2)	21180 (96.2)	42365 (96.2)
Missing	152 (0.7)	125 (0.6)	277 (0.6)
Body mass index (BMI)			
Underweight (<18.5 kg/m^2)	271 (1.2)	304 (1.4)	575 (1.3)

Table 4. Demographic Characteristics – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Placebo (N[a]=22021) n[b] (%)	Total (N[a]=44047) n[b] (%)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	6535 (29.7)	6524 (29.6)	13059 (29.6)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	7670 (34.8)	7558 (34.3)	15228 (34.6)
Obese (≥30.0 kg/m^2)	7543 (34.2)	7629 (34.6)	15172 (34.4)
Missing	7 (0.0)	6 (0.0)	13 (0.0)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (15:19)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_s005_demo_all_p3_saf

Within each age group, most demographic characteristics were similar in the BNT162b2 group and the placebo group. Overall, 4.0% of participants in the younger age group were SARS-CoV-2 baseline positive, and 1.9% of participants in the older age group were SARS-CoV-2 baseline positive, and the proportions were similar in the BNT162b2 and placebo groups. There was a lower proportion of non-Hispanic/non-Latino participants in the younger BNT162b2 and placebo groups (68.6% and 68.8%, respectively) than in the older BNT162b2 and placebo groups (80.9% and 80.7%, respectively).

Within each baseline SARS-CoV-2 status group, demographic characteristics were similar in the BNT162b2 group and the placebo group. Most participants were White regardless of baseline status; however, there was a higher proportion of White participants with a negative baseline status (82.9%) than with a positive baseline status (57.7%). The median age was 43.0 years in participants with a positive baseline status and 51.0 years in participants with a negative baseline status. There were 41.4% and 34.2% of participants who were obese with positive and negative baseline status, respectively.

Baseline Medical History

Participants ≥16 years of age had a diverse medical history profile consistent with that of individuals in the general population in the same age group. In the BNT162b2 group, conditions in the surgical and medical procedures (8430 [38.3%]), metabolism and nutrition disorders (6587 [29.9%]), and immune system disorders (5987 [27.2%]; of which 3303 [15.0%] were seasonal allergy) SOCs were most frequently reported.

Overall, 20.7% had any comorbidity (per the Charlson comorbidity index). The most frequently reported comorbidities were diabetes without chronic complications (7.7%), chronic pulmonary disease (8.1%), and any malignancy (3.6%), which were reported at similar frequencies in each group.

In the younger age group, 13.3% of participants had any comorbidity. The most frequently reported comorbidities were diabetes without chronic complications (3.7%) and chronic pulmonary disease (7.4%), which were reported at similar frequencies in each vaccine group.

In the older age group, 31.6% of participants had any comorbidity. The most frequently reported comorbidities were diabetes without chronic complications (13.6%) and chronic pulmonary disease (9.1%), which were reported at similar frequencies in each vaccine group.

2.7.4.1.2.4.4.1.1. Participants With Confirmed Stable HIV Disease (Phase 3, Study C4591001, Demographic and Other Characteristics of Study Population)

Demographic characteristics for participants with confirmed stable HIV disease were similar in the BNT162b2 and the placebo groups. Overall, 54.5% of participants were Black or African American, 40.5% of participants were White, and all other racial groups were ≤1.5%. There were 16.0% Hispanic/Latino participants. Median age was 49.5 years and 67.5% of participants were male. Obese participants made up 39.0% of this population.

2.7.4.1.2.4.4.2. Participants With At Least 6 Months Follow-Up Time – Original BNT162b2 Participants ≥16 Years of Age (Phase 3, Study C4591001, Demographic and Other Characteristics of Study Population)

Demographic characteristics for all original BNT162b2 Phase 2/3 participants ≥16 years of age and had at least 6 months of follow-up time after Dose 2 are presented in Table 36 in Appendix D. Overall, most participants were White (86.4%), with 7.1% Black or African American participants and 3.8% Asian participants, and other racial groups were ≤1.6%. There were 27.8% Hispanic/Latino participants. Median age was 53.0 years and 50.3% of participants were male. Obese participants made up 34.2% of this safety population.

2.7.4.1.2.4.4.3. Original Placebo Participants ≥16 Years of Age Who Then Received BNT162b2 (Phase 3, Study C4591001, Demographic and Other Characteristics of Study Population)

Demographic characteristics for all original placebo Phase 2/3 participants ≥16 years of age who then received BNT162b2 later during the open-label follow-up period are presented in Table 37 in Appendix D. Overall, most participants were White (83.1%), with 8.3% Black or African American participants and 4.3% Asian participants, and all other racial groups were ≤2.6%. There were 25.5% Hispanic/Latino participants. Median age was 51.0 years and 50.2% of participants were male. Obese participants made up 34.4% of this safety population.

2.7.4.1.2.4.4.4. All Participants (Phase 3, Study C4591001, Demographic and Other Characteristics of Study Population)

Demographic characteristics for all participants (including adolescents 12 through 15 years of age) were similar in the BNT162b2 group and the placebo group.

2.7.4.1.2.4.5. E-Diary Compliance (Phase 3, Study C4591001)

Overall, transmission of e-diary data was ≥90.1% (range: 90.1% to 94.0%) for each day during the 7 days after Dose 1 of BNT162b2. After Dose 2 of BNT162b2, transmission of e-diary data was 76.5% on Day 1 and ranged from 83.8% to 85.6% for each day during Day 2 through Day 7. Transmission rates were similar in the BNT162b2 group and the placebo group.

2.7.4.2. Safety Results for BNT162b2

Safety data for the primary and exploratory safety endpoints (as described in Section 2.7.4.1.1.2.1) for Phase 1, Phase 2, and Phase 3 for Study C4591001 and for Study BNT162-01 are presented in the following sections:

- BNT162-01: Section 2.7.4.2.1
- Phase 1: Section 2.7.4.2.2
- Phase 2: Section 2.7.4.2.3
- Phase 3: Section 2.7.4.2.4

Safety methods are described in Section 2.7.4.1.1 with more details in Appendix B (Section 2.7.4.6.2).

Full details of safety results, including for additional endpoints, are presented as follows:

Study BNT162-01: Module 5.3.5.1 BNT162-01 CSR.

Study C4591001:

- Phase 1, to 1 month after Dose 2: Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR; to 6 months after Dose 2: Module 5.3.5.1 C4591001 6-Month Update Interim CSR
- Phase 2, to 7 days after Dose 2: Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR
- Phase 2/3, to 1 month after Dose 2: Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR; to 6 months after Dose 2: Module 5.3.5.1 C4591001 6-Month Update Interim CSR.

Note that data from Phase 2 participants were included in Phase 3 safety analyses.

2.7.4.2.1. Study BNT162-01

Safety data (reactogenicity and AE analyses) are available up through the data cutoff date (23 October 2020) and are summarized below up to 1 month after Dose 2 for the younger and older age groups. Data from the safety set are presented. This summary focuses on the 10 µg, 20 µg, and 30 µg dose levels, which correspond to the primary dose levels investigated in the Phase 1 part of pivotal registration study, C4591001.

2.7.4.2.1.1. Reactogenicity (Phase 1, Study BNT162-01)

Reactogenicity results are up to 7 days after Dose 1 and Dose 2.

2.7.4.2.1.1.1. Local Reactions (Phase 1, Study BNT162-01)

Overall, solicited local reactions following administration across doses of BNT162b2 were milder and less frequent for participants compared with BNT162b1. Local reactions generally increased in frequency and/or severity with increasing dose level and number of doses of BNT162b1 and BNT162b2. Most local reactions were mild or moderate in severity and resolved within several days of onset.

For BNT162b1, the incidence of any local reactions after each dose was similar between younger and older age groups, but local reactions were generally milder in the older group. For BNT162b2, incidence of local reactions was generally less after each dose in the older group compared with the younger group, and severity of reactions was similar between both age groups.

Full details and outputs regarding local reactions for Study BNT162-01 are in Module 5.3.5.1 BNT162-01 CSR Section 12.3.

2.7.4.2.1.1.2. Systemic Events (Phase 1, Study BNT162-01)

Overall, solicited systemic events following administration across doses of BNT162b2 were milder and less frequent for participants compared with BNT162b1. Systemic events generally increased in frequency and/or severity with increasing dose level and number of doses of BNT162b1 and BNT162b2. Most systemic events were mild or moderate, arose within the first 1 to 2 days after dosing, and were short-lived.

For BNT162b1, the incidence of any systemic events after each dose was similar between younger and older age groups, but systemic events were generally milder in the older group. For BNT162b2, the incidence of systemic events after each dose was similar in the older group compared with the younger group. Reports of severe systemic events were similar between the younger and older BNT162b2 groups and were substantially less frequent than the severe events reported for younger and older BNT162b1 groups.

Full details and outputs regarding systemic events for Study BNT162-01 are in Module 5.3.5.1 BNT162-01 CSR Section 12.4.

2.7.4.2.1.2. Summary of Treatment-Emergent Adverse Events (Phase 1, Study BNT162-01)

Full details and outputs regarding the summary of adverse events for Study BNT162-01 are in Module 5.3.5.1 BNT162-01 CSR Section 12.5.1.

Overall, 40% to 45% of participants who received BNT162b1 and BNT162b2 across age groups and across dose levels reported one or more AEs from Dose 1 through 28 days (ie, 1 month) after Dose 2. There was no overall pattern between vaccine candidates with regard to AE incidence or severity; however, AEs considered by the investigator as related to study intervention (after omitting events captured in paper diaries for reactogenicity) were less frequently reported for BNT162b2 groups compared with BNT162b1.

Most AEs reported were considered by the investigator as not related to study intervention. Most AEs were mild to moderate in severity. All AEs were reported as resolved.

In the BNT162b1 group, 2 younger participants discontinued from the study (see Section 2.7.4.2.1.4.3) and 1 older participant experienced SAE (see Section 2.7.4.2.1.4.2). In the BNT162b2 group, 1 younger participant discontinued from the study (see Section 2.7.4.2.1.4.3) and 1 older participant experienced an SAE (see Section 2.7.4.2.1.4.2). No deaths occurred through the data cutoff date.

2.7.4.2.1.3. Analysis of Treatment-Emergent Adverse Events (Phase 1, Study BNT162-01)

Details and outputs regarding AEs by SOC and PT, related AEs, and severe AEs for Study BNT162-01 are in Module 5.3.5.1 BNT162-01 CSR Section 12.5.2.

2.7.4.2.1.3.1. Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Phase 1, Study BNT162-01)

From Dose 1 up to Day 28 after Dose 2 or Dose 1 (if no Dose 2), after omitting events captured in paper diaries for reactogenicity: In the BNT162b1 younger age group, the most frequently reported SOCs were general disorders and administration site conditions (most common PT: injection site reaction), nervous system disorders (most common PT: headache), and respiratory, thoracic and mediastinal disorders (most common PTs: cough and oropharyngeal pain). In the BNT162b1 older age group, the most frequently reported SOC was respiratory, thoracic and mediastinal disorders (most common PTs: cough and oropharyngeal pain); other SOCs were only reported by 1 or 2 participants each.

From Dose 1 up to Day 28 after Dose 2 or Dose 1 (if no Dose 2), after omitting events captured in paper diaries for reactogenicity: In the BNT162b2 younger age group, the most frequently reported SOC was general disorders and administration site conditions (most common PT: vessel puncture site pain. In the BNT162b2 older age group, the most frequently reported SOC was musculoskeletal and connective tissue disorders (most common PT: back pain).

2.7.4.2.1.3.2. Related Treatment-Emergent Adverse Events (Phase 1, Study BNT162-01)

From Dose 2 up to Day 28 after Dose 2: In the BNT162b1 younger age group, the most frequently reported related SOCs were general disorders and administration site conditions (most common PT: influenza like illness), nervous system disorders (most common PT: headache), and musculoskeletal and connective tissue disorders (most common PT: myalgia). In the BNT162b1 older age group, 1 related TEAE was reported in the 30 µg group in each of the following SOCs: ear and labyrinth disorders, gastrointestinal disorders, and urinary disorders.

From Dose 2 up to Day 28 after Dose 2: In the BNT162b2 younger age group, the most frequently reported related SOC was general disorders and administration site conditions (most common PT: injection site reaction). In the BNT162b2 older age group, 1 related TEAE was reported in the vascular disorders SOC (PT: hot flush).

2.7.4.2.1.3.3. Severe Treatment-Emergent Adverse Events (Phase 1, Study BNT162-01)

The most frequently reported SOC with severe and related TEAEs was general disorders and administration site conditions for the BNT162b1 younger groups. In the BNT162b1 older age group, nervous system disorders was the most frequently reported SOC with severe TEAEs (none were sever and related).

The most frequently reported SOC with severe TEAEs was musculoskeletal and connective tissue disorder and nervous system disorders for the BNT162b2 younger and older age groups, respectively (no severe TEAEs were assessed as related).

2.7.4.2.1.4. Deaths, Serious Adverse Events, Safety-Related Participant Withdrawals, and Other Significant Adverse Events (Phase 1, Study BNT162-01)

Details and outputs regarding deaths, serious adverse events, safety-related participant withdrawals, and other significant adverse events for Study BNT162-01 are in Module 5.3.5.1 BNT162-01 CSR Section 12.6.

2.7.4.2.1.4.1. Deaths (Phase 1, Study BNT162-01)

There were no Study BNT162-01 participants who died through the data cutoff date of 23 October 2020.

2.7.4.2.1.4.2. Treatment-Emergent Serious Adverse Events (Phase 1, Study BNT162-01)

Among BNT162b1 participants, 1 older participant in the 20 µg group had an SAE of severe syncope (considered as not related to study intervention) after Dose 1 and study treatment was withdrawn.

Among BNT162b2 participants, 1 older participant in 20 µg group had an SAE of ankle fracture (considered as not related to study intervention) after receiving both doses, was listed as recovering, and remains in follow-up.

2.7.4.2.1.4.3. Safety-Related Participant Withdrawals (Phase 1, Study BNT162-01)

Among BNT162b1 recipients, 1 younger participant in the 10 µg group discontinued the study due to a moderate AE of malaise (considered as not related to study intervention) after Dose 1 and 1 younger participant in the 60 µg group discontinued due to a dose-limiting toxicity of pyrexia after Dose 1.

Among BNT162b2 recipients, 1 younger participant in the in the 10 µg group discontinued the study due to a moderate AE of nasopharyngitis (considered as not related to study intervention) after Dose 1.

2.7.4.2.1.4.4. Adverse Events of Special Interest (Phase 1, Study BNT162-01)

There were no Study BNT162-01 participants who reported any AEs of special interest through the data cutoff date of 23 October 2020.

2.7.4.2.1.5. Clinical Laboratory Evaluations (Phase 1, Study BNT162-01)

Full details and outputs regarding clinical laboratory evaluations for Phase 1 of Study BNT162-01 are in Module 5.3.5.1 BNT162-01 CSR Section 12.7.

Changes from baseline in lymphocyte (low) count were reported in all dose groups after 48 hours of dosing with both BNT162b1 and BNT162b2 as a pharmacodynamics effect. However, their values came back to normal at the subsequent visit without any clinical consequence and without sequelae.

Changes from baseline were small in all dose groups following the administration of both BNT162b1 and BNT162b2. Likewise, the changes from baseline did not indicate a particular trend in the time course of all clinical chemistry parameters, except for CRP in both BNT162b1 and BNT162b2 younger age groups, as a pharmacodynamics effect. However, their values came back to normal at the subsequent visit without any clinical consequence. In the older participants group, no elevated values of CRP were seen.

There were a few abnormal urinalysis parameters, but none were clinically significant except for 1 elevated value of leukocytes (on Day 50 in younger participant in 1 µg group).

2.7.4.2.1.6. Vital Signs, Physical Findings, and Other Observations Related to Safety (Phase 1, Study BNT162-01)

Full details and outputs regarding physical examination findings for Phase 1 of Study BNT162-01 are in Module 5.3.5.1 BNT162-01 CSR Section 12.8.

A few abnormal vital signs were reported but none of them were clinically relevant abnormalities, except for mild or moderate elevated body temperature reported on Day 2 by 5 participants in the BNT162b1 younger age group. The events were assessed as related TEAEs, and the elevated body temperature values came back to normal at the subsequent visit with medication.

No participants presented clinically significant ECG findings or physical examination findings at screening or when assessed during the ongoing study.

2.7.4.2.1.7. Conclusions (Phase 1, Study BNT162-01)

Based on Phase 1 data from the FIH Study BNT162-01, BNT162b2 was safe and well-tolerated in healthy adults 18 to 85 years of age, with no unanticipated safety findings. Reactogenicity and AEs tended to increase in incidence and/or severity with increasing dose of BNT162b2. Reactogenicity was mostly mild to moderate and short-lived after dosing, and the AE profile and clinical laboratory results did not suggest any safety concerns.

2.7.4.2.2. Phase 1 (Study C4591001)

Safety data are available up through the data cutoff dates noted below and are summarized at various time points relative to Dose 1 or Dose 2 as follows:

- Safety results for Phase 1 vaccine candidates BNT162b1 and BNT162b2 for both adult age groups are presented up to 1 month after Dose 2 (or 24 August 2020 data cutoff date) at the 10 µg, 20 µg, and 30 µg dose levels.

- Safety results for BNT162b1 at the 100 µg dose level in the younger age group are presented up to 3 weeks after Dose 1 or to before Dose 2 based on the data cutoff date of 24 August 2020. Note that the group of participants 18 to 55 years of age who received 100 µg BNT162b1 did not receive a second dose of 100 µg BNT162b2 per IRC decision, and instead, they were given 10 µg for Dose 2. At the time of the data cutoff date, 11 of 12 participants in this group received Dose 2 of BNT162b1 at 10 µg but results for Dose 2 are not yet available at the time of this report.

- Long-term follow-up from 1 month after Dose 2 to approximately 6 months after Dose 2 (as of unblinding date) of AEs and SAEs for Phase 1 participants who received BNT162b2 30 µg are also presented (these data are based on the 13 March 2021 data cutoff date). Note: Adverse event data for the BNT162b2 30 µg group, from Dose 1 to the unblinding date, are summarized in Module 5.3.5.1 C4591001 6-Month Update CSR Section 12.1.2 and Section 12.1.3.

All doses tested for BNT162b1 and BNT162b2 (10 µg, 20 µg, and 30 µg) were safe and well tolerated except for BNT162b1 at 100 µg, which was discontinued after the first dose due to the reactogenicity profile. BNT162b2 at 30 µg was selected to proceed into the Phase 2/3 portion of the study because this dose and construct provided the optimum combination of a favorable reactogenicity profile and a robust immune response.

2.7.4.2.2.1. Reactogenicity (Phase 1, Study C4591001)

Reactogenicity results are up to 7 days after Dose 1 and Dose 2.

2.7.4.2.2.1.1. Local Reactions (Phase 1, Study C4591001)

Overall, for both the BNT162b1 and the BNT162b2 recipients, and in both age groups, pain at the injection site was the most frequent local reaction. Redness and swelling occurred less frequently in the BNT162b2 group and in the BNT162b1 group. In both the BNT162b1 and BNT162b2 groups, the frequency of local reactions was lower in the older age group

compared to the younger age group, and there was a trend of a higher frequency of local reactions with increased dose. Local reactions were short-lived.

Full details and outputs regarding local reactions for Phase 1 of Study C4591001 are in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 12.1.1.

2.7.4.2.2.1.2. Systemic Events (Phase 1, Study C4591001)

Overall, within 7 days after Dose 1, fatigue was generally the most frequently reported systemic event in the both the younger and older BNT162b1 groups and in the older BNT162b2 group; while headache and fatigue were most frequently reported in the younger BNT162b2 dose group. Overall, within 7 days after Dose 2, headache was the most frequently reported systemic event in the both the younger and older BNT162b1 groups and fatigue was the most frequently reported systemic event in the both the younger and older BNT162b2 groups. Chills was generally reported at a higher frequency after Dose 2 and at a higher frequency in the BNT162b1 group than in the BNT162b2 group. Fever was reported more frequently in the younger BNT162b1 group after Dose 2 than in the older BNT162b2 group. For both the BNT162b1 and the BNT162b2 recipients, after the first and second dose and in both age groups, the majority of systemic events were mild or moderate in severity (no Grade 4 systemic events) and generally short-lived.

Full details and outputs regarding systemic events for Phase 1 of Study C4591001 are in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 12.1.2.

2.7.4.2.2.2. Summary of Adverse Events (Phase 1, Study C4591001)

Full details and outputs regarding the summary of adverse events for Phase 1 of Study C4591001 (including for participants in the BNT162b1 100 µg dose group) are in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 12.1.3.1 (24 August 2020 data cutoff date).

All AEs from Dose 1 through the data cutoff date of 24 August 2020 were included in the summary for all dose levels for each vaccine candidate and age group other than BNT162b1 100 µg group for which AEs from Dose 1 to before Dose 2 were summarized. Additionally, long-term follow-up (from 1 month to approximately 4 months after Dose 2 [as of 14 November 2020 cutoff date]) of AEs for Phase 1 participants who received BNT162b2 30 µg were summarized.

Overall, fewer participants reported at least 1 AE after Dose 1 in the older BNT162b2 group (8.3% to 25.0%) compared to the younger (41.7% to 50.0%) and older (25.0% to 58.3%) BNT162b1 groups and the younger BNT162b2 group (33.3% to 41.7%).

No SAEs, AEs leading to withdrawals, or deaths were reported in either age group for either the BNT162b1 or BNT162b2 groups up to 1 month after Dose 2.

To the Data Cutoff Date of 13 March 2021 for BNT162b2 (30 µg)

For the BNT162b2 30 µg group, during the additional follow-up to the unblinding date (approximately 6 months of follow-up after Dose 2), no additional AEs were reported in the

younger or older age group except for 1 severe SAE (neuritis due to an antecubital fossa blood draw) reported in the younger age group (Section 2.7.4.2.2.3.1).

2.7.4.2.2.3. Analysis of Adverse Events (Phase 1, Study C4591001)

Details and outputs regarding AEs by SOC and PT, related AEs, immediate AEs, and severe AEs for Phase 1 of Study C4591001 (including for participants in the BNT162b1 100 µg dose group) are in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 12.1.3.2.

2.7.4.2.2.3.1. Adverse Events by System Organ Class and Preferred Term (Phase 1, Study C4591001)

AE by SOC and PT summaries included AEs from Dose 1 to 1 month after Dose 2 for all groups other than BNT162b1 100-ug group for which AEs from Dose 1 to 3 weeks after Dose 1 or from Dose 1 to before Dose 2 were summarized.

General disorders and administration site conditions was the most commonly reported SOC in the older BNT162b1 group and the younger BNT162b2 group. The most commonly reported SOC was gastrointestinal disorders in the younger BNT162b1 group and nervous system disorders in the older BNT162b2 group. Generally, most PTs were reported by ≤2 participants per dose group.

To the Data Cutoff Date of 13 March 2021 for BNT162b2 (30 µg)

For the BNT162b2 30 µg group, during the additional follow-up to the unblinding date (approximately 6 months of follow-up after Dose 2), an additional severe SAE (neuritis) was reported by 1 participant in the younger age group; per the participant's medical examination and history, this event was linked to a blood draw, and the investigator considered there was a reasonable possibility that the event neuritis was related to clinical trial procedure (antecubital fossa blood draw) but unrelated to vaccination.

2.7.4.2.2.3.2. Related Adverse Events (Phase 1, Study C4591001)

Overall, general disorders and administration site conditions was the most commonly reported SOC for the younger and older BNT162b1 groups and the younger BNT162b2 group. In the older BNT162b2 group, nausea, reported in 1 (8.3%) participant, was the only related AE.

To the Data Cutoff Date of 13 March 2021 for BNT162b2 (30 µg)

Additional follow-up through the unblinding date (approximately 6 months of follow-up after Dose 2) did not identify any additional participants with related AEs in the BNT162b2 30 µg group.

2.7.4.2.2.3.3. Immediate Adverse Events (Phase 1, Study C4591001)

In the BNT162b1 group, no participants in the younger group reported an immediate AE after Dose 1 at the 30 µg dose level, and there were no participants in either age group who reported any immediate AEs after Dose 2 of BNT162b1.

In the BNT162b2 group, 3 participants in the younger age group reported an immediate AE after Dose 1 (including 1 report of injection site pain from a participant in the 30 µg dose group). After Dose 2 of BNT162b2, 1 participant in the 20 µg dose group reported an immediate AE. There were no participants in the older age group who reported any immediate AE after any dose of BNT162b2.

2.7.4.2.2.3.4. Severe Adverse Events (Phase 1, Study C4591001)

In the BNT162b1 group, 2 severe AEs were reported in the younger age group (pyrexia [102.4°F] 2 days after Dose 2 [30 µg dose group] and sleep disorder 1 day after Dose 1 [100 µg dose group]; both were determined by the investigator to be related to study intervention) and 2 severe AEs were reported in the older age group (herpes zoster 2 days after Dose 1 [20 µg dose group], which was considered unrelated, and fatigue 1 day after Dose 2 [30 µg dose group], which was considered related).

In the BNT162b2 younger age group, 1 participant with a history of migraines reported a severe migraine 7 days after Dose 1 (30 µg dose group, considered unrelated). In the BNT162b2 older age group, 2 participants reported a severe AE: muscle spasms 2 days after Dose 2 (30 µg dose group, considered unrelated to BNT162b2) and radiculopathy 3 days after Dose 1 (placebo), considered unrelated to study intervention.

To the Data Cutoff Date of 13 March 2021 for BNT162b2 (30 µg)

Additional follow-up through the unblinding date (approximately 6 months of follow-up after Dose 2) for the BNT162b2 30 µg group identified an additional severe SAE (neuritis due to an antecubital fossa blood draw), reported in the younger age group (Section 2.7.4.2.2.3.1).

2.7.4.2.2.4. Deaths, Serious Adverse Events, Safety-Related Participant Withdrawals, and Other Significant Adverse Events (Phase 1, Study C4591001)

Details and outputs regarding deaths, serious adverse events, safety-related participant withdrawals, and other significant adverse events for Phase 1 of Study C4591001 are in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 12.1.4.

2.7.4.2.2.4.1. Deaths (Phase 1, Study C4591001)

There were no Phase 1 participants who died through the 24 August 2020 data cutoff date and through the unblinding date.

2.7.4.2.2.4.2. Serious Adverse Events (Phase 1, Study C4591001)

There were no Phase 1 participants who reported any SAEs from Dose 1 through the data cutoff date of 24 August 2020.

To the Data Cutoff Date of 13 March 2021 for BNT162b2 (30 µg)

Additional follow-up through the unblinding date (approximately 6 months of follow-up after Dose 2) for the BNT162b2 30 µg group identified an additional severe SAE (neuritis due to an antecubital fossa blood draw), reported in the younger age group (Section 2.7.4.2.2.3.1).

2.7.4.2.2.4.3. Safety-Related Participant Withdrawals (Phase 1, Study C4591001)

There were no Phase 1 participants with any AEs leading to withdrawal from the study through the 24 August 2020 data cutoff date and through the unblinding date.

2.7.4.2.2.4.4. Other Significant Adverse Events (Phase 1, Study C4591001)

AEs of special interest were not defined for Phase 1 of this study.

2.7.4.2.2.4.5. Other Safety Assessments (Phase 1, Study C4591001)

2.7.4.2.2.4.5.1. Pregnancy – Phase 1

Pregnancy was not reported in any Phase 1 participants through the 24 August 2020 data cutoff date and through the unblinding date.

2.7.4.2.2.5. Clinical Laboratory Evaluations (Phase 1, Study C4591001)

Details and outputs regarding clinical laboratory evaluations for Phase 1 of Study C4591001 are in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 12.1.5.

Overall, 1 to 3 days after Dose 1, there were transient decreases in lymphocytes (<0.8 × LLN), which returned to normal by 6 to 8 days after Dose 1, in the younger and older BNT162b1 and BNT162b2 groups. Most shifts were from normal or Grade 1 to Grade 1, 2, or 3 decrease in lymphocyte counts, which returned to normal by 6 to 8 days after Dose 1 and were observed in all age and dose groups. The incidence of decreased lymphocyte counts was lower for BNT162b2 recipients compared with BNT162b1 recipients. Shifts from normal to Grade 1 (younger BNT162b1 group) or Grade 2 (older BNT162b2 group) neutrophil decrease were also observed but were infrequent.

Overall, clinical chemistry and other hematology abnormalities were observed infrequently. None of the laboratory abnormalities were associated with clinical findings.

2.7.4.2.2.6. Physical Examination Findings (Phase 1, Study C4591001)

Overall, there were fewer abnormalities noted during physical examinations after BNT162b2 than after BNT162b1 in both age groups. Full details and outputs regarding physical examination findings for Phase 1 of Study C4591001 are in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 12.1.6.

2.7.4.2.2.7. Narratives (Phase 1, Study C4591001)

Narratives generated for Phase 1 are provided in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 14.

2.7.4.2.2.8. Conclusions (Phase 1, Study C4591001)

Based on Phase 1 data from Study C4591001, BNT162b2 was safe and well-tolerated in younger healthy adults 18 to 55 years of age, and in older healthy adults 65 to 85 years of age, with no unanticipated safety findings. Reactogenicity and AEs were generally milder and less frequent in participants in the older group compared with the younger group and overall tended to increase with increasing BNT162b2 dose. Reactogenicity was mostly mild to moderate and short-lived after dosing, and the AE profile did not suggest any safety concerns. Clinical laboratory evaluations showed a transient decrease in lymphocytes that was observed in all age and dose groups after Dose 1, which resolved within approximately 1 week, was not associated with any other clinical sequelae, and was not considered clinically relevant.

2.7.4.2.3. Phase 2 (Study C4591001)

Reactogenicity, AE, and SAE data for the 360 participants in the Phase 2 portion of the study are presented up to the data cutoff date of 02 September 2020. Adverse event results beyond 7 days after Dose 2, as defined in the protocol objectives, are included in Phase 3 analyses (see Section 2.7.4.2.4).

2.7.4.2.3.1. Reactogenicity (Phase 2, Study C4591001)

Reactogenicity results are up to 7 days after Dose 1 and Dose 2.

2.7.4.2.3.1.1. Local Reactions (Phase 2, Study C4591001)

Details and outputs regarding local reactions for Phase 2 of Study C4591001 are in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 12.2.1.

Frequency and Severity of Local Reactions

After the first and second dose of BNT162b2 and in both age groups, the majority of local reactions were mild or moderate in severity, and no Grade 4 (potentially life-threatening) local reactions were reported. In the BNT162b2 group, pain at the injection site was reported more frequently in the younger age group (N=88 post-dose 1; N=86 post-dose 2) than in the older age group (N=92 post-dose 1; N=91 post-dose 2), and frequency was similar after Dose 1 compared with Dose 2 of BNT162b2 in the younger age group (85.2% vs. 80.2%, respectively) and in the older age group (70.7% vs. 72.5%, respectively). In the placebo group, pain at the injection site was reported at similar frequencies (7.8% to 10.2%) in the younger and older age groups after Dose 1 and Dose 2.

In the BNT162b2 group, redness and swelling were similar in the younger and older age group after Dose 1. After Dose 2, the frequency of redness and swelling was slightly higher in the older age group (7.7% and 12.1%, respectively) than in the younger age group (3.5% and 3.5%, respectively). In the placebo group, only 1 participant in the older age group reported redness after Dose 1, and no swelling was reported.

One participant in the BNT162b2 group (older age group) reported severe injection site pain after Dose 1, and 1 participant in the younger age group reported severe injection site pain

after Dose 2. One participant in the BNT162b2 group (older age group) reported severe redness after Dose 2.

Overall, across age groups, pain at the injection site was the most frequent local reaction and did not increase after Dose 2, and redness and swelling were generally similar in frequency after Dose 1 and Dose 2.

Onset and Duration

Across age groups, local reactions for the BNT162b2 group after either dose had a median onset day between Day 1.0 and Day 3.0 (Day 1.0 was the day of vaccination), and ranges were generally similar in the younger and older age groups. Across age groups, after either dose of BNT162b2, local reactions resolved after a median duration of 1.0 to 3.0 days, which was generally similar in the younger and older age groups.

2.7.4.2.3.1.2. Systemic Events (Phase 2, Study C4591001)

Details and outputs regarding systemic events for Phase 2 of Study C4591001 are in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 12.2.2.

Frequency and Severity of Systemic Events

In the BNT162b2 group, systemic events were generally reported more frequently and were of higher severity in the younger group (N=88 post-dose 1; N=86 post-dose 2) compared with the older group (N=92 post-dose 1; N=91 post-dose 2), with frequencies and severity increasing with number of doses (Dose 1 vs Dose 2). Vomiting and diarrhea were exceptions with vomiting infrequent and similar in both age groups and vomiting and diarrhea similar after each dose. Frequencies of systemic events in the younger and older BNT162b2 groups (Dose 1 vs Dose 2) are listed below:

- Fatigue: younger group (50.0% vs 59.3%) compared to older group (35.9% vs 52.7%)
- Headache: younger group (31.8% vs 51.2%) compared to older group (27.2% vs 36.3%)
- Muscle pain: younger group (23.9% vs 45.3%) compared to older group (14.1% vs 28.6%)
- Chills: younger group (9.1% vs 40.7%) compared to older group (7.6% vs 20.9%)
- Joint pain: younger group (9.1% vs 17.4%) compared to older group (4.3% vs 16.5%)
- Fever: younger group (3.4% vs 17.4%) compared to older group (0.0% vs 11.0%).
- Vomiting: similar in both age groups and after either dose.
- Diarrhea: reported less frequently in the older group and was similar after each dose.

Systemic events were generally reported less frequently in the placebo group than in the BNT162b2 group, for both age groups and doses, with some exceptions. In the younger age group, fever, headache, chills, vomiting, and diarrhea after Dose 1, and vomiting after Dose 2 were reported at similar frequencies in both the placebo and BNT162b2 groups. In the older age group, vomiting, diarrhea, muscle pain, and joint pain after Dose 1, and vomiting and diarrhea after Dose 2 were reported at similar frequencies in the placebo and BNT162b2 groups.

Use of antipyretic/pain medication was slightly less frequent in the older age group after both doses but increased in both age groups overall after Dose 2 as compared with after Dose 1. Use of antipyretic/pain medication was less frequent in the placebo group than in the BNT162b2 group.

After the first and second dose and in both age groups, the majority of systemic events were mild or moderate in severity, and no Grade 4 (potentially life-threatening) systemic events were reported. Across age groups, severe systemic events were only reported after Dose 2 of BNT162b2 overall and included fever (1.1%), fatigue (4.0%), headache (2.8%), chills (2.3%), and muscle pain (1.7%).

Onset and Duration

Across age groups, systemic events after both doses of BNT162b2 had a median onset day between Day 2.0 to Day 3.0 (Day 1.0 was the day of vaccination), and ranges were similar in the younger and older age groups. Across age groups, systemic events for this group after either dose resolved with a median duration of 1 day, which was similar in the younger and older age groups. The median duration of fever and chills after either dose for both age groups was 1 day. There was no clear difference in the durations of systemic events that occurred after Dose 1 compared to those that occurred after Dose 2.

2.7.4.2.3.2. Summary of Adverse Events (Phase 2, Study C4591001)

Full details and outputs regarding the summary of adverse events for Phase 2 of Study C4591001 are in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 12.2.3.1.

AE reporting for 360 participants evaluated in Phase 2 as of the data cutoff date (14 November 2020) includes at least 2 months of follow-up. The number of participants who reported at least 1 AE from Dose 1 to 7 days after Dose 2 was similar in the BNT162b2 group compared with the placebo group, which was generally similar in the 2 vaccine groups in the younger and older age groups. (9.1% vs 11.1% and 4.3% vs 8.9%, respectively). Two severe events were reported for 2 participants in the BNT162b2 younger age group: myalgia (AE) and gastric adenocarcinoma (SAE) (Section 2.7.4.2.3.3.4 and Section 2.7.4.2.3.4.2, respectively). The SAE of gastric adenocarcinoma occurred 23 days after receiving Dose 1. Both events were assessed by the investigator as not related to study intervention.

2.7.4.2.3.3. Analysis of Adverse Events (Phase 2, Study C4591001)

Full details and outputs regarding AEs by SOC and PT, related AEs, immediate AEs, and severe AEs for Phase 2 of Study C4591001 are in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 12.2.3.2.

2.7.4.2.3.3.1. Adverse Events by System Organ Class and Preferred Term (Phase 2, Study C4591001)

The number of participants who reported at least 1 AE was similar in the BNT162b2 group compared to the placebo group from Dose 1 to 7 days after Dose 2.

In the younger age group, 8 (9.1%) and 10 (11.1%) participants reported at least 1 AE in the BNT162b2 group and the placebo group, respectively. In the older age group, 4 (4.3%) and 8 (8.9%) participants reported at least 1 AE in the BNT162b2 group and the placebo group, respectively.

Overall, most AEs reported up to 7 days after Dose 2 were in the SOCs of gastrointestinal disorders (3 [1.7%] in the BNT162b2 group and 2 [1.1%] in the placebo group), general disorders and administration site conditions (3 [1.7%] in the BNT162b2 group and 7 [3.9%] in the placebo group), and musculoskeletal and connective tissue disorders (3 [1.7%] in the BNT162b2 group and 1 [0.6%] in the placebo group).

The most frequently reported AE by PT was injection site pain (3 [3.4%]) in the younger BNT162b2 group, which all occurred on the day of vaccination with Dose 1 during the reporting period for local reactions. Two events resolved within 3 days, and 1 event resolved 11 days later. All other AEs by PT were reported in ≤2 participants in each vaccine group.

One participant in the older BNT162b2 group had an AE of contusion in the upper left arm deltoid region, which was assessed by the investigator as related to study intervention.

2.7.4.2.3.3.2. Related Adverse Events (Phase 2, Study C4591001)

The number of participants with AEs assessed by the investigator as related to study intervention from Dose 1 to 7 days after Dose 2 were low in frequency and similar in the BNT162b2 group and placebo group. Within the BNT162b2 group, a similar proportion of participants in the young and old age groups reported related AEs. Most investigator-assessed related AEs were reactogenicity events in the SOC of general disorders and administration site conditions, and they were reported by a similar proportion of participants in the BNT162b2 group overall compared with the placebo group, with injection site pain being the PT reported most frequently and exclusively in the BNT162b2 younger age group.

2.7.4.2.3.3.3. Immediate Adverse Events (Phase 2, Study C4591001)

There were no immediate AEs after any dose of BNT162b2 30 µg or placebo.

2.7.4.2.3.3.4. Severe or Life-Threatening Adverse Events (Phase 2, Study C4591001)

Two participants (both in the BNT162b2 younger age group) reported severe events of myalgia (AE) and gastric adenocarcinoma (SAE, discussed in Section 2.7.4.2.3.4.2). The

participant who reported myalgia had scapular muscle pain, which began 2 days after Dose 2 and which lasted 12 days. Both events were assessed by the investigator as not related to study intervention.

2.7.4.2.3.4. Deaths, Serious Adverse Events, Safety-Related Participant Withdrawals, and Other Significant Adverse Events (Phase 2, Study C4591001)

Full details and outputs regarding deaths, serious adverse events, safety-related participant withdrawals, and other significant adverse events for Phase 2 of Study C4591001 are in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 12.2.4.

2.7.4.2.3.4.1. Deaths (Phase 2, Study C4591001)

There were no Phase 2 participants who died through the data cutoff date of 02 September 2020.

2.7.4.2.3.4.2. Serious Adverse Events (Phase 2, Study C4591001)

From Dose 1 to 7 days after Dose 2, 1 participant (BNT162b2 younger age group) had an SAE of gastric adenocarcinoma 23 days after Dose 1, which was assessed by the investigator as not related to study intervention. The SAE was ongoing at the time of the data cutoff, and the participant was withdrawn from the study because of the SAE.

2.7.4.2.3.4.3. Safety-Related Participant Withdrawals (Phase 2, Study C4591001)

The participant in the BNT162b2 younger age group who reported an SAE of gastric adenocarcinoma (Section 2.7.4.2.3.4.2) was discontinued from the study on Day 23 after Dose 1 of BNT162b2.

2.7.4.2.3.4.4. Other Significant Adverse Events (Phase 2, Study C4591001)

AEs of special interest were not defined for Phase 2 of this study; however, targeted medical events were monitored throughout the study (see Section 2.7.4.2.4.3.4).

2.7.4.2.3.5. Narratives (Phase 2, Study C4591001)

Narratives for the Phase 2 participants who were withdrawn from the study because of an SAE through the data cutoff date (14 November 2020) are provided in Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR Section 14.

2.7.4.2.3.6. Conclusions (Phase 2, Study C4591001)

Based on Phase 2 data from 360 participants in Study C4591001, BNT162b2 at 30 µg was safe and well-tolerated in adults 18 to 85 years of age. Reactogenicity and AEs were generally milder and less frequent in participants in the older group (≥56 years of age) compared with the younger group (≤55 years of age). Reactogenicity was mostly mild to moderate and short-lived after dosing, and the AE profile did not suggest any serious safety concerns. No treatment-related SAEs were reported, and incidence of discontinuations due to AEs up to the data cutoff date (representing at least 2 months of follow-up after Dose 2) was low. There were no deaths as of the data cutoff date (02 September 2020). Phase 2 safety

data were concordant with safety data in the Phase 1 portion of the study, both overall and with regard to younger and older participants.

2.7.4.2.4. Phase 3 (Study C4591001)

Safety data are available up to the data cutoff date of 13 March 2021. Reactogenicity data are from the 9839 participants in the reactogenicity subset (Section 2.7.4.2.4.1). Adverse Event data are provided for ~44,000 participants as described in Section 2.7.4.2.4.2.

2.7.4.2.4.1. Reactogenicity (Phase 3, Study C4591001)

The reactogenicity data were collected by participants' e-diary for reporting prompted local reactions and systemic events for 7 days after each dose.

Reactogenicity results are up to 7 days after Dose 1 and Dose 2.

2.7.4.2.4.1.1. Local Reactions (Phase 3, Study C4591001)

Details and outputs regarding local reactions for Phase 3 of Study C4591001 are in Module 5.3.5.1 C4591001 6-Month Update CSR Section 12.2.1.

Frequency and Severity of Local Reactions

In the BNT162b2 group, pain at the injection site was reported more frequently in the younger age group (N=2899 post-Dose 1; N=2682 post-Dose 2) than in the older age group (N=2008 post-Dose 1; N=1860 post-Dose 2), and frequency was similar after Dose 1 compared with Dose 2 of BNT162b2 in the younger age group (83.7% vs 78.3%) and in the older group (70.1% vs 66.1%) (Figure 1 and Figure 2, respectively). In the placebo group, pain at the injection site after Doses 1 and 2 was reported at slightly higher frequencies in the younger age group (14.2% and 11.6%, respectively) than in the older age group (9.3% and 7.8%, respectively).

In the BNT162b2 group, frequencies of redness and swelling were similar in the younger and older age group after Doses 1 and 2. Frequencies of redness were similar after Dose 1 compared with Dose 2 of BNT162b2 in the younger age group (5.4% vs 5.6%) and in the older age group (5.3% vs 7.2%). Frequencies of swelling were similar after Dose 1 compared with Dose 2 of BNT162b2 in the younger age group (6.3% vs 6.8%, respectively) and in the older age group (7.0% vs 7.8%). In the placebo group, redness and swelling were reported infrequently in the younger (≤1.0%) and older (≤1.2%) groups after Doses 1 and 2.

Overall, across age groups, pain at the injection site did not increase after Dose 2, and redness and swelling were generally similar in frequency after Dose 1 and Dose 2. Severe redness and swelling were reported infrequently and were similar between the younger and older age groups (≤0.7%) after any dose. Severe pain at the injection site occurred more frequently in the younger age group compared to the older age group (2.5% vs 0.7%). After the first and second dose and in both age groups, the majority of local reactions were mild or moderate in severity, and no Grade 4 local reactions were reported.

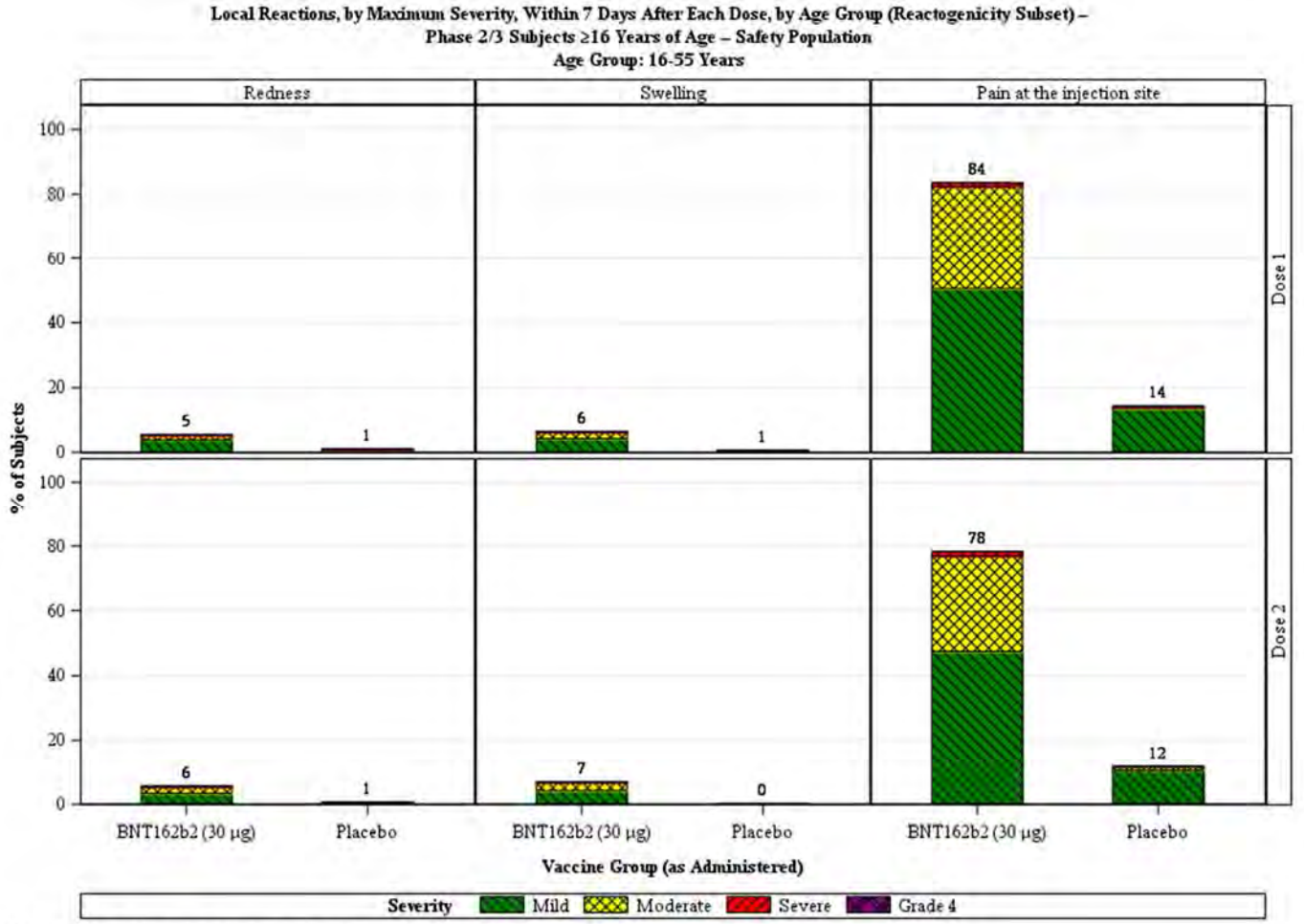
Subgroup Analyses

There were 177 BNT162b2 and 187 placebo participants with baseline positive SARS-CoV-2 status, and 4701 BNT162b2 and 4690 placebo participants with baseline negative SARS-CoV-2 status, respectively. For local reactions the frequency of redness, swelling, and pain at the injection site after any dose of BNT162b2 was 8.5%, 10.2%, and 80.2% compared with 9.9%, 11.1%, and 84.5% for those positive and negative at baseline, respectively. While the frequency of local reactions was numerically higher in those negative at baseline, these differences are not clinically meaningful.

Onset and Duration

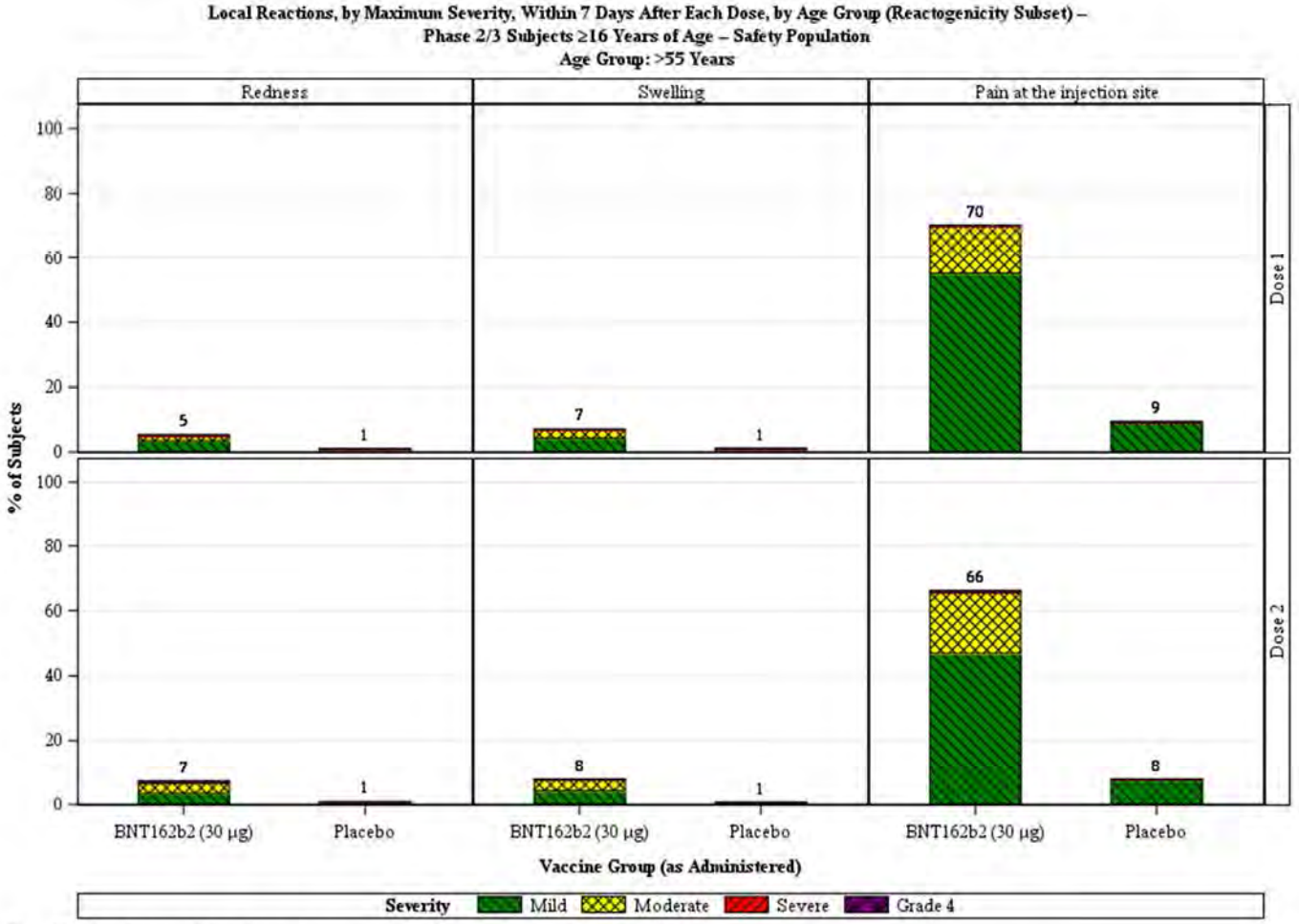
The median onset for local reactions after either dose of BNT162b2 was between Day 1.0 and Day 2.0 (Day 1.0 was the day of vaccination) in the younger age group and between Day 1.0 and Day 3.0 in the older age group. Local reactions resolved with median durations between 1.0 and 2.0 days in both age groups.

Figure 1. Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population
Age Group: 16 Through 55 Years of Age – Safety Population



Note: Number above each bar denotes percentage of subjects reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: /nda2_unblinded/C4591001_BLA/adce_f001_lr_max_age_p3

Figure 2. Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population
Age Group: >55 Years of Age

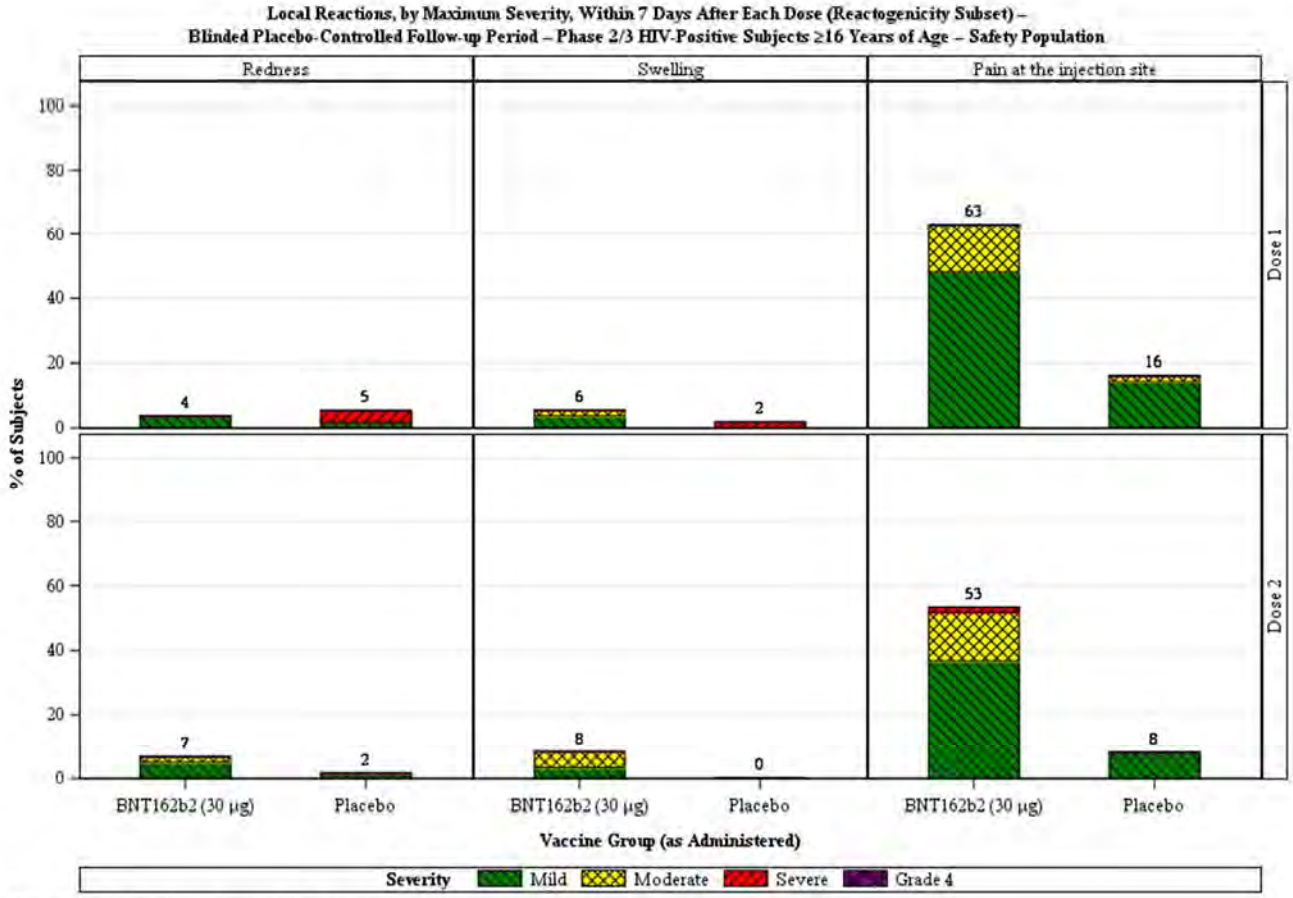


Note: Number above each bar denotes percentage of subjects reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: /nda2_unblinded/C4591001_BLA/adce_f001_lr_max_age_p3

2.7.4.2.4.1.1.1. Participants with Confirmed Stable HIV Disease (Phase 3, Study C4591001, Local Reactions)

Local reactions in participants with confirmed stable HIV disease were similar to those observed for all participants ≥16 years of age by severity (Figure 3), onset day, and median duration. The frequency of pain at the injection site was similar after Dose 1 compared with Dose 2 of BNT162b2 (63.0% vs 53.3%). The frequency of redness and swelling was similar after Dose 1 compared with Dose 2 of BNT162b2 (redness: 3.7% vs 6.7%; swelling: 5.6% vs 8.3%, respectively). There was 1 (1.7%) severe reaction (pain at the injection site) reported after Dose 2 of BNT162b2 and no Grade 4 reactions were reported.

Figure 3. Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population



Abbreviation: HIV = human immunodeficiency virus.
Note: Number above each bar denotes percentage of subjects reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: /nda2_unblinded/C4591001_BLA/adce_f001_lr_max_hiv_p3

2.7.4.2.4.1.2. Systemic Events (Phase 3, Study C4591001)

Details and outputs regarding systemic events for Phase 3 of Study C4591001 are in Module 5.3.5.1 C4591001 6-Month Update CSR Section 12.2.2.

Frequency and Severity of Local Reactions

Systemic events were generally increased in frequency and severity in the younger group (Figure 4) compared with the older group (Figure 5), with frequencies and severity increasing with number of doses (Dose 1 vs Dose 2). Vomiting and diarrhea were exceptions, which were reported similarly infrequently in both age groups and at similar incidences after each dose.

Systemic events in the younger group compared with the older group, with frequencies increasing with number of doses (Dose 1 vs Dose 2), were:

- fatigue: younger group (49.4% vs 61.5%) compared to older group (33.7% vs 51.0%)
- headache: younger group (43.5% vs 54.0%) compared to older group (25.0% vs 39.4%)
- muscle pain: younger group (22.9% vs 39.3%) compared to older group (13.6% vs 28.9%)
- chills: younger group (16.5% vs 37.8%) compared to older group (6.5% vs 23.4%)
- joint pain: younger group (11.8% vs 23.8%) compared to older group (8.7% vs 19.0%)
- fever: younger group (4.1% vs 16.4%) compared to older group (1.3% vs 11.8%)
- vomiting: younger group (1.2% vs 2.2%) compared to the older group (0.5% vs 0.7%)
- diarrhea: younger group (10.7% vs 10.0%) compared to the older group (8.4% vs 8.2%).

Systemic events were generally reported less frequently in the placebo group than in the BNT162b2 group, for both age groups and doses, with some exceptions. In the younger age group, vomiting and diarrhea (after Dose 1 and Dose 2) were reported at similar frequencies in the placebo group and the BNT162b2 group (Figure 4). In the older age group, vomiting and diarrhea (after Dose 1 and Dose 2) were reported at similar frequencies in the placebo group and the BNT162b2 group (Figure 5).

Following both Dose 1 and Dose 2, use of antipyretic/pain medication was slightly less frequent in the older age group (19.0% vs 37.0%) than in the younger age group (27.8% vs 45.2%) after both doses, and medication use increased in both age groups after Dose 2 as compared with after Dose 1. Use of antipyretic/pain medication was less frequent in the placebo group than in the BNT162b2 group and was similar after Dose 1 and Dose 2 in the younger and older placebo groups (ranging from 9.3% to 13.7%).

Severe fever (>38.9°C to 40.0°C) increased in frequency with the number of doses (Dose 1 versus Dose 2) in younger (0.3% vs 1.5%) and older (0.0% vs 0.4%) participants who received BNT162b2 and was reported in 0.1% of participants who received placebo in both age groups after both doses. One participant in the younger BNT162b2 group reported fever of 41.2°C only on Day 2 after Dose 2 and was nonfebrile for all other days of the reporting period. Grade 4 fever was not reported in the older BNT162b2 group or in any placebo participants.

After the first and second dose and in both age groups, the majority of systemic events were mild or moderate in severity.

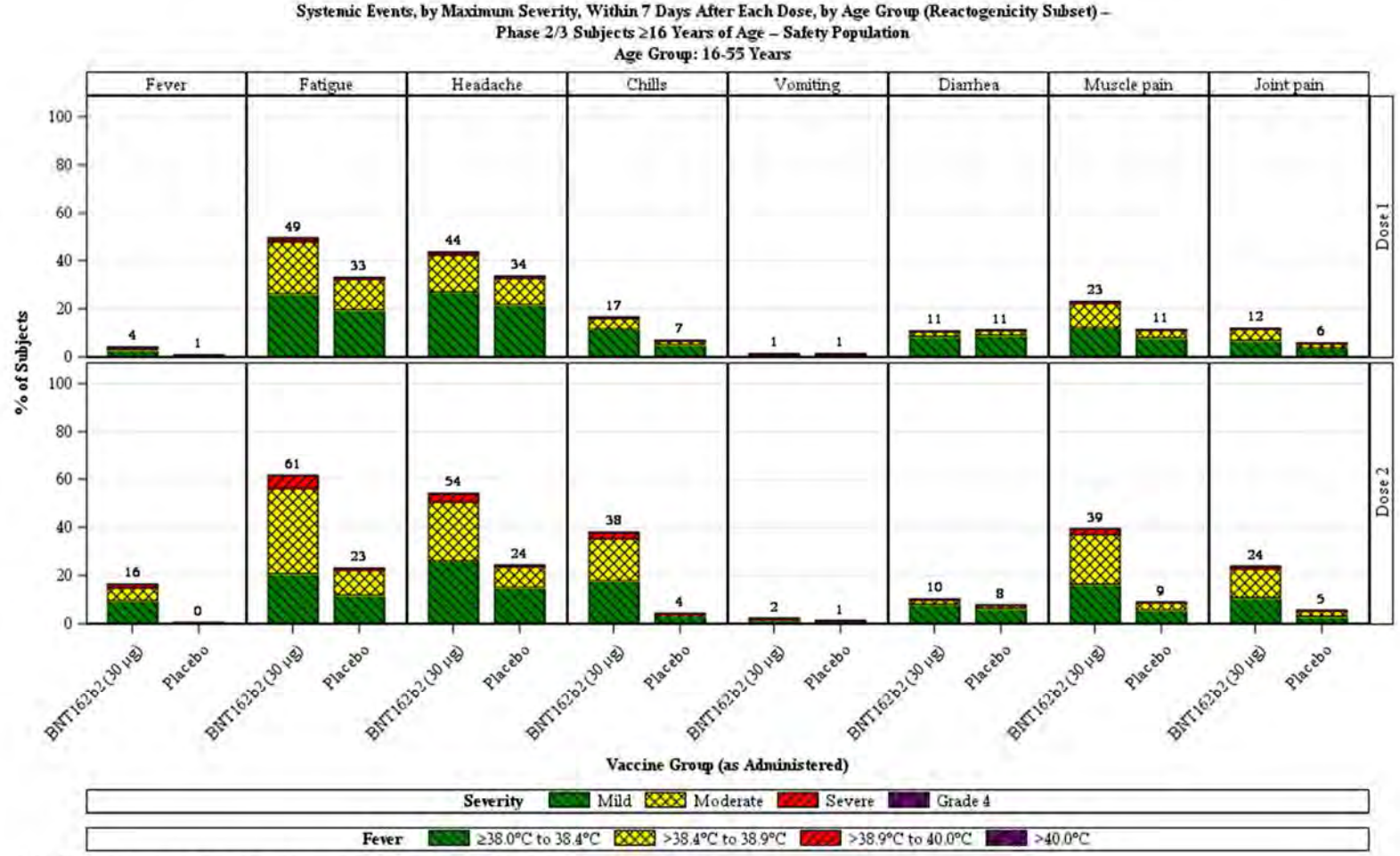
Subgroup Analyses

There were 177 BNT162b2 and 187 placebo participants with baseline positive SARS-CoV-2 status, and 4701 BNT162b2 and 4690 placebo participants with baseline negative SARS-CoV-2 status. For any fever after either dose there were 31 (17.5%) compared to 714 (15.1%) in those positive and negative for SARS-CoV-2 at baseline, respectively. Severe fever (>38.9°C to 40.0°C) was reported in 1 (0.6%) participant and 49 (1.0%) participants in those positive and negative for SARS-CoV-2 at baseline, respectively. The frequency for other systemic events after any dose was numerically lower for those positive at baseline: fatigue, headache and chills the frequency was 54.2%, 49.7% and 32.8% compared with 65%, 57.4%, 34.7% for those positive and negative for SARS-CoV-2 at baseline, respectively. Joint pain was another exception where 27.1% compared to 25.0% were reported between those positive and negative for SARS-CoV-2 at baseline. Note that the baseline SARS-CoV-2 positive subgroup included far fewer participants the negative subgroup, so their results should be interpreted with caution.

Onset and Duration

Systemic events in the younger and older age groups after either dose of BNT162b2 had a median onset day between Day 2.0 and Day 4.0 (Day 1.0 was the day of vaccination) and resolved with a median duration of 1 day in both age groups.

Figure 4. Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, by Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population
Age Group: 16 Through 55 Years



Note: Number above each bar denotes percentage of subjects reporting the event with any severity.
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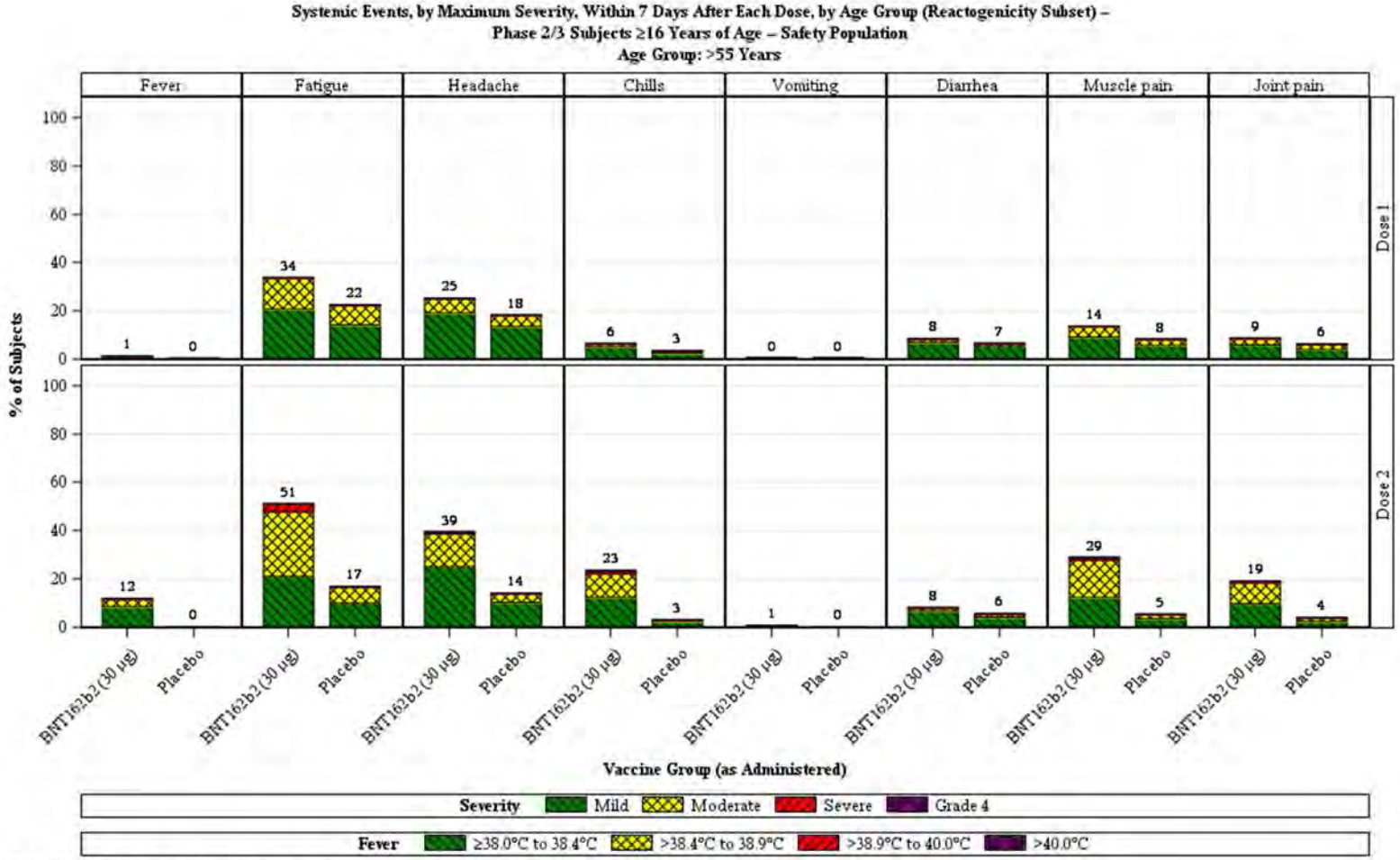
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adce_f001_se_max_age_p3

Figure 5. Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, Age Group (Reactogenicity Subset) – Phase 2/3 Subjects ≥16 Years of Age – Safety Population
Age Group: >55 Years

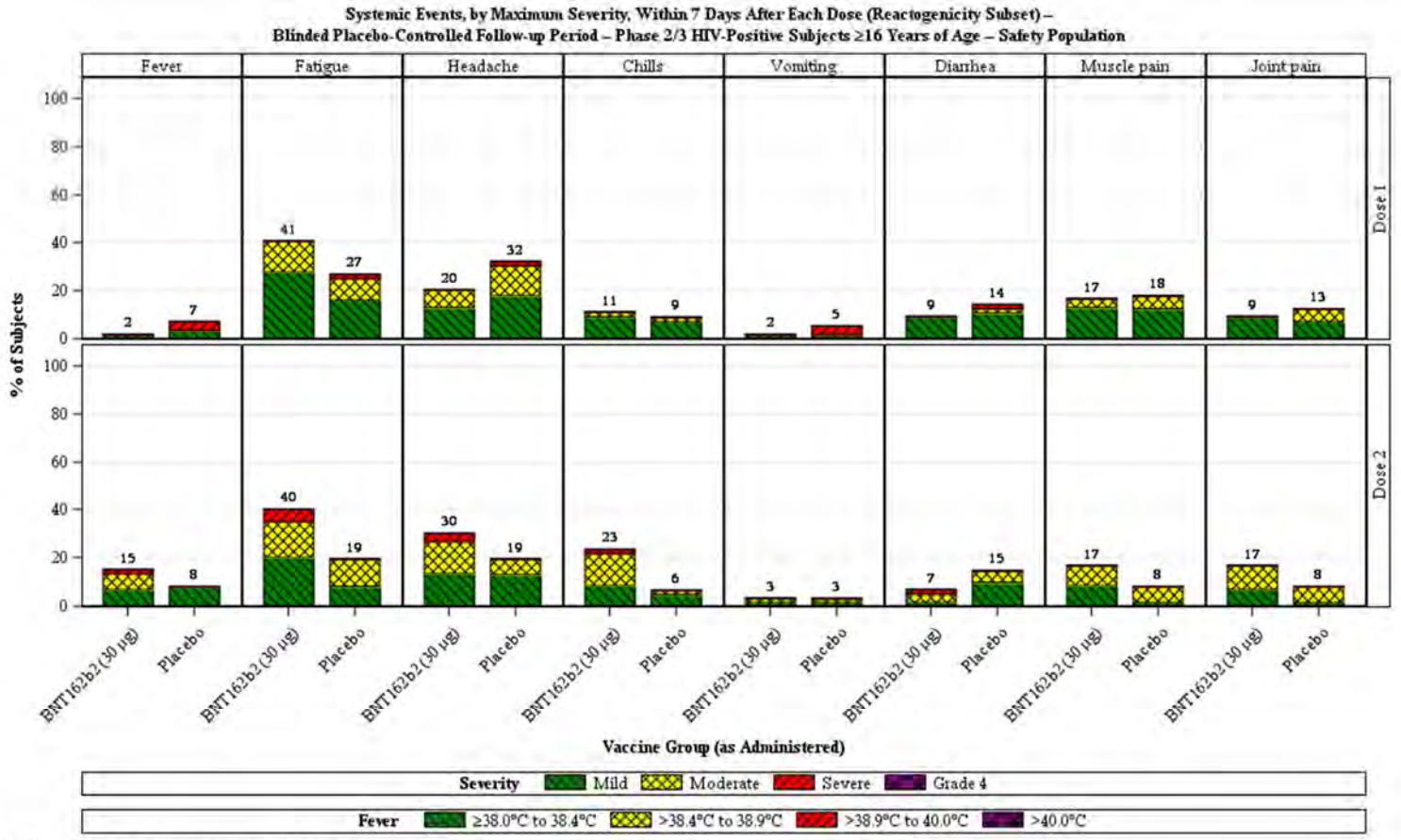


Note: Number above each bar denotes percentage of subjects reporting the event with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: /nda2_unblinded/C4591001_BLA/adce_f001_se_max_age_p3

2.7.4.2.4.1.2.1. Participants with Confirmed Stable HIV Disease (Phase 3, Study C4591001, Systemic Events)

Systemic events from participants with confirmed stable HIV disease were similar to those observed for all participants ≥16 years of age by severity (Figure 6), onset day, and duration. Fever, headache, chills, and joint pain increased in frequency from Dose 1 to Dose 2 while fatigue, vomiting, diarrhea, and muscle pain were similar after each dose. There were no severe systemic events after Dose 1 of BNT162b2 but after Dose 2, there was 1 (1.7%) severe fever (>38.9°C to 40.0°C), 3 (5.0%) participants with severe fatigue, 2 (3.3%) participants with severe headache, 1 (1.7%) participant with severe chills, and 1 (1.7%) participant with severe diarrhea. There were no grade 4 systemic events reported after either dose.

Figure 6. Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose (Reactogenicity Subset) – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 HIV-Positive Subjects ≥16 Years of Age – Safety Population



Abbreviation: HIV = human immunodeficiency virus.
Note: Number above each bar denotes percentage of subjects reporting the event with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:22) Source Data: adfacevd Table Generation: 27MAR2021 (01:55)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: /nda2_unblinded/C4591001_BLA/adce_f001_se_max_hiv_p3

2.7.4.2.4.2. Adverse Events (Phase 3, Study C4591001)

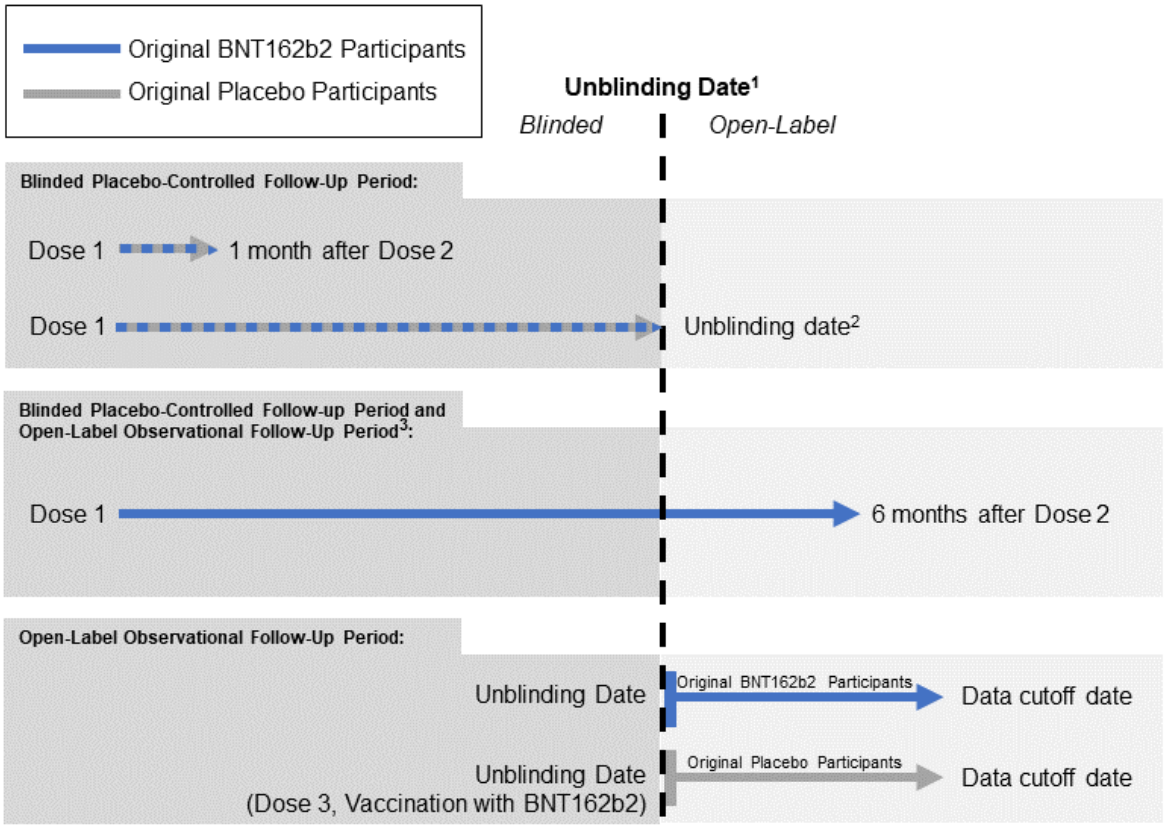
AE safety data are from either the blinded placebo-controlled follow-up period, the open-label observational follow-up period, or both. The time periods and safety analysis groups are presented below and in Figure 7.

- Blinded placebo-controlled follow-up period from Dose 1 to 1 month after Dose 2 (frequencies) (Section 2.7.4.2.4.2.1)
- Blinded placebo-controlled follow-up period from Dose 1 to the unblinding date (IRs) (Section 2.7.4.2.4.2.2)
- Open-label follow-up period – original BNT162b2 participants (IRs) (Section 2.7.4.2.4.2.3)
- Blinded placebo-controlled and open-label follow-up periods from Dose 1 to 6 months after Dose 2 – original BNT162b2 participants (frequencies) (Section 2.7.4.2.4.2.4)
- Open-label follow-up period – original placebo participants who then received BNT162b2 (IRs) (Section 2.7.4.2.4.2.5)

For AE analyses beyond 1 month after Dose 2, and for AEs after unblinding, incidence rates (IRs) per 100 Person-Years are reported (as opposed to frequencies) to account for the variable exposure since unblinding began for individual participants.

In this ongoing study, tables summarizing participant withdrawals may include some participants who were reported as withdrawn but remain in the study and are continuing to be evaluated. These participants are documented in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Errata.

Figure 7 Study C4591001 Phase 3 Safety Analyses: Time Periods and Analysis Groups



[1] Will vary by participant. Adverse event data analyzed from Dose 1 to unblinding date (on or after 14 December 2020), or from unblinding date to data cutoff date, are reported as incidence rates adjusted for exposure time.
[2] Up to ~6 months after Dose 2.
[3] Cumulative BNT162b2 follow-up to at least 6 months after Dose 2.

Full details and outputs regarding adverse events for Phase 3 of Study C4591001 are in Module 5.3.5.1 C4591001 6-Month Update CSR Section 12.2.3.

2.7.4.2.4.2.1. Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2 (Phase 3, Study C4591001)

2.7.4.2.4.2.1.1. Summary of Adverse Events: Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2 (Phase 3, Study C4591001)

An overview of AEs from Dose 1 to 1 month after Dose 2 for the 43,847 participants during the blinded placebo-controlled follow-up period (including those analyzed in Phase 2) is presented in Table 5. The numbers of overall participants who reported at least 1 AE and at least 1 related AE were higher in the BNT162b2 group (30.2% and 23.9%, respectively) as compared with the placebo group (13.9% and 6.0%, respectively). The higher frequencies in the BNT162b2 group was due to terms consistent with reactogenicity reported at greater frequency in the BNT162b2 group vs the placebo group. This pattern is further described in Section 2.7.4.2.4.2.1.2.1. Severe AEs were reported by 1.2% and 0.7% in in the BNT162b2

and placebo groups respectively, and life-threatening AEs were similar (0.1% in both groups).

SAEs and AEs leading to withdrawal were reported by ≤0.6% and ≤0.2%, respectively, in both groups. Discontinuations due to related AEs were reported in 13 participants in the BNT162b2 group and 11 participants in the placebo group (0.1% in both groups).

From Dose 1 to 1 month after Dose 2, there were 3 deaths in the BNT162b2 group and 5 deaths in the placebo group during the blinded follow-up period (Section 2.7.4.2.4.3.1).

In the younger age group, the number of participants who reported at least 1 AE from Dose 1 to 1 month after Dose 2 was 4233 (32.6%) and 1871 (14.4%) in the BNT162b2 and placebo groups, respectively. In the older age group, the number of participants who reported at least 1 AE from Dose 1 to 1 month after Dose 2 was 2384 (26.7%) and 1177 (13.2%) in the BNT162b2 and placebo groups, respectively.

Table 5. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=21926)	Placebo (N[a]=21921)
Adverse Event	n[b] (%)	n[b] (%)
Any event	6617 (30.2)	3048 (13.9)
Related[c]	5241 (23.9)	1311 (6.0)
Severe	262 (1.2)	150 (0.7)
Life-threatening	21 (0.1)	26 (0.1)
Any serious adverse event	127 (0.6)	116 (0.5)
Related[c]	3 (0.0)	0
Severe	71 (0.3)	66 (0.3)
Life-threatening	21 (0.1)	26 (0.1)
Any adverse event leading to withdrawal	32 (0.1)	36 (0.2)
Related[c]	13 (0.1)	11 (0.1)
Severe	10 (0.0)	10 (0.0)
Life-threatening	3 (0.0)	7 (0.0)
Death	3 (0.0)	5 (0.0)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s091_all_pd2_p3_saf1

2.7.4.2.4.2.1.1.1. Participants with Confirmed Stable HIV Disease: Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2 (Phase 3, Study C4591001, Summary of Adverse Events)

From Dose 1 to 1 month after Dose 2, the subset of 200 HIV-positive participants during the blinded placebo-controlled follow-up period showed generally similar trends as the overall population (likewise attributed to reactogenicity reported in the BNT162b2 group). The numbers of HIV-positive participants who reported at least 1 AE and at least 1 related AE were higher in the BNT162b2 group (26.0% and 19.0%, respectively) as compared with the placebo group (13.0% and 3.0%, respectively). In this group, there was 1 severe AE and 1 AE leading to withdrawal (both were in the BNT162b2 group), and there were no SAEs or deaths.

2.7.4.2.4.2.1.2. Analysis of Adverse Events: Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2 (Phase 3, Study C4591001)

2.7.4.2.4.2.1.2.1. Adverse Events by System Organ Class and Preferred Term: Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2 (Phase 3, Study C4591001)

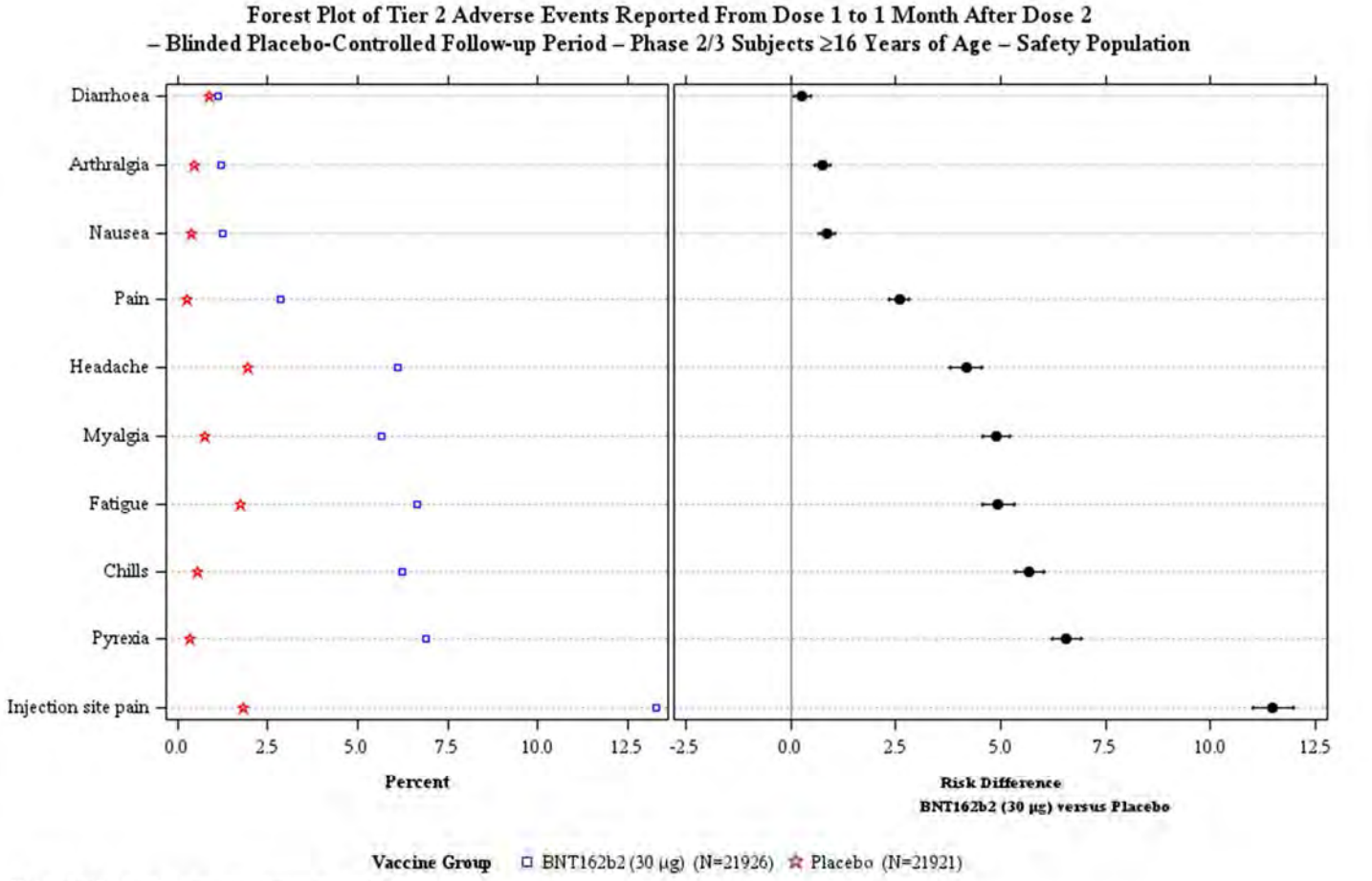
There are no Tier 1 AEs identified for this program.

Tier 2 AEs (defined as an event rate ≥1.0% in any vaccine group [PT level]) reported from Dose 1 to 1 month after Dose 2 are presented in Figure 8.

Most Tier 2 AEs were reactogenicity events and all were reported in 4 SOCs: general disorders and administration site conditions, musculoskeletal and connective tissue disorders, nervous system disorders, and gastrointestinal disorders. The proportions of participants reporting Tier 2 AEs were generally higher in the BNT162b2 group (N=21,926; ranging from 1.1% to 13.3%) than in the placebo group (N=21,921; ranging from 0.3% to 1.9%). Most of the PTs were in the SOC of general disorders and administration site conditions:

- injection site pain (2915 [13.3%] BNT162b2 vs 397 [1.8%] placebo)
- pyrexia (1517 [6.9%] BNT162b2 vs 77 [0.4%] placebo)
- fatigue (1463 [6.7%] BNT162b2 vs 379 [1.7%] placebo)
- chills (1365 [6.2%] BNT162b2 vs 120 [0.5%] placebo)
- pain (628 [2.9%] BNT162b2 vs 61 [0.3%] placebo).

Figure 8. Forest Plot of Tier 2 Adverse Events Reported From Dose 1 to 1 Month After Dose 2 – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population



Note: MedDRA (v23.1) coding dictionary applied.
Note: A MedDRA preferred term is defined as a Tier 2 event if there are at least 1% subjects with the AE term in at least 1 vaccine group.
Note: 2-Sided CI based on the Miettinen and Nurminen method for the difference in proportions (BNT162b2 (30 µg) - placebo) expressed as a percentage. They are not adjusted for multiplicity and should be used for screening purposes only.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (17:59)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: /nda2_unblinded/C4591001_BLA/adae_f001_t2_p3

From Dose 1 to 1 month after Dose 2 during the blinded placebo-controlled follow-up period, 6617 (30.2%) BNT162b2 participants and 3048 (13.9%) placebo participants reported at least 1 AE. Most reported AEs were in SOCs with reactogenicity events. (Table 6).

- general disorders and administration site conditions (4725 [21.5%] BNT162b2 vs 993 [4.5%] placebo)
- musculoskeletal and connective tissue disorders (1804 [8.2%] BNT162b2 vs 527 [2.4%] placebo)
- nervous system disorders (1565 [7.1%] BNT162b2 vs 600 [2.7%] placebo)
- gastrointestinal disorders (699 [3.2%] BNT162b2 vs 464 [2.1%] placebo).

The number of BNT162b2 participants who reported at least 1 AE from Dose 1 to 1 month after Dose 2 was 4233 (32.6%) and 2384 (26.7%) in the younger and older groups, respectively. In the younger versus older BNT162b2 age groups, AE frequencies in above SOCs were:

- general disorders and administration site conditions (3161 [24.3%] vs 1564 [17.5%])
- musculoskeletal and connective tissue disorders (1201 [9.2%] vs 603 [6.8%])
- nervous system disorders (1067 [8.2%] vs 498 [5.6%])
- gastrointestinal disorders (440 [3.4%] vs 259 [2.9%])

As shown in Table 6, the most frequently reported AEs in the BNT162b2 group by PT overall were injection site pain (2915 [13.3%]), pyrexia (1517 [6.9%]), fatigue (1463 [6.7%]), chills (1365 [6.2%]), headache (1339 [6.1%]), and myalgia (1239 [5.7%]). During this time period from Dose 1 to 1 month after Dose 2, most of these AEs were reported during the e-diary 7-day reporting period.

The frequency of AEs in the SOC of investigations was higher in the BNT162b2 group (0.8%) as compared with the placebo group (0.2%) mainly due to the higher frequency of the PT Body Temperature increased (120 in the BNT162b2 group and 12 in the placebo group).

In the skin and subcutaneous tissue disorders SOC, there were 17 participants who reported night sweats in the BNT162b2 group (compared to 3 in the placebo group), and all but 1 of these participants reported the AE within the first 7 days after Dose 1 or 2, respectively, and there were 31 participants who reported hyperhidrosis in the BNT162b2 group (compared to 9 in the placebo group), and all but 3 of these participants reported the AE within the first 7 days after Dose 1 or 2.

Nineteen study participants reported events in the Hepatobiliary Disorders SOC (14 BNT162b2 recipients and 5 placebo recipients) (Table 6). Of the 19 total participants, 3 participants had hepatic events:

- One participant in the placebo group reported hepatic cirrhosis
- One participant in the placebo group reported nonalcoholic fatty liver disease

- One participant in the BNT162b2 group reported alcoholic cirrhosis

The remaining 16 participants reported biliary events (cholecystitis/cholecystitis acute, biliary colic, bile duct stone, and biliary dyskinesia): 13 participants in the BNT162b2 group and 3 participants in the placebo group.

- In the BNT162b2 group, 8 participants reported cholelithiasis (1 reported an event each of cholelithiasis and cholecystitis), 1 participant reported cholecystitis acute, 2 participants reported biliary colic, and 1 participant each reported bile duct stone/biliary dyskinesia.

- In the placebo group, there were 3 participants who reported the following: 1 participant reported an event each of cholecystitis acute and cholelithiasis, 1 participant reported cholecystitis acute, and 1 participant reported cholelithiasis.

In the nervous systems disorder SOC, there were 3 participants who reported facial paralysis in the BNT162b2 group (compared to none in the placebo group). More details are presented in Section 2.7.4.2.4.3.4.1.2.

For lymphadenopathy the frequency in the BNT162b2 group was 0.4% compared to the frequency of 0.0% on the placebo group. Most AEs of lymphadenopathy in the BNT162b2 group were judged by the investigator as related to study intervention (further discussed in Section 2.7.4.2.4.3.4.1.3.

Other events of clinical interest that were identified by the sponsor are discussed in Section 2.7.4.2.4.3.4.

Post Hoc Analysis

Beyond the 9839 participants in the Phase 2/3 reactogenicity subset, events related to reactogenicity are no longer reported using an e-diary but are instead reported as AEs. As previously described in the final analysis interim CSR dated 03 December 2020, an analysis was conducted to evaluate if the imbalance in AEs observed from Dose 1 to 1 month after Dose 2 was attributed to reactogenicity events. The analysis examined the AEs reported within 7 days after each dose, which represented the reactogenicity reporting period. The time period was chosen because many AEs were reported in the SOCs of general disorders and administration site conditions, musculoskeletal and connective tissue disorders, and nervous system disorders, which includes AEs consistent with reactogenicity events, and could only be attributed to reactogenicity if they occurred during this time period as opposed to occurring up to 1 month from each dose.

PTs reported from Dose 1 to 7 days after Dose 1 and from Dose 2 to 7 days after Dose 2 in the SOCs of general disorders and administration site conditions (injection site pain, chills, fatigue, and pyrexia), musculoskeletal and connective tissue disorders (myalgia), and nervous system disorders (headache) represented the majority of PTs reported in those SOCs. AEs reported from Dose 1 to 7 days after Dose 1 and from Dose 2 to 7 days after Dose 2 were largely attributable to reactogenicity events. This observation provides a reasonable

explanation for the greater rates of AEs observed overall in the BNT162b2 group compared with the placebo group, consistent with results previously described in the final analysis interim CSR dated 03 December 2020.

In addition to analysis of AEs corresponding to e-diary terms that were reported within 7 days after Dose 1 or Dose 2 that are attributable to reactogenicity, additional consideration was given to AE terms that are reported at higher frequency in the BNT162b2 group compared to placebo. The following additional AEs were identified: pain in extremity, decreased appetite, lethargy, asthenia, malaise, night sweats, and hyperhidrosis. Careful examination of these terms after either dose of BNT162b2 shows that these events are clustered within the 7-day period when reactogenicity events are known to occur. Since the majority of the participants did not have an e-diary and reported reactogenicity as AEs, there is considerable leeway in how symptoms are described by participants from multiple countries, interpreted by investigators and reported as AEs. As these events are occurring when reactogenicity is being reported, these events are considered to be attributable to the experience of reactogenicity events and are plausibly associated with local reactions and systemic events.

These PTs were reported more frequently in the younger age group.

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	6617 (30.2)	(29.6, 30.8)	3048 (13.9)	(13.4, 14.4)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	105 (0.5)	(0.4, 0.6)	19 (0.1)	(0.1, 0.1)
Lymphadenopathy	83 (0.4)	(0.3, 0.5)	7 (0.0)	(0.0, 0.1)
Iron deficiency anaemia	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Anaemia	4 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Lymph node pain	7 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Blood loss anaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leukocytosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytopenia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypochromic anaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Leukopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenopathy mediastinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Splenomegaly	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	56 (0.3)	(0.2, 0.3)	50 (0.2)	(0.2, 0.3)
Palpitations	6 (0.0)	(0.0, 0.1)	14 (0.1)	(0.0, 0.1)
Tachycardia	13 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Atrial fibrillation	7 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Coronary artery disease	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Acute myocardial infarction	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Cardiac failure congestive	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Left ventricular hypertrophy	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mitral valve incompetence	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arrhythmia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arteriospasm coronary	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrial flutter	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cardiac arrest	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mitral valve prolapse	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial ischaemia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tricuspid valve incompetence	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular extrasystoles	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute left ventricular failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Atrioventricular block complete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atrioventricular block first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bundle branch block left	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac failure acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiovascular disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Junctional ectopic tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left atrial enlargement	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Left ventricular dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pericardial effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pericarditis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ventricular tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Congenital bladder neck obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Type V hyperlipidaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	65 (0.3)	(0.2, 0.4)	43 (0.2)	(0.1, 0.3)
Vertigo	25 (0.1)	(0.1, 0.2)	20 (0.1)	(0.1, 0.1)
Ear pain	11 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Tinnitus	9 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Vertigo positional	8 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Deafness unilateral	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ear discomfort	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerumen impaction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Meniere's disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic otitis media	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness neurosensory	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ear pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eustachian tube dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoacusis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sudden hearing loss	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tympanic membrane perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	13 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Hypothyroidism	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Hypogonadism	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid mass	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Autoimmune thyroiditis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Goitre	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperprolactinaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid cyst	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	60 (0.3)	(0.2, 0.4)	50 (0.2)	(0.2, 0.3)
Cataract	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Eye pain	7 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Eye irritation	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Vision blurred	7 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Chalazion	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vitreous detachment	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blepharitis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Conjunctivitis allergic	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry eye	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Keratitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Ocular hyperaemia	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Glaucoma	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Lacrimation increased	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Photophobia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal detachment	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vitreous floaters	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Asthenopia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blepharospasm	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diplopia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye pruritus	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amaurosis fugax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Conjunctival hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Conjunctival oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Corneal irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dacryostenosis acquired	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diabetic retinopathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Episcleritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye inflammation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eyelid oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelid pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eyelids pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Iritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ocular discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scleral discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ulcerative keratitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Visual acuity reduced	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	699 (3.2)	(3.0, 3.4)	464 (2.1)	(1.9, 2.3)
Diarrhoea	248 (1.1)	(1.0, 1.3)	188 (0.9)	(0.7, 1.0)
Nausea	274 (1.2)	(1.1, 1.4)	87 (0.4)	(0.3, 0.5)
Vomiting	66 (0.3)	(0.2, 0.4)	32 (0.1)	(0.1, 0.2)
Toothache	24 (0.1)	(0.1, 0.2)	27 (0.1)	(0.1, 0.2)
Abdominal pain upper	25 (0.1)	(0.1, 0.2)	15 (0.1)	(0.0, 0.1)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Abdominal pain	19 (0.1)	(0.1, 0.1)	19 (0.1)	(0.1, 0.1)
Gastrooesophageal reflux disease	12 (0.1)	(0.0, 0.1)	16 (0.1)	(0.0, 0.1)
Dyspepsia	12 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Odynophagia	13 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Constipation	7 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Dental caries	8 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Gastritis	3 (0.0)	(0.0, 0.0)	10 (0.0)	(0.0, 0.1)
Haemorrhoids	3 (0.0)	(0.0, 0.0)	10 (0.0)	(0.0, 0.1)
Aphthous ulcer	8 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Abdominal discomfort	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Abdominal distension	6 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Flatulence	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Irritable bowel syndrome	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Dry mouth	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Large intestine polyp	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Abdominal pain lower	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Dysphagia	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Stomatitis	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Diverticulum	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal disorder	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hiatus hernia	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Retching	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Small intestinal obstruction	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cheilitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Food poisoning	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival pain	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia oral	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Lip swelling	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rectal haemorrhage	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Swollen tongue	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tooth impacted	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Umbilical hernia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Colitis microscopic	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticulum intestinal	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Eructation	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glossodynia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematochezia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mouth ulceration	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Noninfective gingivitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal rigidity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abnormal faeces	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute abdomen	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anal pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Angular cheilitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Appendix disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colitis ulcerative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal haemorrhagic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Epiploic appendagitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Femoral hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Frequent bowel movements	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastric polyps	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastric ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastritis erosive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal mucosa hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival bleeding	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gingival swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Glossitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoaesthesia teeth	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Impaired gastric emptying	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Incarcerated inguinal hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Loose tooth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal spasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal varices haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophagitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral lichenoid reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oral mucosa haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Palatal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatic failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peptic ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Proctalgia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland mucocoele	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Teething	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue discolouration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tongue oedema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tooth disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Varices oesophageal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Volvulus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4725 (21.5)	(21.0, 22.1)	993 (4.5)	(4.3, 4.8)
Injection site pain	2915 (13.3)	(12.8, 13.8)	397 (1.8)	(1.6, 2.0)
Fatigue	1463 (6.7)	(6.3, 7.0)	379 (1.7)	(1.6, 1.9)
Pyrexia	1517 (6.9)	(6.6, 7.3)	77 (0.4)	(0.3, 0.4)
Chills	1365 (6.2)	(5.9, 6.6)	120 (0.5)	(0.5, 0.7)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pain	628 (2.9)	(2.6, 3.1)	61 (0.3)	(0.2, 0.4)
Injection site erythema	185 (0.8)	(0.7, 1.0)	28 (0.1)	(0.1, 0.2)
Injection site swelling	140 (0.6)	(0.5, 0.8)	23 (0.1)	(0.1, 0.2)
Malaise	130 (0.6)	(0.5, 0.7)	22 (0.1)	(0.1, 0.2)
Asthenia	76 (0.3)	(0.3, 0.4)	25 (0.1)	(0.1, 0.2)
Injection site pruritus	38 (0.2)	(0.1, 0.2)	5 (0.0)	(0.0, 0.1)
Injection site bruising	13 (0.1)	(0.0, 0.1)	18 (0.1)	(0.0, 0.1)
Influenza like illness	23 (0.1)	(0.1, 0.2)	4 (0.0)	(0.0, 0.0)
Chest pain	12 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Injection site warmth	14 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Axillary pain	14 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Injection site induration	10 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Injection site oedema	12 (0.1)	(0.0, 0.1)	0	(0.0, 0.0)
Non-cardiac chest pain	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Oedema peripheral	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Peripheral swelling	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Chest discomfort	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Feeling hot	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site discomfort	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Swelling face	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Injection site haematoma	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Injection site haemorrhage	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Injection site reaction	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Injection site mass	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site paraesthesia	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Swelling	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Adverse drug reaction	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cyst	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Feeling abnormal	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site discolouration	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site nodule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site papule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site rash	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sensation of foreign body	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Face oedema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Feeling cold	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injury associated with device	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Medical device pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nodule	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sluggishness	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thirst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vessel puncture site bruise	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site haematoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site erythema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Application site rash	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Capsular contracture associated with breast implant	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Effusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Exercise tolerance decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gait disturbance	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site macule	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injection site plaque	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site urticaria	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Medical device site granuloma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mucosal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Therapeutic response unexpected	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site induration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Vaccination site pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vaccination site swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vessel puncture site induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	14 (0.1)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Cholelithiasis	8 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Cholecystitis acute	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Biliary colic	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cirrhosis alcoholic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic cirrhosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nonalcoholic fatty liver disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	22 (0.1)	(0.1, 0.2)	25 (0.1)	(0.1, 0.2)
Seasonal allergy	8 (0.0)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Drug hypersensitivity	7 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Food allergy	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Hypersensitivity	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Allergy to arthropod bite	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Milk allergy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	337 (1.5)	(1.4, 1.7)	365 (1.7)	(1.5, 1.8)
Urinary tract infection	58 (0.3)	(0.2, 0.3)	52 (0.2)	(0.2, 0.3)
Tooth infection	24 (0.1)	(0.1, 0.2)	29 (0.1)	(0.1, 0.2)
Sinusitis	18 (0.1)	(0.0, 0.1)	27 (0.1)	(0.1, 0.2)
Cellulitis	12 (0.1)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Herpes zoster	12 (0.1)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Ear infection	9 (0.0)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Conjunctivitis	9 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Hordeolum	8 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Cystitis	6 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Gastroenteritis	5 (0.0)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Rhinitis	5 (0.0)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Tooth abscess	9 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Upper respiratory tract infection	9 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Diverticulitis	8 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Otitis externa	6 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Otitis media	7 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	5 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Appendicitis	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Gingivitis	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Oral herpes	4 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Acute sinusitis	1 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Pneumonia	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Skin infection	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Vaginal infection	0	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Fungal skin infection	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Onychomycosis	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Periodontitis	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Pharyngitis streptococcal	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pyelonephritis	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Folliculitis	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Furuncle	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Localised infection	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Nasopharyngitis	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Otitis media acute	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Paronychia	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tonsillitis	0	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Genital herpes	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Herpes simplex	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Influenza	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Postoperative wound infection	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tinea versicolour	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bacterial vulvovaginitis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bronchitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Chronic sinusitis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye infection	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Gingival abscess	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impetigo	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Infected bite	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parotitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pustule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcutaneous abscess	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tinea infection	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess limb	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Acarodermatitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Anal abscess	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial vaginosis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
COVID-19	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Conjunctivitis bacterial	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Erysipelas	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastroenteritis viral	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Kidney infection	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Labyrinthitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Laryngitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ophthalmic herpes zoster	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral candidiasis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Papilloma viral infection	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash pustular	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sialoadenitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinusitis bacterial	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Trichomoniasis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess jaw	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess neck	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anal fistula infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial blepharitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bacterial sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Balanitis candida	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bartholin's abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bartholinitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blister infected	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bone abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Campylobacter infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Carbuncle	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cellulitis orbital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clostridium difficile infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coxsackie viral infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental fistula	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis infected	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device related infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eye infection bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Genital herpes simplex	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gonorrhoea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Groin abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Helicobacter gastritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Helicobacter infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatitis A	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatitis C	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lyme disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nail infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral fungal infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oral infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Orchitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Otitis media bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parasitic gastroenteritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pelvic inflammatory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Pharyngitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pilonidal cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary tuberculosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Puncture site infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shigella sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin bacterial infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Soft tissue infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subacute endocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Syphilis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tinea cruris	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillitis bacterial	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Varicella	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Viral infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Viral upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wound infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	215 (1.0)	(0.9, 1.1)	269 (1.2)	(1.1, 1.4)
Fall	48 (0.2)	(0.2, 0.3)	51 (0.2)	(0.2, 0.3)
Ligament sprain	19 (0.1)	(0.1, 0.1)	22 (0.1)	(0.1, 0.2)
Skin laceration	14 (0.1)	(0.0, 0.1)	22 (0.1)	(0.1, 0.2)
Contusion	12 (0.1)	(0.0, 0.1)	19 (0.1)	(0.1, 0.1)
Exposure during pregnancy	10 (0.0)	(0.0, 0.1)	19 (0.1)	(0.1, 0.1)
Muscle strain	14 (0.1)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Road traffic accident	9 (0.0)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Skin abrasion	8 (0.0)	(0.0, 0.1)	13 (0.1)	(0.0, 0.1)
Arthropod bite	12 (0.1)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Limb injury	7 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Foot fracture	5 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Joint injury	5 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Tooth fracture	7 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Procedural pain	8 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Meniscus injury	4 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Animal bite	2 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Arthropod sting	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Facial bones fracture	4 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Joint dislocation	7 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Rib fracture	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Ankle fracture	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Concussion	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Muscle rupture	1 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Wound	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Chest injury	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Corneal abrasion	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ligament rupture	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Thermal burn	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Vaccination complication	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Epicondylitis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Fibula fracture	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hand fracture	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Head injury	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Overdose	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Radius fracture	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tendon rupture	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Wrist fracture	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Bone contusion	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Craniocerebral injury	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle injury	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Spinal compression fracture	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ulna fracture	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Administration related reaction	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns second degree	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical vertebral fracture	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ligament injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Procedural dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Skin injury	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Stress fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Tendon injury	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Upper limb fracture	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaemia postoperative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burn oral cavity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Burns first degree	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Clavicle fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dental restoration failure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear canal abrasion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ear injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Exposure to communicable disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye contusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Femur fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foreign body	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Foreign body aspiration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foreign body in eye	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Limb fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lip injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lumbar vertebral fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Maternal exposure during breast feeding	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mouth injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle contusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Patella fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngeal perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post concussion syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post procedural discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Post procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post procedural swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative ileus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural hypotension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory fume inhalation disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scapula fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Scar	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Soft tissue injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal column injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stab wound	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stoma site rash	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subdural haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sunburn	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tibia fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic haemothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Venom poisoning	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	172 (0.8)	(0.7, 0.9)	37 (0.2)	(0.1, 0.2)
Body temperature increased	120 (0.5)	(0.5, 0.7)	12 (0.1)	(0.0, 0.1)
Blood pressure increased	6 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Blood glucose increased	8 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Heart rate increased	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blood cholesterol increased	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Low density lipoprotein increased	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood thyroid stimulating hormone increased	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Weight decreased	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
High density lipoprotein increased	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Mammogram abnormal	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostatic specific antigen increased	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alanine aminotransferase increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Blood chloride decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood creatinine increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood glucose fluctuation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood potassium decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood pressure diastolic increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood pressure systolic increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood sodium decreased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Blood testosterone decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood testosterone increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Blood triglycerides increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Body temperature decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fractional exhaled nitric oxide increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hepatitis C antibody positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Herpes simplex test positive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intraocular pressure increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mean cell volume decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Monocyte count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Platelet count increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SARS-CoV-2 antibody test positive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid function test abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Troponin increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urine ketone body present	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Weight increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
White blood cell count increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
White blood cells urine positive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	100 (0.5)	(0.4, 0.6)	73 (0.3)	(0.3, 0.4)
Decreased appetite	39 (0.2)	(0.1, 0.2)	9 (0.0)	(0.0, 0.1)
Type 2 diabetes mellitus	8 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Vitamin D deficiency	9 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypercholesterolaemia	4 (0.0)	(0.0, 0.0)	9 (0.0)	(0.0, 0.1)
Hyperlipidaemia	6 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Hypokalaemia	5 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Dyslipidaemia	4 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Gout	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Dehydration	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Hyperglycaemia	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Glucose tolerance impaired	0	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Vitamin B12 deficiency	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypoglycaemia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Insulin resistance	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertriglyceridaemia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypocalcaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obesity	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Polydipsia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetes mellitus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Folate deficiency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Food intolerance	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperkalaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypernatraemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperuricaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypomagnesaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyponatraemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypovolaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Impaired fasting glucose	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Increased appetite	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Iron deficiency	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lactic acidosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1804 (8.2)	(7.9, 8.6)	527 (2.4)	(2.2, 2.6)
Myalgia	1239 (5.7)	(5.3, 6.0)	168 (0.8)	(0.7, 0.9)
Arthralgia	268 (1.2)	(1.1, 1.4)	102 (0.5)	(0.4, 0.6)
Pain in extremity	185 (0.8)	(0.7, 1.0)	44 (0.2)	(0.1, 0.3)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Back pain	97 (0.4)	(0.4, 0.5)	85 (0.4)	(0.3, 0.5)
Neck pain	29 (0.1)	(0.1, 0.2)	33 (0.2)	(0.1, 0.2)
Muscle spasms	27 (0.1)	(0.1, 0.2)	15 (0.1)	(0.0, 0.1)
Osteoarthritis	11 (0.1)	(0.0, 0.1)	16 (0.1)	(0.0, 0.1)
Musculoskeletal stiffness	12 (0.1)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Tendonitis	10 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Intervertebral disc protrusion	8 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Bursitis	10 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Muscular weakness	10 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Musculoskeletal chest pain	10 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Muscle contracture	4 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Rotator cuff syndrome	3 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Plantar fasciitis	4 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Arthritis	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Exostosis	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Flank pain	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Joint swelling	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Joint stiffness	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Musculoskeletal discomfort	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Osteoporosis	0	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Costochondritis	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Joint range of motion decreased	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Muscle fatigue	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle twitching	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Musculoskeletal pain	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Intervertebral disc degeneration	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Limb discomfort	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain in jaw	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovial cyst	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tenosynovitis stenosans	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Bone pain	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Temporomandibular joint syndrome	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Tendon disorder	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Torticollis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arthropathy	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Axillary mass	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Coccydynia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fibromyalgia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Groin pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint effusion	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metatarsalgia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Mobility decreased	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periarthritis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal stenosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spondylitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Synovitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Trigger finger	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arthritis reactive	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bone swelling	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dupuytren's contracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intervertebral disc disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Joint instability	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscle discomfort	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Osteochondrosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteopenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhabdomyolysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rheumatoid arthritis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Scoliosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Systemic lupus erythematosus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tendon pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	32 (0.1)	(0.1, 0.2)	36 (0.2)	(0.1, 0.2)
Basal cell carcinoma	3 (0.0)	(0.0, 0.0)	8 (0.0)	(0.0, 0.1)
Lipoma	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Uterine leiomyoma	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Colon adenoma	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Malignant melanoma	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Prostate cancer	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acrochordon	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Fibroadenoma of breast	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Squamous cell carcinoma of skin	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma pancreas	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenoma benign	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Benign breast neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Benign pancreatic neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chondroma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Glomus tumour	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Infected naevus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphoproliferative disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to liver	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oropharyngeal squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian germ cell teratoma benign	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatic carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Penile squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer metastatic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Seborrhoeic keratosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Squamous cell carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thyroid cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	1565 (7.1)	(6.8, 7.5)	600 (2.7)	(2.5, 3.0)
Headache	1339 (6.1)	(5.8, 6.4)	424 (1.9)	(1.8, 2.1)
Dizziness	78 (0.4)	(0.3, 0.4)	60 (0.3)	(0.2, 0.4)
Paraesthesia	22 (0.1)	(0.1, 0.2)	23 (0.1)	(0.1, 0.2)
Migraine	24 (0.1)	(0.1, 0.2)	11 (0.1)	(0.0, 0.1)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Lethargy	25 (0.1)	(0.1, 0.2)	6 (0.0)	(0.0, 0.1)
Syncope	11 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Sciatica	11 (0.1)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Dysgeusia	12 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Somnolence	9 (0.0)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Tension headache	8 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Presyncope	8 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Hypoaesthesia	5 (0.0)	(0.0, 0.1)	7 (0.0)	(0.0, 0.1)
Tremor	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Burning sensation	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Parosmia	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Subarachnoid haemorrhage	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Cervical radiculopathy	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Disturbance in attention	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hyperaesthesia	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neuropathy peripheral	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Sinus headache	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aphasia	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebrovascular accident	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dizziness postural	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial paralysis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Migraine without aura	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nerve compression	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Radiculopathy	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amnesia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Head discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental impairment	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Migraine with aura	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Post herpetic neuralgia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Restless legs syndrome	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Taste disorder	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Transient ischaemic attack	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Trigeminal neuralgia	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ageusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amyotrophic lateral sclerosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Balance disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cerebellar infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral atrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral capillary telangiectasia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cervicogenic headache	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depressed level of consciousness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Drug withdrawal headache	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dystonia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial paresis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Generalised tonic-clonic seizure	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypersomnia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypogeusia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hyposmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Motor dysfunction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Myoclonus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nystagmus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parkinsonism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Periodic limb movement disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peripheral sensory neuropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Piriformis syndrome	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Sciatic nerve neuropathy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seizure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Spinal cord compression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VIth nerve paralysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abortion spontaneous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
PRODUCT ISSUES	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device breakage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Device connection issue	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	97 (0.4)	(0.4, 0.5)	75 (0.3)	(0.3, 0.4)
Anxiety	21 (0.1)	(0.1, 0.1)	24 (0.1)	(0.1, 0.2)
Insomnia	25 (0.1)	(0.1, 0.2)	8 (0.0)	(0.0, 0.1)
Depression	17 (0.1)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Attention deficit hyperactivity disorder	3 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Irritability	4 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Panic attack	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Anxiety disorder	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Disorientation	5 (0.0)	(0.0, 0.1)	0	(0.0, 0.0)
Sleep disorder	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abnormal dreams	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Depressed mood	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Suicidal ideation	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Alcohol withdrawal syndrome	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bruxism	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mental disorder	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental status changes	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nightmare	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Confusional state	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depression suicidal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal somatic symptom disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Generalised anxiety disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Libido decreased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Libido increased	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Listless	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Mood swings	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic reaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranoia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Post-traumatic stress disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Restlessness	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Schizophrenia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stress	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Substance abuse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	34 (0.2)	(0.1, 0.2)	34 (0.2)	(0.1, 0.2)
Nephrolithiasis	6 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Dysuria	7 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Haematuria	4 (0.0)	(0.0, 0.0)	7 (0.0)	(0.0, 0.1)
Acute kidney injury	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Pollakiuria	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Renal colic	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary retention	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bladder spasm	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chronic kidney disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Costovertebral angle tenderness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hydronephrosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nocturia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive nephropathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oedematous kidney	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Perinephric oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Renal atrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Renal cyst haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urethral discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urinary tract obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urine odour abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	45 (0.2)	(0.1, 0.3)	39 (0.2)	(0.1, 0.2)
Dysmenorrhoea	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Erectile dysfunction	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Ovarian cyst	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pelvic pain	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Amenorrhoea	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Benign prostatic hyperplasia	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast pain	4 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Breast mass	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Menorrhagia	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Prostatitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Vaginal haemorrhage	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Breast cyst	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Genital erythema	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haemorrhagic ovarian cyst	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Menstruation delayed	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Menstruation irregular	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metrorrhagia	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Testicular pain	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine haemorrhage	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Adenomyosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast calcifications	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical polyp	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dysfunctional uterine bleeding	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Endometriosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Haematospermia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mammary duct ectasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menometrorrhagia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nipple pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penile vein thrombosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Polycystic ovaries	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Premenstrual syndrome	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Prostatomegaly	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Scrotal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uterine inflammation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vaginal discharge	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vulvovaginal pruritus	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	194 (0.9)	(0.8, 1.0)	168 (0.8)	(0.7, 0.9)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Oropharyngeal pain	36 (0.2)	(0.1, 0.2)	31 (0.1)	(0.1, 0.2)
Nasal congestion	25 (0.1)	(0.1, 0.2)	32 (0.1)	(0.1, 0.2)
Cough	23 (0.1)	(0.1, 0.2)	15 (0.1)	(0.0, 0.1)
Rhinorrhoea	20 (0.1)	(0.1, 0.1)	13 (0.1)	(0.0, 0.1)
Rhinitis allergic	12 (0.1)	(0.0, 0.1)	11 (0.1)	(0.0, 0.1)
Asthma	12 (0.1)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Dyspnoea	6 (0.0)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Throat irritation	6 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Epistaxis	5 (0.0)	(0.0, 0.1)	8 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Sinus congestion	6 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	4 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Pulmonary embolism	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Sneezing	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Chronic obstructive pulmonary disease	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphonia	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Upper respiratory tract congestion	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Bronchospasm	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Productive cough	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Respiratory tract congestion	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Sleep apnoea syndrome	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wheezing	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute respiratory failure	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Asthma exercise induced	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dry throat	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pharyngeal swelling	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Allergic sinusitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Asthmatic crisis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oropharyngeal discomfort	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonia aspiration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Reflux laryngitis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Allergic respiratory disease	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Atelectasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Emphysema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Haemoptysis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hiccups	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lung infiltration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Nasal discomfort	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal obstruction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal polyps	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal septum deviation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nasal turbinate hypertrophy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pleuritic pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary oedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinalgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rhinitis perennial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sinus disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	224 (1.0)	(0.9, 1.2)	158 (0.7)	(0.6, 0.8)
Rash	54 (0.2)	(0.2, 0.3)	41 (0.2)	(0.1, 0.3)
Pruritus	23 (0.1)	(0.1, 0.2)	18 (0.1)	(0.0, 0.1)
Hyperhidrosis	31 (0.1)	(0.1, 0.2)	9 (0.0)	(0.0, 0.1)
Dermatitis contact	14 (0.1)	(0.0, 0.1)	19 (0.1)	(0.1, 0.1)
Urticaria	15 (0.1)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Night sweats	17 (0.1)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Rash pruritic	7 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Erythema	9 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Alopecia	5 (0.0)	(0.0, 0.1)	4 (0.0)	(0.0, 0.0)
Eczema	6 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Skin lesion	3 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Rash maculo-papular	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Dermatitis	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Dermatitis allergic	3 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Angioedema	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dermal cyst	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash erythematous	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Actinic keratosis	1 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Blister	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hand dermatitis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Papule	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Rash papular	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acne	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alopecia areata	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cold sweat	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug eruption	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pityriasis rosea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pruritus allergic	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Rosacea	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Seborrhoeic dermatitis	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Skin mass	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis acneiform	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dermatitis bullous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dyshidrotic eczema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fixed eruption	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hidradenitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ingrowing nail	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Livedo reticularis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mechanical urticaria	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Onychomadesis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pityriasis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pseudofolliculitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Skin induration	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Skin irritation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Stasis dermatitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urticaria contact	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urticaria papular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Menopause	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
High risk sexual behaviour	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	28 (0.1)	(0.1, 0.2)	19 (0.1)	(0.1, 0.1)
Tooth extraction	6 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Dental implantation	5 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Wisdom teeth removal	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Dental care	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Endodontic procedure	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abortion induced	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Apicectomy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Botulinum toxin injection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac pacemaker replacement	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Carpal tunnel decompression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cataract operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug titration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Facet joint block	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gingival operation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia repair	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lacrimal duct procedure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lens extraction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Medical device implantation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Open reduction of fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Rhinoplasty	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Sclerotherapy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Skin neoplasm excision	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Toe operation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Vasectomy	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Wound drainage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
VASCULAR DISORDERS	83 (0.4)	(0.3, 0.5)	82 (0.4)	(0.3, 0.5)

Table 6. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypertension	42 (0.2)	(0.1, 0.3)	46 (0.2)	(0.2, 0.3)
Hot flush	7 (0.0)	(0.0, 0.1)	9 (0.0)	(0.0, 0.1)
Flushing	11 (0.1)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Deep vein thrombosis	5 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Haematoma	4 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Hypotension	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Orthostatic hypotension	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Varicose vein	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic aneurysm	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertensive crisis	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Accelerated hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Aortic dilatation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Aortic stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Diastolic hypertension	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Essential hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphoedema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphorrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pallor	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Phlebolith	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Raynaud's phenomenon	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subgaleal haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 all pd2 p3 saf

2.7.4.2.4.2.1.2.1.1. Participants with Confirmed Stable HIV Disease: Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2 (Phase 3, Study C4591001, Adverse Events by System Organ Class and Preferred Term)

From Dose 1 to 1 month after Dose 2, and similar to the overall population, most AEs reported for the subset of 200 HIV-positive participants from Dose 1 to 1 month after Dose 2 were in SOCs with reactogenicity events. There were few AEs reported: 26 (26%) in the BNT162b2 group and 13 (13%) in the placebo group.

- general disorders and administration site conditions (19.0% BNT162b2 vs 2.0% placebo)
- musculoskeletal and connective tissue disorders (6.0% BNT162b2 vs 3.0% placebo)
- nervous system disorders (5.0% BNT162b2 vs 0.0% placebo)
- gastrointestinal disorders (3.0% BNT162b2 vs 4.0% placebo)
- infections and infestations (2.0% BNT162b2 vs 2.0% placebo)

2.7.4.2.4.2.1.2.2. Related Adverse Events by System Organ Class and Preferred Term: Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2 (Phase 3, Study C4591001, Analysis of Adverse Events)

Details and outputs regarding related AEs for Phase 3 of Study C4591001 are in Module 5.3.5.1 C4591001 6-Month Update CSR Section 12.2.3.1.2.2.

From Dose 1 to 1 month after Dose 2, AEs assessed as related by the investigator during the blinded placebo-controlled follow-up period were reported by 23.9% of participants in the BNT162b2 group and 6.0% of participants in the placebo group (Table 5). Most related AEs were reactogenicity events and in the SOC of general disorders and administration site conditions, reported by 4650 (21.2%) BNT162b2 recipients and 883 (4.0%) placebo recipients. Among the BNT162b2 participants who had AEs of lymphadenopathy, 62 of 83 participants had events assessed by the investigator as related to study intervention; the majority of lymphadenopathy events occurred in the arm and neck region and were reported within 1 to 4 days after vaccination (Section 2.7.4.2.4.3.4.1.3).

2.7.4.2.4.2.1.2.3. Immediate Adverse Events: Blinded Placebo Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2 (Phase 3, Study C4591001, Analysis of Adverse Events)

Details and outputs regarding immediate AEs for Phase 3 of Study C4591001 are in Module 5.3.5.1 C4591001 6-Month Update CSR Section 12.2.3.1.2.3.

After Dose 1, participants with immediate AEs were low in frequency (≤0.5%). Most immediate AEs after Dose 1 were in the SOC of general disorders and administration site conditions, primarily injection site reactions in the BNT162b2 versus placebo groups, with injection site pain (0.3% vs 0.2%) most frequently reported.

After Dose 2, participants with immediate AEs were low in frequency (0.3%). Most immediate AEs after Dose 2 were in the SOC of general disorders and administration site conditions, primarily injection site reactions, in the BNT162b2 versus placebo groups with injection site pain (0.2% vs 0.1%) most frequently reported.

2.7.4.2.4.2.1.2.4. Severe or Life-Threatening Adverse Events: Blinded Placebo Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2 (Phase 3, Study C4591001, Analysis of Adverse Events)

Details and outputs regarding severe or life-threatening AEs for Phase 3 of Study C4591001 are in Module 5.3.5.1 C4591001 6-Month Update CSR Section 12.2.3.1.2.4.

From Dose 1 to 1 month after Dose 2, severe AEs reported during the blinded follow-up period were low in frequency, reported in 1.2% of BNT162b2 recipients and 0.7% of placebo recipients. Severe events were concentrated in the SOCs of general disorders and administration site conditions, generally reflecting terms consistent with reactogenicity, in the BNT162b2 versus placebo groups (0.4% vs 0.0%).

There were 21 participants (0.1%) in the BNT162b2 group and 26 participants (0.1%) in the placebo group who had at least 1 life-threatening AE from Dose 1 to 1 month after Dose 2. None of the life-threatening AEs were assessed by the investigator as related to study intervention.

No clinically meaningful differences were observed for severe or life-threatening AEs by age group.

2.7.4.2.4.2.2. Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date (Phase 3, Study C4591001)

2.7.4.2.4.2.2.1. Summary of Adverse Events: Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date (Phase 3, Study C4591001)

An overview of AE incidence rates adjusted for exposure time from Dose 1 to the unblinding date for 43,847 participants during the blinded placebo-controlled follow-up (including those analyzed in Phase 2) is presented in Table 7. The IRs/100 PY for participants who reported at least 1 AE were 83.2 in the BNT162b2 group and 43.4 in the placebo group, and IRs for related AEs were 62.9 in the BNT162b2 group and 16.0 in the placebo group.

IRs of severe AEs, SAEs, and AEs leading to withdrawal were ≤4.3, ≤3.3, and ≤0.6 per 100 PY, respectively, in both groups. IRs for discontinuations because of related AEs were 0.2 per 100 PY in the BNT162b2 group and 0.1 per 100 PY in the placebo group.

From Dose 1 to the unblinding date, there were 15 (0.2 per 100 PY) deaths in the BNT162b2 group and 14 (0.2 per 100 PY) deaths in the placebo group.

In the younger age group, the IRs for of participants who reported at least 1 AE from Dose 1 to the unblinding date were 88.4 per 100 PY and 43.5 per 100 PY in the BNT162b2 and placebo groups, respectively. In the older age group, the IRs for participants who reported at least 1 AE from Dose 1 to the unblinding date were 75.7 per 100 PY and 43.3 per 100 PY in the BNT162b2 and placebo groups, respectively.

Table 7. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	6947	83.2	(81.3, 85.2)	3568	43.4	(42.0, 44.9)
Related[f]	5246	62.9	(61.2, 64.6)	1313	16.0	(15.1, 16.9)
Severe	356	4.3	(3.8, 4.7)	256	3.1	(2.7, 3.5)
Life-threatening	48	0.6	(0.4, 0.8)	54	0.7	(0.5, 0.9)
Any serious adverse event	268	3.2	(2.8, 3.6)	268	3.3	(2.9, 3.7)
Related[f]	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Severe	148	1.8	(1.5, 2.1)	156	1.9	(1.6, 2.2)
Life-threatening	48	0.6	(0.4, 0.8)	54	0.7	(0.5, 0.9)
Any adverse event leading to withdrawal	45	0.5	(0.4, 0.7)	51	0.6	(0.5, 0.8)
Related[f]	13	0.2	(0.1, 0.3)	12	0.1	(0.1, 0.3)
Severe	10	0.1	(0.1, 0.2)	12	0.1	(0.1, 0.3)
Life-threatening	15	0.2	(0.1, 0.3)	16	0.2	(0.1, 0.3)
Death	15	0.2	(0.1, 0.3)	14	0.2	(0.1, 0.3)

a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
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Subgroup Analyses

In the BNT162b2 group, there were 674 baseline SARS-CoV-2 positive and 21102 baseline SARS-CoV-2 negative participants, and there were 705 baseline SARS-COV-2 positive and 21092 SARS-CoV-2 negative participants in the placebo group. Similar to what was observed in the overall AE analysis irrespective of baseline status (Table 7), IRs of at least 1 AE in the baseline SARS-CoV-2 positive subgroup were 70.7 per 100 PY in the BNT162b2 group and 31.9 per 100 PY in the placebo group, and IRs of at least 1 AE in the baseline SARS-CoV-2 negative subgroup were 83.6 per 100 PY in the BNT162b2 group and 43.8 per 100 PY in the placebo group. IRs of related AEs in the BNT162b2 group were 51.8 per 100 PY (baseline positive) and 63.2 per 100 PY (baseline negative). The IRs of SAEs,

related SAEs, severe SAEs, and life threatening SAEs were similar in the BNT162b2 and placebo groups, which support these events are not increased in baseline positive participants. Given the differences in exposure (2.5 vs 80.4) by baseline SARS-CoV-2 positive and negative status, respectively, direct comparisons should be interpreted with caution. See Section 2.7.4.2.4.2.2.2 for subgroup analyses of SOCs by baseline status, which supports that there is no evidence that individuals who are positive at baseline report AEs at a higher rate than those who are negative at baseline.

The IR of any AEs and related AEs were similar in those positive and negative at baseline, with the IR for any AE of 70.7 per 100 PY (95% CI: 60.7, 81.9) and 83.6 per 100 PY (95% CI: 81.7, 85.7) and for related AE of 51.8 per 100 PY (95% CI: 43.3, 61.4) and 63.2 per 100 PY (95% CI:61.5, 65.0), respectively. The IR for SAEs was 4.0 per 100 PY (95% CI: 1.9, 7.3) (baseline positive) and 3.2 per 100 PY (95% CI: 2.8, 3.6) (baseline negative), however none of the SAEs in the positive baseline group were related to BNT162b2, as assessed by the investigator. The death rate was also similar: 0.8 per 100 PY (95% CI: 0.1, 2.9) (baseline positive) and 0.2 per 100 PY (95 CI: 0.1, 0.3) (baseline negative).

IRs of at least 1 AE in the BNT162b2 group were 78.4 per 100 PY (95% CI: 74.9, 82.0; n=5684) in Hispanic/Latino and 85.4 per 100 PY (95% CI: 83.1, 87.8; n=16131) in Non-Hispanic/Non-Latino participants. The IRs of SAEs, AEs leading to withdrawal, and death were similar in the Hispanic/Latino and Non-Hispanic/Non-Latino groups. None of the SAEs were considered related to BNT162b2 in the Hispanic/Latino group.

IRs of at least 1 AE in the BNT162b2 group were lower in Black or African American participants (53.5 per 100 PY) compared with White (83.1 per 100 PY) or All Others (120.1 per 100 PY). Other IRs were similar in the groups.

IRs of at least 1 AE in the BNT162b2 group were greater in females (91.0 per 100 PY [95% CI: 88.1, 94.0] than males (76.0 per 100 PY [95% CI: 73.4, 78.6]); that cannot be accounted for by the rates in placebo for females (46.8 [95% CI: 44.7, 49.0]) and males (40.1 [95% CI: 38.2, 42.1]). IRs for related and severe AEs were also greater in females (68.6 per 100 PY [95% CI: 66.1, 71.2] and 4.9 per 100 PY [95% CI: 4.2, 5.6], respectively) than in males (57.5 per 100 PY [95% CI: 55.3, 59.8] and 3.7 per 100 PY [95% CI: 3.2, 4.3], respectively). However, life threatening AEs, SAEs, related SAEs, severe SAEs, life threatening SAEs and death IR were similar in males and females.

2.7.4.2.4.2.2.1.1. Participants with Confirmed Stable HIV Disease: Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date (Phase 3, Study C4591001, Summary of Adverse Events)

The subset of 200 HIV-positive participants during the blinded placebo-controlled follow-up period showed generally similar trends as the overall population. The IRs for HIV-positive participants who reported at least 1 AE and at least 1 related AE were 95.8 per 100 PY and 62.8 per 100 PY, respectively, for the BNT162b2 group and 52.0 per 100 PY and 10.4 per 100 PY, respectively, for the placebo group. There were 2 SAEs in the BNT162b2 group (1 severe and 1 life-threatening) and 2 SAEs in the placebo group (1 life-threatening). There were 2 AEs leading to withdrawal in the BNT162b2 group (1 life-threatening) and 1 AE (life-threatening) leading to withdrawal in the placebo group. There were 2 deaths, 1 each in

the BNT162b2 and placebo groups; neither were assessed by the investigator as related to study intervention (see Section 2.7.4.2.4.3.1).

2.7.4.2.4.2.2.2. Analysis of Adverse Events: Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date (Phase 3, Study C4591001)

2.7.4.2.4.2.2.2.1. Adverse Events by System Organ Class and Preferred Term: Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date (Phase 3, Study C4591001, Analysis of Adverse Events)

Incidence rates of AEs from Dose 1 to the unblinding date during the blinded placebo-controlled follow-up period are presented in Table 7. Results were similar to the Dose 1 to 1 month after Dose 2 follow-up period.

From Dose 1 to the unblinding date, the most common AEs by IRs were reactogenicity events and were reported at higher IRs in the BNT162b2 group than in the placebo group:

- general disorders and administration site conditions (56.9 per 100 PY BNT162b2 vs 12.3 per 100 PY placebo)
- musculoskeletal and connective tissue disorders (22.3 per 100 PY BNT162b2 vs 7.6 per 100 PY placebo)
- nervous system disorders (19.2 per 100 PY BNT162b2 vs 7.7 per 100 PY placebo)
- gastrointestinal disorders (9.0 per 100 PY BNT162b2 vs 6.2 per 100 PY placebo)

In the younger versus older BNT162b2 age groups, AE IRs in these SOCs were:

- general disorders and administration site conditions (63.7 per 100 PY vs 46.9 per 100 PY)
- musculoskeletal and connective tissue disorders (24.6 per 100 PY vs 18.8 per 100 PY)
- nervous system disorders (21.8 per 100 PY vs 15.3 per 100 PY)
- gastrointestinal disorders (9.5 per 100 PY vs 8.2 per 100 PY)

The higher rates of AEs in these SOC is consistent with the reactogenicty analysis showing higher rates of reactogenicty in the younger age group. AEs with the highest IRs in the BNT162b2 group by PT overall were injection site pain (35.0 per 100 PY), pyrexia (18.2 per 100 PY), fatigue (17.6 per 100 PY), chills (16.4 per 100 PY), headache (16.2 per 100 PY), and myalgia (14.9 per 100 PY).

The IR of AEs in the SOC of investigations was higher in the BNT162b2 group (2.2 per 100 PY) than in the placebo group (0.6 per 100 PY) mainly due to the higher IR of body temperature increased in the BNT162b2 group (IR of 1.5 per 100 PY vs 0.2 per 100 PY for the placebo group).

Cases of night sweats and hyperhidrosis are discussed in Section 2.7.4.2.4.2.1.2.1 (most were reported within 7 days after Dose 1 or 2).

In the nervous systems disorder SOC, there were 4 participants who reported facial paralysis in the BNT162b2 group (compared to 1 in the placebo group). There was an additional case of facial paresis in the placebo group. Hence there were 4 cases of facial paralysis/paresis in the in the BNT162b2 group and 2 in the placebo group. See Section 2.7.4.2.4.3.4.1.2.

There was 1 case of COVID-19 pneumonia (reported in the BNT162b2 group) which led to death (Table 16). This participant was diagnosed based on a local COVID-19 test that was not protocol-approved and was not confirmed by a test result from the central laboratory. Therefore, this participant was not included in efficacy analyses.

Among the AEs of lymphadenopathy in the BNT162b2 group, the majority (62 of 87 participants; [0.7 per 100 PY]) were assessed by the investigator as related to study intervention. Most cases occurred in the arm and neck region and were reported within 1 to 4 days after vaccination (Section 2.7.4.2.4.3.4.1.3).

The IRs for hepatobiliary disorders was 0.3 per 100 PY and 0.2 per 100 PY in the BNT162b2 and placebo group, respectively. There were 24 participants in the BNT162b2 group who had AEs in the SOC of hepatobiliary disorders compared to 16 participants in the placebo group. Narratives for these cases are provided (see Section 2.7.4.2.4.4).

A total of 11 cases of reported PTs associated with deafness in the blinded placebo-controlled follow-up period through the unblinding date included: Deafness, Deafness unilateral, Deafness neurosensory, Hypoacusis, and Sudden hearing loss. Six participants were randomized to the BNT162b2 group (age range 43 to 65 years of age), and 5 participants were randomized to placebo (age range 36 to 74 years of age). For 1 participant in each group, onset was 19 days after Dose 1. Onset ranged from 1 to 55 days after Dose 2 for 5 participants in the BNT162b2 and ranged from 2 to 94 days after Dose 2 for 4 participants in the placebo group. The duration ranged from 9 to 155 days after AE onset with 4 events still ongoing at the time of data cutoff (13 March 2021). The toxicity grades were mostly mild (4 in the BNT162b2 group, and 2 in placebo) or moderate (1 in the BNT162b2 group, and 3 in placebo), with one being severe (BNT162b2 group). In the BNT162b2 group, 2 events were deemed related to study vaccine by the investigator. None of the reported events were SAEs.

Other events of clinical interest that were identified by the sponsor and/or from the CDC list of AESIs are discussed in Section 2.7.4.2.4.3.4.

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	6947	83.2	(81.3, 85.2)	3568	43.4	(42.0, 44.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	118	1.4	(1.2, 1.7)	32	0.4	(0.3, 0.5)
Anaemia	8	0.1	(0.0, 0.2)	10	0.1	(0.1, 0.2)
Blood loss anaemia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coagulopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypochromic anaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Iron deficiency anaemia	9	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Leukocytosis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Leukopenia	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymph node pain	7	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Lymphadenitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphadenopathy	87	1.0	(0.8, 1.3)	8	0.1	(0.0, 0.2)
Lymphadenopathy mediastinal	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lymphocytosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphopenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Microcytic anaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Monoclonal B-cell lymphocytosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Neutropenia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Splenomegaly	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Thrombocytopenia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Thrombocytosis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
CARDIAC DISORDERS	87	1.0	(0.8, 1.3)	78	0.9	(0.8, 1.2)
Acute coronary syndrome	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Acute left ventricular failure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Acute myocardial infarction	6	0.1	(0.0, 0.2)	4	0.0	(0.0, 0.1)
Angina pectoris	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angina unstable	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Aortic valve incompetence	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Arrhythmia	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Arrhythmia supraventricular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Arteriosclerosis coronary artery	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Arteriospasm coronary	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atrial fibrillation	13	0.2	(0.1, 0.3)	17	0.2	(0.1, 0.3)
Atrial flutter	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Atrioventricular block complete	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Atrioventricular block first degree	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bradycardia	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Bundle branch block left	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bundle branch block right	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardiac arrest	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Cardiac disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardiac failure acute	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cardiac failure congestive	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiomegaly	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardiovascular disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Coronary artery disease	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Coronary artery dissection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Coronary artery occlusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hypertensive heart disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Junctional ectopic tachycardia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Left atrial enlargement	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Left ventricular dysfunction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Left ventricular hypertrophy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mitral valve incompetence	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Mitral valve prolapse	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myocardial infarction	4	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Myocardial ischaemia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Myocarditis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Palpitations	7	0.1	(0.0, 0.2)	16	0.2	(0.1, 0.3)
Pericardial effusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pericarditis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Postural orthostatic tachycardia syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Sinus bradycardia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Sinus tachycardia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Supraventricular tachycardia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tachyarrhythmia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tachycardia	15	0.2	(0.1, 0.3)	7	0.1	(0.0, 0.2)
Tricuspid valve incompetence	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ventricular arrhythmia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ventricular extrasystoles	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ventricular tachycardia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	4	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Arnold-Chiari malformation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Congenital bladder neck obstruction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Congenital cystic kidney disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Congenital ureteropelvic junction obstruction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Developmental hip dysplasia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastrointestinal arteriovenous malformation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Heart disease congenital	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Protein S deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Type V hyperlipidaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
EAR AND LABYRINTH DISORDERS	76	0.9	(0.7, 1.1)	61	0.7	(0.6, 1.0)
Allergic otitis media	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerumen impaction	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Deafness	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Deafness neurosensory	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Deafness unilateral	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear discomfort	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ear disorder	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Ear pain	13	0.2	(0.1, 0.3)	11	0.1	(0.1, 0.2)
Ear pruritus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eustachian tube dysfunction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyperacusis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypoacusis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Meniere's disease	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Otorrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sudden hearing loss	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tinnitus	9	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)
Tympanic membrane perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vertigo	31	0.4	(0.3, 0.5)	26	0.3	(0.2, 0.5)
Vertigo positional	8	0.1	(0.0, 0.2)	4	0.0	(0.0, 0.1)
ENDOCRINE DISORDERS	17	0.2	(0.1, 0.3)	11	0.1	(0.1, 0.2)
Autoimmune thyroiditis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Goitre	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyperprolactinaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyperthyroidism	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypogonadism	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypothyroidism	8	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Oestrogen deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Thyroid cyst	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Thyroid mass	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
EYE DISORDERS	70	0.8	(0.7, 1.1)	65	0.8	(0.6, 1.0)
Amaurosis fugax	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Angle closure glaucoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Asthenopia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Astigmatism	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blepharitis	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blepharospasm	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Blindness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cataract	7	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Chalazion	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Choroidal neovascularisation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Conjunctival haemorrhage	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Conjunctival hyperaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Conjunctival oedema	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Conjunctivitis allergic	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Corneal irritation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dacryostenosis acquired	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diabetic retinopathy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diplopia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dry age-related macular degeneration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dry eye	1	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Episcleritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Eye allergy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eye haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eye inflammation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eye irritation	6	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Eye pain	7	0.1	(0.0, 0.2)	4	0.0	(0.0, 0.1)
Eye pruritus	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye swelling	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eyelid haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eyelid oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Eyelid pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Eyelids pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Glaucoma	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypermetropia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Iritis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Keratitis	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Lacrimation increased	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Macular oedema	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ocular discomfort	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ocular hyperaemia	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Ophthalmic vein thrombosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Photophobia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retinal artery occlusion	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retinal detachment	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Retinal tear	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Scleral discolouration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Swelling of eyelid	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ulcerative keratitis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Uveitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vision blurred	7	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Visual acuity reduced	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Visual impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vitreous detachment	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vitreous floaters	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	748	9.0	(8.3, 9.6)	511	6.2	(5.7, 6.8)
Abdominal adhesions	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abdominal discomfort	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Abdominal distension	7	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Abdominal hernia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Abdominal pain	23	0.3	(0.2, 0.4)	22	0.3	(0.2, 0.4)
Abdominal pain lower	3	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Abdominal pain upper	27	0.3	(0.2, 0.5)	15	0.2	(0.1, 0.3)
Abdominal rigidity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abnormal faeces	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Acute abdomen	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Anal pruritus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Angular cheilitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Aphthous ulcer	9	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Appendix disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cheilitis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Chronic gastritis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Coeliac artery aneurysm	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Coeliac disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Colitis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Colitis ischaemic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Colitis microscopic	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Colitis ulcerative	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Constipation	10	0.1	(0.1, 0.2)	13	0.2	(0.1, 0.3)
Crohn's disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dental caries	10	0.1	(0.1, 0.2)	8	0.1	(0.0, 0.2)
Diarrhoea	255	3.1	(2.7, 3.5)	189	2.3	(2.0, 2.7)
Diverticular perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diverticulum	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diverticulum intestinal	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Diverticulum intestinal haemorrhagic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dry mouth	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Duodenal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Duodenal ulcer	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dyspepsia	15	0.2	(0.1, 0.3)	14	0.2	(0.1, 0.3)
Dysphagia	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Enterocolitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Epiploic appendagitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Eructation	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Faeces soft	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Femoral hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Flatulence	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Food poisoning	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Frequent bowel movements	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastric antral vascular ectasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastric polyps	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastric ulcer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastric ulcer haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastritis	5	0.1	(0.0, 0.1)	14	0.2	(0.1, 0.3)
Gastritis erosive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastrointestinal disorder	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal haemorrhage	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal mucosa hyperaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastrointestinal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastrointestinal sounds abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastrooesophageal reflux disease	15	0.2	(0.1, 0.3)	23	0.3	(0.2, 0.4)
Gingival bleeding	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gingival discomfort	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gingival pain	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Gingival swelling	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Glossitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Glossodynia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haematemesis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Haematochezia	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haemorrhoidal haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haemorrhoids	5	0.1	(0.0, 0.1)	11	0.1	(0.1, 0.2)
Hiatus hernia	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Hypoaesthesia oral	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypoaesthesia teeth	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ileus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Impaired gastric emptying	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Incarcerated inguinal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Inguinal hernia	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Internal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intestinal obstruction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intestinal perforation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intestinal polyp	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intestinal strangulation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intra-abdominal fluid collection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Irritable bowel syndrome	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Large intestine perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Large intestine polyp	4	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Lip oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lip swelling	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Loose tooth	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mouth ulceration	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Nausea	277	3.3	(2.9, 3.7)	88	1.1	(0.9, 1.3)
Noninfective gingivitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Obstructive pancreatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Odynophagia	13	0.2	(0.1, 0.3)	8	0.1	(0.0, 0.2)
Oesophageal food impaction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oesophageal spasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oesophageal ulcer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oesophageal varices haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oesophagitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Oral discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oral lichenoid reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oral mucosa haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Oral pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Palatal disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pancreatic cyst	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pancreatic failure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pancreatitis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pancreatitis acute	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Paraesthesia oral	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Parotid duct obstruction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peptic ulcer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Precancerous lesion of digestive tract	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Proctalgia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectal haemorrhage	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectal polyp	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Retching	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Retroperitoneal haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Salivary gland calculus	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Salivary gland mucocoele	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Small intestinal obstruction	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Stomatitis	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Swollen tongue	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Teething	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tongue discolouration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tongue discomfort	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tongue oedema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tongue pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tongue ulceration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tooth disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tooth impacted	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Toothache	26	0.3	(0.2, 0.5)	28	0.3	(0.2, 0.5)
Umbilical hernia	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Varices oesophageal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Volvulus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vomiting	68	0.8	(0.6, 1.0)	35	0.4	(0.3, 0.6)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4748	56.9	(55.3, 58.5)	1010	12.3	(11.5, 13.1)
Adverse drug reaction	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Application site erythema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Application site pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Application site pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Application site rash	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Application site reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Asthenia	77	0.9	(0.7, 1.2)	25	0.3	(0.2, 0.4)
Axillary pain	14	0.2	(0.1, 0.3)	3	0.0	(0.0, 0.1)
Capsular contracture associated with breast implant	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Chest discomfort	5	0.1	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Chest pain	17	0.2	(0.1, 0.3)	16	0.2	(0.1, 0.3)
Chills	1368	16.4	(15.5, 17.3)	121	1.5	(1.2, 1.8)
Chronic fatigue syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cyst	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Death	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Drug withdrawal syndrome	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Effusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Exercise tolerance decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Face oedema	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Facial pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Fatigue	1466	17.6	(16.7, 18.5)	379	4.6	(4.2, 5.1)
Feeling abnormal	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Feeling cold	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Feeling hot	8	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Gait disturbance	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Illness	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Induration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Inflammation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Influenza like illness	24	0.3	(0.2, 0.4)	4	0.0	(0.0, 0.1)
Injection site bruising	13	0.2	(0.1, 0.3)	18	0.2	(0.1, 0.3)
Injection site dermatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site discolouration	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site discomfort	6	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Injection site erythema	185	2.2	(1.9, 2.6)	29	0.4	(0.2, 0.5)
Injection site haematoma	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Injection site haemorrhage	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Injection site hyperaesthesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site induration	10	0.1	(0.1, 0.2)	4	0.0	(0.0, 0.1)
Injection site injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Injection site irritation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site lymphadenopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Injection site macule	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site mass	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site nodule	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site oedema	12	0.1	(0.1, 0.3)	0	0.0	(0.0, 0.0)
Injection site pain	2917	35.0	(33.7, 36.2)	399	4.9	(4.4, 5.4)
Injection site papule	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site paraesthesia	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Injection site plaque	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Injection site pruritus	38	0.5	(0.3, 0.6)	6	0.1	(0.0, 0.2)
Injection site rash	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site reaction	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site swelling	140	1.7	(1.4, 2.0)	23	0.3	(0.2, 0.4)
Injection site urticaria	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site warmth	14	0.2	(0.1, 0.3)	5	0.1	(0.0, 0.1)
Injury associated with device	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Malaise	130	1.6	(1.3, 1.8)	22	0.3	(0.2, 0.4)
Mass	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Medical device pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Medical device site granuloma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mucosal disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nodule	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Non-cardiac chest pain	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Oedema peripheral	8	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Pain	628	7.5	(6.9, 8.1)	62	0.8	(0.6, 1.0)
Peripheral swelling	8	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Pyrexia	1520	18.2	(17.3, 19.2)	78	0.9	(0.8, 1.2)
Sensation of foreign body	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sluggishness	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sudden cardiac death	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Swelling	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Swelling face	2	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Temperature intolerance	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Therapeutic response unexpected	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Thirst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vaccination site induration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vaccination site pain	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Vaccination site swelling	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vascular stent occlusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vessel puncture site bruise	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vessel puncture site haematoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vessel puncture site induration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
HEPATOBILIARY DISORDERS	24	0.3	(0.2, 0.4)	16	0.2	(0.1, 0.3)
Bile duct stone	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Biliary colic	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Biliary dyskinesia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholecystitis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Cholecystitis acute	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Cholecystitis chronic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cholelithiasis	11	0.1	(0.1, 0.2)	5	0.1	(0.0, 0.1)
Cirrhosis alcoholic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gallbladder disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hepatic cirrhosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hepatic cyst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatic steatosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hepatocellular injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nonalcoholic fatty liver disease	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	23	0.3	(0.2, 0.4)	34	0.4	(0.3, 0.6)
Allergy to animal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Allergy to arthropod bite	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Allergy to arthropod sting	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Anaphylactic shock	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Drug hypersensitivity	7	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Food allergy	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Hypersensitivity	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Jarisch-Herxheimer reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Milk allergy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Seasonal allergy	8	0.1	(0.0, 0.2)	16	0.2	(0.1, 0.3)
INFECTIONS AND INFESTATIONS	417	5.0	(4.5, 5.5)	499	6.1	(5.6, 6.6)
Abdominal abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Abscess	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Abscess intestinal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abscess jaw	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Abscess limb	0	0.0	(0.0, 0.0)	4	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Abscess neck	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abscess oral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Acarodermatitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Acute sinusitis	1	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Anal abscess	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Anal fistula infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Appendicitis	14	0.2	(0.1, 0.3)	9	0.1	(0.1, 0.2)
Appendicitis perforated	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arthritis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bacterial blepharitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bacterial infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bacterial rhinitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bacterial sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bacterial vaginosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Bacterial vulvovaginitis	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Balanitis candida	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bartholin's abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bartholinitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blister infected	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bone abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Brain abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bronchitis	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.0)	13	0.2	(0.1, 0.3)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Campylobacter infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Carbuncle	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Catheter site infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cellulitis	15	0.2	(0.1, 0.3)	20	0.2	(0.1, 0.4)
Cellulitis orbital	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Chlamydial infection	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Chronic sinusitis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Clostridium difficile infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Complicated appendicitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Conjunctivitis	12	0.1	(0.1, 0.3)	11	0.1	(0.1, 0.2)
Conjunctivitis bacterial	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Coxsackie viral infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cystitis	8	0.1	(0.0, 0.2)	12	0.1	(0.1, 0.3)
Dental fistula	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dermatitis infected	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Device related infection	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diabetic foot infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diverticulitis	10	0.1	(0.1, 0.2)	11	0.1	(0.1, 0.2)
Ear infection	11	0.1	(0.1, 0.2)	17	0.2	(0.1, 0.3)
Emphysematous cholecystitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Empyema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Erysipelas	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Escherichia sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Escherichia urinary tract infection	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Extradural abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eye infection	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Eye infection bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Folliculitis	7	0.1	(0.0, 0.2)	0	0.0	(0.0, 0.0)
Fungal infection	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Fungal skin infection	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Furuncle	3	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Gangrene	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastroenteritis	6	0.1	(0.0, 0.2)	12	0.1	(0.1, 0.3)
Gastroenteritis viral	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Genital herpes	0	0.0	(0.0, 0.0)	5	0.1	(0.0, 0.1)
Genital herpes simplex	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Genitourinary chlamydia infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gingival abscess	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Gingivitis	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Gonorrhoea	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Groin abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Helicobacter gastritis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Helicobacter infection	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Hepatitis A	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hepatitis C	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Herpes ophthalmic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Herpes simplex	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Herpes virus infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Herpes zoster	18	0.2	(0.1, 0.3)	16	0.2	(0.1, 0.3)
Herpes zoster cutaneous disseminated	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Herpes zoster oticus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hordeolum	8	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)
Impetigo	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Infected bite	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Infected dermal cyst	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Infectious mononucleosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Influenza	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Injection site abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Kidney infection	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Labyrinthitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Laryngitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Localised infection	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Lyme disease	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Mastitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mastoiditis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Meningitis bacterial	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nail infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nasopharyngitis	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Onychomycosis	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Ophthalmic herpes zoster	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral candidiasis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Oral fungal infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oral herpes	7	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Oral infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Orchitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Osteomyelitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Otitis externa	6	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Otitis media	9	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Otitis media acute	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Otitis media bacterial	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Papilloma viral infection	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Parasitic gastroenteritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Paronychia	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Parotitis	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Pelvic inflammatory disease	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Penile infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Periodontitis	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Peritoneal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Peritonitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritonsillar abscess	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pharyngitis	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Pharyngitis bacterial	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Pharyngitis streptococcal	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pharyngotonsillitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pilonidal cyst	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pneumonia	4	0.0	(0.0, 0.1)	9	0.1	(0.1, 0.2)
Post procedural infection	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Postoperative wound infection	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Primary syphilis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pulmonary tuberculosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Puncture site infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pustule	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pyelonephritis	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Pyelonephritis acute	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Rash pustular	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Renal abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Respiratory tract infection viral	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Rhinitis	6	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)
Sepsis	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Septic shock	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Shigella sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sialoadenitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sinusitis	20	0.2	(0.1, 0.4)	31	0.4	(0.3, 0.5)
Sinusitis bacterial	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin bacterial infection	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Skin infection	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Soft tissue infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Staphylococcal infection	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Staphylococcal sepsis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subacute endocarditis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subcutaneous abscess	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Suspected COVID-19	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Syphilis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tinea cruris	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tinea infection	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Tinea versicolour	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Tonsillitis	0	0.0	(0.0, 0.0)	6	0.1	(0.0, 0.2)
Tonsillitis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tooth abscess	12	0.1	(0.1, 0.3)	6	0.1	(0.0, 0.2)
Tooth infection	26	0.3	(0.2, 0.5)	33	0.4	(0.3, 0.6)
Trichomoniasis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Upper respiratory tract infection	10	0.1	(0.1, 0.2)	9	0.1	(0.1, 0.2)
Ureaplasma infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Urinary tract infection	74	0.9	(0.7, 1.1)	82	1.0	(0.8, 1.2)
Urosepsis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vaginal infection	0	0.0	(0.0, 0.0)	7	0.1	(0.0, 0.2)
Varicella	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Viral infection	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Viral upper respiratory tract infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vulval abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vulvovaginal candidiasis	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Vulvovaginal mycotic infection	6	0.1	(0.0, 0.2)	10	0.1	(0.1, 0.2)
Vulvovaginitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Wound infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	294	3.5	(3.1, 3.9)	378	4.6	(4.1, 5.1)
Administration related reaction	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Alcohol poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Anaemia postoperative	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Animal bite	3	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Ankle fracture	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Arthropod bite	12	0.1	(0.1, 0.3)	7	0.1	(0.0, 0.2)
Arthropod sting	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Back injury	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Bone contusion	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Bone fissure	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Brain contusion	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Burn oral cavity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Burns first degree	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Burns second degree	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cartilage injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cervical vertebral fracture	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chest injury	5	0.1	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Chillblains	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Clavicle fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Colon injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Concussion	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Contusion	14	0.2	(0.1, 0.3)	22	0.3	(0.2, 0.4)
Corneal abrasion	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Craniocerebral injury	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Delayed recovery from anaesthesia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dental restoration failure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ear canal abrasion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ear injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Epicondylitis	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Exposure during pregnancy	30	0.4	(0.2, 0.5)	42	0.5	(0.4, 0.7)
Exposure to communicable disease	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eye contusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Eyelid injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Facial bones fracture	5	0.1	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Fall	62	0.7	(0.6, 1.0)	76	0.9	(0.7, 1.2)
Femur fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Fibula fracture	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Flail chest	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Foot fracture	7	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)
Forearm fracture	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Foreign body	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Foreign body aspiration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Foreign body in eye	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Fractured sacrum	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hand fracture	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Head injury	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Heat stroke	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hip fracture	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Humerus fracture	0	0.0	(0.0, 0.0)	5	0.1	(0.0, 0.1)
Injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Jaw fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Joint dislocation	8	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Joint injury	6	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)
Ligament injury	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Ligament rupture	2	0.0	(0.0, 0.1)	10	0.1	(0.1, 0.2)
Ligament sprain	21	0.3	(0.2, 0.4)	27	0.3	(0.2, 0.5)
Limb fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Limb injury	8	0.1	(0.0, 0.2)	16	0.2	(0.1, 0.3)
Limb traumatic amputation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lip injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lower limb fracture	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Lumbar vertebral fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Maternal exposure before pregnancy	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Maternal exposure during breast feeding	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Maternal exposure during pregnancy	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Meniscus injury	6	0.1	(0.0, 0.2)	10	0.1	(0.1, 0.2)
Mouth injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Multiple injuries	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Muscle contusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Muscle injury	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Muscle rupture	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Muscle strain	18	0.2	(0.1, 0.3)	17	0.2	(0.1, 0.3)
Overdose	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Patella fracture	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pelvic fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Penis injury	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pharyngeal perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Post concussion syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Post procedural discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Post procedural haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Post procedural haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Post procedural swelling	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Post-traumatic pain	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Postoperative ileus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Procedural dizziness	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Procedural haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Procedural hypotension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Procedural pain	9	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Radius fracture	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Respiratory fume inhalation disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rib fracture	3	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Road traffic accident	16	0.2	(0.1, 0.3)	20	0.2	(0.1, 0.4)
Scapula fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Scar	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin abrasion	8	0.1	(0.0, 0.2)	15	0.2	(0.1, 0.3)
Skin injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Skin laceration	18	0.2	(0.1, 0.3)	24	0.3	(0.2, 0.4)
Skull fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Soft tissue injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Spinal column injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Spinal compression fracture	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Spinal cord injury cervical	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Spinal fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Stab wound	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Stoma site rash	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Stress fracture	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Subdural haematoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sunburn	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tendon injury	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Tendon rupture	0	0.0	(0.0, 0.0)	6	0.1	(0.0, 0.2)
Thermal burn	3	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Tibia fracture	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Tooth fracture	10	0.1	(0.1, 0.2)	10	0.1	(0.1, 0.2)
Tooth injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Toxicity to various agents	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Traumatic haemothorax	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ulna fracture	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Upper limb fracture	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Vaccination complication	5	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Venom poisoning	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vulvovaginal injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Wound	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Wrist fracture	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
INVESTIGATIONS	183	2.2	(1.9, 2.5)	51	0.6	(0.5, 0.8)
Alanine aminotransferase increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Aspartate aminotransferase increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Autoantibody positive	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Biopsy breast normal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood chloride decreased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood cholesterol increased	5	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blood creatinine decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood creatinine increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood glucose abnormal	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood glucose fluctuation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood glucose increased	8	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Blood immunoglobulin E increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood iron decreased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood potassium decreased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood pressure abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Blood pressure diastolic increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood pressure increased	6	0.1	(0.0, 0.2)	10	0.1	(0.1, 0.2)
Blood pressure systolic increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood sodium decreased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood testosterone decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood testosterone increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood thyroid stimulating hormone increased	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Blood triglycerides increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Blood urea increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Body temperature	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Body temperature decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Body temperature increased	121	1.5	(1.2, 1.7)	13	0.2	(0.1, 0.3)
C-reactive protein	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardiac stress test abnormal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Electrocardiogram QT prolonged	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Fractional exhaled nitric oxide increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Glomerular filtration rate decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haemoglobin decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Heart rate increased	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Heart rate irregular	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hepatic enzyme increased	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Hepatitis C antibody positive	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Herpes simplex test positive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
High density lipoprotein increased	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Intraocular pressure increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Liver function test increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Low density lipoprotein increased	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Lymphocyte count decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Mammogram abnormal	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Mean cell haemoglobin decreased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mean cell volume decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Mean cell volume increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Monocyte count increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Platelet count decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Platelet count increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Prostatic specific antigen increased	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Red blood cell morphology abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Respiratory rate increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
SARS-CoV-2 antibody test positive	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Serum ferritin decreased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Thyroid function test abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Troponin increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Urine ketone body present	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Weight decreased	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Weight increased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
White blood cell count increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
White blood cells urine positive	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	129	1.5	(1.3, 1.8)	117	1.4	(1.2, 1.7)
Decreased appetite	39	0.5	(0.3, 0.6)	9	0.1	(0.1, 0.2)
Dehydration	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Diabetes mellitus	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Diabetes mellitus inadequate control	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Diabetic ketoacidosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dyslipidaemia	7	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Fluid retention	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Folate deficiency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Food intolerance	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Glucose tolerance impaired	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Gout	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Hypercholesterolaemia	7	0.1	(0.0, 0.2)	21	0.3	(0.2, 0.4)
Hyperglycaemia	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Hyperkalaemia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyperlipidaemia	9	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)
Hypernatraemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypertriglyceridaemia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyperuricaemia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypocalcaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypocholesterolaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoglycaemia	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Hypokalaemia	8	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Hypomagnesaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyponatraemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypovolaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Impaired fasting glucose	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Increased appetite	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Insulin resistance	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Iron deficiency	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Lactic acidosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Obesity	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Polydipsia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Type 2 diabetes mellitus	14	0.2	(0.1, 0.3)	13	0.2	(0.1, 0.3)
Vitamin B12 deficiency	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Vitamin D deficiency	12	0.1	(0.1, 0.3)	10	0.1	(0.1, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1859	22.3	(21.3, 23.3)	622	7.6	(7.0, 8.2)
Arthralgia	281	3.4	(3.0, 3.8)	122	1.5	(1.2, 1.8)
Arthritis	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Arthritis reactive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Arthropathy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Axillary mass	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Back pain	104	1.2	(1.0, 1.5)	99	1.2	(1.0, 1.5)
Bone disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bone pain	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bone swelling	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bursitis	11	0.1	(0.1, 0.2)	5	0.1	(0.0, 0.1)
Coccydynia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Costochondritis	5	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dupuytren's contracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Exostosis	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Fibromyalgia	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Flank pain	3	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Groin pain	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc compression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intervertebral disc degeneration	4	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Intervertebral disc disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Intervertebral disc protrusion	10	0.1	(0.1, 0.2)	11	0.1	(0.1, 0.2)
Joint effusion	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Joint instability	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Joint range of motion decreased	5	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Joint stiffness	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Joint swelling	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Limb discomfort	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Metatarsalgia	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Mobility decreased	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Muscle contracture	4	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Muscle discomfort	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Muscle fatigue	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Muscle spasms	29	0.3	(0.2, 0.5)	16	0.2	(0.1, 0.3)
Muscle tightness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Muscle twitching	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Muscular weakness	13	0.2	(0.1, 0.3)	3	0.0	(0.0, 0.1)
Musculoskeletal chest pain	11	0.1	(0.1, 0.2)	7	0.1	(0.0, 0.2)
Musculoskeletal discomfort	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Musculoskeletal pain	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Musculoskeletal stiffness	12	0.1	(0.1, 0.3)	6	0.1	(0.0, 0.2)
Myalgia	1245	14.9	(14.1, 15.8)	170	2.1	(1.8, 2.4)
Myalgia intercostal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Neck pain	34	0.4	(0.3, 0.6)	36	0.4	(0.3, 0.6)
Osteitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Osteoarthritis	15	0.2	(0.1, 0.3)	23	0.3	(0.2, 0.4)
Osteochondritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Osteochondrosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Osteopenia	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Osteoporosis	0	0.0	(0.0, 0.0)	6	0.1	(0.0, 0.2)
Pain in extremity	189	2.3	(2.0, 2.6)	52	0.6	(0.5, 0.8)
Pain in jaw	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Patellofemoral pain syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Periarthritis	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Plantar fasciitis	4	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Polyarthritis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Psoriatic arthropathy	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Rhabdomyolysis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rheumatoid arthritis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Rotator cuff syndrome	5	0.1	(0.0, 0.1)	13	0.2	(0.1, 0.3)
Scoliosis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Sinus tarsi syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Spinal disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Spinal osteoarthritis	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Spinal stenosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spondylitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Spondylolisthesis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Synovial cyst	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Synovitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Systemic lupus erythematosus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Temporomandibular joint syndrome	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Tendon disorder	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tendon pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tendonitis	12	0.1	(0.1, 0.3)	10	0.1	(0.1, 0.2)
Tenosynovitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tenosynovitis stenosans	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Torticollis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Trigger finger	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	67	0.8	(0.6, 1.0)	69	0.8	(0.7, 1.1)
Acrochordon	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Acute myeloid leukaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenocarcinoma of colon	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenocarcinoma pancreas	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenoma benign	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adrenal gland cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
B-cell lymphoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Basal cell carcinoma	3	0.0	(0.0, 0.1)	11	0.1	(0.1, 0.2)
Benign breast neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Benign hydatidiform mole	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Benign pancreatic neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Benign uterine neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Biliary cancer metastatic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bladder cancer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Borderline serous tumour of ovary	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Breast cancer	2	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Breast cancer in situ	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Breast cancer stage I	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Carcinoid tumour of the stomach	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Chondroma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Chronic myeloid leukaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Clear cell renal cell carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Colon adenoma	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Fibroadenoma of breast	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Gallbladder cancer stage II	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastric cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Glomus tumour	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Haemangioma of skin	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Infected naevus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Intraductal proliferative breast lesion	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Invasive ductal breast carcinoma	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Leydig cell tumour of the testis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lipoma	5	0.1	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Lobular breast carcinoma in situ	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Lung adenocarcinoma	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphoproliferative disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Malignant melanoma	3	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Malignant melanoma of eyelid	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Meningioma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Meningioma benign	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Metastases to central nervous system	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Metastases to liver	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Metastases to lymph nodes	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Non-Hodgkin's lymphoma recurrent	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Non-small cell lung cancer stage IV	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oropharyngeal cancer recurrent	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oropharyngeal squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ovarian germ cell teratoma benign	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pancreatic carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Papillary serous endometrial carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Papillary thyroid cancer	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Penile neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Penile squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Plasma cell myeloma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Polycythaemia vera	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Prostate cancer	5	0.1	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Prostate cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Seborrhoeic keratosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin papilloma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Squamous cell carcinoma	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Squamous cell carcinoma of head and neck	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Squamous cell carcinoma of skin	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Teratoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Thyroid cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tonsil cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Transitional cell carcinoma	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Uterine cancer	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Uterine leiomyoma	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	1602	19.2	(18.3, 20.2)	635	7.7	(7.1, 8.4)
Ageusia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Amnesia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Amyotrophic lateral sclerosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Aphasia	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Balance disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Burning sensation	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Carpal tunnel syndrome	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Cerebellar infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerebral atrophy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerebral capillary telangiectasia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerebral infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerebrovascular accident	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cervical radiculopathy	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Cervicogenic headache	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dementia Alzheimer's type	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Depressed level of consciousness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diabetic neuropathy	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Disturbance in attention	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dizziness	81	1.0	(0.8, 1.2)	64	0.8	(0.6, 1.0)
Dizziness postural	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug withdrawal headache	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dysgeusia	12	0.1	(0.1, 0.3)	8	0.1	(0.0, 0.2)
Dyskinesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dystonia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Facial paralysis	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facial paresis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Generalised tonic-clonic seizure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Guillain-Barre syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Haemorrhagic stroke	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Head discomfort	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Headache	1348	16.2	(15.3, 17.0)	429	5.2	(4.7, 5.7)
Hemiparaesthesia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hemiplegic migraine	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hyperaesthesia	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hypersomnia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypoaesthesia	5	0.1	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Hypogeusia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hyposmia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Idiopathic intracranial hypertension	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intraventricular haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ischaemic stroke	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Lethargy	25	0.3	(0.2, 0.4)	6	0.1	(0.0, 0.2)
Mental impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Migraine	26	0.3	(0.2, 0.5)	13	0.2	(0.1, 0.3)
Migraine with aura	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Migraine without aura	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Morton's neuralgia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Motor dysfunction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Muscle spasticity	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Myoclonus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nerve compression	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Neuralgia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Neuritis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Neuropathy peripheral	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Nystagmus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Optic neuritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Paraesthesia	23	0.3	(0.2, 0.4)	24	0.3	(0.2, 0.4)
Paraparesis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Parkinsonism	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Parosmia	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Periodic limb movement disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Peripheral nerve lesion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Peripheral sensory neuropathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Piriformis syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Post herpetic neuralgia	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Presyncope	8	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Radiculopathy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Restless legs syndrome	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sciatic nerve neuropathy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Sciatica	13	0.2	(0.1, 0.3)	11	0.1	(0.1, 0.2)
Seizure	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sinus headache	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Somnolence	9	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Spinal cord compression	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subarachnoid haemorrhage	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Syncope	14	0.2	(0.1, 0.3)	13	0.2	(0.1, 0.3)
Taste disorder	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tension headache	11	0.1	(0.1, 0.2)	9	0.1	(0.1, 0.2)
Thoracic radiculopathy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Toxic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Transient global amnesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Transient ischaemic attack	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Tremor	9	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Trigeminal neuralgia	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Uraemic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
VIth nerve paralysis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Abortion incomplete	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Abortion spontaneous	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Abortion spontaneous incomplete	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Retained products of conception	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
PRODUCT ISSUES	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Device breakage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Device connection issue	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
PSYCHIATRIC DISORDERS	112	1.3	(1.1, 1.6)	108	1.3	(1.1, 1.6)
Abnormal dreams	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adjustment disorder with depressed mood	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Alcohol abuse	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Alcohol withdrawal syndrome	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Anxiety	27	0.3	(0.2, 0.5)	31	0.4	(0.3, 0.5)
Anxiety disorder	4	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Attention deficit hyperactivity disorder	5	0.1	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Bipolar disorder	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Bruxism	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Confusional state	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cyclothymic disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Depressed mood	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Depression	23	0.3	(0.2, 0.4)	26	0.3	(0.2, 0.5)
Depression suicidal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Disorientation	5	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.0)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Dysphemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastrointestinal somatic symptom disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Generalised anxiety disorder	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Insomnia	25	0.3	(0.2, 0.4)	13	0.2	(0.1, 0.3)
Irritability	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Libido decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Libido increased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Listless	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Major depression	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mental disorder	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Mental fatigue	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mental status changes	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Mood swings	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nightmare	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Panic attack	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Panic disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Panic reaction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Paranoia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Post-traumatic stress disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Psychotic disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Restlessness	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Schizophrenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sleep disorder	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Stress	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Substance abuse	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Suicidal ideation	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Suicide attempt	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	52	0.6	(0.5, 0.8)	48	0.6	(0.4, 0.8)
Acute kidney injury	6	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Bladder spasm	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Chronic kidney disease	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Costovertebral angle tenderness	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dysuria	8	0.1	(0.0, 0.2)	5	0.1	(0.0, 0.1)
Haematuria	5	0.1	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Hydronephrosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypertonic bladder	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Micturition urgency	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Nephrolithiasis	14	0.2	(0.1, 0.3)	15	0.2	(0.1, 0.3)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Nocturia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Obstructive nephropathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oedematous kidney	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Perinephric oedema	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pollakiuria	5	0.1	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Polyuria	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Renal atrophy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Renal colic	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Renal cyst	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Renal cyst haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Renal failure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subcapsular renal haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ureterolithiasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Urethral discharge	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Urethral stenosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Urinary bladder polyp	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Urinary retention	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Urinary tract obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Urine odour abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vesical fistula	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	50	0.6	(0.4, 0.8)	58	0.7	(0.5, 0.9)
Adenomyosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Adnexal torsion	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Amenorrhoea	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Benign prostatic hyperplasia	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Breast calcifications	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Breast cyst	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Breast hyperplasia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Breast mass	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Breast pain	4	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cervical dysplasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cervical polyp	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dysfunctional uterine bleeding	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dysmenorrhoea	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Ejaculation disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Endometriosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Erectile dysfunction	1	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Genital erythema	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Haematospermia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haemorrhagic ovarian cyst	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mammary duct ectasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Menometrorrhagia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Menorrhagia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Menstruation delayed	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Menstruation irregular	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Metrorrhagia	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Nipple pain	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ovarian cyst	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Ovarian mass	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pelvic pain	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Penile vein thrombosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Polycystic ovaries	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Postmenopausal haemorrhage	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Premenstrual syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Prostatitis	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Prostatomegaly	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pruritus genital	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rectocele	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Scrotal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Testicular pain	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Testicular torsion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Uterine haemorrhage	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Uterine inflammation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Uterine prolapse	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vaginal discharge	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vaginal haemorrhage	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Vaginal prolapse	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Vulvovaginal pruritus	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	224	2.7	(2.3, 3.1)	195	2.4	(2.1, 2.7)
Acute respiratory failure	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Allergic respiratory disease	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Allergic sinusitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Asthma	15	0.2	(0.1, 0.3)	9	0.1	(0.1, 0.2)
Asthma exercise induced	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Asthmatic crisis	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Atelectasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Bronchospasm	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	6	0.1	(0.0, 0.2)	1	0.0	(0.0, 0.1)
Cough	23	0.3	(0.2, 0.4)	15	0.2	(0.1, 0.3)
Dry throat	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dysphonia	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Dyspnoea	6	0.1	(0.0, 0.2)	11	0.1	(0.1, 0.2)
Dyspnoea exertional	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Emphysema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Epistaxis	6	0.1	(0.0, 0.2)	9	0.1	(0.1, 0.2)
Haemoptysis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hiccups	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypoxia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Interstitial lung disease	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Lung infiltration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nasal congestion	30	0.4	(0.2, 0.5)	33	0.4	(0.3, 0.6)
Nasal discomfort	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Nasal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Nasal polyps	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal septum deviation	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal turbinate hypertrophy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nasal valve collapse	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nasopharyngeal polyp	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oropharyngeal discomfort	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Oropharyngeal pain	36	0.4	(0.3, 0.6)	31	0.4	(0.3, 0.5)
Paranasal sinus discomfort	4	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Paranasal sinus hypersecretion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pharyngeal lesion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pharyngeal swelling	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Pleurisy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pleuritic pain	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pneumonia aspiration	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumonitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pneumothorax	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Productive cough	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Pulmonary embolism	8	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Pulmonary hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pulmonary mass	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Pulmonary oedema	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pulmonary pain	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Reflux laryngitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory arrest	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Respiratory failure	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Respiratory tract congestion	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Rhinalgia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rhinitis allergic	13	0.2	(0.1, 0.3)	14	0.2	(0.1, 0.3)
Rhinitis perennial	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rhinorrhoea	21	0.3	(0.2, 0.4)	13	0.2	(0.1, 0.3)
Sinus congestion	6	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Sinus disorder	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Sleep apnoea syndrome	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Sneezing	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Snoring	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Sputum discoloured	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Throat irritation	7	0.1	(0.0, 0.2)	9	0.1	(0.1, 0.2)
Tonsillar hypertrophy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Upper respiratory tract congestion	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Upper-airway cough syndrome	8	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Wheezing	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	254	3.0	(2.7, 3.4)	194	2.4	(2.0, 2.7)
Acne	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Acne cystic	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Actinic keratosis	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Alopecia	5	0.1	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Alopecia areata	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Angioedema	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blister	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Cold sweat	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dermal cyst	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Dermatitis	5	0.1	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Dermatitis acneiform	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dermatitis allergic	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Dermatitis atopic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dermatitis bullous	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dermatitis contact	14	0.2	(0.1, 0.3)	21	0.3	(0.2, 0.4)
Dermatitis exfoliative	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diabetic foot	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Drug eruption	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Dry skin	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dyshidrotic eczema	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ecchymosis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Eczema	7	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Erythema	9	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Erythema nodosum	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Fixed eruption	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hand dermatitis	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hangnail	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hidradenitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyperhidrosis	31	0.4	(0.3, 0.5)	9	0.1	(0.1, 0.2)
Ingrowing nail	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Intertrigo	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lipodystrophy acquired	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Livedo reticularis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Macule	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Mechanical urticaria	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Night sweats	17	0.2	(0.1, 0.3)	3	0.0	(0.0, 0.1)
Onycholysis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Onychomadesis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pain of skin	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Papule	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Peau d'orange	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Perioral dermatitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pityriasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pityriasis rosea	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Pruritus	24	0.3	(0.2, 0.4)	20	0.2	(0.1, 0.4)
Pruritus allergic	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Pseudofolliculitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Psoriasis	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Purpura	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Rash	62	0.7	(0.6, 1.0)	52	0.6	(0.5, 0.8)
Rash erythematous	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Rash maculo-papular	7	0.1	(0.0, 0.2)	4	0.0	(0.0, 0.1)
Rash papular	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Rash pruritic	8	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Rosacea	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Seborrhoeic dermatitis	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
Skin discolouration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Skin induration	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Skin irritation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin lesion	3	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Skin mass	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Skin ulcer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Stasis dermatitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Transient acantholytic dermatosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Urticaria	18	0.2	(0.1, 0.3)	15	0.2	(0.1, 0.3)
Urticaria contact	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Urticaria papular	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
SOCIAL CIRCUMSTANCES	5	0.1	(0.0, 0.1)	0	0.0	(0.0, 0.0)
High risk sexual behaviour	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Menopause	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Miscarriage of partner	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	33	0.4	(0.3, 0.6)	26	0.3	(0.2, 0.5)
Abortion induced	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Apicectomy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Botulinum toxin injection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardiac pacemaker replacement	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardioversion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Carpal tunnel decompression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cataract operation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Chondroplasty	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dental care	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Dental implantation	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Drug titration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Endodontic procedure	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Facet joint block	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Finger amputation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gingival operation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Inguinal hernia repair	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lacrimal duct procedure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lens extraction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mammoplasty	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Medical device implantation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nasal polypectomy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Open reduction of fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Postoperative care	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Retinal operation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Rhinoplasty	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rotator cuff repair	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sclerotherapy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin neoplasm excision	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Toe amputation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Toe operation	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Tonsillectomy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tooth extraction	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Vasectomy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Wisdom teeth removal	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Wound drainage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
VASCULAR DISORDERS	112	1.3	(1.1, 1.6)	118	1.4	(1.2, 1.7)
Accelerated hypertension	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Aortic aneurysm	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Aortic dilatation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Aortic rupture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Aortic stenosis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Arteriosclerosis	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Blood pressure inadequately controlled	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Deep vein thrombosis	7	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)
Diastolic hypertension	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Essential hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Flushing	11	0.1	(0.1, 0.2)	2	0.0	(0.0, 0.1)
Haematoma	4	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Hot flush	7	0.1	(0.0, 0.2)	9	0.1	(0.1, 0.2)
Hypertension	61	0.7	(0.6, 0.9)	68	0.8	(0.6, 1.0)
Hypertensive crisis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypertensive emergency	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hypertensive urgency	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hypotension	6	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Intermittent claudication	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphoedema	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Lymphorrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Orthostatic hypotension	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Pallor	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Peripheral arterial occlusive disease	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Peripheral artery stenosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Table 8. Incidence Rates of at Least 1 Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Phlebitis superficial	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Phlebolith	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Raynaud's phenomenon	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subgaleal haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Systolic hypertension	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Thrombophlebitis superficial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Varicose vein	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Venous thrombosis limb	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:11)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 all exp p3 saf

Subgroup Analyses

In the baseline SARS-CoV-2 positive subgroup, differences in IRs in the BNT162b2 (70.7 per 100 PY) and placebo (31.9 per 100 PY) groups were due to reactogenicity events (chills, fatigue, injection site pain, pyrexia, myalgia, and headache).

In the baseline SARS-CoV-2 negative subgroup, differences in IRs in the BNT162b2 (83.6 per 100 PY) and placebo (43.8 per 100 PY) groups were due to reactogenicity events (diarrhea, vomiting, chill, fatigue, injection site reactions [pain, erythema, swelling], pyrexia, arthralgia, myalgia, and headache) as well as other AEs (lymphadenopathy, nausea, asthenia, malaise, pain, body temperature increase, and pain in extremity).

Given the differences in exposure (2.5 vs 80.4) by baseline SARS-CoV-2 positive and negative status, respectively, direct comparisons should be interpreted with caution. The overall rate of AEs is 70.7 per 100 PY (95% CI: 60.7, 81.9) (baseline positive) compared with 83.6 per 100 PY (95% CI: 81.7, 85.7) (baseline negative). For other SOCs, the IR were either numerically lower or similar for the baseline positive group compared to the baseline

negative group. Overall, there is no evidence that individuals who are positive at baseline report AEs at a higher frequency than those who are negative at baseline.

In the BNT162b2 group, overall IRs for participants reporting at least 1 AE were highest for participants of all other races (120.1 per 100 PY) compared to White participants (83.1 per 100 PY), with Black or African American participants having the lowest IR (53.5 per 100 PY). The IR for nausea in the BNT162b2 group was higher in participants of all other races (4.7 per 100 PY BNT162b2 vs 1.6 per 100 PY placebo) and White participants (3.4 per 100 PY BNT162b2 vs 1.0 per 100 PY placebo) than in Black or African American participants where the IR was similar in both vaccine groups (1.3 per 100 PY BNT162b2 vs 1.2 per 100 PY placebo).

In the BNT162b2 group, the IR for participants reporting at least 1 AE was higher in non-Hispanic/non-Latino participants (85.4 per 100 PY BNT162b2 and 41.6 per 100 PY placebo) and Hispanic/Latino participants (78.4 per 100 PY BNT162b2 and 47.9 per 100 PY placebo) and lowest in the group where ethnicity was not reported (49.4 per 100 PY BNT162b2 and 43.3 per 100 PY placebo). IRs were higher for mainly reactogenicity events (chills, fatigue, myalgia, diarrhea, injection site reactions [pain, erythema, and swelling], pain, pyrexia, and headache) as well as lymphadenopathy, nausea, influenza like illness, malaise, increased body temperature, and pain in extremity.

Overall, females reported a higher IR of AEs (91.0 per 100 PY BNT162b2, 46.8 per 100 PY placebo) than males (76.0 per 100 PY BNT162b2, 40.1 per 100 PY placebo), with a greater difference in the BNT162b2 groups than in the placebo groups . The higher IRs in females were due to reactogenicity AEs (vomiting, chills, fatigue, pyrexia, myalgia, and headache) as well as other AEs (lymphadenopathy, nausea, pain, increased body temperature, and pain in extremity). There were sex appropriate differences as well, such as higher IRs in the SOC of cardiac disorders in males (1.2 per 100 PY) versus females (0.9 per 100 PY) and lower IRs in the SOC of reproductive system and breast disorders in males (0.3 per 100 PY) versus females (0.9 per 100 PY).

2.7.4.2.4.2.2.2.1.1. Participants with Confirmed Stable HIV Disease: Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date (Phase 3, Study C4591001, Analysis of Adverse Events, Adverse Events by System Organ Class and Preferred Term)

From Dose 1 to the unblinding date, and similar to the overall population, most AEs reported for the subset of 200 HIV-positive participants from Dose 1 to the unblinding date were in SOCs with reactogenicity events:

- general disorders and administration site conditions (66.1 per 100 PY BNT162b2 vs 6.9 per 100 PY placebo)
- musculoskeletal and connective tissue disorders (19.8 per 100 PY BNT162b2 vs 10.4 per 100 PY placebo)
- nervous system disorders (16.5 per 100 PY BNT162b2 vs 0.0 placebo per 100 PY)
- gastrointestinal disorders (9.9 per 100 PY BNT162b2 vs 13.9 placebo)

2.7.4.2.4.2.2.2.2. Related Adverse Events by System Organ Class and Preferred Term: Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date (Phase 3, Study C4591001)

From Dose 1 to the unblinding date, IRs of AEs assessed as related by the investigator during the blinded follow-up period were 62.9 per 100 PY and 16.0 per 100 PY in the BNT162b2 group and in the placebo group, respectively (Table 7). The IRs of related AEs were highest for reactogenicity events and in the SOC of general disorders and administration site conditions, IRs were 55.7 per 100 PY and 10.8 per 100 PY for BNT162b2 and placebo recipients, respectively. Additional terms identified as either synonymous with or otherwise plausibly associated with reactogenicity events (ie, secondary to reactogenicity events) occurring within 7 days after each dose were also considered related (pain in extremity, decreased appetite, lethargy, asthenia, malaise, night sweats, and hyperhidrosis) (Section 2.7.4.2.4.2.1.2.1).

Lymphadenopathy is discussed in Section 2.7.4.2.4.3.4.1.3. IRs of related AEs in the younger and older age groups were 70.0 per 100 PY and 52.3 per 100 PY, respectively for the BNT162b2 group and 18.0 per 100 PY and 13.0 per 100 PY, respectively, for the placebo group.

2.7.4.2.4.2.2.2.3. Severe or Life-Threatening Adverse Events: Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date (Phase 3, Study C4591001)

From Dose 1 to the unblinding date, severe AE IRs during the blinded follow-up period were 4.3 per 100 PY (95% CI: 3.8, 4.7) and 3.1 per 100 PY (95% CI: 2.7, 3.5) in BNT162b2 and placebo recipients, respectively. Severe events in the general disorders and administration site conditions were generally reflecting terms consistent with reactogenicity, in the BNT162b2 versus placebo groups (1.2 per 100 PY vs 0.1 per 100 PY) as well as the Musculoskeletal SOC (0.6 per 100 PY vs 0.3 per 100 PY). The IR in all other SOCs were similar in the BNT162b2 and placebo groups.

The IRs for participants who had at least 1 life-threatening AE from Dose 1 to the unblinding date were similar: 0.6 per 100 PY (95% CI: 0.4, 0.8) in the BNT162b2 group and 0.7 per 100 PY (95% CI: 0.5, 0.9) in the placebo group. All of the IRs for the SOCs were similar in the BNT162b2 and placebo groups.

2.7.4.2.4.2.3. Open-Label Follow-Up Period – Original BNT162b2 Participants (Phase 3, Study C4591001)

2.7.4.2.4.2.3.1. Summary of Adverse Events: Open-Label Follow-Up Period – Original BNT162b2 Participants (Phase 3, Study C4591001)

Per protocol AEs are reported through 1 month after the Dose 2 and within 48 hours after a blood draw. SAEs are reported to approximately 6 months after the last dose of study intervention. An overview of IRs of AEs from the unblinding date to the data cutoff date for participants originally randomized to BNT162b2 during the open-label follow-up is presented in Table 9. The IRs for any AE, at least 1 related AE, and severe AE were 8.8 per 100 PY, and 0.7 per 100 PY, and 1.6 per 100 PY, respectively, which is markedly reduced

relative to those from Dose 1 to the unblinding date (83.2, 62.9, 4.3 respectively [Table 7]). The IR of life-threatening AEs is 0.4 per 100 PY (95% CI: 0.2, 0.8), which is similar to the IR from Dose 1 to the unblinding date, 0.6 per 100 PY (95% CI: 0.4, 0.8).

The IR of SAEs during the open-label follow-up period (Table 9), 2.0 per 100 PY (95% CI: 1.5, 2.6) were lower than the IR from Dose 1 to the unblinding date, 3.2 per 100 PY (95% CI: 2.8, 3.6) (Table 7). There was a single related SAE (myocardial infarction) for an individual in the open label follow-up period (see Section 2.7.4.2.4.3.2.3). The IR of AEs leading to withdrawal also decreased (0.1 per 100 PY [95% CI: 0.0, 0.4]) in the open-label follow-up period compared with the blinded placebo-controlled period (0.5 per 100 PY [95% CI: 0.4, 0.7]) but the IR of deaths were similar (0.1 per 100 PY vs 0.2 per 100 PY in the open-label and blinded placebo-controlled follow-up periods, respectively).

Table 9. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021) – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	243	8.8	(7.7, 9.9)
Related[f]	20	0.7	(0.4, 1.1)
Severe	43	1.6	(1.1, 2.1)
Life-threatening	12	0.4	(0.2, 0.8)
Any serious adverse event	55	2.0	(1.5, 2.6)
Related[f]	1	0.0	(0.0, 0.2)
Severe	30	1.1	(0.7, 1.5)
Life-threatening	12	0.4	(0.2, 0.8)
Any adverse event leading to withdrawal	4	0.1	(0.0, 0.4)
Related[f]	0	0.0	(0.0, 0.1)
Severe	0	0.0	(0.0, 0.1)
Life-threatening	4	0.1	(0.0, 0.4)
Death	3	0.1	(0.0, 0.3)

a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from the unblinding date to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s092_unb_cut_p3_saf

2.7.4.2.4.2.3.2. Analysis of Adverse Events: Open-Label Follow-Up Period – Original BNT162b2 Participants ≥16 Years of Age (Phase 3, Study C4591001)

2.7.4.2.4.2.3.2.1. Adverse Events by System Organ Class and Preferred Term: Open-Label Follow-Up Period – Original BNT162b2 Participants ≥16 Years of Age (Phase 3, Study C4591001, Analysis of Adverse Events)

From the unblinding date to the data cutoff date for participants originally randomized to BNT162b2 during the open-label follow-up period, the IR for participants who reported at

least 1 AE was 8.8 per 100 PY compared to 83.2 per 100 PY from Dose 1 to the unblinding date (Table 7).

Overall, the rates in all SOCs after the unblinding date decreased or remained similar to those in the blinded placebo-controlled period.

The IR for the SOC of injury, poisoning and procedural complications was 1.4 per 100 PY, with the PT fall having the highest IR (0.4 per 100 PY). The IR for the SOC of vascular disorders was 0.8 per 100 PY, with the PT hypertension having the highest IR (0.6 per 100 PY).

Table 10. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	243	8.8	(7.7, 9.9)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	5	0.2	(0.1, 0.4)
Lymph node pain	1	0.0	(0.0, 0.2)
Lymphadenopathy	3	0.1	(0.0, 0.3)
Pancytopenia	1	0.0	(0.0, 0.2)
Splenic infarction	1	0.0	(0.0, 0.2)
Splenomegaly	1	0.0	(0.0, 0.2)
CARDIAC DISORDERS	14	0.5	(0.3, 0.8)
Atrial fibrillation	2	0.1	(0.0, 0.3)
Atrial flutter	1	0.0	(0.0, 0.2)
Cardiac failure congestive	1	0.0	(0.0, 0.2)
Cardiomegaly	1	0.0	(0.0, 0.2)
Coronary artery disease	3	0.1	(0.0, 0.3)
Coronary artery occlusion	1	0.0	(0.0, 0.2)
Myocardial infarction	4	0.1	(0.0, 0.4)
Tachycardia	1	0.0	(0.0, 0.2)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	0.0	(0.0, 0.2)
Benign familial pemphigus	1	0.0	(0.0, 0.2)
EAR AND LABYRINTH DISORDERS	2	0.1	(0.0, 0.3)
Vertigo	2	0.1	(0.0, 0.3)
ENDOCRINE DISORDERS	2	0.1	(0.0, 0.3)
Hyperthyroidism	1	0.0	(0.0, 0.2)
Pituitary cyst	1	0.0	(0.0, 0.2)
EYE DISORDERS	6	0.2	(0.1, 0.5)
Blepharitis	1	0.0	(0.0, 0.2)
Dry eye	1	0.0	(0.0, 0.2)
Glaucoma	2	0.1	(0.0, 0.3)
Macular oedema	1	0.0	(0.0, 0.2)
Retinal tear	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	17	0.6	(0.4, 1.0)
Abdominal pain upper	1	0.0	(0.0, 0.2)
Diverticulum	1	0.0	(0.0, 0.2)
Dyspepsia	1	0.0	(0.0, 0.2)
Eosinophilic oesophagitis	1	0.0	(0.0, 0.2)

Table 10. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Gastritis	1	0.0	(0.0, 0.2)
Gastritis alcoholic	1	0.0	(0.0, 0.2)
Gastritis erosive	1	0.0	(0.0, 0.2)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.2)
Gastrooesophageal reflux disease	3	0.1	(0.0, 0.3)
Haematemesis	1	0.0	(0.0, 0.2)
Hiatus hernia	2	0.1	(0.0, 0.3)
Irritable bowel syndrome	2	0.1	(0.0, 0.3)
Pancreatic calcification	1	0.0	(0.0, 0.2)
Rectal haemorrhage	2	0.1	(0.0, 0.3)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	19	0.7	(0.4, 1.1)
Chest pain	2	0.1	(0.0, 0.3)
Chills	3	0.1	(0.0, 0.3)
Fatigue	7	0.3	(0.1, 0.5)
Impaired healing	1	0.0	(0.0, 0.2)
Injection site pain	7	0.3	(0.1, 0.5)
Injection site swelling	1	0.0	(0.0, 0.2)
Non-cardiac chest pain	1	0.0	(0.0, 0.2)
Oedema peripheral	2	0.1	(0.0, 0.3)
Pain	2	0.1	(0.0, 0.3)
Pyrexia	2	0.1	(0.0, 0.3)
HEPATOBILIARY DISORDERS	8	0.3	(0.1, 0.6)
Acute hepatic failure	1	0.0	(0.0, 0.2)
Cholecystitis	1	0.0	(0.0, 0.2)
Cholecystitis acute	2	0.1	(0.0, 0.3)
Cholelithiasis	1	0.0	(0.0, 0.2)
Cholelithiasis obstructive	1	0.0	(0.0, 0.2)
Jaundice	1	0.0	(0.0, 0.2)
Portosplenomesenteric venous thrombosis	1	0.0	(0.0, 0.2)
Steatohepatitis	1	0.0	(0.0, 0.2)
IMMUNE SYSTEM DISORDERS	1	0.0	(0.0, 0.2)
Seasonal allergy	1	0.0	(0.0, 0.2)
INFECTIONS AND INFESTATIONS	39	1.4	(1.0, 1.9)
Appendicitis	1	0.0	(0.0, 0.2)
Bacteraemia	1	0.0	(0.0, 0.2)
Bronchitis	1	0.0	(0.0, 0.2)
Clostridium difficile colitis	1	0.0	(0.0, 0.2)

Table 10. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Ear infection	1	0.0	(0.0, 0.2)
Endocarditis	1	0.0	(0.0, 0.2)
Endometritis	1	0.0	(0.0, 0.2)
Fungal skin infection	2	0.1	(0.0, 0.3)
Furuncle	1	0.0	(0.0, 0.2)
Gastritis viral	1	0.0	(0.0, 0.2)
Gastroenteritis	1	0.0	(0.0, 0.2)
Gonorrhoea	1	0.0	(0.0, 0.2)
Helicobacter gastritis	1	0.0	(0.0, 0.2)
Herpes zoster	1	0.0	(0.0, 0.2)
Herpes zoster oticus	1	0.0	(0.0, 0.2)
Meningitis bacterial	1	0.0	(0.0, 0.2)
Mumps	1	0.0	(0.0, 0.2)
Onychomycosis	1	0.0	(0.0, 0.2)
Pneumonia	1	0.0	(0.0, 0.2)
Post procedural infection	1	0.0	(0.0, 0.2)
Postoperative abscess	1	0.0	(0.0, 0.2)
Sepsis	1	0.0	(0.0, 0.2)
Sinusitis bacterial	1	0.0	(0.0, 0.2)
Subcutaneous abscess	1	0.0	(0.0, 0.2)
Tooth infection	3	0.1	(0.0, 0.3)
Urinary tract infection	10	0.4	(0.2, 0.7)
Viral infection	1	0.0	(0.0, 0.2)
Wound infection	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	40	1.4	(1.0, 2.0)
Animal bite	1	0.0	(0.0, 0.2)
Ankle fracture	2	0.1	(0.0, 0.3)
Bone contusion	1	0.0	(0.0, 0.2)
Burns second degree	1	0.0	(0.0, 0.2)
Burns third degree	1	0.0	(0.0, 0.2)
Chemical burns of eye	1	0.0	(0.0, 0.2)
Clavicle fracture	1	0.0	(0.0, 0.2)
Contusion	3	0.1	(0.0, 0.3)
Exposure during pregnancy	3	0.1	(0.0, 0.3)
Facial bones fracture	1	0.0	(0.0, 0.2)
Fall	10	0.4	(0.2, 0.7)
Foot fracture	1	0.0	(0.0, 0.2)

Table 10. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hip fracture	1	0.0	(0.0, 0.2)
Humerus fracture	3	0.1	(0.0, 0.3)
Injury	1	0.0	(0.0, 0.2)
Ligament rupture	1	0.0	(0.0, 0.2)
Ligament sprain	1	0.0	(0.0, 0.2)
Limb injury	1	0.0	(0.0, 0.2)
Muscle strain	2	0.1	(0.0, 0.3)
Procedural dizziness	1	0.0	(0.0, 0.2)
Procedural pain	4	0.1	(0.0, 0.4)
Radius fracture	1	0.0	(0.0, 0.2)
Rectal injury	1	0.0	(0.0, 0.2)
Rib fracture	2	0.1	(0.0, 0.3)
Road traffic accident	2	0.1	(0.0, 0.3)
Skin laceration	4	0.1	(0.0, 0.4)
Thermal burn	1	0.0	(0.0, 0.2)
Upper limb fracture	1	0.0	(0.0, 0.2)
Wrist fracture	2	0.1	(0.0, 0.3)
INVESTIGATIONS	5	0.2	(0.1, 0.4)
Blood cholesterol increased	1	0.0	(0.0, 0.2)
Blood pressure increased	1	0.0	(0.0, 0.2)
Body temperature increased	1	0.0	(0.0, 0.2)
Intraocular pressure increased	1	0.0	(0.0, 0.2)
SARS-CoV-2 antibody test positive	1	0.0	(0.0, 0.2)
METABOLISM AND NUTRITION DISORDERS	13	0.5	(0.2, 0.8)
Diabetes mellitus	1	0.0	(0.0, 0.2)
Glucose tolerance impaired	1	0.0	(0.0, 0.2)
Hypercholesterolaemia	2	0.1	(0.0, 0.3)
Hyperglycaemia	1	0.0	(0.0, 0.2)
Hyperlipidaemia	3	0.1	(0.0, 0.3)
Hypertriglyceridaemia	1	0.0	(0.0, 0.2)
Metabolic syndrome	1	0.0	(0.0, 0.2)
Type 2 diabetes mellitus	1	0.0	(0.0, 0.2)
Vitamin D deficiency	2	0.1	(0.0, 0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	27	1.0	(0.6, 1.4)
Arthralgia	4	0.1	(0.0, 0.4)
Back pain	3	0.1	(0.0, 0.3)
Flank pain	1	0.0	(0.0, 0.2)

Table 10. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Intervertebral disc protrusion	3	0.1	(0.0, 0.3)
Muscle contracture	1	0.0	(0.0, 0.2)
Muscle spasms	1	0.0	(0.0, 0.2)
Musculoskeletal stiffness	1	0.0	(0.0, 0.2)
Myalgia	5	0.2	(0.1, 0.4)
Neck pain	1	0.0	(0.0, 0.2)
Osteoarthritis	3	0.1	(0.0, 0.3)
Pain in extremity	4	0.1	(0.0, 0.4)
Periarthritis	1	0.0	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	14	0.5	(0.3, 0.8)
Adenocarcinoma pancreas	1	0.0	(0.0, 0.2)
Basal cell carcinoma	2	0.1	(0.0, 0.3)
Brain cancer metastatic	1	0.0	(0.0, 0.2)
Breast cancer	1	0.0	(0.0, 0.2)
Fibroma	1	0.0	(0.0, 0.2)
Haemangioma of skin	1	0.0	(0.0, 0.2)
Hormone receptor positive breast cancer	1	0.0	(0.0, 0.2)
Lipoma	1	0.0	(0.0, 0.2)
Malignant melanoma	1	0.0	(0.0, 0.2)
Metastases to lung	1	0.0	(0.0, 0.2)
Pancreatic carcinoma metastatic	1	0.0	(0.0, 0.2)
Prostate cancer	1	0.0	(0.0, 0.2)
Skin papilloma	1	0.0	(0.0, 0.2)
Uterine cancer	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	18	0.6	(0.4, 1.0)
Carpal tunnel syndrome	1	0.0	(0.0, 0.2)
Cervical radiculopathy	1	0.0	(0.0, 0.2)
Dizziness	3	0.1	(0.0, 0.3)
Dysgeusia	1	0.0	(0.0, 0.2)
Facial paralysis	1	0.0	(0.0, 0.2)
Headache	7	0.3	(0.1, 0.5)
Intracranial aneurysm	1	0.0	(0.0, 0.2)
Restless legs syndrome	1	0.0	(0.0, 0.2)
Sciatica	1	0.0	(0.0, 0.2)
Seizure	1	0.0	(0.0, 0.2)
Seizure like phenomena	1	0.0	(0.0, 0.2)

Table 10. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Tremor	1	0.0	(0.0, 0.2)
Vocal cord paralysis	1	0.0	(0.0, 0.2)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	0.1	(0.0, 0.3)
Abortion spontaneous	1	0.0	(0.0, 0.2)
Exposure during pregnancy	1	0.0	(0.0, 0.2)
PSYCHIATRIC DISORDERS	4	0.1	(0.0, 0.4)
Adjustment disorder	1	0.0	(0.0, 0.2)
Anxiety disorder	1	0.0	(0.0, 0.2)
Bipolar I disorder	1	0.0	(0.0, 0.2)
Insomnia	1	0.0	(0.0, 0.2)
RENAL AND URINARY DISORDERS	5	0.2	(0.1, 0.4)
Bladder irritation	1	0.0	(0.0, 0.2)
Nephrolithiasis	3	0.1	(0.0, 0.3)
Renal haematoma	1	0.0	(0.0, 0.2)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2	0.1	(0.0, 0.3)
Endometrial thickening	1	0.0	(0.0, 0.2)
Endometriosis	1	0.0	(0.0, 0.2)
Menorrhagia	1	0.0	(0.0, 0.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	11	0.4	(0.2, 0.7)
Asthma	1	0.0	(0.0, 0.2)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.2)
Dyspnoea	1	0.0	(0.0, 0.2)
Dyspnoea exertional	1	0.0	(0.0, 0.2)
Epistaxis	1	0.0	(0.0, 0.2)
Pulmonary embolism	1	0.0	(0.0, 0.2)
Respiratory tract congestion	2	0.1	(0.0, 0.3)
Rhinorrhoea	2	0.1	(0.0, 0.3)
Sleep apnoea syndrome	1	0.0	(0.0, 0.2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	14	0.5	(0.3, 0.8)
Alopecia	1	0.0	(0.0, 0.2)
Angioedema	1	0.0	(0.0, 0.2)
Decubitus ulcer	1	0.0	(0.0, 0.2)
Dermatitis	1	0.0	(0.0, 0.2)
Dermatitis contact	1	0.0	(0.0, 0.2)
Hand dermatitis	1	0.0	(0.0, 0.2)
Necrobiosis lipoidica diabeticorum	1	0.0	(0.0, 0.2)

Table 10. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Onycholysis	1	0.0	(0.0, 0.2)
Rash	1	0.0	(0.0, 0.2)
Rash maculo-papular	1	0.0	(0.0, 0.2)
Urticaria	4	0.1	(0.0, 0.4)
SOCIAL CIRCUMSTANCES	2	0.1	(0.0, 0.3)
Job dissatisfaction	1	0.0	(0.0, 0.2)
Stress at work	1	0.0	(0.0, 0.2)
SURGICAL AND MEDICAL PROCEDURES	5	0.2	(0.1, 0.4)
Incisional drainage	1	0.0	(0.0, 0.2)
Meniscus operation	1	0.0	(0.0, 0.2)
Metabolic surgery	1	0.0	(0.0, 0.2)
Radioactive iodine therapy	1	0.0	(0.0, 0.2)
Tooth extraction	1	0.0	(0.0, 0.2)
VASCULAR DISORDERS	23	0.8	(0.5, 1.2)
Aortic aneurysm	2	0.1	(0.0, 0.3)
Arterial occlusive disease	1	0.0	(0.0, 0.2)
Deep vein thrombosis	2	0.1	(0.0, 0.3)
Hot flush	1	0.0	(0.0, 0.2)
Hypertension	17	0.6	(0.4, 1.0)
Peripheral vascular disorder	1	0.0	(0.0, 0.2)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from the unblinding date to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_all_ex_bnt_p3_saf

2.7.4.2.4.2.3.2.2. Related Adverse Events by System Organ Class and Preferred Term: Open-Label Follow-Up Period – Original BNT162b2 Participants (Phase 3, Study C4591001, Analysis of Adverse Events)

From the unblinding date to the data cutoff date for participants originally randomized to BNT162b2, the IR of AEs assessed as related by the investigator during the open-label follow-up period was 0.7 per 100 PY (Table 9). The IRs of related AEs were highest for reactogenicity events and in the SOC of general disorders and administration site conditions (0.5 per 100 PY) reflecting AEs from their initial vaccinations.

One younger participant had a life-threatening SAE of myocardial infarction 71 days after Dose 2 that was assessed by the investigator as related to study intervention, which lasted 1 day and resolved the same day (see Section 2.7.4.2.4.3.2.3).

2.7.4.2.4.2.4. Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Dose 1 to 6 Months After Dose 2 – Original BNT162b2 Participants (Phase 3, Study C4591001)

2.7.4.2.4.2.4.1. Summary of Adverse Events: Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Dose 1 to 6 Months After Dose 2 – Original BNT162b2 Participants (Phase 3, Study C4591001)

There were 12,006 participants who had at least 6 months of follow-up (Table 11). There were 3,454 (28.8%) participants who reported at least 1 AE, and 2,245 (18.7%) participants reported at least 1 related AE. Severe AEs and SAEs were reported by 2.1% and 1.6%, respectively. One participant was reported as discontinued because of an AE (not related); however, this participant remains in the study as the withdrawal was subsequently queried and corrected as described in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Errata. There were no deaths during the blinded and open-label follow-up periods in the group of original BNT162b2 participants with at least 6 months of follow-up after Dose 2.

When frequencies of AEs for participants with at least 6 months of follow-up time are examined by time since the second dose, the frequency of AEs and related AEs is 25.8% and 18.6% through 1 month after Dose 2 compared with 4.8% and 0.1% from 1 month after Dose 2 to 6 months after Dose 2 (Table 12). In the first month after vaccination 0.5% reported SAEs (1 related) and from 1 month to 6 months after Dose 2, the frequency of SAEs increased to 1.1% with 1 related SAE.

In the younger age group, the number of participants who reported at least 1 AE and 1 related AE from Dose 1 to 6 months after Dose 2 was 2,013 (30.2%) and 1,386 (20.8%), respectively. In the older age group, the number of participants who reported at least 1 AE and 1 related AE from Dose 1 to 6 months after Dose 2 was 1,441 (27.0%) and 859 (16.1%), respectively.

Table 11. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2 – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ⩾16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=12006)
Adverse Event	n[b] (%)
Any event	3454 (28.8)
Related[c]	2245 (18.7)
Severe	248 (2.1)
Life-threatening	23 (0.2)
Any serious adverse event	190 (1.6)
Related[c]	2 (0.0)
Severe	116 (1.0)
Life-threatening	23 (0.2)
Any adverse event leading to withdrawal	1 (0.0)
Related[c]	0
Severe	0
Life-threatening	0
Death	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (14:48)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s091 all pd2 p3 saf2

Table 12. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by Time Period – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ⩾16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	Dose 1 to 1 Month Post Dose 2 (N[a]=12006)	After 1 Month Post Dose 2 to 6 Months Post Dose 2 (N[a]=12006)
Adverse Event	**n[b] (%)**	**n[b] (%)**
Any event	3092 (25.8)	572 (4.8)
Related[c]	2239 (18.6)	12 (0.1)
Severe	143 (1.2)	110 (0.9)
Life-threatening	8 (0.1)	15 (0.1)
Any serious adverse event	58 (0.5)	133 (1.1)
Related[c]	1 (0.0)	1 (0.0)
Severe	34 (0.3)	82 (0.7)
Life-threatening	8 (0.1)	15 (0.1)
Any adverse event leading to withdrawal	0	1 (0.0)
Related[c]	0	0
Severe	0	0
Life-threatening	0	0
Death	0	0

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 14APR2021 (08:45)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA RR/adae s091 all pd2 p3 tp saf2

2.7.4.2.4.2.4.2. Analysis of Adverse Events: Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Dose 1 to 6 Months After Dose 2 – Original BNT162b2 Participants (Phase 3, Study C4591001)

2.7.4.2.4.2.4.2.1. Adverse Events by System Organ Class and Preferred Term: Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Dose 1 to 6 Months After Dose 2 – Original BNT162b2 Participants (Phase 3, Study C4591001, Analysis of Adverse Events)

From Dose 1 to 6 Months After Dose 2 during the blinded and open-label follow-up period, 3454 (28.8%) original BNT162b2 participants reported at least 1 AE (Table 13). The most frequently reported AEs were reactogenicity events.

- general disorders and administration site conditions (2016 [16.8%])
- musculoskeletal and connective tissue disorders (905 [7.5%])
- nervous system disorders (726 [6.0%])
- gastrointestinal disorders (407 [3.4%])

The number of original BNT162b2 participants who reported at least 1 AE from Dose 1 to 6 months after Dose 2 was 2013 (30.2%) and 1441 (27.0%) in the younger and older groups, respectively.

In the younger versus older BNT162b2 age groups, AE frequencies in above SOCs were:

- general disorders and administration site conditions (1246 [18.7%] vs 770 [14.4%])
- musculoskeletal and connective tissue disorders (539 [8.1%] vs 366 [6.9%])
- nervous system disorders (449 [6.7%] vs 277 [5.2%])
- gastrointestinal disorders (231 [3.5%] vs 176 [3.3%])

As shown in Table 13, the most frequently reported AEs in the BNT162b2 group were injection site pain (1191 [9.9%]), pyrexia (633 [5.3%]), chills (606 [5.0%]), fatigue (598 [5.0%]), headache (572 [4.8%]), and myalgia (549 [4.6%]).

When AEs are compared from 1 month after Dose 2 and from 1 month after Dose 2 to 6 months after Dose 2, the frequencies of AEs by most SOCs have decreased or remain the same with the additional follow-up time. The overall frequency of any AE for participants from 1 month after Dose 2 to 6 months after Dose 2 (4.8%) was decreased from the frequency during 1 month follow up time after Dose 2 (25.8%).

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	3454 (28.8)	(28.0, 29.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	70 (0.6)	(0.5, 0.7)
Lymphadenopathy	50 (0.4)	(0.3, 0.5)
Anaemia	7 (0.1)	(0.0, 0.1)
Iron deficiency anaemia	5 (0.0)	(0.0, 0.1)
Lymph node pain	3 (0.0)	(0.0, 0.1)
Leukopenia	2 (0.0)	(0.0, 0.1)
Blood loss anaemia	1 (0.0)	(0.0, 0.0)
Coagulopathy	1 (0.0)	(0.0, 0.0)
Lymphadenopathy mediastinal	1 (0.0)	(0.0, 0.0)
Lymphocytosis	1 (0.0)	(0.0, 0.0)
Lymphopenia	1 (0.0)	(0.0, 0.0)
Neutropenia	1 (0.0)	(0.0, 0.0)
Pancytopenia	1 (0.0)	(0.0, 0.0)
Splenic infarction	1 (0.0)	(0.0, 0.0)
Splenomegaly	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	59 (0.5)	(0.4, 0.6)
Atrial fibrillation	9 (0.1)	(0.0, 0.1)
Tachycardia	9 (0.1)	(0.0, 0.1)
Palpitations	7 (0.1)	(0.0, 0.1)
Coronary artery disease	6 (0.0)	(0.0, 0.1)
Acute myocardial infarction	4 (0.0)	(0.0, 0.1)
Angina pectoris	4 (0.0)	(0.0, 0.1)
Myocardial infarction	4 (0.0)	(0.0, 0.1)
Cardiac failure congestive	3 (0.0)	(0.0, 0.1)
Angina unstable	2 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)
Arrhythmia	1 (0.0)	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)
Atrial flutter	1 (0.0)	(0.0, 0.0)
Atrioventricular block first degree	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)
Bundle branch block right	1 (0.0)	(0.0, 0.0)
Cardiac arrest	1 (0.0)	(0.0, 0.0)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Cardiac disorder	1 (0.0)	(0.0, 0.0)
Cardiomegaly	1 (0.0)	(0.0, 0.0)
Coronary artery occlusion	1 (0.0)	(0.0, 0.0)
Left ventricular dysfunction	1 (0.0)	(0.0, 0.0)
Mitral valve prolapse	1 (0.0)	(0.0, 0.0)
Pericarditis	1 (0.0)	(0.0, 0.0)
Sinus tachycardia	1 (0.0)	(0.0, 0.0)
Supraventricular tachycardia	1 (0.0)	(0.0, 0.0)
Ventricular tachycardia	1 (0.0)	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	3 (0.0)	(0.0, 0.1)
Congenital cystic kidney disease	1 (0.0)	(0.0, 0.0)
Gastrointestinal arteriovenous malformation	1 (0.0)	(0.0, 0.0)
Protein S deficiency	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	49 (0.4)	(0.3, 0.5)
Vertigo	21 (0.2)	(0.1, 0.3)
Ear pain	8 (0.1)	(0.0, 0.1)
Tinnitus	6 (0.0)	(0.0, 0.1)
Vertigo positional	4 (0.0)	(0.0, 0.1)
Cerumen impaction	3 (0.0)	(0.0, 0.1)
Deafness neurosensory	2 (0.0)	(0.0, 0.1)
Ear discomfort	2 (0.0)	(0.0, 0.1)
Deafness unilateral	1 (0.0)	(0.0, 0.0)
Hyperacusis	1 (0.0)	(0.0, 0.0)
Sudden hearing loss	1 (0.0)	(0.0, 0.0)
ENDOCRINE DISORDERS	15 (0.1)	(0.1, 0.2)
Hypothyroidism	6 (0.0)	(0.0, 0.1)
Hyperthyroidism	2 (0.0)	(0.0, 0.1)
Hypogonadism	2 (0.0)	(0.0, 0.1)
Thyroid mass	2 (0.0)	(0.0, 0.1)
Goitre	1 (0.0)	(0.0, 0.0)
Hyperprolactinaemia	1 (0.0)	(0.0, 0.0)
Oestrogen deficiency	1 (0.0)	(0.0, 0.0)
Pituitary cyst	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	47 (0.4)	(0.3, 0.5)
Cataract	5 (0.0)	(0.0, 0.1)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ⩾16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Vision blurred	5 (0.0)	(0.0, 0.1)
Chalazion	3 (0.0)	(0.0, 0.1)
Eye irritation	3 (0.0)	(0.0, 0.1)
Eye pain	3 (0.0)	(0.0, 0.1)
Macular oedema	3 (0.0)	(0.0, 0.1)
Vitreous detachment	3 (0.0)	(0.0, 0.1)
Blepharitis	2 (0.0)	(0.0, 0.1)
Diplopia	2 (0.0)	(0.0, 0.1)
Dry eye	2 (0.0)	(0.0, 0.1)
Glaucoma	2 (0.0)	(0.0, 0.1)
Retinal tear	2 (0.0)	(0.0, 0.1)
Asthenopia	1 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)
Conjunctival haemorrhage	1 (0.0)	(0.0, 0.0)
Corneal irritation	1 (0.0)	(0.0, 0.0)
Episcleritis	1 (0.0)	(0.0, 0.0)
Eye pruritus	1 (0.0)	(0.0, 0.0)
Eyelid oedema	1 (0.0)	(0.0, 0.0)
Eyelid pain	1 (0.0)	(0.0, 0.0)
Eyelids pruritus	1 (0.0)	(0.0, 0.0)
Keratitis	1 (0.0)	(0.0, 0.0)
Ophthalmic vein thrombosis	1 (0.0)	(0.0, 0.0)
Photophobia	1 (0.0)	(0.0, 0.0)
Retinal artery occlusion	1 (0.0)	(0.0, 0.0)
Scleral discolouration	1 (0.0)	(0.0, 0.0)
Vitreous floaters	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	407 (3.4)	(3.1, 3.7)
Nausea	140 (1.2)	(1.0, 1.4)
Diarrhoea	123 (1.0)	(0.9, 1.2)
Vomiting	35 (0.3)	(0.2, 0.4)
Toothache	18 (0.1)	(0.1, 0.2)
Abdominal pain	15 (0.1)	(0.1, 0.2)
Gastrooesophageal reflux disease	14 (0.1)	(0.1, 0.2)
Dyspepsia	13 (0.1)	(0.1, 0.2)
Abdominal pain upper	10 (0.1)	(0.0, 0.2)
Odynophagia	10 (0.1)	(0.0, 0.2)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Constipation	7 (0.1)	(0.0, 0.1)
Dental caries	6 (0.0)	(0.0, 0.1)
Irritable bowel syndrome	5 (0.0)	(0.0, 0.1)
Abdominal distension	4 (0.0)	(0.0, 0.1)
Flatulence	4 (0.0)	(0.0, 0.1)
Gastritis	4 (0.0)	(0.0, 0.1)
Hiatus hernia	4 (0.0)	(0.0, 0.1)
Large intestine polyp	4 (0.0)	(0.0, 0.1)
Aphthous ulcer	3 (0.0)	(0.0, 0.1)
Diverticulum	3 (0.0)	(0.0, 0.1)
Food poisoning	3 (0.0)	(0.0, 0.1)
Haemorrhoids	3 (0.0)	(0.0, 0.1)
Colitis	2 (0.0)	(0.0, 0.1)
Gastritis erosive	2 (0.0)	(0.0, 0.1)
Gastrointestinal disorder	2 (0.0)	(0.0, 0.1)
Glossodynia	2 (0.0)	(0.0, 0.1)
Haematochezia	2 (0.0)	(0.0, 0.1)
Impaired gastric emptying	2 (0.0)	(0.0, 0.1)
Oral pain	2 (0.0)	(0.0, 0.1)
Small intestinal obstruction	2 (0.0)	(0.0, 0.1)
Abdominal discomfort	1 (0.0)	(0.0, 0.0)
Abdominal pain lower	1 (0.0)	(0.0, 0.0)
Abdominal rigidity	1 (0.0)	(0.0, 0.0)
Angular cheilitis	1 (0.0)	(0.0, 0.0)
Cheilitis	1 (0.0)	(0.0, 0.0)
Coeliac disease	1 (0.0)	(0.0, 0.0)
Colitis microscopic	1 (0.0)	(0.0, 0.0)
Colitis ulcerative	1 (0.0)	(0.0, 0.0)
Crohn's disease	1 (0.0)	(0.0, 0.0)
Diverticulum intestinal	1 (0.0)	(0.0, 0.0)
Dry mouth	1 (0.0)	(0.0, 0.0)
Dysphagia	1 (0.0)	(0.0, 0.0)
Epiploic appendagitis	1 (0.0)	(0.0, 0.0)
Eructation	1 (0.0)	(0.0, 0.0)
Faeces soft	1 (0.0)	(0.0, 0.0)
Femoral hernia	1 (0.0)	(0.0, 0.0)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ⩾16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Gastric antral vascular ectasia	1 (0.0)	(0.0, 0.0)
Gastric ulcer	1 (0.0)	(0.0, 0.0)
Gastric ulcer haemorrhage	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)
Gastrointestinal pain	1 (0.0)	(0.0, 0.0)
Gingival pain	1 (0.0)	(0.0, 0.0)
Glossitis	1 (0.0)	(0.0, 0.0)
Haematemesis	1 (0.0)	(0.0, 0.0)
Haemorrhoidal haemorrhage	1 (0.0)	(0.0, 0.0)
Hypoaesthesia oral	1 (0.0)	(0.0, 0.0)
Hypoaesthesia teeth	1 (0.0)	(0.0, 0.0)
Inguinal hernia	1 (0.0)	(0.0, 0.0)
Internal hernia	1 (0.0)	(0.0, 0.0)
Intestinal obstruction	1 (0.0)	(0.0, 0.0)
Intestinal polyp	1 (0.0)	(0.0, 0.0)
Intra-abdominal fluid collection	1 (0.0)	(0.0, 0.0)
Lip oedema	1 (0.0)	(0.0, 0.0)
Noninfective gingivitis	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)
Oesophageal spasm	1 (0.0)	(0.0, 0.0)
Oral discomfort	1 (0.0)	(0.0, 0.0)
Oral lichenoid reaction	1 (0.0)	(0.0, 0.0)
Pancreatic calcification	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)
Parotid duct obstruction	1 (0.0)	(0.0, 0.0)
Rectal haemorrhage	1 (0.0)	(0.0, 0.0)
Rectal polyp	1 (0.0)	(0.0, 0.0)
Retching	1 (0.0)	(0.0, 0.0)
Stomatitis	1 (0.0)	(0.0, 0.0)
Swollen tongue	1 (0.0)	(0.0, 0.0)
Tongue oedema	1 (0.0)	(0.0, 0.0)
Tongue pruritus	1 (0.0)	(0.0, 0.0)
Tongue ulceration	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2016 (16.8)	(16.1, 17.5)
Injection site pain	1191 (9.9)	(9.4, 10.5)
Pyrexia	633 (5.3)	(4.9, 5.7)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Chills	606 (5.0)	(4.7, 5.5)
Fatigue	598 (5.0)	(4.6, 5.4)
Pain	277 (2.3)	(2.0, 2.6)
Injection site erythema	91 (0.8)	(0.6, 0.9)
Injection site swelling	60 (0.5)	(0.4, 0.6)
Malaise	46 (0.4)	(0.3, 0.5)
Asthenia	20 (0.2)	(0.1, 0.3)
Injection site pruritus	19 (0.2)	(0.1, 0.2)
Chest pain	14 (0.1)	(0.1, 0.2)
Influenza like illness	10 (0.1)	(0.0, 0.2)
Injection site bruising	8 (0.1)	(0.0, 0.1)
Axillary pain	6 (0.0)	(0.0, 0.1)
Injection site warmth	6 (0.0)	(0.0, 0.1)
Feeling hot	5 (0.0)	(0.0, 0.1)
Injection site induration	5 (0.0)	(0.0, 0.1)
Oedema peripheral	5 (0.0)	(0.0, 0.1)
Peripheral swelling	4 (0.0)	(0.0, 0.1)
Injection site oedema	3 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	3 (0.0)	(0.0, 0.1)
Adverse drug reaction	2 (0.0)	(0.0, 0.1)
Cyst	2 (0.0)	(0.0, 0.1)
Face oedema	2 (0.0)	(0.0, 0.1)
Injection site discomfort	2 (0.0)	(0.0, 0.1)
Injection site haematoma	2 (0.0)	(0.0, 0.1)
Injection site nodule	2 (0.0)	(0.0, 0.1)
Injection site papule	2 (0.0)	(0.0, 0.1)
Swelling	2 (0.0)	(0.0, 0.1)
Application site erythema	1 (0.0)	(0.0, 0.0)
Application site pain	1 (0.0)	(0.0, 0.0)
Application site pruritus	1 (0.0)	(0.0, 0.0)
Application site reaction	1 (0.0)	(0.0, 0.0)
Chest discomfort	1 (0.0)	(0.0, 0.0)
Drug withdrawal syndrome	1 (0.0)	(0.0, 0.0)
Illness	1 (0.0)	(0.0, 0.0)
Induration	1 (0.0)	(0.0, 0.0)
Inflammation	1 (0.0)	(0.0, 0.0)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Injection site discolouration	1 (0.0)	(0.0, 0.0)
Injection site haemorrhage	1 (0.0)	(0.0, 0.0)
Injection site hyperaesthesia	1 (0.0)	(0.0, 0.0)
Injection site irritation	1 (0.0)	(0.0, 0.0)
Injection site lymphadenopathy	1 (0.0)	(0.0, 0.0)
Injection site mass	1 (0.0)	(0.0, 0.0)
Injection site paraesthesia	1 (0.0)	(0.0, 0.0)
Injection site rash	1 (0.0)	(0.0, 0.0)
Injection site reaction	1 (0.0)	(0.0, 0.0)
Medical device pain	1 (0.0)	(0.0, 0.0)
Sensation of foreign body	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)
Sluggishness	1 (0.0)	(0.0, 0.0)
Temperature intolerance	1 (0.0)	(0.0, 0.0)
Thirst	1 (0.0)	(0.0, 0.0)
Vaccination site induration	1 (0.0)	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)
Vessel puncture site bruise	1 (0.0)	(0.0, 0.0)
Vessel puncture site haematoma	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	21 (0.2)	(0.1, 0.3)
Cholelithiasis	7 (0.1)	(0.0, 0.1)
Biliary colic	4 (0.0)	(0.0, 0.1)
Cholecystitis acute	3 (0.0)	(0.0, 0.1)
Bile duct stone	2 (0.0)	(0.0, 0.1)
Biliary dyskinesia	1 (0.0)	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)
Cholelithiasis obstructive	1 (0.0)	(0.0, 0.0)
Gallbladder disorder	1 (0.0)	(0.0, 0.0)
Hepatic steatosis	1 (0.0)	(0.0, 0.0)
Jaundice	1 (0.0)	(0.0, 0.0)
Portosplenomesenteric venous thrombosis	1 (0.0)	(0.0, 0.0)
Steatohepatitis	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	15 (0.1)	(0.1, 0.2)
Seasonal allergy	6 (0.0)	(0.0, 0.1)
Drug hypersensitivity	2 (0.0)	(0.0, 0.1)
Hypersensitivity	2 (0.0)	(0.0, 0.1)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ⩾16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Allergy to arthropod bite	1 (0.0)	(0.0, 0.0)
Allergy to arthropod sting	1 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)
Food allergy	1 (0.0)	(0.0, 0.0)
Jarisch-Herxheimer reaction	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	295 (2.5)	(2.2, 2.7)
Urinary tract infection	57 (0.5)	(0.4, 0.6)
Tooth infection	20 (0.2)	(0.1, 0.3)
Sinusitis	16 (0.1)	(0.1, 0.2)
Appendicitis	10 (0.1)	(0.0, 0.2)
Herpes zoster	10 (0.1)	(0.0, 0.2)
Cellulitis	9 (0.1)	(0.0, 0.1)
Conjunctivitis	8 (0.1)	(0.0, 0.1)
Cystitis	8 (0.1)	(0.0, 0.1)
Ear infection	8 (0.1)	(0.0, 0.1)
Diverticulitis	7 (0.1)	(0.0, 0.1)
Gastroenteritis	7 (0.1)	(0.0, 0.1)
Tooth abscess	7 (0.1)	(0.0, 0.1)
Hordeolum	6 (0.0)	(0.0, 0.1)
Upper respiratory tract infection	6 (0.0)	(0.0, 0.1)
Folliculitis	5 (0.0)	(0.0, 0.1)
Rhinitis	5 (0.0)	(0.0, 0.1)
Nasopharyngitis	4 (0.0)	(0.0, 0.1)
Oral herpes	4 (0.0)	(0.0, 0.1)
Otitis externa	4 (0.0)	(0.0, 0.1)
Vulvovaginal mycotic infection	4 (0.0)	(0.0, 0.1)
Fungal skin infection	3 (0.0)	(0.0, 0.1)
Gingivitis	3 (0.0)	(0.0, 0.1)
Onychomycosis	3 (0.0)	(0.0, 0.1)
Paronychia	3 (0.0)	(0.0, 0.1)
Pharyngitis streptococcal	3 (0.0)	(0.0, 0.1)
Pneumonia	3 (0.0)	(0.0, 0.1)
Pyelonephritis	3 (0.0)	(0.0, 0.1)
Vulvovaginal candidiasis	3 (0.0)	(0.0, 0.1)
Device related infection	2 (0.0)	(0.0, 0.1)
Herpes simplex	2 (0.0)	(0.0, 0.1)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Influenza	2 (0.0)	(0.0, 0.1)
Kidney infection	2 (0.0)	(0.0, 0.1)
Laryngitis	2 (0.0)	(0.0, 0.1)
Localised infection	2 (0.0)	(0.0, 0.1)
Oral candidiasis	2 (0.0)	(0.0, 0.1)
Otitis media	2 (0.0)	(0.0, 0.1)
Otitis media acute	2 (0.0)	(0.0, 0.1)
Periodontitis	2 (0.0)	(0.0, 0.1)
Pustule	2 (0.0)	(0.0, 0.1)
Rash pustular	2 (0.0)	(0.0, 0.1)
Sepsis	2 (0.0)	(0.0, 0.1)
Sinusitis bacterial	2 (0.0)	(0.0, 0.1)
Skin infection	2 (0.0)	(0.0, 0.1)
Viral infection	2 (0.0)	(0.0, 0.1)
Abscess	1 (0.0)	(0.0, 0.0)
Abscess neck	1 (0.0)	(0.0, 0.0)
Abscess oral	1 (0.0)	(0.0, 0.0)
Acute sinusitis	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)
Arthritis bacterial	1 (0.0)	(0.0, 0.0)
Bacteraemia	1 (0.0)	(0.0, 0.0)
Bacterial blepharitis	1 (0.0)	(0.0, 0.0)
Bacterial sepsis	1 (0.0)	(0.0, 0.0)
Bacterial vaginosis	1 (0.0)	(0.0, 0.0)
Bacterial vulvovaginitis	1 (0.0)	(0.0, 0.0)
Bartholinitis	1 (0.0)	(0.0, 0.0)
Bone abscess	1 (0.0)	(0.0, 0.0)
Bronchitis	1 (0.0)	(0.0, 0.0)
Cellulitis orbital	1 (0.0)	(0.0, 0.0)
Chronic sinusitis	1 (0.0)	(0.0, 0.0)
Clostridium difficile colitis	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)
Endocarditis	1 (0.0)	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)
Eye infection	1 (0.0)	(0.0, 0.0)
Fungal infection	1 (0.0)	(0.0, 0.0)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ⩾16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Furuncle	1 (0.0)	(0.0, 0.0)
Gangrene	1 (0.0)	(0.0, 0.0)
Gastroenteritis viral	1 (0.0)	(0.0, 0.0)
Gastrointestinal infection	1 (0.0)	(0.0, 0.0)
Genital herpes simplex	1 (0.0)	(0.0, 0.0)
Helicobacter gastritis	1 (0.0)	(0.0, 0.0)
Helicobacter infection	1 (0.0)	(0.0, 0.0)
Herpes zoster oticus	1 (0.0)	(0.0, 0.0)
Impetigo	1 (0.0)	(0.0, 0.0)
Infected bite	1 (0.0)	(0.0, 0.0)
Injection site abscess	1 (0.0)	(0.0, 0.0)
Mastoiditis	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	1 (0.0)	(0.0, 0.0)
Mumps	1 (0.0)	(0.0, 0.0)
Papilloma viral infection	1 (0.0)	(0.0, 0.0)
Parasitic gastroenteritis	1 (0.0)	(0.0, 0.0)
Penile infection	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)
Peritonitis	1 (0.0)	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.0)
Pharyngitis	1 (0.0)	(0.0, 0.0)
Pharyngotonsillitis	1 (0.0)	(0.0, 0.0)
Pilonidal cyst	1 (0.0)	(0.0, 0.0)
Postoperative abscess	1 (0.0)	(0.0, 0.0)
Respiratory tract infection viral	1 (0.0)	(0.0, 0.0)
Sialoadenitis	1 (0.0)	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)
Subcutaneous abscess	1 (0.0)	(0.0, 0.0)
Tinea versicolour	1 (0.0)	(0.0, 0.0)
Varicella	1 (0.0)	(0.0, 0.0)
Vulval abscess	1 (0.0)	(0.0, 0.0)
Vulvovaginitis	1 (0.0)	(0.0, 0.0)
Wound infection	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	207 (1.7)	(1.5, 2.0)
Fall	47 (0.4)	(0.3, 0.5)
Exposure during pregnancy	22 (0.2)	(0.1, 0.3)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Muscle strain	15 (0.1)	(0.1, 0.2)
Ligament sprain	13 (0.1)	(0.1, 0.2)
Contusion	12 (0.1)	(0.1, 0.2)
Procedural pain	11 (0.1)	(0.0, 0.2)
Road traffic accident	11 (0.1)	(0.0, 0.2)
Skin laceration	11 (0.1)	(0.0, 0.2)
Arthropod bite	7 (0.1)	(0.0, 0.1)
Limb injury	7 (0.1)	(0.0, 0.1)
Tooth fracture	6 (0.0)	(0.0, 0.1)
Ankle fracture	5 (0.0)	(0.0, 0.1)
Chest injury	5 (0.0)	(0.0, 0.1)
Foot fracture	5 (0.0)	(0.0, 0.1)
Hand fracture	5 (0.0)	(0.0, 0.1)
Joint dislocation	5 (0.0)	(0.0, 0.1)
Skin abrasion	5 (0.0)	(0.0, 0.1)
Joint injury	4 (0.0)	(0.0, 0.1)
Meniscus injury	4 (0.0)	(0.0, 0.1)
Wrist fracture	4 (0.0)	(0.0, 0.1)
Animal bite	3 (0.0)	(0.0, 0.1)
Arthropod sting	3 (0.0)	(0.0, 0.1)
Burns second degree	3 (0.0)	(0.0, 0.1)
Cervical vertebral fracture	3 (0.0)	(0.0, 0.1)
Facial bones fracture	3 (0.0)	(0.0, 0.1)
Humerus fracture	3 (0.0)	(0.0, 0.1)
Patella fracture	3 (0.0)	(0.0, 0.1)
Tibia fracture	3 (0.0)	(0.0, 0.1)
Upper limb fracture	3 (0.0)	(0.0, 0.1)
Vaccination complication	3 (0.0)	(0.0, 0.1)
Concussion	2 (0.0)	(0.0, 0.1)
Craniocerebral injury	2 (0.0)	(0.0, 0.1)
Ligament rupture	2 (0.0)	(0.0, 0.1)
Radius fracture	2 (0.0)	(0.0, 0.1)
Rib fracture	2 (0.0)	(0.0, 0.1)
Thermal burn	2 (0.0)	(0.0, 0.1)
Bone contusion	1 (0.0)	(0.0, 0.0)
Bone fissure	1 (0.0)	(0.0, 0.0)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Burn oral cavity	1 (0.0)	(0.0, 0.0)
Burns first degree	1 (0.0)	(0.0, 0.0)
Burns third degree	1 (0.0)	(0.0, 0.0)
Cartilage injury	1 (0.0)	(0.0, 0.0)
Chemical burns of eye	1 (0.0)	(0.0, 0.0)
Corneal abrasion	1 (0.0)	(0.0, 0.0)
Eyelid injury	1 (0.0)	(0.0, 0.0)
Fibula fracture	1 (0.0)	(0.0, 0.0)
Foreign body in eye	1 (0.0)	(0.0, 0.0)
Fractured sacrum	1 (0.0)	(0.0, 0.0)
Head injury	1 (0.0)	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)
Jaw fracture	1 (0.0)	(0.0, 0.0)
Limb fracture	1 (0.0)	(0.0, 0.0)
Limb traumatic amputation	1 (0.0)	(0.0, 0.0)
Maternal exposure before pregnancy	1 (0.0)	(0.0, 0.0)
Maternal exposure during pregnancy	1 (0.0)	(0.0, 0.0)
Muscle contusion	1 (0.0)	(0.0, 0.0)
Muscle rupture	1 (0.0)	(0.0, 0.0)
Overdose	1 (0.0)	(0.0, 0.0)
Pelvic fracture	1 (0.0)	(0.0, 0.0)
Penis injury	1 (0.0)	(0.0, 0.0)
Post concussion syndrome	1 (0.0)	(0.0, 0.0)
Post procedural discomfort	1 (0.0)	(0.0, 0.0)
Post procedural swelling	1 (0.0)	(0.0, 0.0)
Procedural dizziness	1 (0.0)	(0.0, 0.0)
Spinal compression fracture	1 (0.0)	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)
Spinal fracture	1 (0.0)	(0.0, 0.0)
Stress fracture	1 (0.0)	(0.0, 0.0)
Subdural haematoma	1 (0.0)	(0.0, 0.0)
Sunburn	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)
Ulna fracture	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	94 (0.8)	(0.6, 1.0)
Body temperature increased	50 (0.4)	(0.3, 0.5)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Blood glucose increased	8 (0.1)	(0.0, 0.1)
SARS-CoV-2 antibody test positive	5 (0.0)	(0.0, 0.1)
Blood pressure increased	4 (0.0)	(0.0, 0.1)
Blood cholesterol increased	3 (0.0)	(0.0, 0.1)
Alanine aminotransferase increased	2 (0.0)	(0.0, 0.1)
Blood thyroid stimulating hormone increased	2 (0.0)	(0.0, 0.1)
Weight increased	2 (0.0)	(0.0, 0.1)
Aspartate aminotransferase increased	1 (0.0)	(0.0, 0.0)
Blood creatinine decreased	1 (0.0)	(0.0, 0.0)
Blood glucose abnormal	1 (0.0)	(0.0, 0.0)
Blood immunoglobulin E increased	1 (0.0)	(0.0, 0.0)
Blood potassium decreased	1 (0.0)	(0.0, 0.0)
Blood triglycerides increased	1 (0.0)	(0.0, 0.0)
Body temperature decreased	1 (0.0)	(0.0, 0.0)
C-reactive protein	1 (0.0)	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)
Electrocardiogram QT prolonged	1 (0.0)	(0.0, 0.0)
Fractional exhaled nitric oxide increased	1 (0.0)	(0.0, 0.0)
Glomerular filtration rate decreased	1 (0.0)	(0.0, 0.0)
Haemoglobin decreased	1 (0.0)	(0.0, 0.0)
Heart rate increased	1 (0.0)	(0.0, 0.0)
Intraocular pressure increased	1 (0.0)	(0.0, 0.0)
Liver function test increased	1 (0.0)	(0.0, 0.0)
Lymphocyte count decreased	1 (0.0)	(0.0, 0.0)
Mean cell volume decreased	1 (0.0)	(0.0, 0.0)
Platelet count decreased	1 (0.0)	(0.0, 0.0)
Respiratory rate increased	1 (0.0)	(0.0, 0.0)
Troponin increased	1 (0.0)	(0.0, 0.0)
Weight decreased	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	81 (0.7)	(0.5, 0.8)
Decreased appetite	15 (0.1)	(0.1, 0.2)
Hyperlipidaemia	9 (0.1)	(0.0, 0.1)
Type 2 diabetes mellitus	9 (0.1)	(0.0, 0.1)
Vitamin D deficiency	8 (0.1)	(0.0, 0.1)
Hypercholesterolaemia	6 (0.0)	(0.0, 0.1)
Dyslipidaemia	5 (0.0)	(0.0, 0.1)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ⩾16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Glucose tolerance impaired	4 (0.0)	(0.0, 0.1)
Gout	3 (0.0)	(0.0, 0.1)
Hyperglycaemia	3 (0.0)	(0.0, 0.1)
Hypertriglyceridaemia	3 (0.0)	(0.0, 0.1)
Hypoglycaemia	3 (0.0)	(0.0, 0.1)
Hypokalaemia	3 (0.0)	(0.0, 0.1)
Dehydration	2 (0.0)	(0.0, 0.1)
Hyperkalaemia	2 (0.0)	(0.0, 0.1)
Hyperuricaemia	2 (0.0)	(0.0, 0.1)
Obesity	2 (0.0)	(0.0, 0.1)
Diabetes mellitus	1 (0.0)	(0.0, 0.0)
Diabetes mellitus inadequate control	1 (0.0)	(0.0, 0.0)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)
Hypocalcaemia	1 (0.0)	(0.0, 0.0)
Hypocholesterolaemia	1 (0.0)	(0.0, 0.0)
Insulin resistance	1 (0.0)	(0.0, 0.0)
Metabolic syndrome	1 (0.0)	(0.0, 0.0)
Polydipsia	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	905 (7.5)	(7.1, 8.0)
Myalgia	549 (4.6)	(4.2, 5.0)
Arthralgia	153 (1.3)	(1.1, 1.5)
Pain in extremity	93 (0.8)	(0.6, 0.9)
Back pain	62 (0.5)	(0.4, 0.7)
Neck pain	20 (0.2)	(0.1, 0.3)
Muscle spasms	19 (0.2)	(0.1, 0.2)
Osteoarthritis	14 (0.1)	(0.1, 0.2)
Tendonitis	9 (0.1)	(0.0, 0.1)
Musculoskeletal stiffness	8 (0.1)	(0.0, 0.1)
Intervertebral disc protrusion	6 (0.0)	(0.0, 0.1)
Arthritis	5 (0.0)	(0.0, 0.1)
Bursitis	5 (0.0)	(0.0, 0.1)
Muscular weakness	5 (0.0)	(0.0, 0.1)
Musculoskeletal chest pain	5 (0.0)	(0.0, 0.1)
Periarthritis	5 (0.0)	(0.0, 0.1)
Musculoskeletal discomfort	4 (0.0)	(0.0, 0.1)
Intervertebral disc degeneration	3 (0.0)	(0.0, 0.1)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Joint stiffness	3 (0.0)	(0.0, 0.1)
Muscle contracture	3 (0.0)	(0.0, 0.1)
Rotator cuff syndrome	3 (0.0)	(0.0, 0.1)
Arthropathy	2 (0.0)	(0.0, 0.1)
Coccydynia	2 (0.0)	(0.0, 0.1)
Costochondritis	2 (0.0)	(0.0, 0.1)
Flank pain	2 (0.0)	(0.0, 0.1)
Joint range of motion decreased	2 (0.0)	(0.0, 0.1)
Limb discomfort	2 (0.0)	(0.0, 0.1)
Muscle twitching	2 (0.0)	(0.0, 0.1)
Musculoskeletal pain	2 (0.0)	(0.0, 0.1)
Pain in jaw	2 (0.0)	(0.0, 0.1)
Plantar fasciitis	2 (0.0)	(0.0, 0.1)
Spinal osteoarthritis	2 (0.0)	(0.0, 0.1)
Tenosynovitis stenosans	2 (0.0)	(0.0, 0.1)
Bone disorder	1 (0.0)	(0.0, 0.0)
Bone pain	1 (0.0)	(0.0, 0.0)
Groin pain	1 (0.0)	(0.0, 0.0)
Intervertebral disc compression	1 (0.0)	(0.0, 0.0)
Joint effusion	1 (0.0)	(0.0, 0.0)
Joint instability	1 (0.0)	(0.0, 0.0)
Joint swelling	1 (0.0)	(0.0, 0.0)
Mobility decreased	1 (0.0)	(0.0, 0.0)
Muscle fatigue	1 (0.0)	(0.0, 0.0)
Muscle tightness	1 (0.0)	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)
Osteopenia	1 (0.0)	(0.0, 0.0)
Psoriatic arthropathy	1 (0.0)	(0.0, 0.0)
Spinal stenosis	1 (0.0)	(0.0, 0.0)
Spondylitis	1 (0.0)	(0.0, 0.0)
Synovial cyst	1 (0.0)	(0.0, 0.0)
Temporomandibular joint syndrome	1 (0.0)	(0.0, 0.0)
Torticollis	1 (0.0)	(0.0, 0.0)
Trigger finger	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	53 (0.4)	(0.3, 0.6)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Prostate cancer	5 (0.0)	(0.0, 0.1)
Basal cell carcinoma	4 (0.0)	(0.0, 0.1)
Lipoma	4 (0.0)	(0.0, 0.1)
Malignant melanoma	4 (0.0)	(0.0, 0.1)
Breast cancer	3 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	2 (0.0)	(0.0, 0.1)
Skin papilloma	2 (0.0)	(0.0, 0.1)
Transitional cell carcinoma	2 (0.0)	(0.0, 0.1)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.0)
Adenocarcinoma pancreas	1 (0.0)	(0.0, 0.0)
Adenoma benign	1 (0.0)	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)
Benign breast neoplasm	1 (0.0)	(0.0, 0.0)
Benign hydatidiform mole	1 (0.0)	(0.0, 0.0)
Benign uterine neoplasm	1 (0.0)	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.0)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.0)
Brain cancer metastatic	1 (0.0)	(0.0, 0.0)
Breast cancer in situ	1 (0.0)	(0.0, 0.0)
Carcinoid tumour of the stomach	1 (0.0)	(0.0, 0.0)
Chondroma	1 (0.0)	(0.0, 0.0)
Colon adenoma	1 (0.0)	(0.0, 0.0)
Fibroma	1 (0.0)	(0.0, 0.0)
Gallbladder cancer stage II	1 (0.0)	(0.0, 0.0)
Gastric cancer	1 (0.0)	(0.0, 0.0)
Malignant melanoma of eyelid	1 (0.0)	(0.0, 0.0)
Meningioma benign	1 (0.0)	(0.0, 0.0)
Non-small cell lung cancer stage IV	1 (0.0)	(0.0, 0.0)
Seborrhoeic keratosis	1 (0.0)	(0.0, 0.0)
Skin cancer	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma of skin	1 (0.0)	(0.0, 0.0)
Thyroid cancer	1 (0.0)	(0.0, 0.0)
Uterine cancer	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	726 (6.0)	(5.6, 6.5)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Headache	572 (4.8)	(4.4, 5.2)
Dizziness	43 (0.4)	(0.3, 0.5)
Paraesthesia	15 (0.1)	(0.1, 0.2)
Lethargy	14 (0.1)	(0.1, 0.2)
Migraine	14 (0.1)	(0.1, 0.2)
Sciatica	9 (0.1)	(0.0, 0.1)
Tension headache	9 (0.1)	(0.0, 0.1)
Syncope	8 (0.1)	(0.0, 0.1)
Presyncope	6 (0.0)	(0.0, 0.1)
Tremor	6 (0.0)	(0.0, 0.1)
Dysgeusia	5 (0.0)	(0.0, 0.1)
Somnolence	4 (0.0)	(0.0, 0.1)
Disturbance in attention	3 (0.0)	(0.0, 0.1)
Facial paralysis	3 (0.0)	(0.0, 0.1)
Hypoaesthesia	3 (0.0)	(0.0, 0.1)
Sinus headache	3 (0.0)	(0.0, 0.1)
Subarachnoid haemorrhage	3 (0.0)	(0.0, 0.1)
Burning sensation	2 (0.0)	(0.0, 0.1)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)
Cervical radiculopathy	2 (0.0)	(0.0, 0.1)
Dizziness postural	2 (0.0)	(0.0, 0.1)
Migraine without aura	2 (0.0)	(0.0, 0.1)
Nerve compression	2 (0.0)	(0.0, 0.1)
Optic neuritis	2 (0.0)	(0.0, 0.1)
Restless legs syndrome	2 (0.0)	(0.0, 0.1)
Seizure	2 (0.0)	(0.0, 0.1)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)
Aphasia	1 (0.0)	(0.0, 0.0)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.0)
Depressed level of consciousness	1 (0.0)	(0.0, 0.0)
Dyskinesia	1 (0.0)	(0.0, 0.0)
Hyperaesthesia	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)
Intracranial aneurysm	1 (0.0)	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)
Neuralgia	1 (0.0)	(0.0, 0.0)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Parosmia	1 (0.0)	(0.0, 0.0)
Periodic limb movement disorder	1 (0.0)	(0.0, 0.0)
Peripheral nerve lesion	1 (0.0)	(0.0, 0.0)
Peripheral sensory neuropathy	1 (0.0)	(0.0, 0.0)
Post herpetic neuralgia	1 (0.0)	(0.0, 0.0)
Radiculopathy	1 (0.0)	(0.0, 0.0)
Seizure like phenomena	1 (0.0)	(0.0, 0.0)
Toxic encephalopathy	1 (0.0)	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)
Vocal cord paralysis	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	3 (0.0)	(0.0, 0.1)
Abortion spontaneous	2 (0.0)	(0.0, 0.1)
Exposure during pregnancy	1 (0.0)	(0.0, 0.0)
PRODUCT ISSUES	1 (0.0)	(0.0, 0.0)
Device connection issue	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	65 (0.5)	(0.4, 0.7)
Insomnia	17 (0.1)	(0.1, 0.2)
Anxiety	16 (0.1)	(0.1, 0.2)
Depression	11 (0.1)	(0.0, 0.2)
Anxiety disorder	4 (0.0)	(0.0, 0.1)
Abnormal dreams	3 (0.0)	(0.0, 0.1)
Attention deficit hyperactivity disorder	3 (0.0)	(0.0, 0.1)
Irritability	3 (0.0)	(0.0, 0.1)
Sleep disorder	3 (0.0)	(0.0, 0.1)
Disorientation	2 (0.0)	(0.0, 0.1)
Nightmare	2 (0.0)	(0.0, 0.1)
Generalised anxiety disorder	1 (0.0)	(0.0, 0.0)
Libido increased	1 (0.0)	(0.0, 0.0)
Panic attack	1 (0.0)	(0.0, 0.0)
Restlessness	1 (0.0)	(0.0, 0.0)
Suicide attempt	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	42 (0.3)	(0.3, 0.5)
Nephrolithiasis	11 (0.1)	(0.0, 0.2)
Dysuria	6 (0.0)	(0.0, 0.1)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Pollakiuria	5 (0.0)	(0.0, 0.1)
Haematuria	3 (0.0)	(0.0, 0.1)
Acute kidney injury	2 (0.0)	(0.0, 0.1)
Bladder spasm	2 (0.0)	(0.0, 0.1)
Renal colic	2 (0.0)	(0.0, 0.1)
Urinary retention	2 (0.0)	(0.0, 0.1)
Bladder irritation	1 (0.0)	(0.0, 0.0)
Chronic kidney disease	1 (0.0)	(0.0, 0.0)
Hypertonic bladder	1 (0.0)	(0.0, 0.0)
Micturition urgency	1 (0.0)	(0.0, 0.0)
Obstructive nephropathy	1 (0.0)	(0.0, 0.0)
Renal cyst	1 (0.0)	(0.0, 0.0)
Renal haematoma	1 (0.0)	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)
Urethral stenosis	1 (0.0)	(0.0, 0.0)
Urinary tract obstruction	1 (0.0)	(0.0, 0.0)
Vesical fistula	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	36 (0.3)	(0.2, 0.4)
Dysmenorrhoea	4 (0.0)	(0.0, 0.1)
Ovarian cyst	3 (0.0)	(0.0, 0.1)
Benign prostatic hyperplasia	2 (0.0)	(0.0, 0.1)
Breast pain	2 (0.0)	(0.0, 0.1)
Endometriosis	2 (0.0)	(0.0, 0.1)
Genital erythema	2 (0.0)	(0.0, 0.1)
Menorrhagia	2 (0.0)	(0.0, 0.1)
Menstruation irregular	2 (0.0)	(0.0, 0.1)
Amenorrhoea	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)
Cervical dysplasia	1 (0.0)	(0.0, 0.0)
Dysfunctional uterine bleeding	1 (0.0)	(0.0, 0.0)
Endometrial thickening	1 (0.0)	(0.0, 0.0)
Haematospermia	1 (0.0)	(0.0, 0.0)
Mammary duct ectasia	1 (0.0)	(0.0, 0.0)
Menometrorrhagia	1 (0.0)	(0.0, 0.0)
Metrorrhagia	1 (0.0)	(0.0, 0.0)
Pelvic pain	1 (0.0)	(0.0, 0.0)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Polycystic ovaries	1 (0.0)	(0.0, 0.0)
Postmenopausal haemorrhage	1 (0.0)	(0.0, 0.0)
Prostatitis	1 (0.0)	(0.0, 0.0)
Prostatomegaly	1 (0.0)	(0.0, 0.0)
Pruritus genital	1 (0.0)	(0.0, 0.0)
Scrotal pain	1 (0.0)	(0.0, 0.0)
Testicular pain	1 (0.0)	(0.0, 0.0)
Testicular torsion	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)
Vaginal haemorrhage	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	145 (1.2)	(1.0, 1.4)
Oropharyngeal pain	24 (0.2)	(0.1, 0.3)
Nasal congestion	21 (0.2)	(0.1, 0.3)
Cough	17 (0.1)	(0.1, 0.2)
Rhinorrhoea	12 (0.1)	(0.1, 0.2)
Rhinitis allergic	9 (0.1)	(0.0, 0.1)
Asthma	8 (0.1)	(0.0, 0.1)
Dyspnoea	6 (0.0)	(0.0, 0.1)
Pulmonary embolism	6 (0.0)	(0.0, 0.1)
Sleep apnoea syndrome	5 (0.0)	(0.0, 0.1)
Throat irritation	5 (0.0)	(0.0, 0.1)
Upper-airway cough syndrome	5 (0.0)	(0.0, 0.1)
Paranasal sinus discomfort	4 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	3 (0.0)	(0.0, 0.1)
Epistaxis	3 (0.0)	(0.0, 0.1)
Asthmatic crisis	2 (0.0)	(0.0, 0.1)
Bronchospasm	2 (0.0)	(0.0, 0.1)
Nasal polyps	2 (0.0)	(0.0, 0.1)
Productive cough	2 (0.0)	(0.0, 0.1)
Respiratory tract congestion	2 (0.0)	(0.0, 0.1)
Sinus congestion	2 (0.0)	(0.0, 0.1)
Upper respiratory tract congestion	2 (0.0)	(0.0, 0.1)
Wheezing	2 (0.0)	(0.0, 0.1)
Allergic sinusitis	1 (0.0)	(0.0, 0.0)
Atelectasis	1 (0.0)	(0.0, 0.0)
Dry throat	1 (0.0)	(0.0, 0.0)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)
Emphysema	1 (0.0)	(0.0, 0.0)
Haemoptysis	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)
Nasal septum deviation	1 (0.0)	(0.0, 0.0)
Oropharyngeal discomfort	1 (0.0)	(0.0, 0.0)
Paranasal sinus hypersecretion	1 (0.0)	(0.0, 0.0)
Pleurisy	1 (0.0)	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)
Pneumothorax	1 (0.0)	(0.0, 0.0)
Reflux laryngitis	1 (0.0)	(0.0, 0.0)
Respiratory failure	1 (0.0)	(0.0, 0.0)
Sneezing	1 (0.0)	(0.0, 0.0)
Snoring	1 (0.0)	(0.0, 0.0)
Tonsillar hypertrophy	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	153 (1.3)	(1.1, 1.5)
Rash	35 (0.3)	(0.2, 0.4)
Hyperhidrosis	16 (0.1)	(0.1, 0.2)
Pruritus	15 (0.1)	(0.1, 0.2)
Dermatitis contact	11 (0.1)	(0.0, 0.2)
Urticaria	11 (0.1)	(0.0, 0.2)
Night sweats	8 (0.1)	(0.0, 0.1)
Rash pruritic	6 (0.0)	(0.0, 0.1)
Erythema	5 (0.0)	(0.0, 0.1)
Dermal cyst	4 (0.0)	(0.0, 0.1)
Dermatitis	4 (0.0)	(0.0, 0.1)
Eczema	4 (0.0)	(0.0, 0.1)
Acne	3 (0.0)	(0.0, 0.1)
Actinic keratosis	3 (0.0)	(0.0, 0.1)
Dermatitis allergic	3 (0.0)	(0.0, 0.1)
Rash maculo-papular	3 (0.0)	(0.0, 0.1)
Alopecia	2 (0.0)	(0.0, 0.1)
Acne cystic	1 (0.0)	(0.0, 0.0)
Angioedema	1 (0.0)	(0.0, 0.0)
Cold sweat	1 (0.0)	(0.0, 0.0)
Dermatitis exfoliative	1 (0.0)	(0.0, 0.0)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ⩾16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Diabetic foot	1 (0.0)	(0.0, 0.0)
Dry skin	1 (0.0)	(0.0, 0.0)
Ecchymosis	1 (0.0)	(0.0, 0.0)
Erythema nodosum	1 (0.0)	(0.0, 0.0)
Hand dermatitis	1 (0.0)	(0.0, 0.0)
Hangnail	1 (0.0)	(0.0, 0.0)
Intertrigo	1 (0.0)	(0.0, 0.0)
Macule	1 (0.0)	(0.0, 0.0)
Onycholysis	1 (0.0)	(0.0, 0.0)
Onychomadesis	1 (0.0)	(0.0, 0.0)
Pain of skin	1 (0.0)	(0.0, 0.0)
Papule	1 (0.0)	(0.0, 0.0)
Pityriasis	1 (0.0)	(0.0, 0.0)
Pseudofolliculitis	1 (0.0)	(0.0, 0.0)
Psoriasis	1 (0.0)	(0.0, 0.0)
Purpura	1 (0.0)	(0.0, 0.0)
Rash erythematous	1 (0.0)	(0.0, 0.0)
Rash papular	1 (0.0)	(0.0, 0.0)
Rosacea	1 (0.0)	(0.0, 0.0)
Skin discolouration	1 (0.0)	(0.0, 0.0)
Skin irritation	1 (0.0)	(0.0, 0.0)
Skin ulcer	1 (0.0)	(0.0, 0.0)
Transient acantholytic dermatosis	1 (0.0)	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	2 (0.0)	(0.0, 0.1)
High risk sexual behaviour	1 (0.0)	(0.0, 0.0)
Miscarriage of partner	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	29 (0.2)	(0.2, 0.3)
Dental implantation	5 (0.0)	(0.0, 0.1)
Tooth extraction	3 (0.0)	(0.0, 0.1)
Wisdom teeth removal	2 (0.0)	(0.0, 0.1)
Botulinum toxin injection	1 (0.0)	(0.0, 0.0)
Cardioversion	1 (0.0)	(0.0, 0.0)
Carpal tunnel decompression	1 (0.0)	(0.0, 0.0)
Drug titration	1 (0.0)	(0.0, 0.0)
Endodontic procedure	1 (0.0)	(0.0, 0.0)
Facet joint block	1 (0.0)	(0.0, 0.0)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ⩾16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Finger amputation	1 (0.0)	(0.0, 0.0)
Gingival operation	1 (0.0)	(0.0, 0.0)
Inguinal hernia repair	1 (0.0)	(0.0, 0.0)
Lacrimal duct procedure	1 (0.0)	(0.0, 0.0)
Mammoplasty	1 (0.0)	(0.0, 0.0)
Meniscus operation	1 (0.0)	(0.0, 0.0)
Metabolic surgery	1 (0.0)	(0.0, 0.0)
Open reduction of fracture	1 (0.0)	(0.0, 0.0)
Postoperative care	1 (0.0)	(0.0, 0.0)
Radioactive iodine therapy	1 (0.0)	(0.0, 0.0)
Retinal operation	1 (0.0)	(0.0, 0.0)
Rotator cuff repair	1 (0.0)	(0.0, 0.0)
Sclerotherapy	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	78 (0.6)	(0.5, 0.8)
Hypertension	48 (0.4)	(0.3, 0.5)
Deep vein thrombosis	6 (0.0)	(0.0, 0.1)
Hot flush	6 (0.0)	(0.0, 0.1)
Aortic aneurysm	3 (0.0)	(0.0, 0.1)
Haematoma	3 (0.0)	(0.0, 0.1)
Flushing	2 (0.0)	(0.0, 0.1)
Hypotension	2 (0.0)	(0.0, 0.1)
Aortic dilatation	1 (0.0)	(0.0, 0.0)
Arterial occlusive disease	1 (0.0)	(0.0, 0.0)
Essential hypertension	1 (0.0)	(0.0, 0.0)
Intermittent claudication	1 (0.0)	(0.0, 0.0)
Lymphorrhoea	1 (0.0)	(0.0, 0.0)
Peripheral vascular disorder	1 (0.0)	(0.0, 0.0)
Systolic hypertension	1 (0.0)	(0.0, 0.0)
Thrombophlebitis superficial	1 (0.0)	(0.0, 0.0)
Varicose vein	1 (0.0)	(0.0, 0.0)

Table 13. Number (%) of Subjects Reporting at Least 1 Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 all bnt pd2 p3 saf

2.7.4.2.4.2.4.2.2. Related Adverse Events by System Organ Class and Preferred Term: Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Dose 1 to 6 Months After Dose 2 – Original BNT162b2 Participants (Phase 3, Study C4591001, Analysis of Adverse Events)

From Dose 1 to 6 Months After Dose 2 during the blinded and open-label follow-up period, AEs assessed as related by the investigator during the blinded and open-label follow-up period were reported by 18.7% of participants in the BNT162b2 group (Table 11). Most related AEs were reactogenicity events and in the SOC of general disorders and administration site conditions (1944 [16.2%]).

The AE of lymphadenopathy in 29 (0.2%) participants was assessed by the investigator as related to study intervention.

Related AEs in the younger and older age groups were reported in 20.8% and 16.1% of original BNT162b2 participants.

2.7.4.2.4.2.5. Open-Label Follow-Up Period – Original Placebo Participants Who Then Received BNT162b2

2.7.4.2.4.2.5.1. Summary of Adverse Events: Open-Label Follow-Up Period – Original Placebo Participants Who Then Received BNT162b2 (Phase 3, Study C4591001)

Overall, there are 19,525 original placebo participants who then were unblinded and received BNT162b2. An overview of AEs after vaccination with BNT162b2 to the data cutoff date for placebo participants who received BNT162b2 during the open-label follow-up period is presented in Table 14. The IRs for any AE and at least 1 related AE were 205.4 per 100 PY

and 189.5 per 100 PY, respectively. IRs of severe AEs, SAEs, and AEs leading to withdrawal were 6.0 per 100 PY, 2.7 per 100 PY, and 0.8 per 100 PY. The IR for discontinuations because of related AEs was 0.5 per 100 PY, and 2 participants died (Section 2.7.4.2.4.3.1).

The IRs in Table 7 include all AEs reported for these participants including AEs reported while on placebo. Additionally, all of these placebo participants received open-label BNT162b2 and the exposure time is shorter for placebo participants who received BNT162b2 than those who originally were randomized to BNT162b2 (23.8 per 100 PY vs 83.4 per 100 PY, respectively [Table 14 and Table 7]). As expected, in comparison to participants randomized to BNT162b2 from Dose 1 to the unblinding date, the IR for any AE and at least 1 related AE and severe AE for participants who originally received placebo and then received BNT162b2 are greater (205.4 per 100 PY, 189.5 per 100 PY, 6.0 per 100 PY) than the IRs (83.2 per 100 PY, 62.9 per 100 PY, 4.3 per 100 PY) for participants who originally were randomized to BNT162b2, respectively (Table 14 and Table 7). However, the IRs for life-threatening AE, SAE, AEs leading to withdrawal and deaths were similar (0.5 per 100 PY, 2.7 per 100 PY, 0.8 per 100 PY, 0.1 per 100 PY vs 0.6 per 100 PY, 3.2 per 100 PY, 0.5 per 100 PY, 0.2 per 100 PY, respectively). There was 1 related SAE of anaphylactoid reaction for a placebo participant who was vaccinated with BNT162b2 (see Section 2.7.4.2.4.3.2.5).

The IRs of AEs for original placebo participants who then received BNT162b2 were observed by baseline SARS CoV-2 positive and negative status subgroups. Overall, the IRs for AEs were similar between the baseline positive (222.9 per 100 PY; 95% CI: 186.5, 264.3) compared to baseline negative (205 per 100 PY; 95% CI 199.6, 211.3). There were 2 SAEs (not related), 1 AE leading to withdrawal and no deaths in the baseline positive group.

Table 14. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021) – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	4885	205.4	(199.6, 211.2)
Related[f]	4508	189.5	(184.0, 195.1)
Severe	142	6.0	(5.0, 7.0)
Life-threatening	11	0.5	(0.2, 0.8)
Any serious adverse event	65	2.7	(2.1, 3.5)
Related[f]	1	0.0	(0.0, 0.2)
Severe	37	1.6	(1.1, 2.1)
Life-threatening	11	0.5	(0.2, 0.8)
Any adverse event leading to withdrawal	19	0.8	(0.5, 1.2)

Table 14. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021) – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
Adverse Event	n[c]	IR (/100 PY)[d]	(95% CI[e])
Related[f]	12	0.5	(0.3, 0.9)
Severe	2	0.1	(0.0, 0.3)
Life-threatening	4	0.2	(0.0, 0.4)
Death	2	0.1	(0.0, 0.3)

Note: Dose 3 = First dose of BNT162b2 (30 µg).
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Assessed by the investigator as related to investigational product.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s092_cr_cut_p3x_saf

2.7.4.2.4.2.5.2. Analysis of Adverse Events: Open-Label Follow-Up Period – Original Placebo Participants Who Then Received BNT162b2 (Phase 3, Study C4591001)

2.7.4.2.4.2.5.2.1. Adverse Events by System Organ Class and Preferred Term: Open-Label Follow-Up Period – Original Placebo Participants Who Then Received BNT162b2 (Phase 3, Study C4591001, Analysis of Adverse Events)

From vaccination with BNT162b2 for placebo participants to the data cutoff date during the open-label follow-up period, the IR for participants who reported at least 1 AE was 205.4 per 100 PY (Table 15).

Most AEs reported from Dose 3 (first dose of BNT162b2) to the data cutoff date were in SOCs with reactogenicity events.

- general disorders and administration site conditions (175.3 per 100 PY)
- musculoskeletal and connective tissue disorders (52.3 per 100 PY)
- nervous system disorders (50.5 per 100 PY)
- gastrointestinal disorders (14.3 per 100 PY)

As shown in Table 15, the most frequently reported AEs (IRs) overall were injection site pain (123.8 per 100 PY), fatigue (58.0 per 100 PY), headache (46.6 per 100 PY), chills (41.8 per 100 PY), myalgia (38.9 per 100 PY), and pyrexia (38.1 per 100 PY).

After participants who originally received placebo were unblinded and then received BNT162b2 after unblinding, events related to reactogenicity were not reported using an e-diary but were instead reported as AEs. An analysis was conducted to evaluate if the imbalance in AEs observed from Dose 3 to the unblinding date was attributed to reactogenicity events. The analysis examined the AEs reported within 7 days after each dose (Dose 3 and Dose 4), which represented the reactogenicity reporting period.

PTs reported from Dose 3 to 7 days after Dose 3 and from Dose 4 to 7 days after Dose 4 in the SOCs of general disorders and administration site conditions (injection site pain, chills, fatigue, and pyrexia), musculoskeletal and connective tissue disorders (myalgia), and nervous system disorders (headache) represented the majority of PTs reported in those SOCs.

Allergy to vaccine, anaphylactoid reaction, and deep vein thrombosis were reported in 1 participant each from Dose 3 to 7 days after Dose 3.

- One participant reported an AE of Grade 2 allergy to vaccine, which occurred on the day of Dose 3 vaccination, had a duration of 2 days, and resolved; this AE was assessed by the investigator as related to the study intervention.

- One participant with an ongoing medical history significant for drug hypersensitivity and food and seasonal allergies reported a life-threatening SAE of anaphylactoid reaction, which occurred 2 days after Dose 3 and was resolved that same day; this SAE was assessed by the investigator as related to the study intervention (Section 2.7.4.2.4.3.4.1.1).

- One participant with a past medical history significant for deep vein thrombosis, hypertension, pulmonary arterial hypertension, right ventricular enlargement, hypercholesteremia, artherosclerosis and bilateral peripheral neuropathy reported a Grade 2 SAE of deep vein thrombosis (lower right extremity) and Grade 1 SAE of pulmonary embolism, which both occurred 2 days after Dose 3, had both resolved with a duration of 3 days; both SAEs were assessed by the investigator as not related to the study intervention.

In addition to analysis of AEs corresponding to e-diary terms, consideration was given to additional AEs that were reported within 7 days after Dose 3 or Dose 4 such as pain in extremity, decreased appetite, lethargy, asthenia, malaise, night sweats, and hyperhidrosis. Similar to the analysis that examined these events 7 days within Dose 1 and Dose 2 of BNT162b2 in blinded follow-up (Section 2.7.4.2.4.2.1.2.1), these events reported in open-label follow-up are interpreted as attributable to the experience of local reactions and systemic events after vaccination with Dose 3 and Dose 4 (first and second dose of BNT162b2).

These results are consistent with the pattern seen during the blinded placebo-controlled follow-up period from Dose 1 to 1 month after Dose 2 (Section 2.7.4.2.4.2.1.2.1), which confirms that the greater rates of AEs observed overall in the BNT162b2 group compared with the placebo group were largely attributable to reactogenicity events for that time period.

No clinically meaningful differences in IRs of AEs for original placebo participants who then received BNT162b2 were observed by baseline SARS CoV-2 positive (222.9 per 100 PY) and negative (205.4 per 100 PY) status subgroups. The IR for original baseline positive placebo participants who then received BNT162b2 was 222.9 per 100 PY (95% CI: 186.5, 264.3) which was similar to baseline negative placebo participants who then received BNT162b2 is 205.4 per 100 PY (95% CI: 199.6, 211.3). The IR between other SOC were similar in the baseline positive and baseline negative groups except for the musculoskeletal SOC which was higher in the baseline positive group. However, it was driven by myalgia 64.2 per 100 PY (95% CI: 45.4, 88.1) in baseline positive participants compared to 38.3 per 100 PY (95% CI: 35.8, 40.9) in baseline negative participants.

Table 15. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	4885	205.4	(199.6, 211.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	88	3.7	(3.0, 4.6)
Anaemia	2	0.1	(0.0, 0.3)
Coagulopathy	1	0.0	(0.0, 0.2)
Iron deficiency anaemia	2	0.1	(0.0, 0.3)
Lymph node pain	6	0.3	(0.1, 0.5)
Lymphadenitis	2	0.1	(0.0, 0.3)
Lymphadenopathy	76	3.2	(2.5, 4.0)
CARDIAC DISORDERS	17	0.7	(0.4, 1.1)
Acute myocardial infarction	1	0.0	(0.0, 0.2)
Angina pectoris	1	0.0	(0.0, 0.2)
Arrhythmia	1	0.0	(0.0, 0.2)
Arteriospasm coronary	1	0.0	(0.0, 0.2)
Atrial fibrillation	5	0.2	(0.1, 0.5)
Atrial flutter	1	0.0	(0.0, 0.2)
Cardiac failure congestive	1	0.0	(0.0, 0.2)
Cardio-respiratory arrest	1	0.0	(0.0, 0.2)
Cardiovascular disorder	1	0.0	(0.0, 0.2)
Coronary artery disease	1	0.0	(0.0, 0.2)
Ischaemic cardiomyopathy	1	0.0	(0.0, 0.2)
Myocardial infarction	1	0.0	(0.0, 0.2)
Palpitations	1	0.0	(0.0, 0.2)
Supraventricular tachycardia	1	0.0	(0.0, 0.2)
Tachycardia	2	0.1	(0.0, 0.3)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	4	0.2	(0.0, 0.4)
Atrial septal defect	1	0.0	(0.0, 0.2)
BRCA2 gene mutation	1	0.0	(0.0, 0.2)
Factor II mutation	1	0.0	(0.0, 0.2)
Hypertrophic cardiomyopathy	1	0.0	(0.0, 0.2)
EAR AND LABYRINTH DISORDERS	18	0.8	(0.4, 1.2)
Cerumen impaction	1	0.0	(0.0, 0.2)
Deafness neurosensory	1	0.0	(0.0, 0.2)
Deafness unilateral	1	0.0	(0.0, 0.2)
Ear discomfort	1	0.0	(0.0, 0.2)

Table 15. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Ear pain	4	0.2	(0.0, 0.4)
Eustachian tube dysfunction	2	0.1	(0.0, 0.3)
Hypoacusis	1	0.0	(0.0, 0.2)
Meniere's disease	1	0.0	(0.0, 0.2)
Sudden hearing loss	1	0.0	(0.0, 0.2)
Tinnitus	2	0.1	(0.0, 0.3)
Vertigo	6	0.3	(0.1, 0.5)
ENDOCRINE DISORDERS	4	0.2	(0.0, 0.4)
Hypothyroidism	2	0.1	(0.0, 0.3)
Thyroid disorder	1	0.0	(0.0, 0.2)
Thyroid mass	1	0.0	(0.0, 0.2)
EYE DISORDERS	26	1.1	(0.7, 1.6)
Blepharitis	1	0.0	(0.0, 0.2)
Cataract	4	0.2	(0.0, 0.4)
Conjunctival haemorrhage	1	0.0	(0.0, 0.2)
Dacryostenosis acquired	1	0.0	(0.0, 0.2)
Diplopia	1	0.0	(0.0, 0.2)
Dry eye	1	0.0	(0.0, 0.2)
Erythema of eyelid	1	0.0	(0.0, 0.2)
Eye irritation	1	0.0	(0.0, 0.2)
Eye pain	5	0.2	(0.1, 0.5)
Eye swelling	1	0.0	(0.0, 0.2)
Keratitis	2	0.1	(0.0, 0.3)
Lacrimation increased	3	0.1	(0.0, 0.4)
Meibomianitis	1	0.0	(0.0, 0.2)
Ocular discomfort	1	0.0	(0.0, 0.2)
Visual impairment	1	0.0	(0.0, 0.2)
Vitreous floaters	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	339	14.3	(12.8, 15.9)
Abdominal discomfort	4	0.2	(0.0, 0.4)
Abdominal distension	1	0.0	(0.0, 0.2)
Abdominal pain	12	0.5	(0.3, 0.9)
Abdominal pain lower	2	0.1	(0.0, 0.3)
Abdominal pain upper	13	0.5	(0.3, 0.9)
Anal fistula	2	0.1	(0.0, 0.3)
Anal prolapse	1	0.0	(0.0, 0.2)

Table 15. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Chronic gastritis	1	0.0	(0.0, 0.2)
Constipation	4	0.2	(0.0, 0.4)
Dental caries	1	0.0	(0.0, 0.2)
Diarrhoea	91	3.8	(3.1, 4.7)
Dry mouth	3	0.1	(0.0, 0.4)
Duodenitis	1	0.0	(0.0, 0.2)
Dyspepsia	5	0.2	(0.1, 0.5)
Gastric ulcer	1	0.0	(0.0, 0.2)
Gastritis	5	0.2	(0.1, 0.5)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.2)
Gastrointestinal necrosis	1	0.0	(0.0, 0.2)
Gastrointestinal sounds abnormal	1	0.0	(0.0, 0.2)
Gastrooesophageal reflux disease	7	0.3	(0.1, 0.6)
Gingival bleeding	1	0.0	(0.0, 0.2)
Haemorrhoids	1	0.0	(0.0, 0.2)
Hiatus hernia	2	0.1	(0.0, 0.3)
Hyperaesthesia teeth	1	0.0	(0.0, 0.2)
Hypoaesthesia oral	1	0.0	(0.0, 0.2)
Intestinal obstruction	1	0.0	(0.0, 0.2)
Intestinal ulcer perforation	1	0.0	(0.0, 0.2)
Irritable bowel syndrome	2	0.1	(0.0, 0.3)
Large intestine polyp	1	0.0	(0.0, 0.2)
Nausea	160	6.7	(5.7, 7.9)
Oedema mouth	1	0.0	(0.0, 0.2)
Oral mucosal blistering	1	0.0	(0.0, 0.2)
Oral pain	1	0.0	(0.0, 0.2)
Oral pruritus	1	0.0	(0.0, 0.2)
Pancreatitis acute	2	0.1	(0.0, 0.3)
Retching	1	0.0	(0.0, 0.2)
Small intestinal obstruction	1	0.0	(0.0, 0.2)
Stomatitis	2	0.1	(0.0, 0.3)
Submaxillary gland enlargement	1	0.0	(0.0, 0.2)
Tongue disorder	1	0.0	(0.0, 0.2)
Tongue oedema	1	0.0	(0.0, 0.2)
Toothache	1	0.0	(0.0, 0.2)
Umbilical hernia	1	0.0	(0.0, 0.2)

Table 15. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Vomiting	48	2.0	(1.5, 2.7)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4169	175.3	(170.0, 180.7)
Application site pain	2	0.1	(0.0, 0.3)
Asthenia	36	1.5	(1.1, 2.1)
Axillary pain	3	0.1	(0.0, 0.4)
Chest discomfort	2	0.1	(0.0, 0.3)
Chest pain	4	0.2	(0.0, 0.4)
Chills	994	41.8	(39.2, 44.5)
Crying	1	0.0	(0.0, 0.2)
Discomfort	2	0.1	(0.0, 0.3)
Drug withdrawal syndrome	1	0.0	(0.0, 0.2)
Facial pain	1	0.0	(0.0, 0.2)
Fatigue	1379	58.0	(55.0, 61.1)
Feeling abnormal	6	0.3	(0.1, 0.5)
Feeling cold	2	0.1	(0.0, 0.3)
Feeling hot	6	0.3	(0.1, 0.5)
Gait disturbance	1	0.0	(0.0, 0.2)
Implant site pain	1	0.0	(0.0, 0.2)
Inflammation	1	0.0	(0.0, 0.2)
Influenza like illness	1	0.0	(0.0, 0.2)
Injection site bruising	16	0.7	(0.4, 1.1)
Injection site discomfort	3	0.1	(0.0, 0.4)
Injection site erythema	66	2.8	(2.1, 3.5)
Injection site haematoma	2	0.1	(0.0, 0.3)
Injection site haemorrhage	1	0.0	(0.0, 0.2)
Injection site hypersensitivity	1	0.0	(0.0, 0.2)
Injection site hypoaesthesia	2	0.1	(0.0, 0.3)
Injection site induration	1	0.0	(0.0, 0.2)
Injection site irritation	1	0.0	(0.0, 0.2)
Injection site lymphadenopathy	1	0.0	(0.0, 0.2)
Injection site mass	1	0.0	(0.0, 0.2)
Injection site nodule	2	0.1	(0.0, 0.3)
Injection site oedema	2	0.1	(0.0, 0.3)
Injection site pain	2944	123.8	(119.3, 128.3)
Injection site pruritus	18	0.8	(0.4, 1.2)

Table 15. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Injection site rash	4	0.2	(0.0, 0.4)
Injection site reaction	2	0.1	(0.0, 0.3)
Injection site swelling	65	2.7	(2.1, 3.5)
Injection site urticaria	1	0.0	(0.0, 0.2)
Injection site warmth	3	0.1	(0.0, 0.4)
Malaise	83	3.5	(2.8, 4.3)
Non-cardiac chest pain	1	0.0	(0.0, 0.2)
Oedema peripheral	2	0.1	(0.0, 0.3)
Pain	394	16.6	(15.0, 18.3)
Pelvic mass	1	0.0	(0.0, 0.2)
Peripheral swelling	7	0.3	(0.1, 0.6)
Pyrexia	906	38.1	(35.6, 40.6)
Swelling	3	0.1	(0.0, 0.4)
Swelling face	4	0.2	(0.0, 0.4)
Vaccination site pain	3	0.1	(0.0, 0.4)
Vaccination site reaction	1	0.0	(0.0, 0.2)
Vessel puncture site haematoma	1	0.0	(0.0, 0.2)
HEPATOBILIARY DISORDERS	3	0.1	(0.0, 0.4)
Cholecystitis	1	0.0	(0.0, 0.2)
Cholelithiasis	1	0.0	(0.0, 0.2)
Hepatitis acute	1	0.0	(0.0, 0.2)
IMMUNE SYSTEM DISORDERS	7	0.3	(0.1, 0.6)
Allergy to vaccine	1	0.0	(0.0, 0.2)
Anaphylactoid reaction	1	0.0	(0.0, 0.2)
Hypersensitivity	1	0.0	(0.0, 0.2)
Seasonal allergy	4	0.2	(0.0, 0.4)
INFECTIONS AND INFESTATIONS	136	5.7	(4.8, 6.8)
Abscess	1	0.0	(0.0, 0.2)
Appendicitis perforated	1	0.0	(0.0, 0.2)
Asymptomatic bacteriuria	1	0.0	(0.0, 0.2)
COVID-19 pneumonia	1	0.0	(0.0, 0.2)
Candida infection	1	0.0	(0.0, 0.2)
Cellulitis	3	0.1	(0.0, 0.4)
Chlamydial infection	1	0.0	(0.0, 0.2)
Clostridium difficile infection	1	0.0	(0.0, 0.2)
Conjunctivitis	6	0.3	(0.1, 0.5)

Table 15. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Cystitis	1	0.0	(0.0, 0.2)
Demodicidosis	1	0.0	(0.0, 0.2)
Diverticulitis	2	0.1	(0.0, 0.3)
Ear infection	8	0.3	(0.1, 0.7)
Eye infection	1	0.0	(0.0, 0.2)
Focal peritonitis	1	0.0	(0.0, 0.2)
Folliculitis	1	0.0	(0.0, 0.2)
Fungal skin infection	3	0.1	(0.0, 0.4)
Genital herpes	1	0.0	(0.0, 0.2)
Genital herpes simplex	2	0.1	(0.0, 0.3)
Helicobacter gastritis	1	0.0	(0.0, 0.2)
Herpes simplex	2	0.1	(0.0, 0.3)
Herpes zoster	8	0.3	(0.1, 0.7)
Hordeolum	2	0.1	(0.0, 0.3)
Infected cyst	1	0.0	(0.0, 0.2)
Infection	1	0.0	(0.0, 0.2)
Labyrinthitis	1	0.0	(0.0, 0.2)
Localised infection	2	0.1	(0.0, 0.3)
Mastitis	1	0.0	(0.0, 0.2)
Onychomycosis	1	0.0	(0.0, 0.2)
Oral candidiasis	1	0.0	(0.0, 0.2)
Oral herpes	3	0.1	(0.0, 0.4)
Osteomyelitis	1	0.0	(0.0, 0.2)
Otitis externa	2	0.1	(0.0, 0.3)
Otitis media	2	0.1	(0.0, 0.3)
Pelvic abscess	1	0.0	(0.0, 0.2)
Pneumonia	2	0.1	(0.0, 0.3)
Postoperative wound infection	1	0.0	(0.0, 0.2)
Rhinitis	2	0.1	(0.0, 0.3)
Sinusitis	7	0.3	(0.1, 0.6)
Subcutaneous abscess	2	0.1	(0.0, 0.3)
Suspected COVID-19	1	0.0	(0.0, 0.2)
Taeniasis	1	0.0	(0.0, 0.2)
Tinea infection	1	0.0	(0.0, 0.2)
Tinea pedis	2	0.1	(0.0, 0.3)
Tonsillitis	2	0.1	(0.0, 0.3)

Table 15. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Tooth abscess	4	0.2	(0.0, 0.4)
Tooth infection	12	0.5	(0.3, 0.9)
Urinary tract infection	30	1.3	(0.9, 1.8)
Urosepsis	1	0.0	(0.0, 0.2)
Vulvitis	1	0.0	(0.0, 0.2)
Vulvovaginal candidiasis	3	0.1	(0.0, 0.4)
Vulvovaginal mycotic infection	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	90	3.8	(3.0, 4.7)
Animal bite	1	0.0	(0.0, 0.2)
Ankle fracture	2	0.1	(0.0, 0.3)
Arthropod bite	3	0.1	(0.0, 0.4)
Chest injury	1	0.0	(0.0, 0.2)
Contusion	9	0.4	(0.2, 0.7)
Corneal abrasion	1	0.0	(0.0, 0.2)
Exposure during pregnancy	5	0.2	(0.1, 0.5)
Eye contusion	1	0.0	(0.0, 0.2)
Facial bones fracture	1	0.0	(0.0, 0.2)
Fall	20	0.8	(0.5, 1.3)
Fibula fracture	2	0.1	(0.0, 0.3)
Foot fracture	4	0.2	(0.0, 0.4)
Frostbite	1	0.0	(0.0, 0.2)
Hand fracture	3	0.1	(0.0, 0.4)
Head injury	1	0.0	(0.0, 0.2)
Injection related reaction	1	0.0	(0.0, 0.2)
Joint dislocation	1	0.0	(0.0, 0.2)
Ligament injury	1	0.0	(0.0, 0.2)
Ligament sprain	6	0.3	(0.1, 0.5)
Limb injury	4	0.2	(0.0, 0.4)
Lip injury	1	0.0	(0.0, 0.2)
Lower limb fracture	1	0.0	(0.0, 0.2)
Maternal exposure during pregnancy	3	0.1	(0.0, 0.4)
Meniscus injury	1	0.0	(0.0, 0.2)
Muscle rupture	1	0.0	(0.0, 0.2)
Muscle strain	2	0.1	(0.0, 0.3)
Postoperative ileus	1	0.0	(0.0, 0.2)
Procedural pain	6	0.3	(0.1, 0.5)

Table 15. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Radius fracture	1	0.0	(0.0, 0.2)
Road traffic accident	2	0.1	(0.0, 0.3)
Scapula fracture	1	0.0	(0.0, 0.2)
Seroma	1	0.0	(0.0, 0.2)
Skin abrasion	2	0.1	(0.0, 0.3)
Skin laceration	10	0.4	(0.2, 0.8)
Spinal fracture	1	0.0	(0.0, 0.2)
Subdural haematoma	1	0.0	(0.0, 0.2)
Tendon injury	1	0.0	(0.0, 0.2)
Tendon rupture	1	0.0	(0.0, 0.2)
Thermal burn	2	0.1	(0.0, 0.3)
Tooth fracture	6	0.3	(0.1, 0.5)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.2)
Upper limb fracture	2	0.1	(0.0, 0.3)
Wound	1	0.0	(0.0, 0.2)
Wrist fracture	1	0.0	(0.0, 0.2)
INVESTIGATIONS	107	4.5	(3.7, 5.4)
Alanine aminotransferase increased	2	0.1	(0.0, 0.3)
Antinuclear antibody positive	1	0.0	(0.0, 0.2)
Aspartate aminotransferase increased	2	0.1	(0.0, 0.3)
Blood cholesterol increased	3	0.1	(0.0, 0.4)
Blood pressure increased	6	0.3	(0.1, 0.5)
Blood testosterone decreased	2	0.1	(0.0, 0.3)
Body temperature increased	91	3.8	(3.1, 4.7)
C-reactive protein increased	1	0.0	(0.0, 0.2)
Heart rate increased	1	0.0	(0.0, 0.2)
SARS-CoV-2 antibody test positive	1	0.0	(0.0, 0.2)
Troponin increased	1	0.0	(0.0, 0.2)
METABOLISM AND NUTRITION DISORDERS	29	1.2	(0.8, 1.8)
Decreased appetite	14	0.6	(0.3, 1.0)
Diabetes mellitus	1	0.0	(0.0, 0.2)
Diabetes mellitus inadequate control	1	0.0	(0.0, 0.2)
Dyslipidaemia	2	0.1	(0.0, 0.3)
Glucose tolerance impaired	2	0.1	(0.0, 0.3)
Gout	1	0.0	(0.0, 0.2)
Hypercholesterolaemia	1	0.0	(0.0, 0.2)

Table 15. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hyperglycaemia	2	0.1	(0.0, 0.3)
Insulin resistance	2	0.1	(0.0, 0.3)
Lactic acidosis	1	0.0	(0.0, 0.2)
Type 2 diabetes mellitus	2	0.1	(0.0, 0.3)
Vitamin D deficiency	1	0.0	(0.0, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1245	52.3	(49.5, 55.3)
Arthralgia	149	6.3	(5.3, 7.4)
Arthritis	3	0.1	(0.0, 0.4)
Back pain	32	1.3	(0.9, 1.9)
Bursitis	1	0.0	(0.0, 0.2)
Flank pain	2	0.1	(0.0, 0.3)
Foot deformity	1	0.0	(0.0, 0.2)
Groin pain	1	0.0	(0.0, 0.2)
Intervertebral disc protrusion	2	0.1	(0.0, 0.3)
Joint range of motion decreased	2	0.1	(0.0, 0.3)
Joint swelling	1	0.0	(0.0, 0.2)
Limb discomfort	1	0.0	(0.0, 0.2)
Mobility decreased	1	0.0	(0.0, 0.2)
Muscle fatigue	2	0.1	(0.0, 0.3)
Muscle spasms	1	0.0	(0.0, 0.2)
Muscular weakness	4	0.2	(0.0, 0.4)
Musculoskeletal chest pain	1	0.0	(0.0, 0.2)
Musculoskeletal pain	1	0.0	(0.0, 0.2)
Musculoskeletal stiffness	12	0.5	(0.3, 0.9)
Myalgia	925	38.9	(36.4, 41.5)
Neck pain	11	0.5	(0.2, 0.8)
Osteoarthritis	9	0.4	(0.2, 0.7)
Osteoporosis	1	0.0	(0.0, 0.2)
Pain in extremity	154	6.5	(5.5, 7.6)
Periarthritis	1	0.0	(0.0, 0.2)
Plantar fasciitis	3	0.1	(0.0, 0.4)
Rheumatoid arthritis	1	0.0	(0.0, 0.2)
Rotator cuff syndrome	2	0.1	(0.0, 0.3)
Sacroiliitis	1	0.0	(0.0, 0.2)
Sjogren's syndrome	1	0.0	(0.0, 0.2)
Synovial cyst	1	0.0	(0.0, 0.2)

Table 15. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Temporomandibular joint syndrome	1	0.0	(0.0, 0.2)
Tendonitis	1	0.0	(0.0, 0.2)
Trigger finger	1	0.0	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	13	0.5	(0.3, 0.9)
Bladder neoplasm	1	0.0	(0.0, 0.2)
Bowen's disease	1	0.0	(0.0, 0.2)
Brain neoplasm	1	0.0	(0.0, 0.2)
Breast cancer	1	0.0	(0.0, 0.2)
Breast cancer stage II	1	0.0	(0.0, 0.2)
Hepatic cancer	1	0.0	(0.0, 0.2)
Lipoma	1	0.0	(0.0, 0.2)
Meningioma	1	0.0	(0.0, 0.2)
Neoplasm	1	0.0	(0.0, 0.2)
Non-small cell lung cancer stage III	1	0.0	(0.0, 0.2)
Rectal cancer	1	0.0	(0.0, 0.2)
Seborrhoeic keratosis	1	0.0	(0.0, 0.2)
Skin papilloma	1	0.0	(0.0, 0.2)
Squamous cell carcinoma	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	1201	50.5	(47.7, 53.4)
Amnesia	1	0.0	(0.0, 0.2)
Arachnoid cyst	1	0.0	(0.0, 0.2)
Balance disorder	2	0.1	(0.0, 0.3)
Brachial plexopathy	1	0.0	(0.0, 0.2)
Carpal tunnel syndrome	1	0.0	(0.0, 0.2)
Cerebrovascular accident	4	0.2	(0.0, 0.4)
Cervical radiculopathy	1	0.0	(0.0, 0.2)
Cognitive disorder	1	0.0	(0.0, 0.2)
Disturbance in attention	4	0.2	(0.0, 0.4)
Dizziness	47	2.0	(1.5, 2.6)
Dysgeusia	2	0.1	(0.0, 0.3)
Encephalopathy	1	0.0	(0.0, 0.2)
Facial paralysis	3	0.1	(0.0, 0.4)
Head discomfort	1	0.0	(0.0, 0.2)
Headache	1108	46.6	(43.9, 49.4)
Hemiplegia	1	0.0	(0.0, 0.2)

Table 15. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Hyperaesthesia	2	0.1	(0.0, 0.3)
Hypoaesthesia	2	0.1	(0.0, 0.3)
Hypogeusia	1	0.0	(0.0, 0.2)
Lethargy	9	0.4	(0.2, 0.7)
Loss of consciousness	1	0.0	(0.0, 0.2)
Mental impairment	2	0.1	(0.0, 0.3)
Migraine	6	0.3	(0.1, 0.5)
Migraine with aura	1	0.0	(0.0, 0.2)
Nerve compression	1	0.0	(0.0, 0.2)
Paraesthesia	14	0.6	(0.3, 1.0)
Parosmia	1	0.0	(0.0, 0.2)
Piriformis syndrome	1	0.0	(0.0, 0.2)
Presyncope	1	0.0	(0.0, 0.2)
Radiculopathy	1	0.0	(0.0, 0.2)
Sciatica	1	0.0	(0.0, 0.2)
Seizure	1	0.0	(0.0, 0.2)
Somnolence	13	0.5	(0.3, 0.9)
Speech disorder	1	0.0	(0.0, 0.2)
Syncope	4	0.2	(0.0, 0.4)
Transient ischaemic attack	2	0.1	(0.0, 0.3)
Tremor	2	0.1	(0.0, 0.3)
Visual field defect	1	0.0	(0.0, 0.2)
PSYCHIATRIC DISORDERS	43	1.8	(1.3, 2.4)
Abnormal dreams	1	0.0	(0.0, 0.2)
Alcohol withdrawal syndrome	1	0.0	(0.0, 0.2)
Anxiety	9	0.4	(0.2, 0.7)
Attention deficit hyperactivity disorder	3	0.1	(0.0, 0.4)
Bipolar disorder	1	0.0	(0.0, 0.2)
Completed suicide	1	0.0	(0.0, 0.2)
Confusional state	2	0.1	(0.0, 0.3)
Depression	3	0.1	(0.0, 0.4)
Generalised anxiety disorder	1	0.0	(0.0, 0.2)
Insomnia	12	0.5	(0.3, 0.9)
Irritability	2	0.1	(0.0, 0.3)
Major depression	1	0.0	(0.0, 0.2)
Mental fatigue	1	0.0	(0.0, 0.2)

Table 15. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Mental status changes	1	0.0	(0.0, 0.2)
Restlessness	2	0.1	(0.0, 0.3)
Sleep disorder	2	0.1	(0.0, 0.3)
Suicidal ideation	1	0.0	(0.0, 0.2)
Suicide attempt	1	0.0	(0.0, 0.2)
Thinking abnormal	1	0.0	(0.0, 0.2)
RENAL AND URINARY DISORDERS	21	0.9	(0.5, 1.3)
Acute kidney injury	1	0.0	(0.0, 0.2)
Bladder neck obstruction	1	0.0	(0.0, 0.2)
Chronic kidney disease	1	0.0	(0.0, 0.2)
Dysuria	6	0.3	(0.1, 0.5)
Haematuria	1	0.0	(0.0, 0.2)
Hypertonic bladder	2	0.1	(0.0, 0.3)
Nephrolithiasis	4	0.2	(0.0, 0.4)
Pollakiuria	1	0.0	(0.0, 0.2)
Urinary bladder polyp	1	0.0	(0.0, 0.2)
Urinary hesitation	1	0.0	(0.0, 0.2)
Urinary retention	1	0.0	(0.0, 0.2)
Urinary tract obstruction	1	0.0	(0.0, 0.2)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	12	0.5	(0.3, 0.9)
Benign prostatic hyperplasia	3	0.1	(0.0, 0.4)
Breast cyst	1	0.0	(0.0, 0.2)
Breast discharge	1	0.0	(0.0, 0.2)
Endometriosis	1	0.0	(0.0, 0.2)
Metrorrhagia	2	0.1	(0.0, 0.3)
Ovarian cyst	1	0.0	(0.0, 0.2)
Pelvic pain	1	0.0	(0.0, 0.2)
Sexual dysfunction	1	0.0	(0.0, 0.2)
Testicular pain	1	0.0	(0.0, 0.2)
Uterine haemorrhage	1	0.0	(0.0, 0.2)
Vaginal lesion	1	0.0	(0.0, 0.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	37	1.6	(1.1, 2.1)
Acute respiratory failure	2	0.1	(0.0, 0.3)
Asthma	1	0.0	(0.0, 0.2)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.2)
Cough	3	0.1	(0.0, 0.4)

Table 15. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Dyspnoea	2	0.1	(0.0, 0.3)
Epistaxis	3	0.1	(0.0, 0.4)
Immune-mediated pneumonitis	1	0.0	(0.0, 0.2)
Nasal congestion	5	0.2	(0.1, 0.5)
Nasal septum deviation	1	0.0	(0.0, 0.2)
Oropharyngeal pain	1	0.0	(0.0, 0.2)
Paranasal sinus discomfort	1	0.0	(0.0, 0.2)
Pleuritic pain	1	0.0	(0.0, 0.2)
Pulmonary embolism	4	0.2	(0.0, 0.4)
Rhinitis allergic	4	0.2	(0.0, 0.4)
Rhinorrhoea	6	0.3	(0.1, 0.5)
Sinus congestion	1	0.0	(0.0, 0.2)
Upper respiratory tract congestion	1	0.0	(0.0, 0.2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	85	3.6	(2.9, 4.4)
Acne	1	0.0	(0.0, 0.2)
Actinic keratosis	3	0.1	(0.0, 0.4)
Alopecia	2	0.1	(0.0, 0.3)
Angioedema	1	0.0	(0.0, 0.2)
Cold sweat	1	0.0	(0.0, 0.2)
Dermatitis	2	0.1	(0.0, 0.3)
Dermatitis contact	6	0.3	(0.1, 0.5)
Dry skin	1	0.0	(0.0, 0.2)
Ecchymosis	3	0.1	(0.0, 0.4)
Erythema	2	0.1	(0.0, 0.3)
Erythema nodosum	1	0.0	(0.0, 0.2)
Hyperhidrosis	15	0.6	(0.4, 1.0)
Ingrowing nail	3	0.1	(0.0, 0.4)
Lichen sclerosus	1	0.0	(0.0, 0.2)
Night sweats	7	0.3	(0.1, 0.6)
Petechiae	1	0.0	(0.0, 0.2)
Pruritus	6	0.3	(0.1, 0.5)
Rash	16	0.7	(0.4, 1.1)
Rash erythematous	2	0.1	(0.0, 0.3)
Rash pruritic	1	0.0	(0.0, 0.2)
Rash vesicular	1	0.0	(0.0, 0.2)
Skin lesion	4	0.2	(0.0, 0.4)

Table 15. Incidence Rates of at Least 1 Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Skin ulcer	1	0.0	(0.0, 0.2)
Urticaria	7	0.3	(0.1, 0.6)
SURGICAL AND MEDICAL PROCEDURES	9	0.4	(0.2, 0.7)
Blepharoplasty	1	0.0	(0.0, 0.2)
Chondroplasty	1	0.0	(0.0, 0.2)
Finger repair operation	1	0.0	(0.0, 0.2)
Hysterectomy	2	0.1	(0.0, 0.3)
Injection	1	0.0	(0.0, 0.2)
Spinal fusion surgery	1	0.0	(0.0, 0.2)
Tooth extraction	2	0.1	(0.0, 0.3)
VASCULAR DISORDERS	45	1.9	(1.4, 2.5)
Aortic aneurysm	1	0.0	(0.0, 0.2)
Aortic arteriosclerosis	1	0.0	(0.0, 0.2)
Aortic stenosis	1	0.0	(0.0, 0.2)
Blood pressure fluctuation	1	0.0	(0.0, 0.2)
Deep vein thrombosis	3	0.1	(0.0, 0.4)
Flushing	5	0.2	(0.1, 0.5)
Haematoma	2	0.1	(0.0, 0.3)
Hot flush	2	0.1	(0.0, 0.3)
Hypertension	25	1.1	(0.7, 1.6)
Hypotension	1	0.0	(0.0, 0.2)
Peripheral coldness	1	0.0	(0.0, 0.2)
Thrombosis	1	0.0	(0.0, 0.2)
Venous thrombosis limb	1	0.0	(0.0, 0.2)

Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (17:36)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 exp age p3x saf

2.7.4.2.4.2.5.2.2. Related Adverse Events by System Organ Class and Preferred Term: Open-Label Follow-Up Period – Original Placebo Participants Who Then Received BNT162b2 (Phase 3, Study C4591001, Analysis of Adverse Events)

From vaccination with BNT162b2 to the data cutoff date for placebo participants, the IR of AEs assessed as related by the investigator during the open-label follow-up period was 189.5 per 100 PY (Table 14). The IRs of related AEs were highest for reactogenicity events and in the SOC of general disorders and administration site conditions (4147 [174.3 per 100 PY]) for the following PTs:

- injection site pain (2938 [123.5 per 100 PY])
- pyrexia (905 [38.0 per 100 PY])
- fatigue (1373 [57.7 per 100 PY])
- chills (993 [41.7 per 100 PY])

2.7.4.2.4.2.5.2.3. Immediate Adverse Events: Open-Label Follow-Up Period – Original Placebo Participants Who Then Received BNT162b2 (Phase 3, Study C4591001, Analysis of Adverse Events)

After vaccination with BNT162b2 (Dose 3/4), placebo participants who received BNT162b2 with immediate AEs were low in frequency (0.6%). Most immediate AEs after BNT162b2 doses were in the SOC of general disorders and administration site conditions, primarily injection site reactions, with injection site pain (0.4%) most frequently reported.

Other immediate AEs were reported in the following, and were assessed by the investigator as related to study intervention:

- One participant in the younger age group reported 2 immediate AEs of oedema mouth and tongue edema (both mild in severity) after Dose 4; both AEs were assessed by the investigator as related to study intervention. The AE of tongue oedema resolved the same day and the AE of oedema mouth resolved the following day.

- One participant in the younger age group reported an immediate AE of hypoaesthesia oral (mild) after Dose 3 and resolved the same day.

- One participant in the younger age group reported 3 immediate AEs of swelling face, allergy to vaccine, and flushing after Dose 3, which were all were moderate in severity. All 3 AEs resolved the following day. The participant also reported nausea and urticaria (hives abdomen) (both mild in severity) on the same day but were not immediate. The AE of nausea resolved the same day and the AE of urticaria resolved the following day. These 2 AEs were also assessed by the investigator as related to study intervention.

- One participant in the older age group reported an immediate AE of urticaria (hive on back of neck; moderate in severity) after Dose 4 and is ongoing at the time of the data cutoff date.

2.7.4.2.4.2.5.2.4. Severe or Life-Threatening Adverse Events: Open-Label Follow-Up Period – Original Placebo Participants Who Then Received BNT162b2 (Phase 3, Study C4591001, Analysis of Adverse Events)

Severe Adverse Events

From Dose 3 (first Dose of BNT162b2) to the data cutoff date, the severe AE IR was 6.0 per 100 PY in original placebo participants. Severe AEs included:

- One participant in the younger age group reported a severe AE of hypersensitivity on 13 days after Dose 3, which resolved the following day and was assessed by the investigator as not related to study intervention.

- One participant in the older age group reported a severe SAE of COVID-19 pneumonia 8 days after Dose 3, which resolved 4 days later and was assessed by the investigator as not related to study intervention.

- One participant in the older age group reported a severe SAE of cerebrovascular accident 16 days after Dose 4, which was assessed by the investigator as not related to study intervention and ongoing at the time of the data cutoff date.

- One participant in the younger age group reported a severe SAE of pulmonary embolism 5 days after Dose 4, which resolved the following day and was assessed by the investigator as not related to study intervention.

- One participant in the older age group reported 1 severe SAE each of pulmonary embolism and thrombosis (occlusive thrombus in the right calf) 2 days after Dose 3. Both events resolved the following day, and both were assessed by the investigator as not related to study intervention.

- One participant in the younger age group reported 2 AEs of urticaria (moderate and severe) at 3 and 4 days after Dose 3, respectively. The moderate AE of urticaria (intermittent generalized) resolved the same day. The severe AE of urticaria (left arm) resolved 8 days later. Both events were assessed by the investigator as related to study intervention.

Life-Threatening Adverse Events

The IR for original placebo participants who had at least 1 life-threatening AE from Dose 3 to the data cutoff date was 0.5 per 100 PY. The following life-threatening events were reported and with the exception of anaphylactoid reaction, all were considered unrelated to vaccine as assessed by the investigator.

- A Grade 4 life-threatening SAE of cardio-respiratory arrest was reported in one participant in the older age group. The event occurred 25 days after Dose 3 and the outcome was fatal.

- One participant in the younger age group had a Grade 4 life-threatening SAE of gastrointestinal necrosis 29 days after Dose 4. The outcome was not recovered/not resolved at the time of this report.

- One participant in the younger age group had a Grade 4 life-threatening SAE of pulmonary embolism and a Grade 4 life-threatening SAE of deep vein thrombosis. Both events of pulmonary embolism and deep vein thrombosis occurred 11 days after Dose 4 and the outcome for both events was recovering/resolving.

- A Grade 4 life-threatening SAE of anaphylactoid reaction was reported in one participant in the younger age group 2 days after Dose 3. The outcome was recovered/resolved and the event was considered related to vaccine. This participant is also discussed under Section 2.7.4.2.4.3.4.1.1.

2.7.4.2.4.2.6. Original Placebo Participants, had COVID-19 Occurrence After Dose 1, and Then Received BNT162b2: Open-Label Follow-Up Period (Phase 3, Study C4591001)

2.7.4.2.4.2.6.1. Summary of Adverse Events: Original Placebo Participants, had COVID-19 Occurrence After Dose 1, and Then Received BNT162b2: Open-Label Follow-Up Period (Phase 3, Study C4591001)

There were 853 original placebo participants who developed COVID-19 and subsequently were vaccinated with BNT162b2. For original placebo participants who had COVID-19 occurrence after Dose 1 and then received BNT162b2, IRs for any AE and at least 1 related AE from Dose 3 (first dose of BNT162b2 30 µg) were 256.8 per 100 PY and 240.9 per 100 PY, respectively. IRs of severe AEs, SAEs, and AEs leading to withdrawal were 4.6 per 100 PY, 3.4 per 100 PY, and 3.4 per 100 PY. The IR for discontinuations because of related AEs was 3.4 per 100 PY, and no participants died.

IRs for SAEs were similar for the placebo participants who developed COVID-19 and subsequently were vaccinated with BNT162b2 (3.4 per 100 PY; 95% CI: 0.7, 10.0) and participants originally randomized to BNT162b2 (3.2 per 100 PY; 95% CI: 2.8, 3.6) (Table 7), respectively. None of the SAEs in the original placebo participants who developed COVID-19 and subsequently were vaccinated with BNT162b2 were related to BNT162b2. There were 3 participants with AEs leading to withdrawal that were assessed as related to BNT162b2: 1 participant with an AE of allergy to vaccine, 1 participant with an AE of pain, and 1 participant with 5 AEs (chills, injection site pain, myalgia, headache, and diarrhea). No deaths were reported in placebo participants who developed COVID-19 and subsequently were vaccinated with BNT162b2.

While the exposure time between the placebo participants who developed COVID-19 and subsequently were vaccinated with BNT162b2 is small (0.9) compared to the exposure time for the blinded placebo controlled period (83.4) (Table 7), direct comparisons must be interpreted with caution, the rate of SAE were similar between the groups (3.4 per 100 PY vs 3.2 per 100 PY, respectively).

2.7.4.2.4.2.6.2. Analysis of Adverse Events: Original Placebo Participants, had COVID-19 Occurrence After Dose 1, and Then Received BNT162b2: Open-Label Follow-Up Period (Phase 3, Study C4591001)

For original placebo participants who had COVID-19 occurrence after Dose 1 and then received BNT162b2, the IR for at least 1 AE was 256.8 per 100 PY.

Most AEs reported from Dose 3 (the first dose of BNT162b2) to the data cutoff date were in SOCs with reactogenicity events.

- general disorders and administration site conditions (236.3 per 100 PY)
- musculoskeletal and connective tissue disorders (47.9 per 100 PY)
- nervous system disorders (66.2 per 100 PY)
- gastrointestinal disorders (17.1 per 100 PY).

2.7.4.2.4.3. Deaths, Serious Adverse Events, Safety-Related Participant Withdrawals, and Other Significant Adverse Events (Phase 3, Study C4591001)

Full details and outputs regarding deaths, SAEs, safety-related participant withdrawals, and other significant AEs for Phase 3 of Study C4591001 are in Module 5.3.5.1 C4591001 6-Month Update CSR Section 12.2.4.

2.7.4.2.4.3.1. Deaths (Phase 3, Study C4591001)

There were 15 deaths in the BNT162b2 group and 14 deaths in the placebo group from Dose 1 to the unblinding date during the blinded placebo-controlled follow-up period (Table 16). None of these deaths were assessed by the investigator as related to study intervention.

Table 16. Incidence Rates of Deaths From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Deaths	15	0.2	(0.1, 0.3)	14	0.2	(0.1, 0.3)
Cause of death[f]						
Acute respiratory failure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Aortic rupture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Arteriosclerosis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Biliary cancer metastatic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardiac arrest	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiac failure congestive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Death	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dementia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Emphysematous cholecystitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Haemorrhagic stroke	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hypertensive heart disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Metastases to liver	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Missing	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Myocardial infarction	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Overdose	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pneumonia	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Septic shock	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Shigella sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Unevaluable event	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

Table 16. Incidence Rates of Deaths From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])

a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified cause of death.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Multiple causes of death can be reported for each subject.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: dd Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/addd s001 p3 saf

From the unblinding date to the data cutoff date of the open-label follow-up period, there were 3 deaths in original BNT162b2 participants (all in the older age group, one each due to road traffic accident, lung metastases, and myocardial infarction) and 2 deaths in original placebo participants who then received BNT162b2 (all in the older age group, one each due to cardiorespiratory arrest or completed suicide). None of these deaths were assessed by the investigator as related to study intervention.

Among participants with confirmed stable HIV disease, 2 deaths were reported as of the cutoff date, and none of these deaths were assessed by the investigator as related to study intervention:

- One female participant in the younger age group died due to COVID-19 pneumonia reported 75 days after receiving Dose 2 of placebo. This participant was diagnosed based on a local COVID-19 test that could not be confirmed as protocol-approved and was not confirmed by a test result from the central laboratory. Therefore, this participant was not included in efficacy analyses.

- One female participant in the older age group died due to a road traffic accident occurring 73 days after receiving Dose 2.

2.7.4.2.4.3.1.1. Death Narratives (Phase 3, Study C4591001)

Narratives for the participants who died through the data cutoff date (13 March 2021) are provided (see Section 2.7.4.2.4.4).

2.7.4.2.4.3.2. Serious Adverse Events (Phase 3, Study C4591001)

Details and outputs regarding serious adverse events for Phase 3 of Study C4591001 are in Module 5.3.5.1 C4591001 6-Month Update CSR Section 12.2.4.2.

2.7.4.2.4.3.2.1. Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2 (Phase 3, Study C4591001, Serious Adverse Events)

From Dose 1 to 1 month after Dose 2 the proportions of participants who reported at least 1 SAE was similar in the BNT162b2 group (0.6%) and in the placebo group (0.5%) (Table 17). The numbers of participants who reported at least 1 SAE were lower in the younger age group (52 [0.4%] and 49 [0.4%] for the BNT162b2 and placebo groups, respectively) than in the older age groups was (75 [0.8%] and 67 [0.8%] for the BNT162b2 and placebo groups, respectively) similar.

Three of the SAEs in the BNT162b2 group and none in the placebo group were assessed by the investigator as related to study intervention (Table 5).

In the BNT162b2 group, there were 2 participants in the younger age group (previously reported in the final analysis interim C4591001 CSR dated 03 December 2020) and 1 participant in the older age group with an SAE each assessed by the investigator as related to study intervention:

- One participant in the younger age group had an SAE of lymphadenopathy (right axilla) 13 days after Dose 1 which lasted 66 days and resolved. The participant was a 48-year-old woman with a relevant medical history of eczema and topical crisaborole use who was administered BNT162b2 vaccine in the left deltoid and had right axillary pain and lymphadenopathy. She had no injuries to the right arm, no fever, and no history of a similar incident. Her WBC was normal with a normal lymphocyte count and a right axilla ultrasound showed 4 enlarged lymph nodes (largest 2.5 × 1.1 × 2.4 cm). A biopsy was performed and was reported to be normal and without markers for lymphoma or other cancer. A follow-up visit with oncology (and possible repeat ultrasound) was planned for 3 months' time.

- One participant in the younger age group had an SAE of shoulder injury related to vaccine administration (SIRVA, erroneously administered into or near the shoulder joint capsule) after Dose 2, which lasted 153 days and resolved.

- One participant in the older age group with a past medical history significant for AV block with pacemaker, sinus node dysfunction, atrial fibrillation, and supraventricular tachycardia had an SAE of ventricular arrhythmia that occurred 1 day after Dose 2 and lasted for 8 days and resolved.

Table 17. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	127 (0.6)	(0.5, 0.7)	116 (0.5)	(0.4, 0.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Neutropenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Thrombocytopenia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	20 (0.1)	(0.1, 0.1)	21 (0.1)	(0.1, 0.1)
Atrial fibrillation	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Acute myocardial infarction	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Coronary artery disease	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Aortic valve incompetence	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac arrest	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac failure congestive	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Acute left ventricular failure	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina pectoris	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Angina unstable	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Arteriospasm coronary	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac failure acute	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coronary artery dissection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Junctional ectopic tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial ischaemia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pericarditis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Tachyarrhythmia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachycardia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Ventricular arrhythmia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Congenital bladder neck obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Heart disease congenital	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 17. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
EYE DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Retinal artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	9 (0.0)	(0.0, 0.1)	12 (0.1)	(0.0, 0.1)
Small intestinal obstruction	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis acute	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abdominal adhesions	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal pain upper	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Colitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diarrhoea	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Gastrointestinal mucosa hyperaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Incarcerated inguinal hernia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Inguinal hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intestinal obstruction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Oesophageal food impaction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oesophageal varices haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Salivary gland calculus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Umbilical hernia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Volvulus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	4 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chest pain	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Influenza like illness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Cholecystitis acute	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cholelithiasis	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 17. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Bile duct stone	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cholecystitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anaphylactic shock	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	27 (0.1)	(0.1, 0.2)	21 (0.1)	(0.1, 0.1)
Appendicitis	7 (0.0)	(0.0, 0.1)	3 (0.0)	(0.0, 0.0)
Pneumonia	2 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Cellulitis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Urinary tract infection	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
COVID-19	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diverticulitis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Postoperative wound infection	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyelonephritis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abdominal abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Abscess intestinal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Anal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Bacterial sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Brain abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Complicated appendicitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningitis bacterial	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteomyelitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Peritonitis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pyelonephritis acute	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shigella sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Staphylococcal infection	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subacute endocarditis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Subcutaneous abscess	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Suspected COVID-19	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Upper respiratory tract infection	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Urosepsis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 17. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	8 (0.0)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Overdose	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial bones fracture	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Road traffic accident	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Colon injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Fall	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Femur fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Flail chest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Foot fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Forearm fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Head injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hip fracture	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Humerus fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lower limb fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Multiple injuries	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Procedural haemorrhage	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rib fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal column injury	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subdural haematoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Toxicity to various agents	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic haemothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ulna fracture	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Blood glucose abnormal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hepatic enzyme increased	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fluid retention	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypoglycaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hypokalaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	7 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)

Table 17. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Intervertebral disc protrusion	3 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Osteoarthritis	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arthralgia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Back pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Muscular weakness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	13 (0.1)	(0.0, 0.1)	10 (0.0)	(0.0, 0.1)
Prostate cancer	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Malignant melanoma	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine leiomyoma	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adenocarcinoma pancreas	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast cancer	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic myeloid leukaemia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Intraductal proliferative breast lesion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Invasive ductal breast carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Leydig cell tumour of the testis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Meningioma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to liver	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Oropharyngeal squamous cell carcinoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pancreatic carcinoma	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Penile neoplasm	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Prostate cancer metastatic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Thyroid cancer	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	14 (0.1)	(0.0, 0.1)	15 (0.1)	(0.0, 0.1)
Subarachnoid haemorrhage	4 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Syncope	1 (0.0)	(0.0, 0.0)	4 (0.0)	(0.0, 0.0)
Cerebrovascular accident	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient ischaemic attack	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Amyotrophic lateral sclerosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)

Table 17. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Cervicogenic headache	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Hemiplegic migraine	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Paraesthesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Spinal cord compression	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abortion spontaneous	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Abortion spontaneous incomplete	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Suicidal ideation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Bipolar disorder	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Depression suicidal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Disorientation	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Mental disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Psychotic disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	5 (0.0)	(0.0, 0.1)	1 (0.0)	(0.0, 0.0)
Nephrolithiasis	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Acute kidney injury	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Renal colic	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Urinary bladder polyp	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian cyst	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Ovarian mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	7 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Pulmonary embolism	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Acute respiratory failure	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonia aspiration	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Chronic obstructive pulmonary disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 17. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Hypoxia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pneumothorax	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pulmonary mass	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	7 (0.0)	(0.0, 0.1)	5 (0.0)	(0.0, 0.1)
Deep vein thrombosis	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypertension	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Orthostatic hypotension	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Aortic stenosis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive crisis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Hypertensive urgency	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_ser_all_pd2_p3_saf

2.7.4.2.4.3.2.1.1. Participants with Confirmed Stable HIV Disease: Blinded Follow-Up Period From Dose 1 to 1 Month After Dose 2 (Phase 3, Study C4591001, Serious Adverse Events)

No participants with confirmed stable HIV disease reported an SAE from Dose 1 to 1 month after Dose 2.

2.7.4.2.4.3.2.2. Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date (Phase 3, Study C4591001, Serious Adverse Events)

From Dose 1 to the unblinding date, IRs of at least 1 SAE were similar in the BNT162b2 group (3.2 per 100 PY) and in the placebo group (3.3 per 100 PY) (Table 18). The IR was lower in the younger age groups (2.1 per 100 PY and 2.4 per 100 PY for the BNT162b2 and

placebo groups, respectively) than in the older age groups (4.9 per 100 PY and 4.6 per 100 PY for the BNT162b2 and placebo groups respectively).

Four of the SAEs in the BNT162b2 group and 1 in the placebo group were assessed by the investigator as related to study intervention. In addition to the 3 related SAEs in the BNT162b2 group described in Section 2.7.4.2.4.3.2.1, there were 2 related SAEs that occurred from Dose 1 to the unblinding date:

- One participant in the BNT162b2 younger age group with a medical history significant for occipital neuralgia, and migraines had an SAE of paraesthesia (right leg) 47 days after Dose 2 which was recovering/resolving at the data cutoff date.

- One participant in the placebo younger age group had an SAE of psoriatic arthropathy 38 days after Dose 2 which was continuing at the data cutoff date.

Table 18. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	268	3.2	(2.8, 3.6)	268	3.3	(2.9, 3.7)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Anaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Lymphadenopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Microcytic anaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Neutropenia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Thrombocytopenia	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
CARDIAC DISORDERS	42	0.5	(0.4, 0.7)	39	0.5	(0.3, 0.6)
Acute coronary syndrome	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Acute left ventricular failure	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Acute myocardial infarction	6	0.1	(0.0, 0.2)	3	0.0	(0.0, 0.1)
Angina pectoris	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Angina unstable	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Aortic valve incompetence	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Arrhythmia supraventricular	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Arteriosclerosis coronary artery	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Arteriospasm coronary	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Atrial fibrillation	5	0.1	(0.0, 0.1)	9	0.1	(0.1, 0.2)
Atrioventricular block complete	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bradycardia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)

Table 18. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Cardiac arrest	6	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Cardiac failure acute	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cardiac failure congestive	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coronary artery disease	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Coronary artery dissection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Coronary artery occlusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hypertensive heart disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Junctional ectopic tachycardia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Myocardial infarction	4	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Myocardial ischaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pericarditis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tachyarrhythmia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tachycardia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ventricular arrhythmia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ventricular tachycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Congenital bladder neck obstruction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Congenital ureteropelvic junction obstruction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Heart disease congenital	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Vertigo	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
EYE DISORDERS	5	0.1	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Blindness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Choroidal neovascularisation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diplopia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Eye haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ophthalmic vein thrombosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Retinal artery occlusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Visual impairment	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	23	0.3	(0.2, 0.4)	21	0.3	(0.2, 0.4)
Abdominal adhesions	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abdominal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abdominal pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abdominal pain upper	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Colitis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Colitis ischaemic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Table 18. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Constipation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diarrhoea	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diverticular perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diverticulum intestinal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Duodenal obstruction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Enterocolitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Food poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastrointestinal haemorrhage	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Gastrointestinal mucosa hyperaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Haemorrhoids	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hiatus hernia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ileus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Impaired gastric emptying	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Incarcerated inguinal hernia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Inguinal hernia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Intestinal obstruction	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intestinal perforation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intestinal strangulation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Large intestine perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Obstructive pancreatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oesophageal food impaction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oesophageal varices haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pancreatic cyst	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pancreatitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pancreatitis acute	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Retroperitoneal haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Salivary gland calculus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Small intestinal obstruction	4	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Umbilical hernia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Volvulus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	10	0.1	(0.1, 0.2)	4	0.0	(0.0, 0.1)
Asthenia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Chest pain	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Death	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Drug withdrawal syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Influenza like illness	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Table 18. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Non-cardiac chest pain	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Shoulder injury related to vaccine administration	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sudden cardiac death	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vascular stent occlusion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
HEPATOBILIARY DISORDERS	12	0.1	(0.1, 0.3)	7	0.1	(0.0, 0.2)
Bile duct stone	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Biliary colic	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cholecystitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cholecystitis acute	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Cholecystitis chronic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cholelithiasis	5	0.1	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hepatocellular injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
IMMUNE SYSTEM DISORDERS	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Anaphylactic shock	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Drug hypersensitivity	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	50	0.6	(0.4, 0.8)	57	0.7	(0.5, 0.9)
Abdominal abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Abscess intestinal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Anal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Appendicitis	14	0.2	(0.1, 0.3)	9	0.1	(0.1, 0.2)
Appendicitis perforated	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Arthritis bacterial	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Bacterial sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Brain abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.0)	13	0.2	(0.1, 0.3)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cellulitis	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Complicated appendicitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Device related infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diabetic foot infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Diverticulitis	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Emphysematous cholecystitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Empyema	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Escherichia urinary tract infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Extradural abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gangrene	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

Table 18. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Gastroenteritis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Meningitis bacterial	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Osteomyelitis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Penile infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Peritoneal abscess	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Peritonitis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peritonsillar abscess	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumonia	4	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Post procedural infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Postoperative wound infection	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pyelonephritis	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pyelonephritis acute	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Renal abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Respiratory tract infection viral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sepsis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Septic shock	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Shigella sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Staphylococcal infection	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Staphylococcal sepsis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subacute endocarditis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subcutaneous abscess	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Suspected COVID-19	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tooth infection	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Upper respiratory tract infection	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Urinary tract infection	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Urosepsis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	19	0.2	(0.1, 0.4)	26	0.3	(0.2, 0.5)
Alcohol poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ankle fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Brain contusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cervical vertebral fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Colon injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Concussion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Craniocerebral injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Delayed recovery from anaesthesia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Facial bones fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Fall	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Femur fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Table 18. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Flail chest	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Foot fracture	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Forearm fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Head injury	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hip fracture	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Humerus fracture	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Ligament rupture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Lower limb fracture	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Lumbar vertebral fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Meniscus injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Multiple injuries	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Overdose	3	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Patella fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pelvic fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Post procedural haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Post-traumatic pain	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Procedural haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Radius fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rib fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Road traffic accident	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Spinal column injury	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Spinal cord injury cervical	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Subdural haematoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Tibia fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Toxicity to various agents	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Traumatic haemothorax	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ulna fracture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Upper limb fracture	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Wrist fracture	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
INVESTIGATIONS	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Blood glucose abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Blood pressure increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cardiac stress test abnormal	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hepatic enzyme increased	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Red blood cell morphology abnormal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
METABOLISM AND NUTRITION DISORDERS	4	0.0	(0.0, 0.1)	10	0.1	(0.1, 0.2)
Diabetes mellitus inadequate control	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Table 18. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Diabetic ketoacidosis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Fluid retention	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hyperglycaemia	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Hypoglycaemia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Hypokalaemia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Hyponatraemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Type 2 diabetes mellitus	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	13	0.2	(0.1, 0.3)	11	0.1	(0.1, 0.2)
Arthralgia	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Arthritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Back pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intervertebral disc compression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intervertebral disc degeneration	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Intervertebral disc protrusion	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Muscular weakness	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Osteoarthritis	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Osteochondritis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Psoriatic arthropathy	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Spondylolisthesis	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	39	0.5	(0.3, 0.6)	35	0.4	(0.3, 0.6)
Acute myeloid leukaemia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenocarcinoma of colon	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adenocarcinoma pancreas	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Adrenal gland cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
B-cell lymphoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Benign hydatidiform mole	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Biliary cancer metastatic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bladder cancer	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Borderline serous tumour of ovary	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Breast cancer	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Breast cancer in situ	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Breast cancer stage I	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Carcinoid tumour of the stomach	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Chronic myeloid leukaemia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Clear cell renal cell carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Colon adenoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

Table 18. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Gallbladder cancer stage II	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Gastric cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intraductal proliferative breast lesion	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Invasive ductal breast carcinoma	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Leydig cell tumour of the testis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lipoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lobular breast carcinoma in situ	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Lung adenocarcinoma	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Malignant melanoma	1	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Meningioma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Metastases to central nervous system	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Metastases to liver	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Metastases to lymph nodes	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Non-Hodgkin's lymphoma recurrent	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Non-small cell lung cancer stage IV	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Oropharyngeal cancer recurrent	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Oropharyngeal squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pancreatic carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Papillary serous endometrial carcinoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Papillary thyroid cancer	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Penile neoplasm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Plasma cell myeloma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Polycythaemia vera	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Prostate cancer	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Prostate cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Skin cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Squamous cell carcinoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Squamous cell carcinoma of head and neck	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Teratoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Thyroid cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Tonsil cancer	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Transitional cell carcinoma	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Uterine cancer	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Uterine leiomyoma	0	0.0	(0.0, 0.0)	3	0.0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	25	0.3	(0.2, 0.4)	23	0.3	(0.2, 0.4)
Amnesia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Table 18. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Amyotrophic lateral sclerosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Carpal tunnel syndrome	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Cerebral infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerebrovascular accident	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cervicogenic headache	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dementia Alzheimer's type	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dizziness	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Guillain-Barre syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Haemorrhagic stroke	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hemiplegic migraine	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Idiopathic intracranial hypertension	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Intraventricular haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ischaemic stroke	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Optic neuritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Paraesthesia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Peripheral nerve lesion	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Spinal cord compression	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Subarachnoid haemorrhage	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Syncope	2	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)
Toxic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Transient global amnesia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Transient ischaemic attack	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Uraemic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Abortion incomplete	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Abortion spontaneous	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Abortion spontaneous incomplete	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Retained products of conception	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	5	0.1	(0.0, 0.1)	9	0.1	(0.1, 0.2)
Alcohol abuse	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Bipolar disorder	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Depression	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Depression suicidal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Disorientation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Major depression	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Mental disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Panic attack	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Table 18. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Psychotic disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Suicidal ideation	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Suicide attempt	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
RENAL AND URINARY DISORDERS	11	0.1	(0.1, 0.2)	8	0.1	(0.0, 0.2)
Acute kidney injury	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hydronephrosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Nephrolithiasis	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)
Renal colic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Subcapsular renal haematoma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ureterolithiasis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Urinary bladder polyp	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Adnexal torsion	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Breast hyperplasia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Endometriosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Ovarian cyst	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Ovarian mass	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rectocele	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Uterine prolapse	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vaginal prolapse	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	14	0.2	(0.1, 0.3)	14	0.2	(0.1, 0.3)
Acute respiratory failure	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Asthma	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Asthmatic crisis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Dyspnoea	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hypoxia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Interstitial lung disease	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Nasal septum deviation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pneumonia aspiration	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Pneumonitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pneumothorax	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pulmonary embolism	5	0.1	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Pulmonary mass	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Respiratory arrest	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Respiratory failure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Table 18. Incidence Rates of at Least 1 Serious Adverse Event From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
SOCIAL CIRCUMSTANCES	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Miscarriage of partner	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Finger amputation	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
VASCULAR DISORDERS	12	0.1	(0.1, 0.3)	13	0.2	(0.1, 0.3)
Accelerated hypertension	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Aortic aneurysm	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Aortic rupture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Aortic stenosis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Arteriosclerosis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Deep vein thrombosis	3	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)
Hypertension	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypertensive crisis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypertensive emergency	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hypertensive urgency	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Orthostatic hypotension	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Peripheral artery stenosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 sae exp p3 saf

Subgroup Analyses

Overall, no clinically meaningful differences in IRs of SAEs were observed by baseline SARS-CoV-2 status, ethnicity, race, or sex subgroups.

IRs of SAEs were similar by baseline SARS-CoV-2 status in the BNT162b2 and placebo groups for baseline positive (4.0 per 100 PY [95% CI: 1.9, 7.3] and 1.9 per 100 PY [95% CI: 0.6, 4.4]) and baseline negative (3.2 per 100 PY [95% CI: 2.8, 3.6] and 3.3 per 100 PY [95%

CI: 2.9, 3.7]) participants. IRs of SAEs in the baseline positive BNT162b2 group were similar (4.0 per 100 PY [95% CI: 1.9, 7.3]) to those in the baseline negative BNT162b2 group (3.2 per 100 PY [95% CI: 2.8, 3.6]), and similar to what was observed in the overall SAE analysis irrespective of baseline status (Table 7).

While there are differences in exposure (2.5 vs 80.4) by baseline SARS-CoV-2 positive and negative status, respectively, IRs were numerically low or similar by baseline SARS-CoV-2 status, so there is no evidence that individuals who are positive at baseline report AEs at a higher frequency than those who are negative at baseline.

IRs of SAEs were similar in the BNT162b2 and placebo groups for Hispanic/Latino (3.5 per 100 PY [95% CI: 2.8, 4.3] and 3.6 per 100 PY [95% CI: 2.9, 4.5]), Non-Hispanic/Non-Latino (3.1 per 100 PY [95% CI: 2.7, 3.6] for each), and Not Reported (2.4 per 100 PY [95% CI: 0.1, 13.1] and 2.3 per 100 PY [95% CI: 0.1, 12.7]) participants.

IRs of SAEs were similar in the BNT162b2 and placebo groups for White (3.3 per 100 PY [95%CI: 2.9, 3.8]and 3.5 per 100 PY [95% CI: 3.1, 4.0]), Black or African American (2.5 per 100 PY [95% CI: 1.6, 3.9] and 2.6 per 100 PY [95% CI: 1.6, 4.0]), and greater in the BNT162b2 group for All Others compared to placebo (2.7 per 100 PY [95% CI: 1.6, 4.3] and 1.4 per 100 PY [95% CI: 0.6, 2.7]).

IRs of SAEs were similar by sex in the BNT162b2 and placebo groups for males (3.5 per 100 PY[95% CI: 3.0, 4.1] and 3.4 per 100 PY [95% CI: 2.8, 4.0]) and females (2.9 per 100 PY [95% CI: 2.4, 3.5] and 3.2 per 100 PY [95% CI: 2.6, 3.7]).

2.7.4.2.4.3.2.2.1. Participants with Confirmed Stable HIV Disease: Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date (Phase 3, Study C4591001, Serious Adverse Events)

From Dose 1 to the unblinding date, IRs of at least 1 SAE in participants with stable HIV disease were similar in the BNT162b2 group (6.6 per 100 PY [95% CI:0.8, 23.9]) and the placebo group (6.9 per 100 PY [95% CI: 0.8, 25.1]) with 2 participants reporting at least 1 SAE in each group. None of the SAEs were assessed by the investigator as related to study intervention.

- One older participant in the BNT162b2 group had an SAE of pneumonia 86 days after Dose 2 which lasted 8 days and resolved.
- One older participant in the BNT162b2 group had a fatal SAE of road traffic accident 73 days after Dose 2.
- One younger participant in the placebo group had an SAE of breast cancer 71 days after Dose 2 that was continuing at the data cutoff date.
- One younger participant in the placebo group had an SAE of diabetes mellitus 68 days after Dose 2, and COVID-19 pneumonia 72 days after Dose 2 which lasted 4 days and resulted in death (Section 2.7.4.2.4.3.1). The participant had a history of asthma, HIV, hypertension, and obesity and then was diagnosed with diabetes

mellitus 68 days after Dose 2. Four days after the diagnosis, the participant presented in the ER with an elevated blood glucose level and was admitted. Laboratory tests on the following day included a SARS-CoV-2 PCR test, which was positive. Two days later, a second test confirmed the COVID-19 positive diagnosis. The following day, 75 days after Dose 2, the participant died due to disease progression and COVID-19 pneumonia. The investigator concluded that the diabetes mellitus and COVID-19 pneumonia were not related to study intervention. This participant was diagnosed based on a local COVID-19 test that could not be confirmed as protocol-approved and was not confirmed by a test result from the central laboratory, therefore, this participant was not included in efficacy analyses.

2.7.4.2.4.3.2.3. Open-Label Follow-Up Period – Original BNT162b2 Participants (Phase 3, Study C4591001, Serious Adverse Events)

From unblinding date to the data cutoff date, the IR of at least 1 SAE was 2.0 per 100 PY (95% CI: 1.5, 2.6) in original BNT162b2 participants (Table 19).

One younger participant with no past medical history had a life-threatening SAE of myocardial infarction 71 days after Dose 2 that was assessed by the investigator as related to study intervention, which lasted 1 day and resolved the same day.

Table 19. Incidence Rates of at Least 1 Serious Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	55	2.0	(1.5, 2.6)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1	0.0	(0.0, 0.2)
Pancytopenia	1	0.0	(0.0, 0.2)
CARDIAC DISORDERS	8	0.3	(0.1, 0.6)
Atrial fibrillation	1	0.0	(0.0, 0.2)
Atrial flutter	1	0.0	(0.0, 0.2)
Cardiac failure congestive	1	0.0	(0.0, 0.2)
Coronary artery occlusion	1	0.0	(0.0, 0.2)
Myocardial infarction	4	0.1	(0.0, 0.4)
EYE DISORDERS	1	0.0	(0.0, 0.2)
Retinal tear	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	3	0.1	(0.0, 0.3)
Abdominal pain upper	1	0.0	(0.0, 0.2)
Haematemesis	1	0.0	(0.0, 0.2)
Rectal haemorrhage	1	0.0	(0.0, 0.2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1	0.0	(0.0, 0.2)
Impaired healing	1	0.0	(0.0, 0.2)
HEPATOBILIARY DISORDERS	6	0.2	(0.1, 0.5)
Acute hepatic failure	1	0.0	(0.0, 0.2)
Cholecystitis	1	0.0	(0.0, 0.2)
Cholecystitis acute	2	0.1	(0.0, 0.3)
Cholelithiasis obstructive	1	0.0	(0.0, 0.2)
Portosplenomesenteric venous thrombosis	1	0.0	(0.0, 0.2)
INFECTIONS AND INFESTATIONS	10	0.4	(0.2, 0.7)
Appendicitis	1	0.0	(0.0, 0.2)
Bacteraemia	1	0.0	(0.0, 0.2)
Clostridium difficile colitis	1	0.0	(0.0, 0.2)
Endocarditis	1	0.0	(0.0, 0.2)
Herpes zoster oticus	1	0.0	(0.0, 0.2)
Meningitis bacterial	1	0.0	(0.0, 0.2)
Pneumonia	1	0.0	(0.0, 0.2)
Post procedural infection	1	0.0	(0.0, 0.2)
Postoperative abscess	1	0.0	(0.0, 0.2)

Table 19. Incidence Rates of at Least 1 Serious Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Sepsis	1	0.0	(0.0, 0.2)
Subcutaneous abscess	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	8	0.3	(0.1, 0.6)
Ankle fracture	1	0.0	(0.0, 0.2)
Burns second degree	1	0.0	(0.0, 0.2)
Burns third degree	1	0.0	(0.0, 0.2)
Clavicle fracture	1	0.0	(0.0, 0.2)
Fall	1	0.0	(0.0, 0.2)
Humerus fracture	1	0.0	(0.0, 0.2)
Injury	1	0.0	(0.0, 0.2)
Procedural dizziness	1	0.0	(0.0, 0.2)
Procedural pain	1	0.0	(0.0, 0.2)
Rib fracture	1	0.0	(0.0, 0.2)
Road traffic accident	2	0.1	(0.0, 0.3)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1	0.0	(0.0, 0.2)
Osteoarthritis	1	0.0	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	5	0.2	(0.1, 0.4)
Adenocarcinoma pancreas	1	0.0	(0.0, 0.2)
Brain cancer metastatic	1	0.0	(0.0, 0.2)
Hormone receptor positive breast cancer	1	0.0	(0.0, 0.2)
Metastases to lung	1	0.0	(0.0, 0.2)
Pancreatic carcinoma metastatic	1	0.0	(0.0, 0.2)
Uterine cancer	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	3	0.1	(0.0, 0.3)
Dizziness	1	0.0	(0.0, 0.2)
Intracranial aneurysm	1	0.0	(0.0, 0.2)
Seizure	1	0.0	(0.0, 0.2)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	1	0.0	(0.0, 0.2)
Abortion spontaneous	1	0.0	(0.0, 0.2)
PSYCHIATRIC DISORDERS	1	0.0	(0.0, 0.2)
Bipolar I disorder	1	0.0	(0.0, 0.2)
RENAL AND URINARY DISORDERS	2	0.1	(0.0, 0.3)
Nephrolithiasis	2	0.1	(0.0, 0.3)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	1	0.0	(0.0, 0.2)

Table 19. Incidence Rates of at Least 1 Serious Adverse Event From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Endometrial thickening	1	0.0	(0.0, 0.2)
Endometriosis	1	0.0	(0.0, 0.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	5	0.2	(0.1, 0.4)
Asthma	1	0.0	(0.0, 0.2)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.2)
Dyspnoea	1	0.0	(0.0, 0.2)
Dyspnoea exertional	1	0.0	(0.0, 0.2)
Pulmonary embolism	1	0.0	(0.0, 0.2)
VASCULAR DISORDERS	3	0.1	(0.0, 0.3)
Aortic aneurysm	2	0.1	(0.0, 0.3)
Arterial occlusive disease	1	0.0	(0.0, 0.2)
Deep vein thrombosis	1	0.0	(0.0, 0.2)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from the unblinding date to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 sae ex bnt p3 saf

2.7.4.2.4.3.2.4. Blinded Placebo-Controlled and Open-Label Follow-Up Periods to 6 Months After Dose 2 – Original BNT162b2 Participants (Phase 3, Study C4591001, Serious Adverse Events)

From Dose 1 to 6 months after Dose 2, during the blinded and open-label follow-up periods, 190 (1.6%) participants in the BNT162b2 group reported at least 1 SAE (Table 20).

Two of the SAEs in the BNT162b2 group (SIRVA and paraesthesia, see Section 2.7.4.2.4.3.2.1 and Section 2.7.4.2.4.3.2.2) were assessed by the investigator as related to study intervention (Table 11)

The number of participants who reported at least 1 SAE was 73 (1.1%) and 117 (2.2%) in the younger and older age groups, respectively.

Comparison of SAEs reported from Dose 1 to 1 month after Dose 2 to SAEs reported from 1 month after Dose 2 to 6 months Dose 2 shows that the frequency of SAEs increased from 0.5% to 1.1%, respectively. The following SOCs had the largest increase in SAEs (Dose 1 to 1 month after Dose 2 vs 1 month after Dose 2 to 6 months after Dose 2):

- Neoplasms, benign, malignant, and unspecified (including cysts and polyps): 4 (0.0%) vs 21 (0.2%)
- Injury, poisoning, and procedural complications: 2 (0.0%) vs 14 (0.1%)
- Infections and infestations: 14 (0.1%) vs 22 (0.2%)
- Gastrointestinal disorders: 4 (0.0%) vs 10 (0.1%)
- Respiratory, thoracic, and mediastinal disorders: 2 (0.0%) vs 8 (0.1%)
- Hepatobiliary disorders: 3 (0.0%) vs 8 (0.1%)

Table 20. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ⩾16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	190 (1.6)	(1.4, 1.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)
Pancytopenia	1 (0.0)	(0.0, 0.0)
CARDIAC DISORDERS	27 (0.2)	(0.1, 0.3)
Acute myocardial infarction	4 (0.0)	(0.0, 0.1)
Atrial fibrillation	4 (0.0)	(0.0, 0.1)
Myocardial infarction	4 (0.0)	(0.0, 0.1)
Angina pectoris	3 (0.0)	(0.0, 0.1)
Angina unstable	2 (0.0)	(0.0, 0.1)
Cardiac failure congestive	2 (0.0)	(0.0, 0.1)
Acute coronary syndrome	1 (0.0)	(0.0, 0.0)
Arrhythmia supraventricular	1 (0.0)	(0.0, 0.0)
Atrial flutter	1 (0.0)	(0.0, 0.0)
Bradycardia	1 (0.0)	(0.0, 0.0)
Cardiac arrest	1 (0.0)	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.0)
Coronary artery occlusion	1 (0.0)	(0.0, 0.0)
Pericarditis	1 (0.0)	(0.0, 0.0)
Ventricular tachycardia	1 (0.0)	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)
Vertigo	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	4 (0.0)	(0.0, 0.1)
Choroidal neovascularisation	1 (0.0)	(0.0, 0.0)
Diplopia	1 (0.0)	(0.0, 0.0)
Ophthalmic vein thrombosis	1 (0.0)	(0.0, 0.0)
Retinal tear	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	14 (0.1)	(0.1, 0.2)
Colitis	2 (0.0)	(0.0, 0.1)
Gastritis	2 (0.0)	(0.0, 0.1)
Small intestinal obstruction	2 (0.0)	(0.0, 0.1)
Abdominal pain upper	1 (0.0)	(0.0, 0.0)
Food poisoning	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)

Table 20. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ⩾16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Haematemesis	1 (0.0)	(0.0, 0.0)
Haemorrhoids	1 (0.0)	(0.0, 0.0)
Impaired gastric emptying	1 (0.0)	(0.0, 0.0)
Intestinal obstruction	1 (0.0)	(0.0, 0.0)
Obstructive pancreatitis	1 (0.0)	(0.0, 0.0)
Pancreatitis	1 (0.0)	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	7 (0.1)	(0.0, 0.1)
Chest pain	2 (0.0)	(0.0, 0.1)
Non-cardiac chest pain	2 (0.0)	(0.0, 0.1)
Asthenia	1 (0.0)	(0.0, 0.0)
Shoulder injury related to vaccine administration	1 (0.0)	(0.0, 0.0)
Vascular stent occlusion	1 (0.0)	(0.0, 0.0)
HEPATOBILIARY DISORDERS	11 (0.1)	(0.0, 0.2)
Cholecystitis acute	3 (0.0)	(0.0, 0.1)
Cholelithiasis	3 (0.0)	(0.0, 0.1)
Bile duct stone	2 (0.0)	(0.0, 0.1)
Biliary colic	2 (0.0)	(0.0, 0.1)
Cholecystitis	1 (0.0)	(0.0, 0.0)
Cholelithiasis obstructive	1 (0.0)	(0.0, 0.0)
Portosplenomesenteric venous thrombosis	1 (0.0)	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	2 (0.0)	(0.0, 0.1)
Anaphylactic reaction	1 (0.0)	(0.0, 0.0)
Drug hypersensitivity	1 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	36 (0.3)	(0.2, 0.4)
Appendicitis	10 (0.1)	(0.0, 0.2)
Diverticulitis	3 (0.0)	(0.0, 0.1)
Pneumonia	3 (0.0)	(0.0, 0.1)
Cellulitis	2 (0.0)	(0.0, 0.1)
Pyelonephritis	2 (0.0)	(0.0, 0.1)
Abscess	1 (0.0)	(0.0, 0.0)
Appendicitis perforated	1 (0.0)	(0.0, 0.0)
Arthritis bacterial	1 (0.0)	(0.0, 0.0)
Bacteraemia	1 (0.0)	(0.0, 0.0)
Bacterial sepsis	1 (0.0)	(0.0, 0.0)
Clostridium difficile colitis	1 (0.0)	(0.0, 0.0)

Table 20. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ⩾16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Device related infection	1 (0.0)	(0.0, 0.0)
Empyema	1 (0.0)	(0.0, 0.0)
Endocarditis	1 (0.0)	(0.0, 0.0)
Escherichia urinary tract infection	1 (0.0)	(0.0, 0.0)
Gangrene	1 (0.0)	(0.0, 0.0)
Gastroenteritis	1 (0.0)	(0.0, 0.0)
Herpes zoster oticus	1 (0.0)	(0.0, 0.0)
Meningitis bacterial	1 (0.0)	(0.0, 0.0)
Penile infection	1 (0.0)	(0.0, 0.0)
Peritoneal abscess	1 (0.0)	(0.0, 0.0)
Peritonitis	1 (0.0)	(0.0, 0.0)
Peritonsillar abscess	1 (0.0)	(0.0, 0.0)
Postoperative abscess	1 (0.0)	(0.0, 0.0)
Sepsis	1 (0.0)	(0.0, 0.0)
Subcutaneous abscess	1 (0.0)	(0.0, 0.0)
Urinary tract infection	1 (0.0)	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	16 (0.1)	(0.1, 0.2)
Ankle fracture	2 (0.0)	(0.0, 0.1)
Road traffic accident	2 (0.0)	(0.0, 0.1)
Wrist fracture	2 (0.0)	(0.0, 0.1)
Burns second degree	1 (0.0)	(0.0, 0.0)
Burns third degree	1 (0.0)	(0.0, 0.0)
Cervical vertebral fracture	1 (0.0)	(0.0, 0.0)
Craniocerebral injury	1 (0.0)	(0.0, 0.0)
Facial bones fracture	1 (0.0)	(0.0, 0.0)
Fall	1 (0.0)	(0.0, 0.0)
Head injury	1 (0.0)	(0.0, 0.0)
Humerus fracture	1 (0.0)	(0.0, 0.0)
Patella fracture	1 (0.0)	(0.0, 0.0)
Pelvic fracture	1 (0.0)	(0.0, 0.0)
Procedural dizziness	1 (0.0)	(0.0, 0.0)
Spinal cord injury cervical	1 (0.0)	(0.0, 0.0)
Tibia fracture	1 (0.0)	(0.0, 0.0)
Traumatic intracranial haemorrhage	1 (0.0)	(0.0, 0.0)
Upper limb fracture	1 (0.0)	(0.0, 0.0)

Table 20. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ⩾16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
INVESTIGATIONS	1 (0.0)	(0.0, 0.0)
Cardiac stress test abnormal	1 (0.0)	(0.0, 0.0)
METABOLISM AND NUTRITION DISORDERS	3 (0.0)	(0.0, 0.1)
Diabetic ketoacidosis	1 (0.0)	(0.0, 0.0)
Hypoglycaemia	1 (0.0)	(0.0, 0.0)
Hypokalaemia	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	9 (0.1)	(0.0, 0.1)
Osteoarthritis	4 (0.0)	(0.0, 0.1)
Arthritis	1 (0.0)	(0.0, 0.0)
Intervertebral disc compression	1 (0.0)	(0.0, 0.0)
Intervertebral disc degeneration	1 (0.0)	(0.0, 0.0)
Intervertebral disc protrusion	1 (0.0)	(0.0, 0.0)
Osteochondritis	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	25 (0.2)	(0.1, 0.3)
Breast cancer	2 (0.0)	(0.0, 0.1)
Invasive ductal breast carcinoma	2 (0.0)	(0.0, 0.1)
Prostate cancer	2 (0.0)	(0.0, 0.1)
Acute myeloid leukaemia	1 (0.0)	(0.0, 0.0)
Adenocarcinoma pancreas	1 (0.0)	(0.0, 0.0)
Adrenal gland cancer	1 (0.0)	(0.0, 0.0)
Benign hydatidiform mole	1 (0.0)	(0.0, 0.0)
Bladder cancer	1 (0.0)	(0.0, 0.0)
Borderline serous tumour of ovary	1 (0.0)	(0.0, 0.0)
Brain cancer metastatic	1 (0.0)	(0.0, 0.0)
Breast cancer in situ	1 (0.0)	(0.0, 0.0)
Carcinoid tumour of the stomach	1 (0.0)	(0.0, 0.0)
Colon adenoma	1 (0.0)	(0.0, 0.0)
Gallbladder cancer stage II	1 (0.0)	(0.0, 0.0)
Gastric cancer	1 (0.0)	(0.0, 0.0)
Malignant melanoma	1 (0.0)	(0.0, 0.0)
Non-small cell lung cancer stage IV	1 (0.0)	(0.0, 0.0)
Skin cancer	1 (0.0)	(0.0, 0.0)
Squamous cell carcinoma	1 (0.0)	(0.0, 0.0)
Thyroid cancer	1 (0.0)	(0.0, 0.0)

Table 20. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ⩾16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Transitional cell carcinoma	1 (0.0)	(0.0, 0.0)
Uterine cancer	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	23 (0.2)	(0.1, 0.3)
Subarachnoid haemorrhage	3 (0.0)	(0.0, 0.1)
Cerebrovascular accident	2 (0.0)	(0.0, 0.1)
Dizziness	2 (0.0)	(0.0, 0.1)
Optic neuritis	2 (0.0)	(0.0, 0.1)
Syncope	2 (0.0)	(0.0, 0.1)
Transient ischaemic attack	2 (0.0)	(0.0, 0.1)
Carpal tunnel syndrome	1 (0.0)	(0.0, 0.0)
Idiopathic intracranial hypertension	1 (0.0)	(0.0, 0.0)
Intracranial aneurysm	1 (0.0)	(0.0, 0.0)
Ischaemic stroke	1 (0.0)	(0.0, 0.0)
Paraesthesia	1 (0.0)	(0.0, 0.0)
Peripheral nerve lesion	1 (0.0)	(0.0, 0.0)
Seizure	1 (0.0)	(0.0, 0.0)
Toxic encephalopathy	1 (0.0)	(0.0, 0.0)
Transient global amnesia	1 (0.0)	(0.0, 0.0)
Uraemic encephalopathy	1 (0.0)	(0.0, 0.0)
PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	2 (0.0)	(0.0, 0.1)
Abortion spontaneous	2 (0.0)	(0.0, 0.1)
PSYCHIATRIC DISORDERS	1 (0.0)	(0.0, 0.0)
Suicide attempt	1 (0.0)	(0.0, 0.0)
RENAL AND URINARY DISORDERS	9 (0.1)	(0.0, 0.1)
Nephrolithiasis	5 (0.0)	(0.0, 0.1)
Acute kidney injury	2 (0.0)	(0.0, 0.1)
Renal colic	1 (0.0)	(0.0, 0.0)
Subcapsular renal haematoma	1 (0.0)	(0.0, 0.0)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	3 (0.0)	(0.0, 0.1)
Breast hyperplasia	1 (0.0)	(0.0, 0.0)
Endometrial thickening	1 (0.0)	(0.0, 0.0)
Endometriosis	1 (0.0)	(0.0, 0.0)
Ovarian cyst	1 (0.0)	(0.0, 0.0)
Uterine prolapse	1 (0.0)	(0.0, 0.0)

Table 20. Number (%) of Subjects Reporting at Least 1 Serious Adverse Event From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ⩾16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	10 (0.1)	(0.0, 0.2)
Pulmonary embolism	4 (0.0)	(0.0, 0.1)
Chronic obstructive pulmonary disease	2 (0.0)	(0.0, 0.1)
Dyspnoea	1 (0.0)	(0.0, 0.0)
Dyspnoea exertional	1 (0.0)	(0.0, 0.0)
Interstitial lung disease	1 (0.0)	(0.0, 0.0)
Pneumonitis	1 (0.0)	(0.0, 0.0)
SOCIAL CIRCUMSTANCES	1 (0.0)	(0.0, 0.0)
Miscarriage of partner	1 (0.0)	(0.0, 0.0)
SURGICAL AND MEDICAL PROCEDURES	1 (0.0)	(0.0, 0.0)
Finger amputation	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	6 (0.0)	(0.0, 0.1)
Aortic aneurysm	3 (0.0)	(0.0, 0.1)
Deep vein thrombosis	2 (0.0)	(0.0, 0.1)
Arterial occlusive disease	1 (0.0)	(0.0, 0.0)
Hypertension	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s130 pd2 ser p3 saf

2.7.4.2.4.3.2.5. Open-Label Follow-Up Period – Original Placebo Participants Who Then Received BNT162b2 (Phase 3, Study C4591001, Serious Adverse Events)

From Dose 3 (first dose of BNT162b2) to the data cutoff date, the IR of at least 1 SAE in original placebo participants who then received BNT162b2 was 2.7 per 100 PY (95% CI: 2.1, 3.5) (Table 21). One SAE was assessed by the investigator as related to study intervention (Table 14).

- One participant in the younger age group with a history of food and seasonal allergies and drug hypersensitivity), who was originally randomized to the placebo group and unblinded to receive BNT162b2, had an anaphylactoid reaction 2 days post Dose 3 (first dose of BNT162b2), with an event duration of 1 day; the event was reported as an SAE, reported as resolved, and the participant withdrew from the study.

There were 2 participants who reported SAEs for baseline positive original placebo participants who then received BNT162b2. A meaningful comparison with baseline negative participants is not possible.

Table 21. Incidence Rates of at Least 1 Serious Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	65	2.7	(2.1, 3.5)
CARDIAC DISORDERS	8	0.3	(0.1, 0.7)
Acute myocardial infarction	1	0.0	(0.0, 0.2)
Arrhythmia	1	0.0	(0.0, 0.2)
Arteriospasm coronary	1	0.0	(0.0, 0.2)
Atrial fibrillation	2	0.1	(0.0, 0.3)
Cardiac failure congestive	1	0.0	(0.0, 0.2)
Cardio-respiratory arrest	1	0.0	(0.0, 0.2)
Cardiovascular disorder	1	0.0	(0.0, 0.2)
Ischaemic cardiomyopathy	1	0.0	(0.0, 0.2)
Myocardial infarction	1	0.0	(0.0, 0.2)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	1	0.0	(0.0, 0.2)
Hypertrophic cardiomyopathy	1	0.0	(0.0, 0.2)
EAR AND LABYRINTH DISORDERS	1	0.0	(0.0, 0.2)
Vertigo	1	0.0	(0.0, 0.2)
EYE DISORDERS	1	0.0	(0.0, 0.2)
Diplopia	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	8	0.3	(0.1, 0.7)
Anal prolapse	1	0.0	(0.0, 0.2)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.2)
Gastrointestinal necrosis	1	0.0	(0.0, 0.2)
Gastrooesophageal reflux disease	1	0.0	(0.0, 0.2)
Intestinal obstruction	1	0.0	(0.0, 0.2)
Intestinal ulcer perforation	1	0.0	(0.0, 0.2)
Pancreatitis acute	2	0.1	(0.0, 0.3)
Small intestinal obstruction	1	0.0	(0.0, 0.2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	3	0.1	(0.0, 0.4)
Drug withdrawal syndrome	1	0.0	(0.0, 0.2)
Fatigue	1	0.0	(0.0, 0.2)
Pelvic mass	1	0.0	(0.0, 0.2)
HEPATOBILIARY DISORDERS	2	0.1	(0.0, 0.3)
Cholecystitis	1	0.0	(0.0, 0.2)
Hepatitis acute	1	0.0	(0.0, 0.2)

Table 21. Incidence Rates of at Least 1 Serious Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
IMMUNE SYSTEM DISORDERS	1	0.0	(0.0, 0.2)
Anaphylactoid reaction	1	0.0	(0.0, 0.2)
INFECTIONS AND INFESTATIONS	4	0.2	(0.0, 0.4)
Appendicitis perforated	1	0.0	(0.0, 0.2)
COVID-19 pneumonia	1	0.0	(0.0, 0.2)
Clostridium difficile infection	1	0.0	(0.0, 0.2)
Focal peritonitis	1	0.0	(0.0, 0.2)
Pelvic abscess	1	0.0	(0.0, 0.2)
Pneumonia	1	0.0	(0.0, 0.2)
Urosepsis	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	6	0.3	(0.1, 0.5)
Ankle fracture	1	0.0	(0.0, 0.2)
Fall	1	0.0	(0.0, 0.2)
Lower limb fracture	1	0.0	(0.0, 0.2)
Postoperative ileus	1	0.0	(0.0, 0.2)
Scapula fracture	1	0.0	(0.0, 0.2)
Spinal fracture	1	0.0	(0.0, 0.2)
Traumatic intracranial haemorrhage	1	0.0	(0.0, 0.2)
METABOLISM AND NUTRITION DISORDERS	1	0.0	(0.0, 0.2)
Diabetes mellitus inadequate control	1	0.0	(0.0, 0.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	4	0.2	(0.0, 0.4)
Myalgia	1	0.0	(0.0, 0.2)
Osteoarthritis	3	0.1	(0.0, 0.4)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	5	0.2	(0.1, 0.5)
Brain neoplasm	1	0.0	(0.0, 0.2)
Breast cancer	1	0.0	(0.0, 0.2)
Breast cancer stage II	1	0.0	(0.0, 0.2)
Hepatic cancer	1	0.0	(0.0, 0.2)
Non-small cell lung cancer stage III	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	9	0.4	(0.2, 0.7)
Brachial plexopathy	1	0.0	(0.0, 0.2)
Cerebrovascular accident	4	0.2	(0.0, 0.4)
Seizure	1	0.0	(0.0, 0.2)
Syncope	1	0.0	(0.0, 0.2)

Table 21. Incidence Rates of at Least 1 Serious Adverse Event From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ⩾ 16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Transient ischaemic attack	2	0.1	(0.0, 0.3)
PSYCHIATRIC DISORDERS	5	0.2	(0.1, 0.5)
Alcohol withdrawal syndrome	1	0.0	(0.0, 0.2)
Anxiety	1	0.0	(0.0, 0.2)
Bipolar disorder	1	0.0	(0.0, 0.2)
Completed suicide	1	0.0	(0.0, 0.2)
Depression	1	0.0	(0.0, 0.2)
Major depression	1	0.0	(0.0, 0.2)
Suicide attempt	1	0.0	(0.0, 0.2)
RENAL AND URINARY DISORDERS	2	0.1	(0.0, 0.3)
Nephrolithiasis	1	0.0	(0.0, 0.2)
Urinary tract obstruction	1	0.0	(0.0, 0.2)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	8	0.3	(0.1, 0.7)
Acute respiratory failure	2	0.1	(0.0, 0.3)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.2)
Dyspnoea	1	0.0	(0.0, 0.2)
Pulmonary embolism	4	0.2	(0.0, 0.4)
VASCULAR DISORDERS	5	0.2	(0.1, 0.5)
Aortic stenosis	1	0.0	(0.0, 0.2)
Deep vein thrombosis	2	0.1	(0.0, 0.3)
Hypertension	1	0.0	(0.0, 0.2)
Thrombosis	1	0.0	(0.0, 0.2)

Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 sae exp p3x saf

2.7.4.2.4.3.2.5.1. Original Placebo Participants, had COVID-19 Occurrence After Dose 1, and Then Received BNT162b2 (Phase 3, Study C4591001, Serious Adverse Events)

For original placebo participants who had COVID-19 occurrence after Dose 1 and then received BNT162b2, the IR for at least 1 SAE was 3.4 per 100 PY (95% CI: 0.7, 10.0). These SAEs occurred in 3 participants.

- One participant with a significant past history of a deep vein thrombosis and COVID-19 in the placebo-controlled follow-up period, had a Grade 3 SAE of pulmonary embolism, 6 days post Dose 4, which lasted 2 days and resolved with sequelae. The SAE was assessed as not related to the study intervention by the investigator.

- One participant with a past medical history of hypertension, hypercholesterolemia, coronary artery disease, and a coronary artery bypass in 2006, had a Grade 3 SAE of myocardial infarction, 16 days post Dose 3, which lasted 4 days and resolved with sequelae. The SAE was assessed and not related to the study intervention by the investigator.

- One participant in the older age group had 4 SAEs:

    - 2 Grade 3 SAEs, urosepsis and acute hypoxic respiratory failure, both occurred 7 days post Dose 3, lasted 5 days, and resolved. These SAEs were assessed as not related to the study intervention by the investigator.

    - Grade 3 SAE of non-small cell lung cancer (stage III), occurred 31 days post Dose 4 and was continuing at the data cutoff date. This SAE was assessed as not related to the study intervention by the investigator.

    - Grade 2 SAE of Clostridium difficile infection occurred 47 days post Dose 4 and was continuing at the data cutoff date. This SAE was assessed as not related to the study intervention by the investigator.

2.7.4.2.4.3.2.6. Serious Adverse Event Narratives (Phase 3, Study C4591001)

Narratives for the Phase 3 participants who reported SAEs assessed as related to study intervention by the investigator who completed their visit at 1 month after Dose 2 and through the data cutoff date (13 March 2021) are provided (see Section 2.7.4.2.4.4).

2.7.4.2.4.3.3. Safety-Related Participant Withdrawals (Phase 3, Study C4591001)

Details and outputs regarding safety-related participant withdrawals for Phase 3 of Study C4591001 are in Module 5.3.5.1 C4591001 6-Month Update CSR Section 12.2.4.3.

In this ongoing study, tables summarizing participant withdrawals may include some participants who were reported as withdrawn but remain in the study and are continuing to be evaluated. These participants are documented in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Errata.

2.7.4.2.4.3.3.1. Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2 (Phase 3, Study C4591001, Safety-Related Participant Withdrawals)

From Dose 1 to 1 month after Dose 2, few participants in the BNT162b2 group (0.1%) and in the placebo group (0.2%) were withdrawn because of AEs (Table 22).

There were 32 participants in the BNT162b2 group and 36 participants in the placebo group had an AE leading to withdrawal, which included:

- 6 participants in the BNT162b2 group and 2 participants in the placebo group who withdrew from the study due to AEs in the SOC of General Disorders and Administration Site Conditions (BNT162b2 group: injection site pain [2 participants] and chills, facial pain, injection site dermatitis, injection site swelling, pyrexia, and swelling face [1 participant each]; placebo group: death and fatigue [1 participant each]).

- 5 participants in the BNT162b2 group and 6 participants in the placebo group withdrew from the study due to AEs in the SOC of Injury, Poisoning and Procedural Complications (BNT162b2 group: exposure during pregnancy, maternal exposure during pregnancy [2 participants each] and alcohol poisoning [1 participant]; placebo group: exposure during pregnancy [5 participants] and overdose [1 participant].

- 3 participants in the BNT162b2 group and 5 participants in the placebo group withdrew from the study due to AEs in the SOC Cardiac Disorders (BNT162b2 group: cardiac arrest, coronary artery disease and tachycardia [1 participant each]; placebo group: atrial fibrillation [2 participants], cardiac failure congestive, coronary artery occlusion, and myocardial infarction [1 participant each]).

- 3 participants in the BNT162b2 group and 6 participants in the placebo group withdrew from the study due to AEs in the SOC of Nervous System Disorders (BNT162b2 group: headache [3 participants]; placebo group: dizziness [2 participants], amnesia, cerebral infarction, hemorrhagic stroke, paraparesis, and Parkinsonism [1 participant each]).

- 3 participants in the BNT162b2 group and 6 participants in the placebo group withdrew from the study due to AEs in the SOC of Gastrointestinal Disorders (BNT162b2 group: abdominal pain upper, gastrointestinal haemorrhage, and paraesthesia oral [1 participant each]; placebo group: diarrhoea [2 participants], diverticular perforation, dry mouth, dysphagia, and nausea [1 participant each]).

- 3 participants in the BNT162b2 group and 1 participant in the placebo group withdrew from the study due to AEs in the SOC of Neoplasms Benign, Malignant and Unspecified (incl Cysts and Polyps) (BNT162b2 group:adenocarcinoma gastric, lymphoproliferative disorder, and metastases to central nervous system [1 participant each]; placebo group: biliary cancer metastatic and metastases to liver [1 participant each]).

- 1 participant each in the BNT162b2 group and the placebo group withdrew from the study due to AEs in the SOC of Ear and Labyrinth Disorders (BNT162b2 group: deafness unilateral [1 participant]; placebo group: vertigo [1 participant]).

- 1 participant each in the BNT162b2 group and the placebo group withdrew from the study due to AEs in the SOC of Musculoskeletal and Connective Tissue Disorders (myalgia [1 participant in each group]).

- No participant in the BNT162b2 group and 2 participants in the placebo group withdrew from the study due to AEs in the SOC of Immune System Disorders (placebo group: drug hypersensitivity [2 participants]).

- 1 participant in the BNT162b2 group and no participants in the placebo group withdrew from the study due to an AE in the SOC of Blood and Lymphatic System Disorders (BNT162b2 group: lymphadenopathy [1 participant]).

- 1 participant each in the BNT162b2 group and the placebo group withdrew from the study due to AEs in the SOC of Eye Disorders (BNT162b2 group: eye pain [1 participant]; placebo group: visual impairment [1 participant]).

- 1 participant in the BNT162b2 group and no participants in the placebo group withdrew from the study due to an AE in the SOC of Infections and Infestations (BNT162b2 group: Shigella sepsis [1 participant]).

- No participants in the BNT162b2 group and 1 participant in the placebo group withdrew from the study due to an AE in the SOC of Investigations (placebo group: irregular heart rate [1 participant]).

No clinically meaningful differences in AEs leading to withdrawal were observed by age subgroups.

Table 22. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Any event	32 (0.1)	(0.1, 0.2)	36 (0.2)	(0.1, 0.2)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Lymphadenopathy	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
CARDIAC DISORDERS	3 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Atrial fibrillation	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Cardiac arrest	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Cardiac failure congestive	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Coronary artery disease	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Coronary artery occlusion	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myocardial infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Tachycardia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Deafness unilateral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Vertigo	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
EYE DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Eye pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Visual impairment	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
GASTROINTESTINAL DISORDERS	3 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Diarrhoea	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Abdominal pain upper	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Diverticular perforation	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dry mouth	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Dysphagia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Gastrointestinal haemorrhage	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Nausea	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraesthesia oral	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	6 (0.0)	(0.0, 0.1)	2 (0.0)	(0.0, 0.0)
Injection site pain	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Chills	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Death	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Facial pain	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Fatigue	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Injection site dermatitis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 22. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Injection site swelling	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Pyrexia	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Swelling face	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Drug hypersensitivity	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
INFECTIONS AND INFESTATIONS	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Shigella sepsis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5 (0.0)	(0.0, 0.1)	6 (0.0)	(0.0, 0.1)
Exposure during pregnancy	2 (0.0)	(0.0, 0.0)	5 (0.0)	(0.0, 0.1)
Maternal exposure during pregnancy	2 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Alcohol poisoning	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Overdose	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
INVESTIGATIONS	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Heart rate irregular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Myalgia	1 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	3 (0.0)	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Adenocarcinoma gastric	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Biliary cancer metastatic	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Lymphoproliferative disorder	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to central nervous system	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Metastases to liver	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
NERVOUS SYSTEM DISORDERS	3 (0.0)	(0.0, 0.0)	6 (0.0)	(0.0, 0.1)
Headache	3 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Dizziness	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Amnesia	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Cerebral infarction	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Haemorrhagic stroke	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Paraparesis	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Parkinsonism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
PSYCHIATRIC DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Depression	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Depression suicidal	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Panic attack	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Table 22. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 1 Month After Dose 2, by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)			
	BNT162b2 (30 µg) (N[a]=21926)		Placebo (N[a]=21921)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])	n[b] (%)	(95% CI[c])
Suicide attempt	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	0	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Pulmonary embolism	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Respiratory arrest	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2 (0.0)	(0.0, 0.0)	3 (0.0)	(0.0, 0.0)
Urticaria	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Diabetic foot	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)
Eczema	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Pruritus	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
Rash maculo-papular	0	(0.0, 0.0)	1 (0.0)	(0.0, 0.0)
VASCULAR DISORDERS	2 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Hypertension	1 (0.0)	(0.0, 0.0)	2 (0.0)	(0.0, 0.0)
Arteriosclerosis	1 (0.0)	(0.0, 0.0)	0	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:10)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_1md2_wd_p3_saf

2.7.4.2.4.3.3.2. Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date (Phase 3, Study C4591001, Safety-Related Participant Withdrawals)

From Dose 1 to the unblinding date, the IRs of participants withdrawn because of AEs were 0.5 per 100 PY in the BNT162b2 group and 0.6 per 100 PY in the placebo group (Table 23).

There were 45 participants in the BNT162b2 group and 51 participants in the placebo group had an AE leading to withdrawal, which included:

- 9 participants in the BNT162b2 group and 8 participants in the placebo group withdrew from the study due to AEs in the SOC Cardiac Disorders (BNT162b2 group: cardiac arrest [4 participants]; cardiac failure congestive, cardio-respiratory arrest, coronary artery disease, hypertensive heart disease and tachycardia [1 participant each]; placebo group: atrial fibrillation and myocardial infarction [2

participants each]; cardiac arrest, cardiac failure congestive, cardio respiratory arrest, and coronary artery occlusion [1 participant each]).

- 3 participants in the BNT162b2 group and 6 participants in the placebo group withdrew from the study due to AEs in the SOC of Gastrointestinal Disorders (BNT162b2 group: abdominal pain upper, gastrointestinal haemorrhage, and paraesthesia oral [1 participant each]; placebo group: diarrhoea [2 participants], diverticular perforation, dry mouth, dysphagia, and nausea [1 participant each]).

- 7 participants in the BNT162b2 group and 2 participants in the placebo group withdrew from the study due to AEs in the SOC of General Disorders and Administration Site Conditions (BNT162b2 group: injection site pain [2 participants], chills, facial pain, injection site dermatitis, injection site swelling, pyrexia, sudden cardiac death and swelling face [1 participant each]; placebo group: death and fatigue [1 participant each]).

- 4 participants in the BNT162b2 group and 3 participants in the placebo group withdrew from study due to AEs in the SOC Infections and Infestations (BNT162b2 group: COVID-19 pneumonia, emphysematous cholecystitis, sepsis, septic shock and Shigella sepsis [1 participant each]; placebo group: COVID-19, pneumonia, and septic shock [1 participant each]).

No clinically meaningful differences in IRs of AEs leading to withdrawal were observed in the younger and older age groups.

Table 23. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	45	0.5	(0.4, 0.7)	51	0.6	(0.5, 0.8)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphadenopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
CARDIAC DISORDERS	9	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)
Atrial fibrillation	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Cardiac arrest	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardiac failure congestive	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Cardio-respiratory arrest	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Coronary artery disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Coronary artery occlusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Hypertensive heart disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Myocardial infarction	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Tachycardia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
EAR AND LABYRINTH DISORDERS	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Deafness unilateral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Vertigo	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
EYE DISORDERS	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Eye pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Visual impairment	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
GASTROINTESTINAL DISORDERS	3	0.0	(0.0, 0.1)	6	0.1	(0.0, 0.2)
Abdominal pain upper	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diarrhoea	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Diverticular perforation	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dry mouth	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dysphagia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Nausea	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Paraesthesia oral	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	7	0.1	(0.0, 0.2)	2	0.0	(0.0, 0.1)
Chills	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Death	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Facial pain	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Fatigue	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Injection site dermatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Injection site pain	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)

Table 23. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Injection site swelling	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pyrexia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Sudden cardiac death	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Swelling face	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
IMMUNE SYSTEM DISORDERS	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Drug hypersensitivity	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
INFECTIONS AND INFESTATIONS	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
COVID-19	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Emphysematous cholecystitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pneumonia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Septic shock	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Shigella sepsis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	5	0.1	(0.0, 0.1)	10	0.1	(0.1, 0.2)
Alcohol poisoning	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Exposure during pregnancy	2	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)
Maternal exposure during pregnancy	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Overdose	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
INVESTIGATIONS	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Heart rate irregular	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
Myalgia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	4	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Adenocarcinoma gastric	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Biliary cancer metastatic	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Breast cancer	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Lung cancer metastatic	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Lymphoproliferative disorder	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Malignant melanoma	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Metastases to central nervous system	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Metastases to liver	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
NERVOUS SYSTEM DISORDERS	3	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)
Amnesia	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Cerebral infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)

Table 23. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])
Dementia Alzheimer's type	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Dizziness	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)
Haemorrhagic stroke	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Headache	3	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Paraparesis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Parkinsonism	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
PSYCHIATRIC DISORDERS	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
Depression	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Depression suicidal	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Panic attack	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Suicide attempt	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Acute respiratory failure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Chronic obstructive pulmonary disease	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Pulmonary embolism	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Respiratory arrest	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Dermatitis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Diabetic foot	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Eczema	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Pruritus	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Rash maculo-papular	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Urticaria	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)
VASCULAR DISORDERS	3	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)
Aortic rupture	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)
Arteriosclerosis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)
Hypertension	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)

Table 23. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 1 to Unblinding Date, by System Organ Class and Preferred Term – Phase 2/3 Subjects ≥16 Years of Age – Safety Population

	Vaccine Group (as Administered)					
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:09)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adae s131 wd exp p3 saf

2.7.4.2.4.3.3.3. Open-Label Follow-Up Period – Original BNT162b2 Participants (Phase 3, Study C4591001, Safety-Related Participant Withdrawals)

From the unblinding date to the data cutoff date, IRs of original BNT162b2 participants withdrawn because of AEs were 0.1 per 100 PY (Table 24).

Table 24. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Unblinding Date to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received BNT162b2 – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=20309, TE[b]=27.7)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	4	0.1	(0.0, 0.4)
CARDIAC DISORDERS	1	0.0	(0.0, 0.2)
Myocardial infarction	1	0.0	(0.0, 0.2)
HEPATOBILIARY DISORDERS	1	0.0	(0.0, 0.2)
Acute hepatic failure	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1	0.0	(0.0, 0.2)
Injury	1	0.0	(0.0, 0.2)
Road traffic accident	1	0.0	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1	0.0	(0.0, 0.2)
Metastases to lung	1	0.0	(0.0, 0.2)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from the unblinding date to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s131_wd_exp_bnt_p3_saf

2.7.4.2.4.3.3.4. Blinded Placebo-Controlled and Open-Label Follow-Up Periods to 6 Months After Dose 2 – Original BNT162b2 Participants (Phase 3, Study C4591001, Safety-Related Participant Withdrawals)

From Dose 1 to 6 months after Dose 2 during the blinded and open-label follow-up period, 1 participant in the older BNT162b2 group was reported as withdrawn because of AEs (dermatitis) (Table 25). However, this participant remains in the study as the withdrawal was

subsequently queried and corrected, as described in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Errata.

Table 25. Number (%) of Subjects Withdrawn Because of Adverse Events From Dose 1 to 6 Months After Dose 2, by System Organ Class and Preferred Term – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)	
	BNT162b2 (30 µg) (N[a]=12006)	
System Organ Class Preferred Term	n[b] (%)	(95% CI[c])
Any event	1 (0.0)	(0.0, 0.0)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (0.0)	(0.0, 0.0)
Dermatitis	1 (0.0)	(0.0, 0.0)

Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 27MAR2021 (02:16)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adae_s130_pd2_wd_p3_saf

2.7.4.2.4.3.3.5. Open-Label Follow-Up Period – Original Placebo Participants Who Then Received BNT162b2 (Phase 3, Study C4591001, Safety-Related Participant Withdrawals)

From Dose 3 data to the data cutoff date, IR of original placebo participants withdrawn because of AEs was 0.8 per 100 PY (Table 26).

Table 26. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding - Phase 2/3 Subjects ≥16 Years of Age - Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])
Any event	19	0.8	(0.5, 1.2)
CARDIAC DISORDERS	2	0.1	(0.0, 0.3)
Angina pectoris	1	0.0	(0.0, 0.2)
Cardio-respiratory arrest	1	0.0	(0.0, 0.2)
GASTROINTESTINAL DISORDERS	2	0.1	(0.0, 0.3)
Diarrhoea	1	0.0	(0.0, 0.2)
Gastrointestinal haemorrhage	1	0.0	(0.0, 0.2)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	7	0.3	(0.1, 0.6)
Chills	2	0.1	(0.0, 0.3)
Fatigue	2	0.1	(0.0, 0.3)
Injection site pain	3	0.1	(0.0, 0.4)
Pain	1	0.0	(0.0, 0.2)
IMMUNE SYSTEM DISORDERS	2	0.1	(0.0, 0.3)
Allergy to vaccine	1	0.0	(0.0, 0.2)
Anaphylactoid reaction	1	0.0	(0.0, 0.2)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	3	0.1	(0.0, 0.4)
Maternal exposure during pregnancy	3	0.1	(0.0, 0.4)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1	0.0	(0.0, 0.2)
Myalgia	1	0.0	(0.0, 0.2)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	1	0.0	(0.0, 0.2)
Hepatic cancer	1	0.0	(0.0, 0.2)
NERVOUS SYSTEM DISORDERS	2	0.1	(0.0, 0.3)
Headache	2	0.1	(0.0, 0.3)
PSYCHIATRIC DISORDERS	1	0.0	(0.0, 0.2)
Completed suicide	1	0.0	(0.0, 0.2)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1	0.0	(0.0, 0.2)
Angioedema	1	0.0	(0.0, 0.2)
Urticaria	1	0.0	(0.0, 0.2)

Table 26. Incidence Rates of Subjects Withdrawn Because of Adverse Events From Dose 3 to Data Cutoff Date (13MAR2021), by System Organ Class and Preferred Term – Open-Label Follow-up Period – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding - Phase 2/3 Subjects ≥16 Years of Age - Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=19525, TE[b]=23.8)		
System Organ Class Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])

Note: Dose 3 = First dose of BNT162b2 (30 µg).
Note: MedDRA (v23.1) coding dictionary applied.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 3 to data cutoff date. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event. For "any event," n = number of subjects reporting at least 1 occurrence of any event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 31MAR2021 (18:33)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA1/adae s131 wd exp p3x saf

2.7.4.2.4.3.3.6. Narratives of Safety-Related Participant Withdrawals (Phase 3, Study C4591001)

Narratives for the Phase 2/3 participants with any AEs leading to withdrawal from the study through the data cutoff date (13 March 2021) are provided (see Section 2.7.4.2.4.4).

2.7.4.2.4.3.4. Other Significant Adverse Events (Phase 3, Study C4591001)

AEs of clinical interest were evaluated based on regulatory agency feedback and sponsor medical review. Terms requested for analysis by the FDA were summarize and detailed for any such cases reported. Other terms of clinical interest, such as the CDC's list of AESIs for COVID-19 vaccines, which both include terms potentially indicative of severe COVID-19 or serious autoimmune and neuroinflammatory disorders, were considered in the review of reported events. Numerical imbalances for AESIs were based on the evaluation of AEs in the blinded placebo-controlled period. These safety evaluations are summarized below.

2.7.4.2.4.3.4.1. FDA-Requested Adverse Events of Clinical Interest

Safety evaluations were conducted for AEs of clinical interest: anaphylaxis, Bell's Palsy, lymphadenopathy, and appendicitis based on feedback from the FDA. These are summarized by term below.

2.7.4.2.4.3.4.1.1. Hypersensitivity/Anaphylaxis

During the blinded placebo-controlled follow-up period of Study C4591001 in participants ≥16 years of age, there were 3 allergic reactions reported as SAEs (previously reported at 14 November cutoff date):

- Anaphylactic reaction following a bee sting in a BNT162b2 recipient (8 days after Dose 2)
- Drug hypersensitivity to an antibiotic in a BNT162b2 recipient (9 days after Dose 2)
- Anaphylactic shock due to an ant bite in a placebo recipient (18 days after Dose 2).

All 3 cases of allergic reaction above were considered by the investigator as not related to study treatment.

During the open-label observational follow-up period of this study in participants ≥16 years of age, 1 participant who received BNT162b2 at Dose 3 (after originally being randomized to placebo) experienced an SAE of anaphylactoid reaction, which was assessed as related to study intervention. This participant (Subject C4591001 1129 11291260) was a female adolescent with a medical history significant for multiple allergies since infancy. Two days after Dose 3, the participant experienced hives on the left arm (deltoid) and self-administered an epinephrine pen 24 minutes later (given the history of anaphylaxis to multiple allergens). Six minutes after injection, the participant experienced shortness of breath. Hives and shortness of breath resolved within 10 and 30 minutes, respectively, of epinephrine treatment. The participant did not seek additional medical attention. As a result of the anaphylactoid reaction, the participant was permanently withdrawn from the study.

Narratives for the events of anaphylactic reaction and anaphylactic shock are provided in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 14 Anaphylaxis (see Subject C4591001 1261 12611006 for the participant with the SAE of drug hypersensitivity).

Hypersensitivity is also assessed as a CDC-defined AESI in Section 2.7.4.2.4.3.4.2.

2.7.4.2.4.3.4.1.2. Bell's Palsy/Facial Paralysis

During the blinded placebo-controlled follow-up period in participants ≥16 years of age, there were 6 adults who developed one-sided facial paralysis (Bell's palsy, including facial paresis): 4 were randomized to BNT162b2 (all male) and 2 were randomized to placebo (1 male; 1 female). Regarding the 4 vaccinated participants (previously reported at 14 November 2020 cutoff date), their ages ranged from 40 to 70 (71 to 73 years of age in placebo participants). Events began from 3 to 48 days after their last dose, were mild to moderate in severity (moderate in the placebo participants), and duration ranged from 3 to 68 days (15 days in 1 placebo participant and ongoing in the other). Of the 4 cases in participants randomized to BNT162b2, 2 were considered by the investigator to be related to study intervention. The remaining 4 cases (2 in participants originally randomized to BNT162b2 and 2 in participants originally randomized to placebo) were assessed as not related to study intervention.

During the open-label observational follow-up period in participants ≥16 years of age, 3 participants who received BNT162b2 at Dose 3 or Dose 4 (were originally randomized to placebo) experienced facial paralysis (Subjects 12471244, 10071441, and 12181015). All were female and their ages ranged from 19 to 34 years. Events began 3 to 8 days after Dose 3 and were mild to severe in severity. One case had a duration of 12 days while the other 2 were ongoing as of the data cutoff date. All these events of facial paralysis were considered by the investigator as related to study intervention.

During the open-label follow-up period for participants originally randomized to BNT162b2, a 51 year old male developed Bell's palsy 154 days after receiving Dose 2.

Narratives for these events are provided in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 14 Bell's Palsy.

Bell's palsy is also assessed as an AESI in Section 2.7.4.2.4.3.4.3.

2.7.4.2.4.3.4.1.3. Lymphadenopathy

During the blinded placebo-controlled follow-up period in participants ≥16 years of age, lymphadenopathy was reported in 87 (1.0 per 100 PY) participants in the BNT162b2 group compared to 8 (0.1 per 100 PY) participants in the placebo group. The majority of events were mild to moderate; only 3 severe events of lymphadenopathy were reported (all in the BNT162b2 group). The median onset of lymphadenopathy after Dose 1 and before Dose 2 was 5.5 days in the BNT162b2 group and 5.0 days in the placebo group; median onset after Dose 2 was shorter in the BNT162b2 group versus the placebo group (2.0 days vs 7.0 days). The median duration of lymphadenopathy was 5.5 days in the BNT162b2 group and 4.0 days in the placebo group. As previously reported in the final analysis interim C4591001 CSR dated 03 December 2020, 1 was a related SAE.

Narratives for these events (including those reported during the open-label follow-up period) are located in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 14 Lymphadenopathy (see Subject C4591001 1178 11781107 for the narrative of the participant with the related SAE).

2.7.4.2.4.3.4.1.4. Appendicitis

Cases of appendicitis were examined in the placebo-controlled period of the study (including PTs of appendicitis perforated and complicated appendicitis). There were 14 cases of appendicitis and 1 case of appendicitis perforated in the BNT162b2 group, and 9 cases of appendicitis, 2 cases of complicated appendicitis, and 1 appendicitis perforated in the placebo group. Appendicitis cases were all reported as SAEs, and none of the cases were considered related to study intervention.

Narratives for these events are in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 14 Appendicitis.

2.7.4.2.4.3.4.2. CDC Adverse Events of Special Interest – Select Standard MedDRA Queries for COVID-19

CDC-defined AESIs associated with COVID-19 vaccination were evaluated in the blinded placebo-controlled period of the study, where reported in the Phase 2/3 safety population.

After a review of AEs using the CDC's AESI list, the following terms were not found reported in the study: acute disseminated encephalomyelitis, transverse myelitis, multiple sclerosis, chronic inflammatory demyelinating polyneuropathy, encephalitis, myelitis, encephalomyelitis, meningoencephalitis, ataxia, narcolepsy, cataplexy, immune thrombocytopenia, thrombotic thrombocytopenic purpura, disseminated intravascular coagulation, Kawasaki disease, multisystem inflammatory syndrome in children (MIS-C) and in adults (MIS-A), and acute respiratory distress syndrome.

There were 2 cases of bacterial meningitis reported but they were not analyzed further as there is an immediate and self-evident cause to their illness.

Terms that were present in the safety population are summarized below. For a given SMQ, if there was no imbalance between the BNT162b2 group versus placebo, the PTs within the SMQ were not further examined. In the case of an imbalance, the PTs responsible for the imbalance are further described and the nature of the events characterized with regard to plausible associated with vaccination.

Overall, the number and percentage of participants with any unsolicited AEs within the selected SMQs was similar in the BNT162b2 (224 [1.02%]) and placebo (217 [0.99%]) groups from Dose 1 to the unblinding date (Table 27).

From analysis of terms corresponding to AESIs from the CDC's list, individual SMQs are discussed below.

Table 27. Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=21926)	Placebo (N[a]=21921)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)
	Subjects with any unsolicited adverse events within SMQ	224 (1.02)	217 (0.99)
Angioedema (SMQ)	Any unsolicited adverse events within Angioedema (SMQ)	30 (0.14)	29 (0.13)
	Eye disorders	2 (0.01)	2 (0.01)
	Conjunctival oedema	0	1 (0.00)
	Eye swelling	0	1 (0.00)
	Eyelid oedema	1 (0.00)	0
	Swelling of eyelid	1 (0.00)	0
	Gastrointestinal disorders	6 (0.03)	3 (0.01)
	Gingival swelling	0	1 (0.00)
	Lip oedema	1 (0.00)	0
	Lip swelling	2 (0.01)	1 (0.00)
	Swollen tongue	2 (0.01)	1 (0.00)
	Tongue oedema	1 (0.00)	0
	General disorders and administration site conditions	4 (0.02)	7 (0.03)
	Face oedema	2 (0.01)	0
	Swelling face	2 (0.01)	7 (0.03)
	Respiratory, thoracic and mediastinal disorders	1 (0.00)	3 (0.01)
	Pharyngeal swelling	1 (0.00)	3 (0.01)
	Skin and subcutaneous tissue disorders	21 (0.10)	18 (0.08)
	Angioedema	3 (0.01)	2 (0.01)
	Urticaria	18 (0.08)	15 (0.07)
	Urticaria papular	0	1 (0.00)
Arthritis (SMQ)	Any unsolicited adverse events within Arthritis (SMQ)	35 (0.16)	48 (0.22)
	Infections and infestations	1 (0.00)	0
	Arthritis bacterial	1 (0.00)	0
	Metabolism and nutrition disorders	5 (0.02)	3 (0.01)
	Gout	5 (0.02)	3 (0.01)
	Musculoskeletal and connective tissue disorders	29 (0.13)	45 (0.21)
	Arthritis	6 (0.03)	6 (0.03)
	Arthritis reactive	1 (0.00)	0

Table 27. Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=21926)	Placebo (N[a]=21921)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)
	Osteoarthritis	15 (0.07)	23 (0.10)
	Patellofemoral pain syndrome	0	1 (0.00)
	Periarthritis	4 (0.02)	1 (0.00)
	Polyarthritis	0	1 (0.00)
	Rheumatoid arthritis	0	2 (0.01)
	Spinal osteoarthritis	2 (0.01)	4 (0.02)
	Spondylitis	1 (0.00)	1 (0.00)
	Synovitis	0	2 (0.01)
	Temporomandibular joint syndrome	1 (0.00)	4 (0.02)
Convulsions (SMQ)	Any unsolicited adverse events within Convulsions (SMQ)	2 (0.01)	2 (0.01)
	Nervous system disorders	2 (0.01)	2 (0.01)
	Generalised tonic-clonic seizure	0	1 (0.00)
	Seizure	2 (0.01)	1 (0.00)
Demyelination (SMQ)	Any unsolicited adverse events within Demyelination (SMQ)	2 (0.01)	1 (0.00)
	Nervous system disorders	2 (0.01)	1 (0.00)
	Guillain-Barre syndrome	0	1 (0.00)
	Optic neuritis	2 (0.01)	0
Hypersensitivity (SMQ)	Any unsolicited adverse events within Hypersensitivity (SMQ)	182 (0.83)	161 (0.73)
	Ear and labyrinth disorders	0	1 (0.00)
	Allergic otitis media	0	1 (0.00)
	Eye disorders	5 (0.02)	5 (0.02)
	Conjunctival oedema	0	1 (0.00)
	Conjunctivitis allergic	3 (0.01)	2 (0.01)
	Eye allergy	0	1 (0.00)
	Eye swelling	0	1 (0.00)
	Eyelid oedema	1 (0.00)	0
	Swelling of eyelid	1 (0.00)	0
	Gastrointestinal disorders	6 (0.03)	3 (0.01)
	Gingival swelling	0	1 (0.00)
	Lip oedema	1 (0.00)	0
	Lip swelling	2 (0.01)	1 (0.00)

Table 27. Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=21926)	Placebo (N[a]=21921)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)
	Swollen tongue	2 (0.01)	1 (0.00)
	Tongue oedema	1 (0.00)	0
	General disorders and administration site conditions	8 (0.04)	9 (0.04)
	Application site rash	0	1 (0.00)
	Face oedema	2 (0.01)	0
	Injection site dermatitis	1 (0.00)	0
	Injection site rash	2 (0.01)	1 (0.00)
	Injection site urticaria	1 (0.00)	0
	Swelling face	2 (0.01)	7 (0.03)
	Immune system disorders	10 (0.05)	13 (0.06)
	Anaphylactic reaction	1 (0.00)	0
	Anaphylactic shock	0	1 (0.00)
	Drug hypersensitivity	7 (0.03)	7 (0.03)
	Hypersensitivity	2 (0.01)	5 (0.02)
	Infections and infestations	5 (0.02)	1 (0.00)
	Dermatitis infected	0	1 (0.00)
	Pustule	3 (0.01)	0
	Rash pustular	2 (0.01)	0
	Injury, poisoning and procedural complications	3 (0.01)	0
	Administration related reaction	2 (0.01)	0
	Stoma site rash	1 (0.00)	0
	Investigations	1 (0.00)	0
	Blood immunoglobulin E increased	1 (0.00)	0
	Respiratory, thoracic and mediastinal disorders	19 (0.09)	21 (0.10)
	Allergic respiratory disease	0	1 (0.00)
	Allergic sinusitis	2 (0.01)	0
	Bronchospasm	3 (0.01)	3 (0.01)
	Pharyngeal swelling	1 (0.00)	3 (0.01)
	Rhinitis allergic	13 (0.06)	14 (0.06)
	Skin and subcutaneous tissue disorders	134 (0.61)	119 (0.54)
	Angioedema	3 (0.01)	2 (0.01)
	Dermatitis	5 (0.02)	4 (0.02)
	Dermatitis acneiform	1 (0.00)	0

Table 27. Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=21926)	Placebo (N[a]=21921)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)
	Dermatitis allergic	3 (0.01)	5 (0.02)
	Dermatitis atopic	0	1 (0.00)
	Dermatitis bullous	0	1 (0.00)
	Dermatitis contact	14 (0.06)	21 (0.10)
	Dermatitis exfoliative	1 (0.00)	0
	Drug eruption	0	2 (0.01)
	Eczema	7 (0.03)	3 (0.01)
	Erythema nodosum	1 (0.00)	0
	Fixed eruption	1 (0.00)	0
	Hand dermatitis	2 (0.01)	2 (0.01)
	Perioral dermatitis	0	1 (0.00)
	Pruritus allergic	0	2 (0.01)
	Rash	62 (0.28)	52 (0.24)
	Rash erythematous	2 (0.01)	3 (0.01)
	Rash maculo-papular	7 (0.03)	4 (0.02)
	Rash papular	1 (0.00)	0
	Rash pruritic	8 (0.04)	6 (0.03)
	Urticaria	18 (0.08)	15 (0.07)
	Urticaria contact	0	1 (0.00)
	Urticaria papular	0	1 (0.00)
Peripheral neuropathy (SMQ)	Any unsolicited adverse events within Peripheral neuropathy (SMQ)	3 (0.01)	6 (0.03)
	Nervous system disorders	3 (0.01)	6 (0.03)
	Guillain-Barre syndrome	0	1 (0.00)
	Neuralgia	1 (0.00)	1 (0.00)
	Neuritis	0	1 (0.00)
	Neuropathy peripheral	1 (0.00)	3 (0.01)
	Peripheral sensory neuropathy	1 (0.00)	0

Table 27. Selected Standard MedDRA Queries From Dose 1 to Unblinding Date – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

		Vaccine Group (as Administered)	
		BNT162b2 (30 µg) (N[a]=21926)	Placebo (N[a]=21921)
SMQ	Overall SMQ System Organ Class Preferred Term	n[b] (%)	n[b] (%)

a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects reporting at least 1 occurrence of the specified event category. For "any event," n = the number of subjects reporting at least 1 occurrence of any event.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 14APR2021 (10:22)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA_RR/adae_smq_nzud_16_saf

2.7.4.2.4.3.4.2.1. Angioedema

Overall, the number and percentage of participants with any unsolicited AE within the SMQ of angioedema were low and similar in the BNT162b2 group (30 [0.14%]) and placebo group (29 [0.13%]) (Table 27). AEs were most frequently reported in the SOC of skin and subcutaneous tissue disorders (21 [0.10%] BNT162b2 vs 18 [0.08%] placebo) with urticaria the most frequently reported PT.

In the SOC of gastrointestinal disorders within the SMQ of angioedema, lip edema, or lip swelling was observed in 3 participants in the BNT162b2 group versus 1 participant in the placebo group. Swollen tongue or tongue edema was observed in 3 participants in the BNT162b2 group versus 1 participant in the placebo group. Lip swelling in 1 participant in the BNT162b2 group and swollen tongue in 1 participant in the placebo group were considered as related to the study intervention:

- In the BNT162b2 group, 1 participant experienced mild upper and lower lip swelling 14 and 19 days after Dose 1 which lasted 2 days before resolving and was considered as related to the study intervention. This same participant also experienced upper lip swelling and drug hypersensitivity 2 days after Dose 2, which were recovering/resolving as of the data cutoff date and were considered related to study intervention by the investigator.

- In the placebo group, 1 participant experienced moderate swollen tongue as well as moderate pharyngeal swelling 21 days after Dose 2; both resolved after 9 days; this participant also experienced moderate drug hypersensitivity and mild rash (on chin, elbows, knees, neck and back) 2 days after Dose 2 which lasted for 28 days and 30

days, respectively, and resolved. Swollen tongue as well as these other AEs were all considered related to the study intervention by the investigator.

Narratives for related angioedema SMQ events are provided (see Section 2.7.4.2.4.4). Refer to the following participants:

Subject C4591001 1044 10441139
Subject C4591001 1111 11111099
Subject C4591001 1246 12461025
Subject C4591001 1005 10051214
Subject C4591001 1111 11111092
Subject C4591001 1027 10271105
Subject C4591001 1068 10681066
Subject C4591001 1090 10901507
Subject C4591001 1117 11171121
Subject C4591001 1091 10911274
Subject C4591001 1092 10921123
Subject C4591001 1140 11401035

Angioedema events in the other SMQs were all reported at low percentages in the BNT162b2 (≤0.02) and placebo groups (≤0.03%) (Table 27).

2.7.4.2.4.3.4.2.2. Arthritis

Overall, the number and percentage of participants with any unsolicited AE within the SMQ of arthritis was lower in the BNT162b2 group (35 [0.16%]) than in placebo group (48 [0.22%]) (Table 27). AEs were most frequently reported within the SOC musculoskeletal and connective tissue disorders (0.13% BNT162b2 vs 0.21% placebo) with osteoarthritis the most frequently reported PT.

2.7.4.2.4.3.4.2.3. Convulsions

Overall, the number and percentage of participants with any unsolicited AE within the SMQ of convulsions was low and equal in the BNT162b2 group and placebo group (2 participants [0.01%] in each group) (Table 27). All events were in the SOC of nervous system disorders: seizure (2 participants in the BNT162b2 group) and generalized tonic-clonic seizure (1 participant in the placebo group).

2.7.4.2.4.3.4.2.4. Demyelination

Overall, the number and percentage of participants with any unsolicited AE within the SMQ of demyelination was low: 2 (0.01%) participants in the BNT162b2 group and 1 (0.00%) participant in the placebo group. All events were in the SOC of nervous system disorders.

Optic neuritis was observed in 2 participants in the BNT162b2 group and none in the placebo group; 1 case occurring in a male participant and 1 case occurring in a female participant. Both participants were in the younger age group. These events occurred 79 and 81 days after their last vaccination of BNT162b2. Both were considered not related to BNT162b2. Both events were reported as SAEs. Narratives for optic neuritis cases (Subject C4591001 1008 10081152 and Subject C4591001 1231 12313028) are provided (see Section 2.7.4.2.4.4).

Guillain-Barre syndrome was reported as an SAE in 1 participant (Subject C4591001 1135 11351368) in the placebo group (see Section 2.7.4.2.4.4 regarding narrative).

These events of optic neuritis and Guillain-Barre syndrome are also included in safety analyses by medical category (SMQ and SOC) in Section 2.7.4.2.4.3.4.3.

2.7.4.2.4.3.4.2.5. Hypersensitivity

Overall, the number and percentage of participants with any unsolicited AE within the SMQ of hypersensitivity was higher in the BNT162b2 group (182 [0.83%]) than in the placebo group (161 [0.73%]) (Table 27).

The difference was mainly due to:

Skin and subcutaneous tissue disorders (134 [0.61%] BNT162b2 vs 119 [0.54%] placebo):

- rash (62 [0.28%] BNT162b2 vs 52 [0.24%] placebo)
- rash maculo-papular (7 [0.03%] BNT162b2 vs 4 [0.02%] placebo)
- rash papular (1 [0.00%] BNT162b2 vs 0 placebo)

Rash was assessed as related to study intervention at a higher IR in the BNT162b2 group (0.3) than in the placebo group (0.1).

In the SMQ of hypersensitivity in the SOC of infections and infestations: pustule and rash pustular were reported only in the BNT162b2 group by 3 (0.01%) and 2 (0.01%) participants, respectively. In the SOC of injury, poisoning and procedural complications, administration related reaction (2 participants) and stoma site rash (1 participant) were reported only in the BNT162b2 group.

Additionally, in the SMQ of hypersensitivity in the SOC of gastrointestinal disorders, lip edema, lip swelling, swollen tongue, and tongue edema were observed more frequently in the BNT162b2 group versus the placebo group. Refer to the Angioedema section (Section 2.7.4.2.4.3.4.2.1) for details.

Anaphylactic reaction was observed in 1 participant in the BNT162b2 group (refer to Section 2.7.4.2.4.3.4.1.1 for more detail).

In the SMQ of hypersensitivity in the SOC of investigations, increased blood IgE was observed in 1 participant in the BNT162b2 group.

2.7.4.2.4.3.4.2.6. Peripheral Neuropathy

Overall, the number and percentage of participants with any unsolicited AE within the SMQ of peripheral neuropathy was lower in the BNT162b2 group (3 [0.01%]) than in the placebo group (6 [0.03%]). All PTs were in the SOC of nervous system disorders (Table 27).

2.7.4.2.4.3.4.3. Other Non-CDC Adverse Events of Special Interest – Select Standard MedDRA Queries for COVID-19

Additional terms beyond those designated by the CDC as AESIs were evaluated to assess potential imbalances between the BNT162b2 and placebo groups, and further characterized such an imbalance. PTs associated with these AE categories and by SOC/PT were identified during the blinded placebo-controlled follow-up period (Table 28). These events are summarized below.

Table 28. Incidence Rates of at Least 1 Adverse Event Category of Special Interest From Dose 1 to Unblinding Date, by Adverse Event Category and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)			Difference	
Adverse Event Category Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])	IRD (/100 PY)[f]	(95% CI[g])
ACUTE MYOCARDIAL INFARCTION								
Acute coronary syndrome	1	0.0	(0.0, 0.1)	4	0.0	(0.0, 0.1)	-0.04	(-0.09, 0.02)
Acute myocardial infarction	6	0.1	(0.0, 0.2)	4	0.0	(0.0, 0.1)	0.02	(-0.05, 0.10)
Coronary artery occlusion	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Myocardial infarction	4	0.0	(0.0, 0.1)	8	0.1	(0.0, 0.2)	-0.05	(-0.13, 0.03)
ANAPHYLAXIS								
Anaphylactic reaction	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
Anaphylactic shock	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
APPENDICITIS								
Appendicitis	14	0.2	(0.1, 0.3)	9	0.1	(0.1, 0.2)	0.06	(-0.06, 0.17)
Appendicitis perforated	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	-0.00	(-0.03, 0.03)
Complicated appendicitis	0	0.0	(0.0, 0.0)	2	0.0	(0.0, 0.1)	-0.02	(-0.06, 0.01)
ARTHRITIS/ARTHRALGIA								
Arthralgia	281	3.4	(3.0, 3.8)	122	1.5	(1.2, 1.8)	1.88	(1.41, 2.36)
Arthritis	6	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)	-0.00	(-0.08, 0.08)
Arthritis reactive	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
BELL'S PALSY								
Facial paralysis	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.04	(-0.02, 0.09)
Facial paresis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
COVID-19 DISEASE								
COVID-19	0	0.0	(0.0, 0.0)	13	0.2	(0.1, 0.3)	-0.16	(-0.24, -0.07)
COVID-19 pneumonia	1	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	-0.00	(-0.03, 0.03)
DEATH								
Death	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
ENCEPHALOPATHY								
Toxic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
Uraemic encephalopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
GUILLAIN-BARRE SYNDROME								
Guillain-Barre syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)

Table 28. Incidence Rates of at Least 1 Adverse Event Category of Special Interest From Dose 1 to Unblinding Date, by Adverse Event Category and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)			Difference	
Adverse Event Category Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])	IRD (/100 PY)[f]	(95% CI[g])
MULTISYSTEM INFLAMMATORY SYNDROME IN CHILDREN (MIS-C) AND IN ADULTS (MIS-A)								
Multiple organ dysfunction syndrome	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
MYOCARDITIS								
Myocarditis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
NON-ANAPHYLACTIC ALLERGIC REACTIONS								
Angioedema	3	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)	0.01	(-0.04, 0.06)
Hypersensitivity	2	0.0	(0.0, 0.1)	5	0.1	(0.0, 0.1)	-0.04	(-0.10, 0.03)
Lip swelling	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.01	(-0.03, 0.05)
Pruritus	24	0.3	(0.2, 0.4)	20	0.2	(0.1, 0.4)	0.04	(-0.11, 0.20)
Rash	62	0.7	(0.6, 1.0)	52	0.6	(0.5, 0.8)	0.11	(-0.14, 0.36)
Rash pruritic	8	0.1	(0.0, 0.2)	6	0.1	(0.0, 0.2)	0.02	(-0.07, 0.11)
Swelling face	2	0.0	(0.0, 0.1)	7	0.1	(0.0, 0.2)	-0.06	(-0.13, 0.01)
Swollen tongue	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.01	(-0.03, 0.05)
Urticaria	18	0.2	(0.1, 0.3)	15	0.2	(0.1, 0.3)	0.03	(-0.10, 0.17)
OPTIC NEURITIS								
Optic neuritis	2	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.02	(-0.01, 0.06)
PERICARDITIS								
Pericarditis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
PULMONARY EMBOLISM								
Pulmonary embolism	8	0.1	(0.0, 0.2)	8	0.1	(0.0, 0.2)	-0.00	(-0.10, 0.09)
SEIZURE/CONVULSION								
Generalised tonic-clonic seizure	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Seizure	2	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.01	(-0.03, 0.05)
STROKE, HEMORRHAGIC								
Haemorrhagic stroke	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Intraventricular haemorrhage	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Subarachnoid haemorrhage	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.04	(-0.02, 0.09)
STROKE, ISCHEMIC								

Table 28. Incidence Rates of at Least 1 Adverse Event Category of Special Interest From Dose 1 to Unblinding Date, by Adverse Event Category and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)			Difference	
Adverse Event Category Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])	IRD (/100 PY)[f]	(95% CI[g])
Cerebellar infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Cerebral infarction	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Cerebrovascular accident	4	0.0	(0.0, 0.1)	1	0.0	(0.0, 0.1)	0.04	(-0.02, 0.09)
Ischaemic stroke	2	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)	-0.00	(-0.05, 0.05)
Transient ischaemic attack	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)	-0.01	(-0.07, 0.04)
THROMBOCYTOPENIA								
Platelet count decreased	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
Thrombocytopenia	1	0.0	(0.0, 0.1)	2	0.0	(0.0, 0.1)	-0.01	(-0.05, 0.03)
VACCINATION DURING PREGNANCY AND ADVERSE PREGNANCY OUTCOMES								
Abortion incomplete	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Abortion spontaneous	2	0.0	(0.0, 0.1)	3	0.0	(0.0, 0.1)	-0.01	(-0.07, 0.04)
Abortion spontaneous incomplete	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Exposure during pregnancy	30	0.4	(0.2, 0.5)	42	0.5	(0.4, 0.7)	-0.15	(-0.35, 0.05)
Retained products of conception	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
VENOUS THROMBOEMBOLISM								
Coagulopathy	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
Deep vein thrombosis	7	0.1	(0.0, 0.2)	7	0.1	(0.0, 0.2)	-0.00	(-0.09, 0.09)
Ophthalmic vein thrombosis	1	0.0	(0.0, 0.1)	0	0.0	(0.0, 0.0)	0.01	(-0.01, 0.04)
Penile vein thrombosis	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)
Venous thrombosis limb	0	0.0	(0.0, 0.0)	1	0.0	(0.0, 0.1)	-0.01	(-0.04, 0.01)

Table 28. Incidence Rates of at Least 1 Adverse Event Category of Special Interest From Dose 1 to Unblinding Date, by Adverse Event Category and Preferred Term – Blinded Placebo-Controlled Follow-up Period – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)							
	BNT162b2 (30 µg) (N[a]=21926, TE[b]=83.4)			Placebo (N[a]=21921, TE[b]=82.2)			Difference	
Adverse Event Category Preferred Term	n[c]	IR (/100 PY)[d]	(95% CI[e])	n[c]	IR (/100 PY)[d]	(95% CI[e])	IRD (/100 PY)[f]	(95% CI[g])

Note: MedDRA (v23.1) coding dictionary applied.
Note: The 95% confidence interval quantifies the precision of the incidence rate difference estimate. Confidence intervals are not adjusted for multiplicity. They should only be used to identify potentially important adverse events.
a. N = number of subjects in the specified group.
b. TE = total exposure time in 100 person-years across all subjects in the specified group. Exposure time for a subject is the time from Dose 1 to the end of blinded follow-up. This value is the denominator for the incidence rate calculation.
c. n = Number of subjects reporting at least 1 occurrence of the specified event.
d. Incidence rate (IR) is calculated as number of subjects reporting the event/total exposure time in 100 person-years (PY) across all subjects in the specified group.
e. 2-sided CI based on Poisson distribution.
f. Difference in incidence rate (BNT162b2 [30 µg] - placebo).
g. 2-sided Wald CI for the incidence rate difference.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (20:15) Source Data: adae Table Generation: 16APR2021 (13:49)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA1/adae s131 aesi cat p3 saf

Acute Myocardial Infarction

Acute myocardial infarctions were searched with the PTs of acute myocardial infarction, acute coronary syndrome, coronary artery occlusion, and myocardial infarction. A total of 6 acute myocardial infarctions, 4 myocardial infarctions and 1 acute coronary syndrome (total of 11 events) were identified in the BNT162b2 group, and 4 acute myocardial infarctions, 8 myocardial infarctions, 4 acute coronary syndrome, and 1 coronary artery occlusion in the placebo group (total of 17 events), respectively. Slightly more than half of these events had onset distant to (ie, >30 days following) receipt of vaccine or placebo . None of these events were assessed by the investigator as related to study intervention . Outcome was resolved in all participants in the BNT162b2 group; outcome in the placebo group was fatal in 2 and resolved in the other participants.

Anaphylaxis

Overall, the category of anaphylaxis included 1 participant with anaphylactic reaction in the BNT162b2 group and 1 participant with anaphylactic shock in the placebo group. These events are further described in Section 2.7.4.2.4.3.4.1.1.

Appendicitis

Overall, the category of appendicitis (including appendicitis perforated and complicated appendicitis) included 15 participants in the BNT162b2 group and 12 participants in the placebo group. These events are further described in Section 2.7.4.2.4.3.4.1.4.

Arthritis/Arthralgia

Arthralgia not associated with reactogenicity was evaluated starting from Day 8 after either dose of BNT162b2. The IR of arthralgia assessed from Day 8 (ie, beyond the 7-day reactogenicity period in which arthralgia is recorded in e-dairies for the reactogenicity subset) after each dose was lower in the BNT162b2 group (0.6) than in the placebo group (0.8).

Autoimmune Disease

There are no search term SMQ that would reliably capture all potential autoimmune diseases. Hence a comprehensive manual medical review of all reported AEs in the blinded placebo-controlled period was undertaken to identify PTs potentially indicative of autoimmune disease. These PTs are summarized by vaccine group.

In the BNT162b2 group there were 10 autoimmune disease cases identified. There were 1 case each in the BNT162b2 group: autoimmune thyroiditis, ulcerative colitis, Crohn's disease, reactive arthritis, fibromyalgia, systemic lupus erythematosus, alopecia areata, psoriasis, and 2 cases of psoriatic arthropathy.

In the placebo group there were 15 autoimmune cases identified. There were 1 case each in the placebo group: autoimmune thyroiditis, celiac disease, alopecia areata, psoriasis, Raynaud's phenomenon, and 2 cases of psoriatic arthropathy, 2 cases of psoriasis, 2 cases of ulcerative colitis, 2 cases of rheumatoid arthritis, 3 cases of fibromyalgia.

Bell's Palsy/Facial Paralysis

Overall, the category of Bell's Palsy (facial paralysis and facial paresis) included 4 participants in the BNT162b2 group and 2 participants in the placebo group. These events are further described in Section 2.7.4.2.4.3.4.1.2.

Multiple Cases of COVID-19

There were 5 participants, all randomized to placebo, who developed 2 separate and clinically symptomatic instances of COVID-19 confirmed by NAAT at the central laboratory. All of the second confirmed COVID-19 cases occurred during the period before their first dose of BNT162b2 except for 1 participant (Subject 12211002) who developed his second COVID-19 diagnosis 4 days after his second dose of BNT162b2. All participants were N binding antibody negative prior to their first instance of COVID-19. The time interval between the first and second COVID-19 episode varied from 1 to 5 months. Narratives for these cases are provided in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 14 COVID-19 Case (Severe and/or Multiple).

Death

One death in the placebo group was captured as a potential AESI as there was no reported primary cause of death at the time of the data cutoff. A narrative is provided (see Section 2.7.4.2.4.4 [Subject C4591001 1152 11521085]). This death is also captured in Table 16 in the analysis of deaths reported from Dose 1 to the unblinding date (Section 2.7.4.2.4.3.1).

Encephalopathy

Overall, the category of encephalopathy included 2 participants in the BNT162b2 group and none in the placebo group. One participant reported an SAE of toxic encephalopathy 64 days after Dose 2 in the setting of diverticulosis and a urinary tract infection, which resolved 8 days later, and the other participant reported an SAE of uraemic encephalopathy 36 days after Dose 2, which resolved 3 days later. Both events were assessed by the investigator as not related to study intervention.

Guillain-Barre Syndrome

One participant in the placebo group reported an SAE of Guillain-Barre syndrome. This case was also captured as a CDC AESI in Section 2.7.4.2.4.3.4.2.

Multisystem Inflammatory Syndrome

One participant in the placebo group reported an SAE of multiple organ dysfunction syndrome.

Myocarditis

One case in the placebo group was reported.

Non-Anaphylactic Allergic Reactions

Overall, there was no imbalance in each of the PTs in non-anaphylactic allergic reactions (123 in the BNT162b2 group and 109 in the placebo group) (Table 28). Selected events are also captured as CDC AESIs under SMQ of Angioedema and Hypersensitivity in Section 2.7.4.2.4.3.4.2.

Optic Neuritis

Two participants in the BNT162b2 group reported an SAE each of optic neuritis. This case was also captured as a CDC AESI in Section 2.7.4.2.4.3.4.2.

Pericarditis

There was 1 participant in the older BNT162b2 age group with pericarditis. The event had an onset of 28 days after Dose 2, was ongoing at the data cutoff date, and was assessed by the

investigator as not related to the study intervention. A narrative for this event is provided (see Section 2.7.4.2.4.4 [Subject C4591001 1231 12315632]).

Pulmonary Embolism

PTs associated with pulmonary embolism were searched in the blinded placebo-controlled period: Pulmonary embolism, Pulmonary thrombosis, Pulmonary venous thrombosis, and Pulmonary artery thrombosis. There were 8 cases of pulmonary embolism in the BNT162b2 group and 8 cases in the placebo group.

Stroke, Hemorrhagic

PTs associated with hemorrhagic stroke were searched in the blinded placebo-controlled follow-up period: Haemorrhagic stroke, Cerebral haemorrhage, Haemorrhagic cerebral infarction, Basal ganglia haemorrhage, Brain stem haemorrhage, Cerebellar haemorrhage, subarachnoid hemorrrhage, and Intraventricular hemorrhage.

Overall, there were 4 hemorraghic strokes in the BNT162b2 and 3 in the placebo group. In the BNt162b2 group there were 4 subarachnoid haemorrhages and in the placebo group there was 1 subarachnoid haemorrhage, 1 intraventricular haemorrhage, and 1 haemorrhagic stroke (Table 28). Narratives for these events are provided (see Section 2.7.4.2.4.4). Refer to the following participants:

Subject C4591001 1111 11111130
Subject C4591001 1226 12261571
Subject C4591001 1042 10421166
Subject C4591001 1054 10541173
Subject C4591001 1156 11561001
Subject C4591001 1090 10901175
Subject C4591001 1231 12313972

Stroke, Ischemic

PTs associated with ischemic stroke were searched in the blinded placebo-controlled follow-up period: Ischaemic stroke, Ischaemic cerebral infarction, Cerebral infarction, Lacunar infarction, Cerebral ischaemia, Cerebellar stroke, Brain stem stroke, Vertebrobasilar stroke, Embolic stroke, Thrombotic stroke, Thrombotic and cerebral infarction, Cerebral vascular accident, transient ischemic attack, and Cerebellelar infarction.

There are a total of 8 of these PTs in the BNt162b2 group and 8 in the placebo group. There were 2 ischemic strokes, 4 cerebral vascular accidents, 2 transient ischemic attacks identified in the BNT162b2 group. In the placebo group there are 2 ischemic strokes, 3 transient ischemic attacks, 1 cerebral vascular accident, 1 cerebral infarction and 1 cerebellar infarction.

Thrombocytopenia

PTs associated with thrombocytopenia were searched in the blinded placebo-controlled period and included Thrombocytopenia and platelet count decreased. The BNT162b2 group

had 1 case of thrombocytopenia and 1 case of platelet count decreased, and the placebo group had 2 cases of thrombocytopenia.

Vaccination During Pregancy and Pregnancy Outcomes

There was no imbalance between the BNT162b2 group versus the placebo group with regard to pregnancy and maternal exposure. Pregnancy and maternal exposure reported during the study is discussed in Section 2.7.4.2.4.3.6.2. Narratives for these events are provided (see Section 2.7.4.2.4.4).

Venous Thromboembolism

PTs associated with venous thromboembolism were searched in the blinded placebo-controlled period: Cerebral venous sinus thrombosis, Cerebral venous thrombosis, Cerebral thrombosis, Superior sagittal sinus thrombosis, Deep vein thrombosis, Venous thrombosis limb, Retinal vein thrombosis, Retinal vein occlusion, Mesenteric vein thrombosis, Thrombosis mesenteric vessel, Splenic thrombosis, Splenic vein thrombosis, Splenic embolism, Visceral venous thrombosis, Hepatic vein thrombosis, Hepatic vein embolism, Vena cava thrombosis, Vena cava embolism, Renal vein thrombosis, Renal vein embolism, Venous thrombosis, Thrombosis, Embolism, and Thrombotic microangiopathy.

Overall, there were 9 thrombotic events in the BNT162b2 group and 9 in the placebo group. In the BNT162b2 group included 7 deep vein thromboses, 1 coagulopathy, and 1 ophthalmic vein thrombosis and in the placebo group included 7 deep vein thromboses, 1 penile vein thrombosis, and 1 venous thrombosis limb (Table 28) . None of the venous events were associated with thrombocytopenia.

2.7.4.2.4.3.4.4. Narratives of Other Significant Adverse Events (Phase 3, Study C4591001)

Narratives of other significant AEs for Phase 3 participants through the data cutoff date (13 March 2021) are provided (see Section 2.7.4.2.4.4).

2.7.4.2.4.3.5. Analysis of Adverse Events by Organ System or Syndrome (Phase 3, Study C4591001)

Safety data from Phase 3 of Study C4591001 were reviewed and Adverse Reactions (ADRs) – adverse events for which there is reason to conclude that the vaccine caused the event - were identified. The review included AE data, as well as local reactions and systemic events collected systematically by e-diaries. The CIOMS frequency categories for adverse reactions are as follows:

- Very common: ≥10%
- Common: ≥1% and <10%
- Uncommon: ≥0.1% and <1%
- Rare: ≥0.01% and <0.1%
- Very rare: <0.01%

Reactogenicity ADRs that occurred with a very common frequency, based on any dose in the BNT162b2 group, from the reactogenicity subset of data as of 13 March 2021, are:

- Injection site pain: 4153/4924 (84.3%)
- Fatigue: 3185/4924 (64.7%)
- Headache: 2814/4924 (57.1%)
- Muscle pain: 1980/4924 (40.2%)
- Chills: 1707/4924 (34.7%)
- Joint pain: 1232/4924 (25.0%)
- Fever: 749/4924 (15.2%)
- Injection site swelling: 546/4924 (11.1%)

A reactogenicity ADR that occurred with a common frequency, based on any dose in the BNT162b2 group from the reactogenicity subset of data as of 13 March 2021, was injection site redness:

- Injection site redness: 486/4924 (9.9%)

ADRs considered as common (nausea) and uncommon (lymphadenopathy and malaise) in the BNT162b2 group were identified from AE data in the safety population as of 13 March 2021, compared to placebo for reference:

- Nausea: 274/21,926 (1.2%) in the BNT162b2 group vs 87/21,921 (0.4%) in the placebo group

- Lymphadenopathy: 83/21,926 (0.4%) in the BNT162b2 group vs 7/21,921 (0.0%) in the placebo group

- Malaise: 130/21,926 (0.6%) in the BNT162b2 group vs 22/21,921 (0.1%) in the placebo group

The following additional ADRs were identified in the post-authorization setting. Frequencies for these ADRs were obtained from clinical trial data (Study C4591001) when possible, as per labeling guidance.

- Diarrhea (very common)
- Vomiting (common)
- Pain in Extremity (uncommon)
- Rash (uncommon)
- Pruritus (uncommon)
- Urticaria (uncommon)
- Angioedema (rare)
- Anaphylaxis (unknown)

It should be noted that at the time of conditional approval of BNT162b2 by EMA, the sponsor was asked to include the following as ADRs in the SmPC even though they were not

considered ADRs in the Core Data Sheet (CDS). The frequencies in the initial EMA-approved SmPC reflected data from the initial conditional approval submission (data cutoff date: 14 November 2020):

- Acute peripheral facial paralysis 3/18801 = 0.02% (rare)
- Injection site pruritus 27/18801 = 0.1% (uncommon)
- Insomnia 23/18801 = 0.1% (uncommon)

The following ADRs have been identified from the clinical study data and are supported by reports in the post-authorization setting. The CIOMS frequency category for these reactions is uncommon (based on clinical trial data [Study C4591001]): lethargy, asthenia, decreased appetite, hyperhidrosis, and night sweats. These ADRs will be added to the CDS and subsequently proposed for all BNT162b2 labels. The additional ADRs further characterize the safety profile of BNT162b2 but do not impact its favorable risk:benefit profile.

2.7.4.2.4.3.6. Other Safety Assessments (Phase 3, Study C4591001)

2.7.4.2.4.3.6.1. Severe COVID-19 Illness (Phase 3, Study C4591001)

The protocol had prespecified stopping rules that included monitoring of severe COVID-19 cases, and these stopping criteria were not met. The confinement of the majority of severe cases to the placebo groups suggests no evidence for vaccine-associated enhanced disease (VAED) including vaccine-associated enhanced respiratory disease (VAERD).

A description of severe COVID-19 cases evaluated for efficacy in Phase 2/3 is presented in Sections 11.1.1.3 and 11.1.2.3.2 of the final analysis interim CSR (Module 5.3.5.1 C4591001 Efficacy Final Analysis Interim CSR). A description of severe COVID-19 cases in the updated analysis of efficacy in Phase 2/3 is presented in Section 11.1.2.2.1 of the 6-Month Update CSR (Module 5.3.5.1 C4591001 6-Month Update CSR).

2.7.4.2.4.3.6.2. Pregnancy (Phase 3, Study C4591001)

At the time of the data cutoff date (13 March 2021), a total of 50 participants who had received BNT162b2 had reported pregnancies, including 42 participants originally randomized to the BNT162b2 group and 8 participants originally randomized to the placebo group who then received BNT162b2. In total, 12 participants (n=6 each in the randomized BNT162b2 and placebo groups) withdrew from the blinded placebo-controlled vaccination period of the study due to pregnancy, and 4 participants originally randomized to placebo who then received BNT162b2 withdrew from the open-label vaccination period due to pregnancy (Table 31). These participants continue to be followed for pregnancy outcomes.

Narratives for participants who reported a pregnancy during the study, including any reported outcomes, are provided (see Section 2.7.4.2.4.4).

2.7.4.2.4.4. Narratives (Phase 3, Study C4591001)

Narratives for Phase 3 participants (including for deaths, SAEs, AEs leading to withdrawal, other significant AEs, COVID-19 cases, and pregnancies) are provided in Module 5.3.5.1 C4591001 6-Month Update Interim CSR Section 14.

2.7.4.2.4.5. Conclusions (Phase 3, Study C4591001)

Based on Phase 2/3 data from approximately 44,000 participants ≥16 years of age with up to at least 6 months of follow-up after Dose 2 in Study C4591001, BNT162b2 at 30 µg was safe and well-tolerated across age groups. Reactogenicity AEs were generally milder and less frequent in participants in the older group (>55 years of age) compared with the younger group (≤55 years of age). Reactogenicity was mostly mild to moderate and short-lived after dosing for both younger and older age groups (ie, median onset between 1 to 3 days after dosing and resolution within 1 to 2 days after onset). The incidence of SAEs and deaths were low in the context of the number of participants enrolled and comparable between BNT162b2 and placebo. The incidence of discontinuations due to AEs was also generally low and similar between BNT162b2 and placebo groups.

Cumulative safety follow-up to at least 6 months after Dose 2 for approximately 12,000 Phase 2/3 participants originally randomized to BNT162b2, comprising the combined blinded and open-label periods, showed no new safety signals or suggested any new safety concerns arising from longer-term follow-up.

Similarly, open-label follow-up of participants originally randomized to placebo from the time of unblinding to receive BNT162b2 until the data cutoff date showed no new safety signals or concerns.

Safety analysis results for subgroups based on demographics (age, race, ethnicity) and by baseline SARS-CoV-2 positive versus negative status have not shown any clinically important differences in the BNT162b2 safety profile. Analysis of the subset of individuals with stable HIV did not suggest any safety concerns in this population. Analysis of participants originally randomized to placebo who then received BNT162b2 (Dose 3) by demographic subgroups and based on prior evidence of SARS-CoV-2 infection or prior COVID-19 did not suggest any safety concerns.

Phase 2/3 safety data were generally concordant with safety data in Phase 1 of the study, both overall and with regard to younger and older participants.

2.7.4.2.5. Discussion

Safety data in the Phase 1 BNT162b2 30 µg groups of younger and older adults, evaluated up to approximately 6 months after Dose 2, continue to support the safety and tolerability profile of BNT162b2.

In the Phase 2/3 portion of the study, safety data in participants ≥16 years of age are available for ~44,000 participants, of which ~12,000 had a total exposure time of ≥6 months after Dose 2 of BNT162b2 at the time of the data cutoff date (13 March 2021). The prompted local and systemic reactogenicity profile was consistent with results previously reported in the final analysis interim C4591001 CSR dated 03 December 2020. Increases in systemic reactogenicity were observed after Dose 2 compared with after Dose 1. Older adults generally reported milder and lower frequencies of local and systemic reactogenicity events compared with younger adults. Most prompted local and systemic reactogenicity events were short-lived, and only 1 Grade 4 event of fever lasting 1 day was reported. Median onset

day for most local and systemic reactions occurred within the first 3 days following vaccination and resolved with median durations within 3 days without sequela. This pattern of reactogenicity is also observed in participants with stable HIV infection.

The Phase 2/3 AE profile of BNT162b2 at 30 µg was also consistent with results previously reported in the final analysis interim C4591001 CSR dated 03 December 2020. During the blinded placebo-controlled follow-up period, AEs from Dose 1 to 1 month after Dose 2 and from Dose 1 to the unblinding date of AEs were mostly mild or moderate with higher frequencies/IRs in the BNT162b2 group than in the placebo group. Since many AEs were in SOCs that contain AEs consistent with reactogenicity events, an analysis of AEs within 7 days after each dose showed that the AEs during this time period in the BNT162b2 group were largely attributed to reactogenicity events. For participants who did not have an e-diary, they reported their experience as AEs. As such they were not prompted to report specific terms within 7 days after either dose. The analysis of AEs reported in the placebo-controlled period of the study identified several terms that are reported more frequently in the vaccine group than placebo. These include pain in the extremity, decreased appetite, lethargy, asthenia, malaise, night sweats and hyperhidrosis. The majority of the events started soon after vaccination and for most of these events the rates were higher after Dose 2 than Dose 1. This suggest that these terms describe the participants' unprompted experience of reactogenicity within 7 days after each dose.

Cumulative safety data for 12,006 Phase 2/3 participants with at least 6 months follow-up after Dose 2 for participants originally randomized to BNT162b2, comprising the combined blinded and open-label periods, showed no new safety signals arising from longer-term follow-up. Importantly, the additional follow-up time allowed for more opportunity to collect SAEs. However, related SAEs did not increase during this time period and it remained very low.

Similarly, open-label observational follow-up of original BNT162b2 participants after unblinding and original placebo participants who then received BNT162b2 after unblinding showed no new safety signals or concerns.

CDC-defined AESIs were evaluated in the blinded placebo-controlled follow-up period. MedDRA search terms were used to identify AE that fit the medical concept and then the resultant events were evaluated for numerical imbalances where the events were higher in the vaccine group than placebo and then narratives were provide only for those AESIs with the numerical imbalance.

The analysis showed that most AESI are reported in higher numbers in the placebo group or were equal between vaccine and placebo. The allergic reactions evaluation did not identify anaphylactic reactions associated with the vaccine. Note, there was an anaphylactoid reaction reported 2 days after receiving open-label BNT162b2 (Dose 3) in an originally placebo-randomized participant who was unblinded to receive BNT162b2, and who had a significant ongoing medical history of drug hypersensitivity and other allergies. For angioedema the frequencies were low and very similar in the BNT162b2 (0.14%) and placebo (0.13%) groups. For hypersensitivity reactions most of the reactions were due to rash, rash maculo-papular, and rash papular and were not reported within 7 days after either dose. Overall, the

evaluation of cases reporting allergic reactions supports standard precautions for allergic reactions should be taken in the clinic when vaccinating.

There were 2 cases of optic neuritis reported in the vaccine group that occurred 79 and 81 days after vaccination with BNT162b2. Both were considered not related to vaccine. Given the few number of events, non-proximity to vaccination and investigators judgment, there is not enough information to assess causality at this time.

AESI evaluations were performed for blinded placebo-controlled follow-up. There were 4 cases of Bell's palsy reported in the BNT162b2 group (previously reported in the final analysis interim C4591001 CSR dated 03 December 2020). Since then there have been 2 additional cases in the placebo group during blinded placebo-controlled follow-up, and there have been 4 additional cases of Bell's palsy identified during the open-label follow up period that are included for completeness: 3 cases in placebo participants who became unblinded and were then vaccinated with BNT162b2, and 1 participant who was originally randomized to BNT162b2, was unblinded, and developed Bell's palsy 154 days after the second dose of BNT162b2.

There were 2 cases of encephalopathy in the vaccine group and none in the placebo. Both cases had clear etiologic causes (uremia and toxic encephalopathy after a fall with hypotension, diverticulum, and a urinary tract infection) and hence are not associated with the vaccine.

SAEs assessed by the investigator as related to study intervention were:

- 5 SAEs total during blinded placebo-controlled follow-up: 3 SAEs (lymphadenopathy, shoulder injury related to vaccine administration [SIRVA], and ventricular arrhythmia) in the BNT162b2 group from Dose 1 to 1 month after Dose 2, and 2 SAEs (paraesthesia [BNT162b2 group] and psoriatic arthropathy [placebo]) to the unblinding date.

- 2 SAEs total during open-label follow-up: 1 SAE of myocardial infarction in 1 original BNT162b2 participant and 1 SAE of anaphylactoid reaction in 1 original placebo participant who then received BNT162b2.

During blinded placebo-controlled follow-up, there were a total of 15 deaths in the BNT162b2 group and 14 deaths in the placebo group, with 3 and 5 deaths occurring from Dose 1 to 1 month after Dose 2 in the BNT162b2 and placebo groups, respectively. Of these, there were 2 deaths in participants (1 BNT162b2 and 1 placebo) with confirmed stable HIV disease.

During the open-label follow-up period, there were 3 deaths in original BNT162b2 participants and 2 deaths in original placebo participants who then received BNT162b2.

None of the deaths were assessed by the investigator as related to study intervention.

Subgroup analyses by baseline SARS-CoV-2 status, ethnicity, race, and sex did not reveal any clinically meaningful differences in safety results. Analysis of participants originally

randomized to placebo who then received BNT162b2 (Dose 3) by demographic subgroups and based on prior evidence of SARS-CoV-2 infection or prior COVID-19 did not suggest any safety concerns. Importantly, there were 5 cases of individuals randomized to placebo who developed COVID-19 twice (ie, a new clinical episode with different symptoms and separated by at least a month apart confirmed by NAAT by the central laboratory). Each of these participants received BNT162b2 after unblinding without reported safety events. Taken together individuals who had evidence of infection with SARS-CoV-2 at baseline or developed COVID-19 once or twice before receiving BNT162b2 tolerated the vaccine well.

Overall, the available evidence up to 6 months of follow-up from the Phase 2/3 pivotal study continues to support the safety and tolerability of BNT162b2 at 30 µg administered as a 2-dose regimen (21 days apart) to individuals ≥16 years of age for the prevention of COVID-19.

2.7.4.3. Safety in Special Groups and Situations

2.7.4.3.1. Intrinsic Factors

2.7.4.3.1.1. Geriatric Use

Clinical studies of BNT162b2 (30 µg) include participants 65 years of age and older and their data contributes to the overall assessment of safety and efficacy.

The ongoing pivotal Study C4591001 has enrolled participant groups >65 years of age as an older 65-85 years of age cohort during the Phase 1 dose-finding portion of the study and in the >55 years of age stratum in the larger Phase 2/3 portion of the study. Safety data analyses have described the clinical outcomes for these older adults in the Phase 1 portion of the study (Section 2.7.4.2.2), which was subsequently confirmed in the Phase 2 portion of the study (Section 2.7.4.2.3), joined by pivotal safety data including older adults in Phase 3 (Section 2.7.4.2.4).

Descriptive differences between older and younger adults have been observed in all phases; namely, that older adults tend to have milder and less frequent reactogenicity events, which are generally known to be commonly age-related. Overall, available clinical data demonstrate a predominantly mild reactogenicity profile in older adults.

At the time of this application, vaccine safety in elderly individuals is evident from the totality of clinical safety data.

2.7.4.3.1.2. Pediatric Use

Further study of pediatric use of the vaccine and/or immunobridging study will be undertaken to characterize the vaccine response in children.

2.7.4.3.1.3. Use in Immunocompromised Individuals

Individuals who are immunocompromised or taking immunosuppressive therapy at the time of vaccine administration may have diminished response to immunization. Pivotal Study C4591001 included enrollment of individuals with medical history of immunocompromised

medical condition or immunosuppressive therapy (Section 2.7.4.1.1.2.3). There are limited data on the safety of the vaccine in this patient population at the time of this application.

2.7.4.3.2. Extrinsic Factors

Not applicable.

2.7.4.3.3. Drug Interactions

Refer to Module 5.3.5.1 C4591001 Protocol Section 6.5 for details regarding prior and concomitant vaccines, medications and procedures that were allowed or prohibited.

2.7.4.3.4. Use in Pregnancy and Lactation

Study BNT162-01

There were no pregnancies reported through the data cutoff date of 13 August 2020.

Study C4591001

Women who were pregnant or breastfeeding were not eligible to participate in Study C4591001 (Section 2.7.4.1.1.2.3). At the time of the most recent data cutoff in Study C4591001 (13 March 2021), a total of 50 participants had reported pregnancies in the safety database. Further details are provided in Section 2.7.4.2.4.3.6.2. These participants continue to be followed for pregnancy outcomes.

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. Available data on BNT162b2 administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. In a DART study, no vaccine-related adverse effects on female fertility, fetal development, or postnatal development were reported.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for vaccination with BNT162b2 and any potential adverse effects on the breastfed child from BNT162b2 or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

Narratives for pregnancy are provided (Section 2.7.4.2.4.3.6).

2.7.4.3.5. Overdose

In Study C4591001, any dose of study intervention greater than 30 µg within a 24-hour time period was considered an overdose (refer to Module 5.3.5.1 C4591001 Protocol Section 8.4 for more information). An error in dilution during the study resulted in 52 participants receiving a higher than intended dose of BNT162b2; instead of receiving 30 µg of BNT162b2, 58 µg of BNT162b2 was administered. The participants did not report an increase in reactogenicity or adverse events.

2.7.4.3.6. Drug Abuse

Not applicable.

2.7.4.3.7. Withdrawal and Rebound

Not applicable.

2.7.4.3.8. Effects on Ability to Drive or Operate Machinery or Impairment of Mental Ability

BNT162b2 has no or negligible influence on the ability to drive and use machines.

2.7.4.4. Post-Authorization Data

Post-authorization safety data are continually monitored by Pfizer and BioNTech for pharmacovigilance and risk management purposes. Pfizer's safety database contains cases of AEs reported spontaneously to Pfizer, cases reported by the health authorities, cases published in the medical literature, cases from Pfizer-sponsored marketing programs, non-interventional studies, and cases of serious AEs reported from clinical studies regardless of causality assessment. Through 28 February 2021, there were a total of 42,086 case reports (25,379 medically confirmed and 16,707 non-medically confirmed) containing 158,893 events. Cases were received from 63 countries.

Consistent with what was seen in Phase 2/3 of Study C4591001, most reported AEs were in SOCs with reactogenicity events: general disorders and administration site conditions (51,335), nervous system disorders (25,957), musculoskeletal and connective tissue disorders (17,283), and gastrointestinal disorders (14,096). Post-authorization data have also informed the addition of ADRs related to the experience of reactogenicity to the product labeling (see Section 2.7.4.2.4.3.5 for additional information regarding ADRs).

Aside from addition of anaphylaxis and hypersensitivity, the analyses of cumulative post-authorization safety data, including a review of AESIs, are consistent with the analysis of this pivotal clinical trial. Review of post-authorization data has not revealed any novel safety concerns, except for anaphylaxis, and has confirmed the favorable benefit-risk profile of the vaccine.

Further details regarding the cumulative analysis of post-authorization safety data are presented in Module 5.3.6.

2.7.4.5. Overall Conclusions

Phase 1 data from Study BNT162-01 and Study C4591001 showed that BNT162b1 and BNT162b2 were well tolerated and both vaccines had a satisfactory reactogenicity profile in both younger and older adults. However, BNT162b2 has a more favorable reactogenicity profile than BNT162b1. Additionally, BNT162b2 showed less frequent systemic events in the older compared to the younger population. BNT162b2 at 30 µg was selected for further development in the Phase 2/3 part of the study.

In Phase 2/3, data analyzed in Study C4591001 were from blinded placebo-controlled and open-label follow-up periods, comprised of approximately 44,000 participants ≥16 years of age. The results were concordant with what was seen in Phase 1 and continue to show that BNT162b2 at 30 µg, administered as 2-dose schedule (21 days apart), has an acceptable tolerability and safety profile in individuals ≥16 years of age.

From December 2020 until April 2021, >100 million doses of BNT162b2 have been administered to individuals ≥16 years of age in the US under EUA.[3,4] It is reassuring that the most commonly reported AEs in the post-authorization review (which includes global safety reporting) reflect the same profile observed in the blinded placebo-controlled follow-up period of the pivotal clinical study, primarily reflecting short-lived and resolving reactogenicity events. Further, the same pattern was observed for pivotal study participants originally randomized to the placebo group who were unblinded (per protocol) to receive BNT162b2: these participants, in the open-label setting, also reported mostly reactogenicity events similar to those in the blinded follow-up. AEs of clinical interest were not reported frequently in the controlled clinical study and continue to be evaluated in the post-authorization setting.

Overall, the risk-benefit of BNT162b2 30 µg remains favorable.

2.7.4.6. APPENDICES

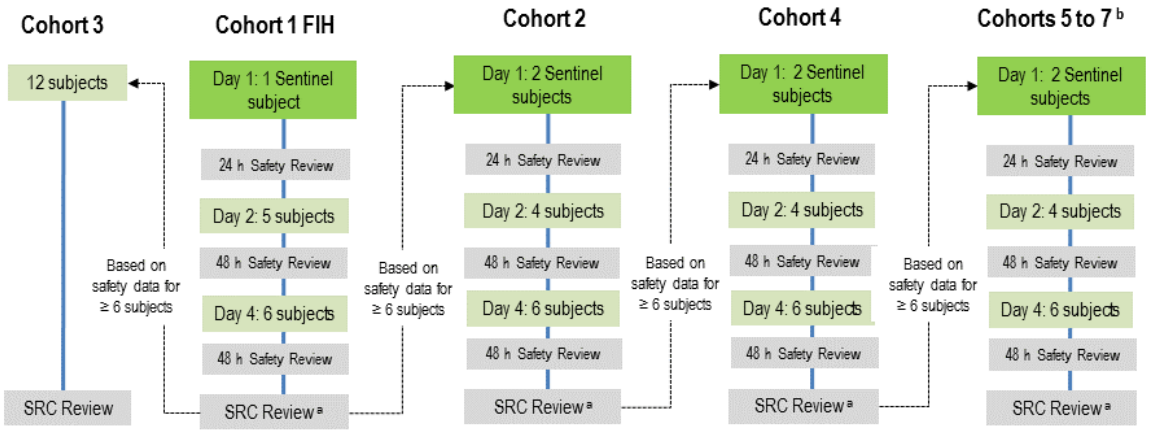
2.7.4.6.1. Appendix A: Study BNT162-01 Safety Evaluation Plan

The BNT162-01 protocol is included in Module 5.3.5.1 BNT162-01 Protocol.

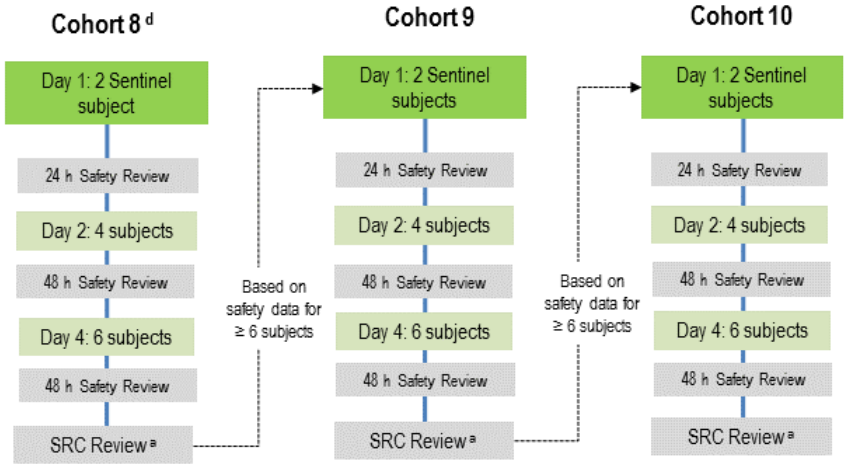
2.7.4.6.1.1. Study BNT162-01 Part A Study Schema

Dose cohort schema for BNT162b1 and BNT162b2 (P/B)[c]

Cohorts with younger adults



Cohorts with older adults



a) The data assessed by the SRC for progressing comprises 48 h data for 6 subjects.

b) If these cohorts use doses lower than already tested, 12 subjects may be dosed on one day in these cohorts and the cohorts may be conducted in parallel to each other / to any dose escalation cohorts. If they use doses higher than already tested, subjects will be dosed using a sentinel dosing/subject (2-4-6) staggering process.

c) For the dose regimens, see Section 2.7.4.1.1.1.2

d) Administration of the planned 10 µg dose in Cohort 8 requires that at least a 10 µg dose has shown acceptable tolerability in younger adults.

2.7.4.6.1.2. Schedule of Activities (Study BNT162-01)

Procedure / Assessment	Visit 0	Visit 1 Pre-dose	Visit 1 Dosing & Post-dose	Visit 2 at 24±2h	Phone call at 48±2h	Visit 3	Visit 4 Pre-dose	Visit 4 Dosing & Post-dose	Phone call at 48±2h	Visit 5 ~7 d from Visit 4	Visit 6 ~21 d from Visit 4	Visit 7 ~28 d from Visit 4 (EoS Visit)	Visit 8 ~63 d from Visit 4 (FU Visit)	Visit 9 ~162 d from Visit 4 (FU Visit)
Day [h]	**-30 to 0**	**1**	**1**	**2**		**8**	**22**	**22**		**29**	**43**	**50**	**85**	**184**
Informed consent	X													
Inclusion/exclusion criteria	X	X (review)												
Medical history	X	X (update)												
Physical examination incl. height	X	X [a]		X [a]		X [a]	X [a]			X [a]	X [a]	X [a]		
Vital signs, body weight [c]	X	X	X [b]	X		X	X	X [b]		X	X	X	X	X
12-lead ECG	X	X												
Urine pregnancy test for WOCBP	X	X					X							
Urine drugs of abuse screen [d]	X	X												
Alcohol breath test	X	X												
Urine collection for clinical laboratory [e]	X	X		X		X				X		X		
Blood draw for clinical laboratory [f]	X (15 mL)	X (15 mL)		X (15 mL)		X (15 mL)				X (15 mL)		X (15 mL)		
Blood draw for viral screening [g]	X (5 mL)													
Blood draw for SARS-CoV-2 testing [k]	X (2.6 mL)													
Oral swipe for SARS-CoV-2 testing		X [m]												

Procedure / Assessment	Visit 0	Visit 1 Pre-dose	Visit 1 Dosing & Post-dose	Visit 2 at 24±2h	Phone call at 48±2h	Visit 3	Visit 4 Pre-dose	Visit 4 Dosing & Post-dose	Phone call at 48±2h	Visit 5 ~7 d from Visit 4	Visit 6 ~21 d from Visit 4	Visit 7 ~28 d from Visit 4 (EoS Visit)	Visit 8 ~63 d from Visit 4 (FU Visit)	Visit 9 ~162 d from Visit 4 (FU Visit)
Day [h]	-30 to 0	1	1	2		8	22	22		29	43	50	85	184
Allocation to IMP		X												
Dosing [l]			X					X						
Blood draw for immunogenicity [n]		X (10 mL)				X (10 mL)	X (10 mL)			X (10 mL)	X (10 mL)	X (10 mL)	X (10 mL)	X (10 mL)
Blood draw for HLA		X (4 mL EDTA-blood) [p]												
Blood draw for CMI (100 mL) [n, o]		X								X				
Blood draw for research		← Up to 5 blood draws for explorative biomarker/immunogenicity research purposes. Blood draw volumes may vary. The total blood volume drawn will not exceed 200 mL per participant over the complete study, i.e., over approximately 7 months. →												
Participant hotline availability	Start	=>	=>	=>		=>	=>	=>		=>	=>	=>	=>	End
Issue participant diaries		X		X		X	X			X	X	X		
Collect participant diaries				X	X [i]	X	X			X	X	X	X	
Record AEs since last visit		X		X		X	X			X	X	X	X [j]	X [j]
Local reaction assessment/ systemic events			X [b]	X		X	X	X [b]		X	X	X		
Concomitant medication	X	X		X		X	X			X	X	X		
Participant wellbeing questioning					X [i]				X [i]					

[a] Brief (symptom-directed) physical examination; no height measurement

[b] At 1, 3, and 6 h (±15 min) after dosing.

[c] Vital signs: systolic/diastolic blood pressure, pulse rate, respiratory rate, and body temperature; body weight only at Visit 0.

[d] Urine screening for drugs of abuse (amphetamines, benzodiazepines, barbiturates, cocaine, cannabinoids, opiates, methadone, methamphetamines, phencyclidine, tricyclic antidepressants).

[e] Dipstick urine analysis: glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, and leukocytes. Microscopic urinalysis: if warranted by dipstick results, urine sediment was microscopically examined for the presence of red blood cells, white blood cells, casts, crystals, epithelial cells, and bacteria.

[f] Clinical laboratory tests: (Chemistry) alkaline phosphatase, creatinine, ferritin, C-reactive protein, albumin, alanine aminotransferase, amylase, aspartate aminotransferase, gamma glutamyl transpeptidase, total bilirubin, blood urea nitrogen, glucose, lipase, sodium, potassium, calcium; (Hematology) hemoglobin, hematocrit, red blood cell count, white blood cell count and differential (neutrophils, lymphocytes, monocytes, eosinophils, basophils), platelet count. Only in women who are not WOCBP: follicle stimulating hormone (FSH) at Visit 0.

[g] Viral screening for Human Immunodeficiency Virus (HIV) 1 or 2, Hepatitis B, Hepatitis C.

[h] Flexibility for visit days: Visit 3 Day 8±1 d; Visit 4 Day 22±2 d; Visit 5 Day 29±3 d; Visit 6 Day 43±4 d; Visit 7 Day 50±4 d; Visit 8 Day 85±7 d; Visit 9 Day 184±9d.

[i] Only for the first 6 participants per dose group. Questioning on and documentation of AEs as well as systemic and local reactions, the latter in case of upcoming dose decision meetings.

[j] Only IMP-related AEs.

[k] Blood draw for anti-SARS-CoV-2 antibodies (samples will be stored until a test is commercially available).

[l] For dose groups 1 and 8, dosing with at least 1 h intervals between participants for the first 6 participants and then with of at least 30 min intervals for the remaining 6 participants. For all other dose groups, dosing with at least 30 min intervals between participants.

[m] Oral swipe for SARS-CoV-2 testing either on Day -1 or at the Visit 1 on Day 1.

[n] The listed blood draw days may be adapted if justified by the collected data. Leftover blood after completion of the immunogenicity assessments may be used for additional analyses as described in Protocol Section 8.7 (Genetics) and/or Protocol Section 8.8 (Biomarkers).

[o] For participants who have given consent, one aliquot of the blood sample drawn for analysis of CMI may be used for HLA typing to allow additional analysis of T-cell receptor repertoire and / or phenotypic characterization of T-cells specific to vaccine-encoded antigens.

[p] If HLA typing using the blood sample collected with Lithium Heparin is not conclusive, EDTA-blood was drawn for HLA testing.

Abbreviations: AE = adverse event; CMI = cell-mediated immune testing; D or d = day; ECG = electrocardiogram; EDTA = ethylenediamine tetraacetic acid; EoS = end of study (Visit); FU = follow-up (visit); h = hour(s); HLA = human leukocyte antigen; Day 0 = 1 d before Day 1; IMP = investigational medicinal product; min = minute(s); SARS-CoV-2 = the virus leading to COVID-19; WOCBP = women of childbearing potential.

2.7.4.6.1.3. Study BNT162-01: Safety Assessments

2.7.4.6.1.3.1. Physical Examinations, Vital Signs, and Electrocardiograms (Study BNT162-01)

Complete physical examinations were performed at screening. Brief physical examinations were performed at later time points including prior boost immunizations.

- A complete physical examination included, at a minimum, assessments of the cardiovascular, respiratory, gastrointestinal and neurological systems. Height (in cm) was also recorded during complete physical examinations.

- A brief (symptom directed) physical examination included an overall health judgement. In-depth physical examinations were required if obvious pathological signs were visible or in the case the subject states any signs or symptoms.

Vital signs included body temperature, pulse rate, respiratory rate, and blood pressure. Normal ranges of the vital sign parameters are presented in Module 5.3.5.1 BNT162-01 Statistical Analysis Plan Table 4. Body weight will also be recorded.

Standard 12-lead ECGs were recorded and judged by the investigator to be clinically significant or not.

2.7.4.6.1.3.2. Subject Diaries (Study BNT162-01)

Subjects were given subject diaries at Visit 1 and were asked to record any reactions between visits, solicited local reactions at the injection site (pain, tenderness, erythema/redness, induration/swelling) and solicited systemic reactions (nausea, vomiting, diarrhea, headache, fatigue, myalgia, arthralgia, chills, loss of appetite, malaise, and fever [ie, ≥38°C]). Subject diaries were collected at the visits as described in the SoA (Section 2.7.4.6.1.2).

2.7.4.6.1.3.2.1. Local Reactions (Study BNT162-01)

Assessment of local reactions after IM immunization was used to validate the solicited assessment of local reactions in the patient diary and potentially support AE reporting.

Local reactions (both investigator assessed and solicited in the subject diaries) weree graded using criteria based on the guidance given in US FDA Guidance for Industry “Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials” for “Local Reaction to Injectable Products”. The grades are Grade 0 (Absent), Grade 1 (Mild), Grade 2 (Moderate), Grade 3 (Severe) and Grade 4 (Potentially life threatening).

The solicited local reactions were evaluated for the following time intervals:

- Prime immunization up to day 7 (inclusive) after initial immunization

- Boost immunization up to day 7 (inclusive) after boost immunization

- Both intervals combined

The intervals started with the date and time of the immunization.

2.7.4.6.1.3.2.2. Systemic Reactions (Study BNT162-01)

Systemic reactions after IM immunization were assessed via daily solicited reports in the subject diaries and at the times given in the SoA (Section 2.7.4.6.1.2).

Systemic reactions were graded using criteria based on the guidance given in US FDA Guidance for Industry "Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials" for "Systemic reaction grading scale". The grades are Grade 0 (Absent), Grade 1 (Mild), Grade 2 (Moderate), Grade 3 (Severe) and Grade 4 (Potentially life threatening). Fever was graded as Mild (38.0-38.4°C), Moderate (38.5-38.9°C), Severe (39.0-40.0°C and Potentially life threatening (>40.0°C).

The solicited systemic reactions were evaluated for the following time intervals:

Prime immunization up to day 7 (inclusive) after initial immunization

Boost immunization up to day 7 (inclusive) after boost immunization

Both intervals combined

The intervals started with the date and time of the immunization. Further details regarding the analysis of local reactions are provided in the SAP (Module 5.3.5.1 BNT162-01 Statistical Analysis Plan Section 6.4.2).

2.7.4.6.1.3.3. Adverse Events and Serious Adverse Events (Study BNT162-01)

Adverse Events

An AE is any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention.

NOTE: An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding that is clinically significant), symptom, or disease (new or exacerbated) temporally associated with the use of study intervention.

Events after signing ICD and before study intervention administration were handled as AEs.

AEs were coded using the Updated Version MedDRA® 23.0 including specific terms for COVID-19 to get a SOC and PT for each AE.

A TEAE is defined as any AE with an onset date on or after the first administration of study intervention (if the AE was absent before the first administration of study intervention) or worsened after the first administration of IMP (if the AE was present before the first administration of study intervention). AEs with an onset date more than 28 d after the last administration of study intervention will be considered as treatment emergent only if assessed as related to study intervention by the investigator.

For more details regarding how adverse events were defined, refer to Module 5.3.5.1 BNT162-01 Protocol Section 10.3.1.1 and Section 10.3.1.2.

Suspected Adverse Reactions

A Suspected Adverse Reaction was defined as all untoward and unintended responses to a study intervention related to any dose administered.

- The definition also covers medication errors and uses outside what is foreseen in the protocol, including misuse and abuse of the study intervention.
- The definition implies a reasonable possibility of a causal relationship between the event and the study intervention. This means that there are facts (evidence) or arguments to suggest a causal relationship.

Serious Adverse Events

If an event was not an AE per the definition above, then it could not be an SAE even if serious conditions were met (eg, hospitalization for signs/symptoms of the disease under trial, death due to progression of disease).

An SAE was defined as any untoward medical occurrence that, at any dose:

- Results in death
- Is life-threatening

  The term "life-threatening" in the definition of "serious" refers to an event in which the trial subject was at risk of death at the time of the event. It does not refer to an event which hypothetically might have caused death if it were more severe.
- Requires trial subject hospitalization or prolongation of existing hospitalization
  - In general, hospitalization signifies that the trial subject has been detained (usually involving at least an overnight stay) at the hospital or emergency ward for observation and/or treatment that would not have been appropriate in the physician's office or out trial subject setting. Complications that occur during hospitalization are AEs. If a complication prolongs hospitalization or fulfills any other serious criteria, the event is serious. When in doubt as to whether "hospitalization" occurred or was necessary, the AE should be considered serious.
- Results in persistent disability/incapacity
- Is a congenital anomaly or a birth defect.

AEs of Proven COVID-19 Disease of Moderate or Severe Intensity

Any case of proven COVID-19 disease occurring during the observation period was reported as an SAE, where the intensity of the respective AE is rated as "moderate" or "severe" (according to the criteria provided in Module 5.3.5.1 BNT162-01 Protocol Section 10.3.1.7). If none of the other SAE definitions were deemed suitable, then the SAE criterion of being a

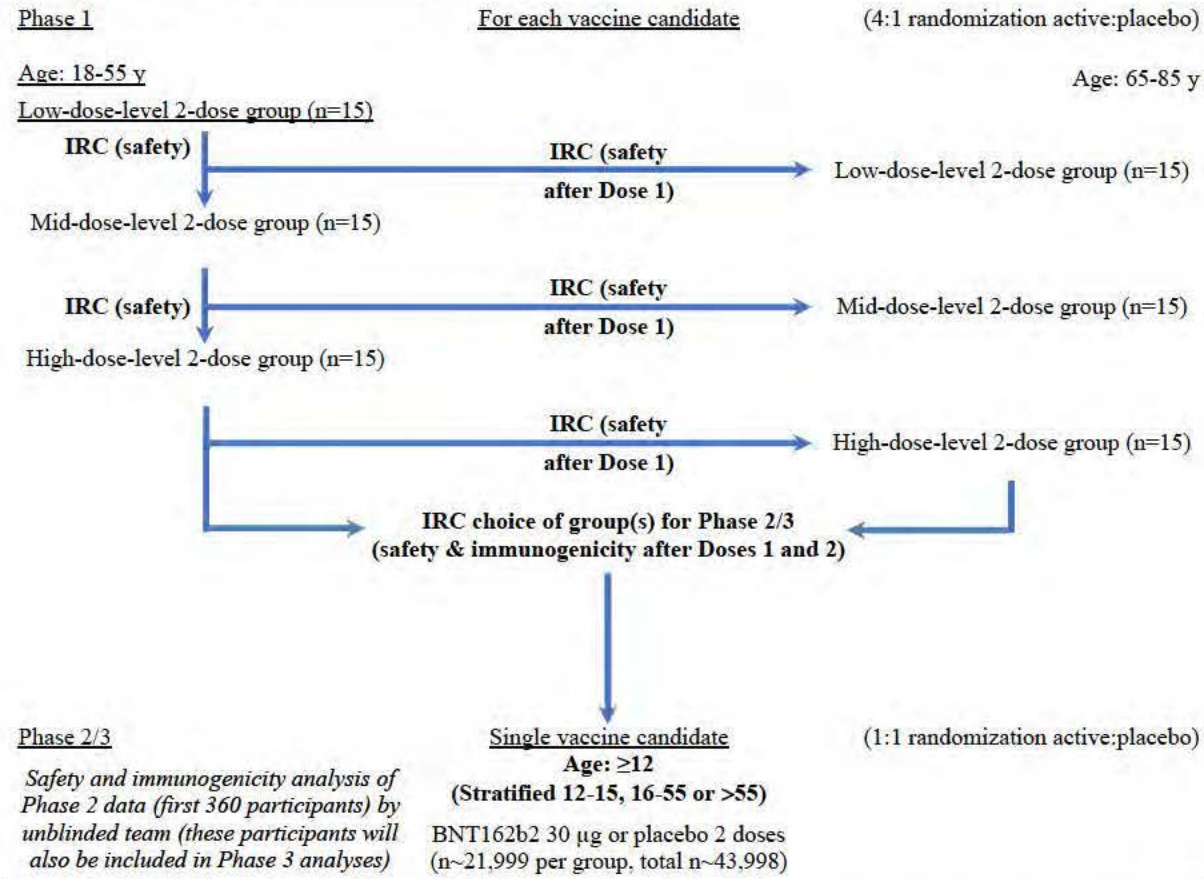
"medically important event" was applied (according to the definitions provided in Module 5.3.5.1 BNT162-01 Protocol Section 10.3.1.4).

For more details regarding serious adverse events, refer to Module 5.3.5.1 BNT162-01 Protocol Section 10.3.

2.7.4.6.2. Appendix B: Study C4591001 Safety Evaluation Plan

The C4591001 protocol is included in Module 5.3.5.1 C4591001 Protocol.

2.7.4.6.2.1. Study C4591001 Study Schema



Note: Participants ≥16 years of age who originally received placebo were offered the opportunity to receive BNT162b2 at defined points as part of the study.

2.7.4.6.2.2. Schedule of Activities (Study C4591001)

2.7.4.6.2.2.1. Study C4591001 Phase 1 SoA

An unplanned potential COVID-19 illness visit and unplanned potential COVID-19 convalescent visit are required at any time between Visit 1 (Vaccination 1) and Visit 10 (24-month follow-up visit) that COVID-19 is suspected.

Administration of BNT162b2 to Those Originally Assigned to Placebo: If a participant became eligible for receipt of BNT162b2 or another COVID-19 vaccine according to recommendations detailed separately, and available in the electronic study reference portal, the participant was advised to contact the site to determine whether he or she could receive BNT162b2 in a phased manner as part of the study. When contacted, the site conducted a phone visit to confirm eligibility and, if eligible and wanting to receive BNT162b2 if the participant originally received placebo, unblinded study intervention allocation to determine whether the participant received BNT162b1, BNT162b2, or placebo. If he or she originally received placebo and wanted to receive BNT162b2, the participant moved to the SoA in Section 2.7.4.6.2.2.3 for his or her remaining visits. Participants who received BNT162b1 or BNT162b2 (at any dose level) continued in the study as originally planned.

All other participants were advised to contact the site to determine whether they can receive BNT162b2 as part of the study no later than at the approximate time participants in Phase 2/3 reach Visit 4. When contacted, the site unblinded study intervention allocation to determine whether the participant received BNT162b1, BNT162b2, or placebo. If he or she originally received placebo and wanted to receive BNT162b2, the participant moved to the SoA in Section 2.7.4.6.2.2.3 for his or her remaining visits.

Visit Number	Screening	1	2	3	4	5	6	7		Unplanned	Unplanned
Visit Description	**Screening**	**Vax 1**	**Next-Day Follow-up Visit (Vax 1)**	**1-Week Follow-up Visit (Vax 1)**	**Vax 2**	**1-Week Follow-up Visit (Vax 2)**	**2-Week Follow-up Visit (Vax 2)**	**1-Month Follow-up Visit**	***Study procedures for Visit 8 onwards continue on the next table***	**Potential COVID-19 Illness Visit[a]**	**Potential COVID-19 Convalescent Visit**
Visit Window (Days)	**0 to 28 Days Before Visit 1**	**Day 1**	**1 to 3 Days After Visit 1**	**6 to 8 Days After Visit 1**	**19 to 23 Days After Visit 1**	**6 to 8 Days After Visit 4**	**12 to 16 Days After Visit 4**	**28 to 35 Days After Visit 4**		**Optimally Within 3 Days After Potential COVID-19 Illness Onset**	**28 to 35 Days After Potential COVID-19 Illness Visit**
Obtain informed consent	X								*Continued on table below*		
Assign participant number	X										
Obtain demography and medical history data	X										
Obtain details of medications currently taken	X										
Perform physical examination	X	X	X	X	X	X	X				
Measure vital signs (including body temperature)	X	X	X	X	X	X	X				
Collect blood sample for hematology and chemistry laboratory tests[b]	~10 mL		~10 mL	~10 mL	~10 mL	~10 mL					
Collect screening blood sample for HIV, HBsAg, HBc Ab, and HCV Ab tests	~10 mL										
Serological test for prior COVID-19 infection	~20 mL										
Perform urine pregnancy test (if appropriate)	X	X			X						
Obtain nasal (midturbinate) swab(s)[c]		X			X					X	
Collect nonstudy vaccine information	X	X	X	X	X	X	X	X			
Confirm eligibility	X	X			X						
Collect prohibited medication use			X	X	X	X	X	X		X	X

Visit Number	Screening	1	2	3	4	5	6	7	*Study procedures for Visit 8 onwards continue on the next table*	Unplanned	Unplanned
Visit Description	**Screening**	**Vax 1**	**Next-Day Follow-up Visit (Vax 1)**	**1-Week Follow-up Visit (Vax 1)**	**Vax 2**	**1-Week Follow-up Visit (Vax 2)**	**2-Week Follow-up Visit (Vax 2)**	**1-Month Follow-up Visit**		**Potential COVID-19 Illness Visit[a]**	**Potential COVID-19 Convalescent Visit**
Visit Window (Days)	**0 to 28 Days Before Visit 1**	**Day 1**	**1 to 3 Days After Visit 1**	**6 to 8 Days After Visit 1**	**19 to 23 Days After Visit 1**	**6 to 8 Days After Visit 4**	**12 to 16 Days After Visit 4**	**28 to 35 Days After Visit 4**		**Optimally Within 3 Days After Potential COVID-19 Illness Onset**	**28 to 35 Days After Potential COVID-19 Illness Visit**
Review hematology and chemistry results		X		X	X	X	X		*Continued on table below*		
Review temporary delay criteria		X			X						
Confirm use of contraceptives (if appropriate)	X	X	X	X	X	X	X	X			
Obtain randomization number and study intervention allocation		X									
Collect blood sample for immunogenicity assessment		~50 mL		~50 mL	~50 mL	~50 mL + optional[e] ~170 mL	~50 mL + optional[e] ~170 mL	~50 mL + optional[e] ~170 mL			~20 mL
Administer study intervention		X			X						
Assess acute reactions for at least 30 minutes after study intervention administration[d]		X			X						
Explain participant communication methods (including for e-diary completion), assist the participant with downloading the app, or issue provisioned device, if required		X									
Provide thermometer and measuring device		X			X						
Review reactogenicity e-diary data (daily review is optimal during the active diary period)		◄	———	►		◄	———	►			

Visit Number	Screening	1	2	3	4	5	6	7		Unplanned	Unplanned
Visit Description	**Screening**	**Vax 1**	**Next-Day Follow-up Visit (Vax 1)**	**1-Week Follow-up Visit (Vax 1)**	**Vax 2**	**1-Week Follow-up Visit (Vax 2)**	**2-Week Follow-up Visit (Vax 2)**	**1-Month Follow-up Visit**	***Study procedures for Visit 8 onwards continue on the next table***	**Potential COVID-19 Illness Visit[a]**	**Potential COVID-19 Convalescent Visit**
Visit Window (Days)	**0 to 28 Days Before Visit 1**	**Day 1**	**1 to 3 Days After Visit 1**	**6 to 8 Days After Visit 1**	**19 to 23 Days After Visit 1**	**6 to 8 Days After Visit 4**	**12 to 16 Days After Visit 4**	**28 to 35 Days After Visit 4**		**Optimally Within 3 Days After Potential COVID-19 Illness Onset**	**28 to 35 Days After Potential COVID-19 Illness Visit**
Review ongoing reactogenicity e-diary symptoms and obtain stop dates					X		X		*Continued on table below*		
Collect AEs and SAEs as appropriate	X	X	X	X	X	X	X	X		X	X
Collect e-diary or assist the participant to delete application											
Collection of COVID-19–related clinical and laboratory information (including local diagnosis)										X	X

Abbreviations: e-diary = electronic diary; HBc Ab = hepatitis B core antibody; HBsAg = hepatitis B surface antigen; HCV Ab = hepatitis C virus antibody; HIV = human immunodeficiency virus; NAAT = nucleic acid amplification test; vax = vaccination.

a. The COVID-19 illness visit may be conducted as an in-person or telehealth visit.
b. Hematology: hemoglobin, complete blood count with differential, and platelets. Blood chemistry: alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase, total bilirubin, blood urea nitrogen (BUN), and creatinine.
c. Two swabs will be taken at Visits 1 and 4. One will be tested (if possible at the site, otherwise at the central laboratory) within 24 hours and vaccination will only proceed if it is NAAT-negative for SARS-CoV-2 genomes. The second will be sent to the central laboratory for potential later testing.
d. The first 5 participants in in each group will be observed at the site for at least 4 hours after study intervention administration. Further vaccination will commence no sooner than 24 hours after the fifth participant received his or her vaccination.
e. An optional blood draw of ~170 mL will be taken at 1 of the visits (from selected participants who consent) for exploratory COVID-19 research.

Continuation of table above

Visit Number	8	8a	8b	8c	9	10	Unplanned	Unplanned
Visit Description	**6-Month Follow-up Visit**	**Vax 3**	**1-Week Follow-up Visit (After Vax 3)**	**1-Month Follow-up Visit (After Vax 3)**	**12-Month Follow-up Visit**	**24-Month Follow-up Visit**	**Potential COVID-19 Illness Visit[a]**	**Potential COVID-19 Convalescent Visit**
Visit Window (Days)	**175 to 189 Days After Visit 4**	**175 to 315 Days After Visit 4**	**6 to 8 Days After Visit 8a**	**28 to 35 Days After Visit 8a**	**350 to 378 Days After Visit 4**	**714 to 742 Days After Visit 4**	**Optimally Within 3 Days After Potential COVID-19 Illness Onset**	**28 to 35 Days After Potential COVID-19 Illness Visit**
		ONLY FOR THOSE PARTICIPANTS ORIGINALLY ASSIGNED TO BNT162 at 10 µg, 20 µg, or 30 µg **Those participants who decline to receive a third dose of BNT162 move directly from Visit 8 to Visit 9**			**ONLY FOR THOSE PARTICIPANTS ORIGINALLY ASSIGNED TO BNT162 OR PLACEBO RECIPIENTS WHO DECLINE BNT162b2 (ie, those participants who do not transition from placebo to BNT162b2)**			
Obtain informed consent		X						
Confirm participant originally received 10 to 30 µg of BNT162b1 or BNT162b2		X						
Perform urine pregnancy test (if appropriate)		X						
Confirm use of contraceptives (if appropriate)		X	X	X				
Collect prohibited medication use	X	X	X	X	X	X	X	X
Collect nonstudy vaccine information	X	X	X	X				
Measure body temperature		X						
Confirm eligibility		X						
Review temporary delay criteria		X						
Collect blood sample for immunogenicity assessment	~20 mL	~20 mL	~20 mL	~20 mL	~20 mL	~20 mL		~20 mL

Continuation of table above

Visit Number	8	8a	8b	8c	9	10	Unplanned	Unplanned
Visit Description	**6-Month Follow-up Visit**	**Vax 3**	**1-Week Follow-up Visit (After Vax 3)**	**1-Month Follow-up Visit (After Vax 3)**	**12-Month Follow-up Visit**	**24-Month Follow-up Visit**	**Potential COVID-19 Illness Visit[a]**	**Potential COVID-19 Convalescent Visit**
Visit Window (Days)	**175 to 189 Days After Visit 4**	**175 to 315 Days After Visit 4**	**6 to 8 Days After Visit 8a**	**28 to 35 Days After Visit 8a**	**350 to 378 Days After Visit 4**	**714 to 742 Days After Visit 4**	**Optimally Within 3 Days After Potential COVID-19 Illness Onset**	**28 to 35 Days After Potential COVID-19 Illness Visit**
		ONLY FOR THOSE PARTICIPANTS ORIGINALLY ASSIGNED TO BNT162 at 10 µg, 20 µg, or 30 µg **Those participants who decline to receive a third dose of BNT162 move directly from Visit 8 to Visit 9**			**ONLY FOR THOSE PARTICIPANTS ORIGINALLY ASSIGNED TO BNT162 OR PLACEBO RECIPIENTS WHO DECLINE BNT162b2 (ie, those participants who do not transition from placebo to BNT162b2)**			
Obtain nasal (midturbinate) swab(s)		X					X	
Obtain the participant's vaccine vial allocation using the IRT system		X						
Administer 30-µg dose of BNT162b2		X						
Assess acute reactions for at least 30 minutes after study intervention administration		X						
Provide thermometer and measuring device		X						
Remind participant of e-diary technologies		X						
Review reactogenicity e-diary data (daily review is optimal during the active diary period)		←	→					

Continuation of table above

Visit Number	8	8a	8b	8c	9	10	Unplanned	Unplanned
Visit Description	**6-Month Follow-up Visit**	**Vax 3**	**1-Week Follow-up Visit (After Vax 3)**	**1-Month Follow-up Visit (After Vax 3)**	**12-Month Follow-up Visit**	**24-Month Follow-up Visit**	**Potential COVID-19 Illness Visit[a]**	**Potential COVID-19 Convalescent Visit**
Visit Window (Days)	**175 to 189 Days After Visit 4**	**175 to 315 Days After Visit 4**	**6 to 8 Days After Visit 8a**	**28 to 35 Days After Visit 8a**	**350 to 378 Days After Visit 4**	**714 to 742 Days After Visit 4**	**Optimally Within 3 Days After Potential COVID-19 Illness Onset**	**28 to 35 Days After Potential COVID-19 Illness Visit**
		ONLY FOR THOSE PARTICIPANTS ORIGINALLY ASSIGNED TO BNT162 at 10 µg, 20 µg, or 30 µg Those participants who decline to receive a third dose of BNT162 move directly from Visit 8 to Visit 9			**ONLY FOR THOSE PARTICIPANTS ORIGINALLY ASSIGNED TO BNT162 OR PLACEBO RECIPIENTS WHO DECLINE BNT162b2 (ie, those participants who do not transition from placebo to BNT162b2)**			
Review ongoing reactogenicity e-diary symptoms and obtain stop dates				X				
Collect AEs and SAEs as appropriate	X	X	X	X	X[b]	X[b]	X	X
Collect e-diary or assist the participant to delete application						X		
Collection of COVID-19–related clinical and laboratory information (including local diagnosis)							X	X

Abbreviations: IRT = interactive response technology; vax = vaccination.

a. The COVID-19 illness visit may be conducted as an in-person or telehealth visit.

b. Any AEs occurring up to 48 hours after the blood draw must be recorded (see Module 5.3.5.1 C4591001 Protocol Section 8.3.1)

2.7.4.6.2.2.2. Study C4591001 Phase 2/3 SoA

An unplanned potential COVID-19 illness visit and unplanned potential COVID-19 convalescent visit are required at any time between Visit 1 (Vaccination 1) and Visit 6 (24-month follow-up visit) that potential COVID-19 symptoms are reported, including MIS-C.

Administration of BNT162b2 to Those Originally Assigned to Placebo: If a participant ≥16 years of age became eligible for receipt of BNT162b2 or another COVID-19 vaccine according to recommendations detailed separately, and available in the electronic study reference portal, the participant was advised to contact the site to determine whether he or she could receive BNT162b2 in a phased manner as part of the study. When contacted, the site conducted a phone visit to confirm eligibility and, if eligible and wanting to receive BNT162b2 if the participant originally received placebo, unblinded study intervention allocation to determine whether the participant received BNT162b2 or placebo. If he or she originally received placebo and wanted to receive BNT162b2, the participant moved to the SoA in Section 2.7.4.6.2.2.3 for his or her remaining visits. Participants who received BNT162b2 continued in the study as originally planned.

All other participants ≥16 years of age who had not been offered the opportunity to receive BNT162b2 were given this opportunity no later than 6 months after Vaccination 2 (at the time of the originally planned Visit 4). If they wanted to receive BNT162b2, they were unblinded and those who did originally receive placebo moved to the SoA in Section 2.7.4.6.2.2.3 for their remaining visits.

Visit Number	1	2	3	4	5	6	Unplanned	Unplanned
Visit Description	**Vaccination 1**	**Vaccination 2**	**1-Month Follow-up Visit**	**6-Month Follow-up Visit**	**12-Month Follow-up Visit**	**24-Month Follow-up Visit**	**Potential COVID-19 Illness Visit[a]**	**Potential COVID-19 Convalescent Visit**
Visit Window (Days)	**Day 1[b]**	**19 to 23 Days After Visit 1**	**28 to 35 Days After Visit 2**	**175 to 189 Days After Visit 2**	**350 to 378 Days After Visit 2**	**714 to 742 Days After Visit 2**	**Optimally Within 3 Days After Potential COVID-19 Illness Onset**	**28 to 35 Days After Potential COVID-19 Illness Visit**
					ONLY FOR THOSE PARTICIPANTS ORIGINALLY ASSIGNED TO BNT162b2 OR PLACEBO RECIPIENTS WHO DECLINE BNT162b2			
Obtain informed consent	X							
Assign participant number	X							
Obtain demography and medical history data	X							
Perform clinical assessment[c]	X							
For participants who are HIV-positive, record latest CD4 count and HIV viral load	X		X	X	X	X		
Measure height and weight	X							
Measure temperature (body)	X	X						
Perform urine pregnancy test (if appropriate)	X	X						
Confirm use of contraceptives (if appropriate)	X	X	X					
Collect nonstudy vaccine information	X	X	X	X				
Collect prohibited medication use		X	X	X	X	X	X	X
Confirm eligibility	X	X						
Review temporary delay criteria	X	X						
Collect blood sample for immunogenicity assessment[d]	~20 mL/ ~10 mL		~20 mL/ ~10 mL	~20 mL/ ~10 mL	~20 mL/ ~10 mL	~20 mL/ ~10 mL		~20 mL/ ~10 mL
Obtain nasal (midturbinate) swab	X	X					X	
Obtain randomization number and study intervention allocation	X							
Administer study intervention	X	X						

Visit Number	1	2	3	4	5	6	Unplanned	Unplanned
Visit Description	**Vaccination 1**	**Vaccination 2**	**1-Month Follow-up Visit**	**6-Month Follow-up Visit**	**12-Month Follow-up Visit**	**24-Month Follow-up Visit**	**Potential COVID-19 Illness Visit[a]**	**Potential COVID-19 Convalescent Visit**
Visit Window (Days)	**Day 1[b]**	**19 to 23 Days After Visit 1**	**28 to 35 Days After Visit 2**	**175 to 189 Days After Visit 2**	**350 to 378 Days After Visit 2**	**714 to 742 Days After Visit 2**	**Optimally Within 3 Days After Potential COVID-19 Illness Onset**	**28 to 35 Days After Potential COVID-19 Illness Visit**
					ONLY FOR THOSE PARTICIPANTS ORIGINALLY ASSIGNED TO BNT162b2 OR PLACEBO RECIPIENTS WHO DECLINE BNT162b2			
Assess acute reactions for at least 30 minutes after study intervention administration	X	X						
Explain participant communication methods (including for e-diary completion), assist the participant with downloading the app, or issue provisioned device, if required	X							
Provide/ensure the participant has a thermometer (all participants) and measuring device (reactogenicity subset participants only)	X	X						
Review reactogenicity e-diary data (daily review is optimal during the active diary period)[e]	←	←						
Review ongoing reactogenicity e-diary symptoms and obtain stop dates[e]		X	X					
Collect AEs and SAEs as appropriate	X	X	X	X[f]	X[f]	X[f]	X	X[f]
According to eligibility, ascertain willingness to receive BNT162b2 if originally received placebo; if willing, unblind the participant's study intervention assignment (if not already done), and move placebo recipients to the SoA in Section 2.7.4.6.2.2.3			X	← X				
Collect e-diary or assist the participant to delete application						X		

Visit Number	1	2	3	4	5	6	Unplanned	Unplanned
Visit Description	Vaccination 1	Vaccination 2	1-Month Follow-up Visit	6-Month Follow-up Visit	12-Month Follow-up Visit	24-Month Follow-up Visit	Potential COVID-19 Illness Visit[a]	Potential COVID-19 Convalescent Visit
Visit Window (Days)	Day 1[b]	19 to 23 Days After Visit 1	28 to 35 Days After Visit 2	175 to 189 Days After Visit 2	350 to 378 Days After Visit 2	714 to 742 Days After Visit 2	Optimally Within 3 Days After Potential COVID-19 Illness Onset	28 to 35 Days After Potential COVID-19 Illness Visit
					ONLY FOR THOSE PARTICIPANTS ORIGINALLY ASSIGNED TO BNT162b2 OR PLACEBO RECIPIENTS WHO DECLINE BNT162b2			
Collection of COVID-19–related clinical and laboratory information (including local diagnosis)							X	X

Abbreviations: HIV = human immunodeficiency virus; e-diary = electronic diary.

a. The COVID-19 illness visit may be conducted as an in-person or telehealth visit.
b. The visit may be conducted across 2 consecutive days; if so, all steps from assessing the inclusion and exclusion criteria onwards must be conducted on the same day.
c. Including, if indicated, a physical examination.
d. 20 mL is to be collected from participants ≥16 years of age; 10 mL is to be collected from participants 12 to 15 years of age.
e. Reactogenicity subset participants only.
f. Any AEs occurring up to 48 hours after the blood draw must be recorded (see Module 5.3.5.1 C4591001 Protocol Section 8.3.1).

2.7.4.6.2.2.3. Administration of BNT162b2 to Those Originally Assigned to Placebo

Participants ≥16 years of age who originally received placebo and became eligible for receipt of BNT162b2 according to recommendations detailed separately, and available in the electronic study reference portal, had the opportunity to receive BNT162b2 in a phased manner as part of the study. Any placebo recipient ≥16 years of age who had not already been offered the opportunity to receive BNT162b2 was given this opportunity no later than 6 months after Vaccination 2.

Visit Number	101	102	103	104	105	Unplanned	Unplanned
Visit Description	**Vaccination 3**	**Vaccination 4**	**1-Month Telephone Contact**	**6-Month Telephone Contact**	**18-Month Telephone Contact**	**Potential COVID-19 Illness Visit**	**Potential COVID-19 Convalescent Visit**
Visit Window (Days)	**From Recommendation[a] or At Least 175 Days After Vaccination 2[b]**	**19 to 23 Days After Visit 101**	**28 to 35 Days After Visit 102**	**175 to 189 Days After Visit 102**	**532 to 560 Days After Visit 102**	**Optimally Within 3 Days After Potential COVID-19 Illness Onset**	**28 to 35 Days After Potential COVID-19 Illness Visit**
Confirm participant meets local/national recommending criteria or is at least 175 days after Vaccination 2 (Visit 4/Visit 2)	X						
Obtain informed consent	X						
Confirm participant originally received placebo	X						
Perform urine pregnancy test (if appropriate)	X	X					
Confirm use of contraceptives (if appropriate)	X	X					
Collect prohibited medication use	X	X	X	X	X	X	X
For participants who are HIV-positive, record latest CD4 count and HIV viral load	X		X	X	X		
Review and consider eligibility	X	X					
Review temporary delay criteria	X	X					
Collect blood sample for immunogenicity assessment[c]	~20 mL						~20 mL
Obtain nasal (midturbinate) swab	X	X				X	
Obtain vaccine vial allocation via IRT	X	X					
Administer BNT162b2	X	X					
Assess acute reactions for at least 30 minutes after study intervention administration	X	X					
Collect AEs and SAEs as appropriate	X	X	X	X		X[d]	X[d]
Contact the participant by telephone			X	X	X		
Request the participant return the e-diary or assist the participant to delete the application					X		
Collection of COVID-19–related clinical and laboratory information (including local diagnosis)						X	X

Visit Number	101	102	103	104	105	Unplanned	Unplanned
Visit Description	Vaccination 3	Vaccination 4	1-Month Telephone Contact	6-Month Telephone Contact	18-Month Telephone Contact	Potential COVID-19 Illness Visit	Potential COVID-19 Convalescent Visit
Visit Window (Days)	From Recommendation[a] or At Least 175 Days After Vaccination 2[b]	19 to 23 Days After Visit 101	28 to 35 Days After Visit 102	175 to 189 Days After Visit 102	532 to 560 Days After Visit 102	Optimally Within 3 Days After Potential COVID-19 Illness Onset	28 to 35 Days After Potential COVID-19 Illness Visit

Abbreviations: HIV = human immunodeficiency virus; IRT = interactive response technology.

a. For participants who become eligible according to recommendations detailed separately and available in the electronic study reference portal.
b. For any remaining Phase 2/3 placebo recipients who wish to receive BNT162b2; may be combined with Visit 4 for Phase 2/3 participants.
c. Only if the participant has no blood sample collected in the previous 7 days.
d. AEs need only be recorded if the participant remains in the AE reporting period (see Module 5.3.5.1 C4591001 Protocol Section 8.3.1).

2.7.4.6.2.3. Study C4591001: Safety Assessments

Safety Assessments are described in Module 5.3.5.1 C4591001 Protocol Section 8.2 and Appendix 3.

2.7.4.6.2.3.1. Electronic Diary (Study C4591001)

Certain participants were required to complete a reactogenicity e-diary (see Module 5.3.5.1 C4591001 Protocol Section 8.2.2). All participants in Phase 1, and a subset of at least the first 6000 participants randomized in Phase 2/3, were asked to monitor and record local reactions, systemic events, and antipyretic medication usage for 7 days following administration of the study intervention. Any participants in Phase 3 who are HIV-positive or 12 to 15 years of age may also have been included in this subset (will be reported at a later time). In addition, participants 16 through 17 years of age enrolled under Protocol Amendment 9 and onwards will be included in the reactogenicity subset. All other participants, including those who originally received placebo and then received BNT162b2 under protocol amendment 10 and onwards, will not complete a reactogenicity e-diary but will have their local reactions and systemic events detected and reported as AEs in accordance with Module 5.3.5.1 C4591001 Protocol Section 8.3.2.

2.7.4.6.2.3.1.1. Local Reactions (Study C4591001)

During the reactogenicity e-diary reporting period, participants were asked to assess redness, swelling, and pain at the injection site (from Day 1 through Day 7 after each dose, where Day 1 is the day of each dose) and to record the symptoms in the reactogenicity e-diary. If a local reaction persisted beyond the end of the reactogenicity e-diary period following vaccination, the participant was requested to report that information.

Redness and swelling was measured and recorded in measuring device units (range: 1 to 21) and then categorized during analysis as absent, mild, moderate, or severe based on the grading scale in Table 29. Pain at the injection site was assessed by the participant as absent, mild, moderate, or severe according the grading scale in Table 29.

If a Grade 3 local reaction was reported in the reactogenicity e-diary, a telephone contact occurred to ascertain further details and determine whether a site visit was clinically indicated. Only an investigator or medically qualified person was able to classify a participant's local reaction as Grade 4. If a participant experienced a confirmed Grade 4 local reaction, the investigator was to immediately notify the sponsor and, if it was determined to be related to the administration of the study intervention, further vaccinations were to be discontinued in that participant.

Table 29. Local Reaction Grading Scale (Study C4591001)

	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Potentially Life Threatening (Grade 4)
Pain at the injection site	Does not interfere with activity	Interferes with activity	Prevents daily activity	Emergency room visit or hospitalization for severe pain
Redness	>2.0 cm to 5.0 cm (5 to 10 measuring device units)	>5.0 cm to 10.0 cm (11 to 20 measuring device units)	>10 cm (≥21 measuring device units)	Necrosis or exfoliative dermatitis
Swelling	>2.0 cm to 5.0 cm (5 to 10 measuring device units)	>5.0 cm to 10.0 cm (11 to 20 measuring device units)	>10 cm (≥21 measuring device units)	Necrosis

2.7.4.6.2.3.1.2. Systemic Events (Study C4591001)

During the reactogenicity e-diary reporting period, participants were asked to assess vomiting, diarrhea, headache, fatigue, chills, new or worsened muscle pain, and new or worsened joint pain (from Day 1 through Day 7 after each dose, where Day 1 is the day of each dose) and to record the symptoms in the reactogenicity e-diary. The symptoms were assessed by the participant as absent, mild, moderate, or severe according to the grading scale in Table 30.

If a Grade 3 systemic event was reported in the reactogenicity e-diary, a telephone contact occurred to ascertain further details and determine whether a site visit was clinically indicated. Only an investigator or medically qualified person is able to classify a participant's systemic event as Grade 4. If a participant experienced a confirmed Grade 4 systemic event, the investigator was to immediately notify the sponsor and, if it was determined to be related to the administration of the study intervention, further vaccinations were to be discontinued in that participant.

Table 30. Systemic Event Grading Scale (Study C4591001)

	Mild (Grade 1)	Moderate (Grade 2)	Severe (Grade 3)	Potentially Life Threatening (Grade 4)
Vomiting	1-2 times in 24 hours	>2 times in 24 hours	Requires IV hydration	Emergency room visit or hospitalization for hypotensive shock
Diarrhea	2 to 3 loose stools in 24 hours	4 to 5 loose stools in 24 hours	6 or more loose stools in 24 hours	Emergency room visit or hospitalization for severe diarrhea
Headache	Does not interfere with activity	Some interference with activity	Prevents daily routine activity	Emergency room visit or hospitalization for severe headache
Fatigue/ tiredness	Does not interfere with activity	Some interference with activity	Prevents daily routine activity	Emergency room visit or hospitalization for severe fatigue
Chills	Does not interfere with activity	Some interference with activity	Prevents daily routine activity	Emergency room visit or hospitalization for severe chills
New or worsened muscle pain	Does not interfere with activity	Some interference with activity	Prevents daily routine activity	Emergency room visit or hospitalization for severe new or worsened muscle pain
New or worsened joint pain	Does not interfere with activity	Some interference with activity	Prevents daily routine activity	Emergency room visit or hospitalization for severe new or worsened joint pain

2.7.4.6.2.3.1.3. Fever (Study C4591001)

Temperature was collected in the reactogenicity e-diary in the evening daily during the reactogenicity e-diary reporting period. It was also collected at any time during the reactogenicity e-diary data collection periods when fever was suspected. Fever was defined as an oral temperature of ≥38.0°C (100.4°F). The highest temperature for each day was to be recorded in the reactogenicity e-diary. Temperature was to be measured and recorded to 1 decimal place and then categorized during analysis according to the scale shown in Module 5.3.5.1 C4591001 Protocol Table 3.

If a fever of ≥39.0°C (102.1°F) was reported in the reactogenicity e-diary, a telephone contact was to occur to ascertain further details and determine whether a site visit was clinically indicated. Only an investigator or medically qualified person is able to confirm a participant's fever as >40.0°C (>104.0°F). If a participant experienced a confirmed fever >40.0°C (>104.0°F), the investigator was to immediately notify the sponsor and, if it was determined to be related to the administration of the study intervention, further vaccinations was to be discontinued in that participant.

2.7.4.6.2.3.2. Adverse Events and Serious Adverse Events (Study C4591001)

Definition of AE

An AE is defined as any untoward medical occurrence in a patient or clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention.

NOTE: An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study intervention.

Additional details regarding events that meet the AE definition and events that do not meet the AE definition are provided in Module 5.3.5.1 C4591001 Protocol Section 10.3.1.

Definition of SAE

If an event is not an AE per the definition above, then it cannot be an SAE even if serious conditions are met (eg, hospitalization for signs/symptoms of the disease under study, death due to progression of disease). An SAE is defined as any untoward medical occurrence that, at any dose:

- Results in death
- Is life-threatening
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent disability/incapacity

Is a congenital anomaly/birth defect

- Other situations (as described in the protocol)

Additional details regarding SAEs are presented in Module 5.3.5.1 C4591001 Protocol Section 10.3.2.

AEs will be reported by the participant (or, when appropriate, by a caregiver, surrogate, or the participant's legal guardian).

Time Period and Frequency for Collecting AE and SAE Information

The time period for actively eliciting and collecting AEs and SAEs (“active collection period”) for each participant begins from the time the participant/parent(s)/legal guardian provides informed consent, which is obtained before the participant’s participation in the study (ie, before undergoing any study-related procedure and/or receiving study intervention), through and including Visit 7 for Phase 1 participants, and Visit 3 for Phase 2/3 participants. In addition, any AEs occurring up to 48 hours after each subsequent blood draw must be recorded on the CRF.

SAEs will be collected from the time the participant/parent(s)/legal guardian provides informed consent to approximately 6 months after the last dose of study intervention (Visit 8 for Phase 1 participants, and Visit 4 for Phase 2/3 participants).

Additionally, for those participants who originally received placebo but went on to receive BNT162b2 at Vaccinations 3 and 4, AEs were collected from the time the participant provided informed consent (for receipt of Vaccinations 3 and 4) through and including Visit 103. SAEs were collected from the time the participant provides informed consent (for receipt of Vaccinations 3 and 4) to approximately 6 months after the second dose of BNT162b2 (Visit 104).

AEs and SAEs reported during the open-label follow-up period will be summarized separately for participants who were unblinded at the time of being eligible for receipt of BNT162b2 according to recommendations detailed separately, and available in the electronic study reference portal, or no later than at approximately Visit 4.

For Phase 1 participants who went on to receive a third dose of BNT162, AEs and SAEs were collected from the time the participant provided informed consent (for receipt of Vaccination 3) through and including Visit 8c (1 month after the third dose).

Follow-up by the investigator continues throughout and after the active collection period and until the AE or SAE or its sequelae resolve or stabilize at a level acceptable to the investigator and Pfizer concurs with that assessment.

For additional details regarding data collection for adverse events, refer to Module 5.3.5.1 C4591001 Protocol Section 8.3 and Module 5.3.5.1 C4591001 Statistical Analysis Plan Section 3.1.1.4.

Intensity for each AE and SAE reported during the study was assessed as mild (Grade 1), moderate (Grade 2), severe (Grade 3), or life-threatening (Grade 4) and assessed for causality as described in Module 5.3.5.1 Protocol Section 10.3.3.

For information regarding recording/reporting and follow-up of AEs and/or SAEs, refer to Module 5.3.5.1 Protocol Section 10.3.3 and 10.3.4.

2.7.4.6.2.3.2.1. Disease-Related Events and/or Disease-Related Outcomes Not Qualifying as AEs or SAEs

Potential COVID-19 illnesses and their sequelae that are consistent with the clinical endpoint definition should not be recorded as AEs. These data will be captured as efficacy assessment data only on the relevant pages of the CRF, as these are expected endpoints.

Potential COVID-19 illnesses and their sequelae will not be reported according to the standard process for expedited reporting of SAEs, even though the event may meet the definition of an SAE. These events will be recorded on the COVID-19 illness pages in the participant's CRF within 1 day.

NOTE: However, if either of the following conditions applies, then the event must be recorded and reported as an SAE (instead of a disease-related event):

> The event is, in the investigator's opinion, of greater intensity, frequency, or duration than expected for the individual participant.
>
> OR
>
> The investigator considers that there is a reasonable possibility that the event was related to study intervention.

Potential COVID-19 illness events and their sequelae will be reviewed by a group of internal blinded case reviewers. Any SAE that is determined by the internal case reviewers NOT to meet endpoint criteria is reported back to the investigator site of incidence. The investigator must report the SAE to Pfizer Safety within 24 hours of being made aware that the SAE did not meet endpoint criteria. The investigator's SAE awareness date is the date on which the investigator site of incidence receives the SAE back from the internal case reviewers.

2.7.4.6.2.3.3. Phase 1 Stopping Rules (Study C4591001)

Stopping rules were in place for all Phase 1 participants, based on review of AE data and e-diary reactogenicity data, until the start of Phase 2/3 or 30 days after the administration of the second dose of study intervention in Phase 1, whichever was later.

Refer to Module 5.3.5.1 C4591001 Protocol Section 8.2.3 for additional details on Phase 1 stopping rules.

2.7.4.6.2.3.4. Surveillance of Events That Could Represent Enhanced COVID-19 and Phase 2/3 Stopping Rule (Study C4591001)

As this was a sponsor open-label study during Phase 1, the sponsor conducted unblinded reviews of the data during the course of the study, including for the purpose of safety assessment. Any NAAT-confirmed COVID-19 cases in Phase 1 were to be reviewed contemporaneously by the IRC and the DMC.

In Phase 2/3, the unblinded team supporting the DMC, including an unblinded medical monitor, will review cases of severe COVID-19 as they are received and will review AEs at least weekly for additional potential cases of severe COVID-19. At any point, the unblinded team may discuss with the DMC chair whether the DMC should review cases for an adverse imbalance of cases of COVID-19 and/or severe COVID-19 between the vaccine and placebo groups.

Stopping and alert rules were to be applied (see Module 5.3.5.1 C4591001 Protocol Section 8.2.4). Participants were instructed when to contact the site due to potential COVID-19 illness (see Module 5.3.5.1 C4591001 Protocol Section 8.13). Reporting and review of potential COVID-19 illness is further detailed in Module 5.3.5.1 C4591001 Protocol Section 8.3.7.

2.7.4.6.2.3.5. Exposure During Pregnancy or Breastfeeding, and Occupational Exposure

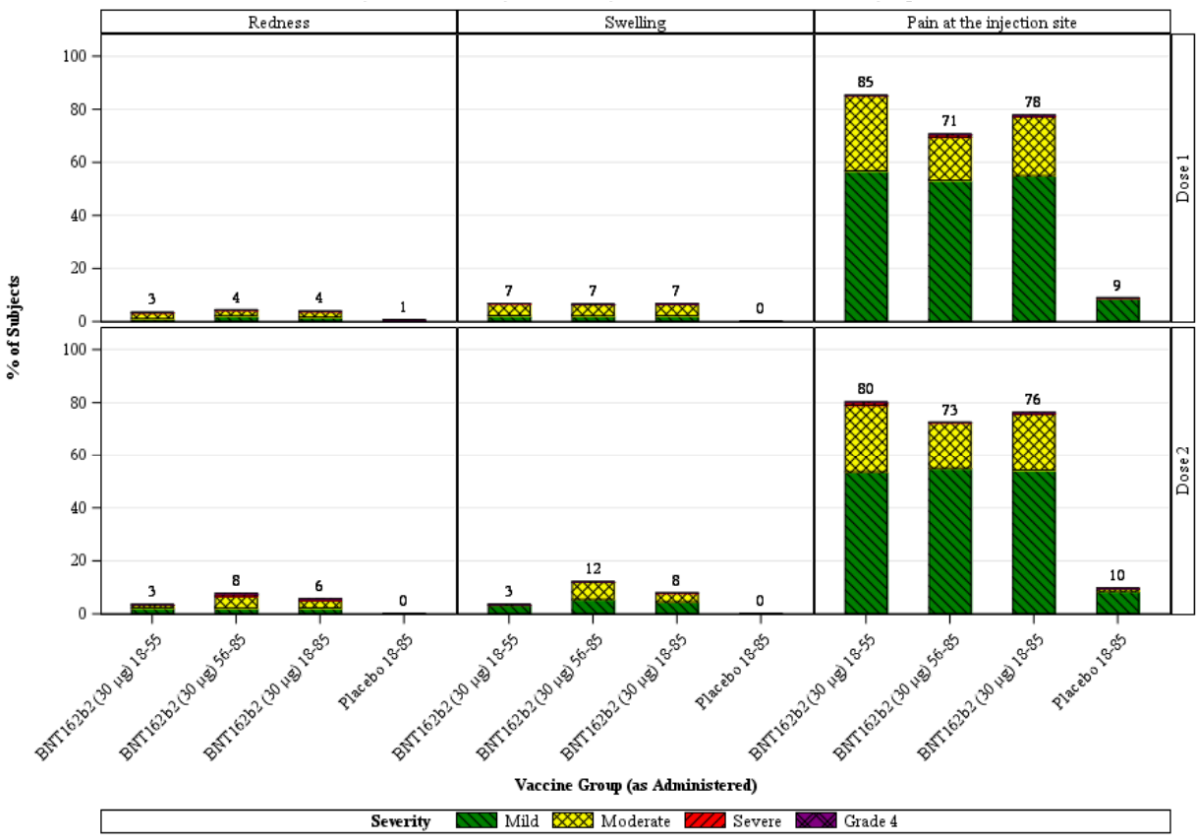
Details regarding exposure during pregnancy or breastfeeding and occupational exposure are presented in Module 5.3.5.1 C4591001 Protocol Section 8.3.5.

2.7.4.6.3. Appendix C: Phase 2 Study C4591001 Post-text Tables

2.7.4.6.3.1. Reactogenicity (Phase 2, Study C4591001, Post-text Tables and Figures)

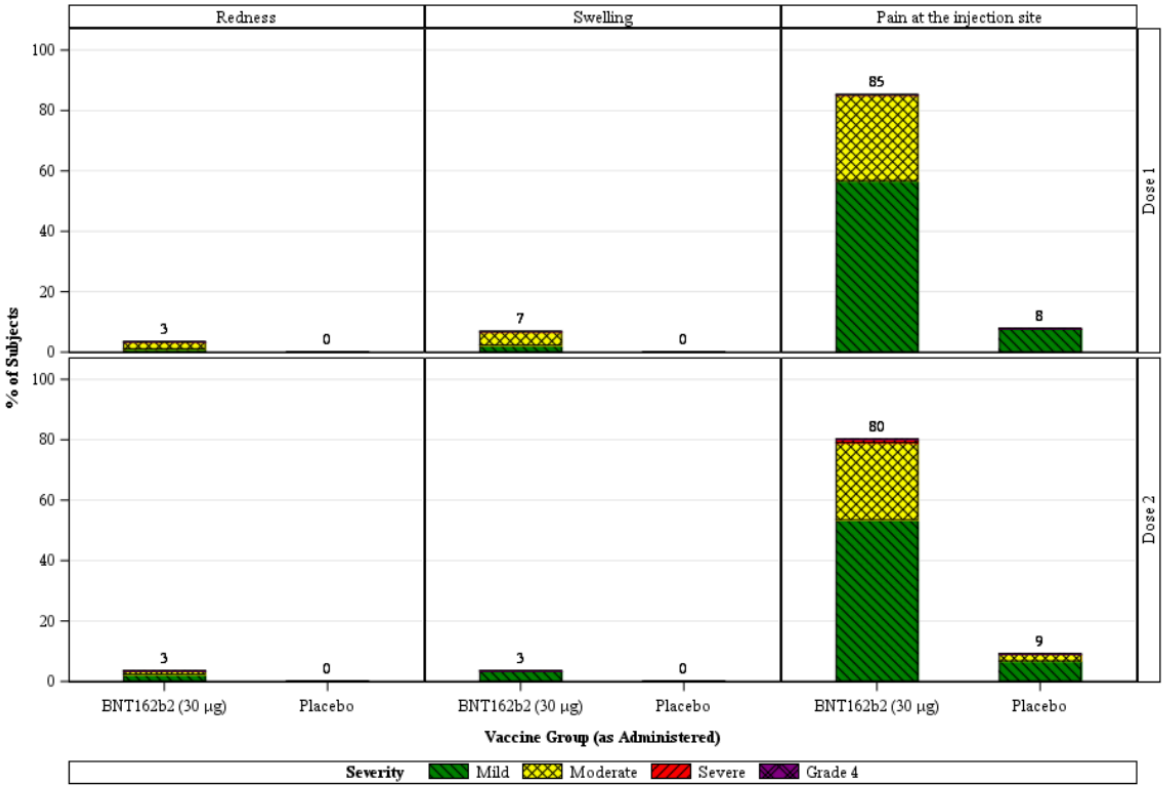
2.7.4.6.3.1.1. Local Reactions (Phase 2, Study C4591001, Post-text Tables and Figures)

Figure 9. Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose – Phase 2 – Safety Population



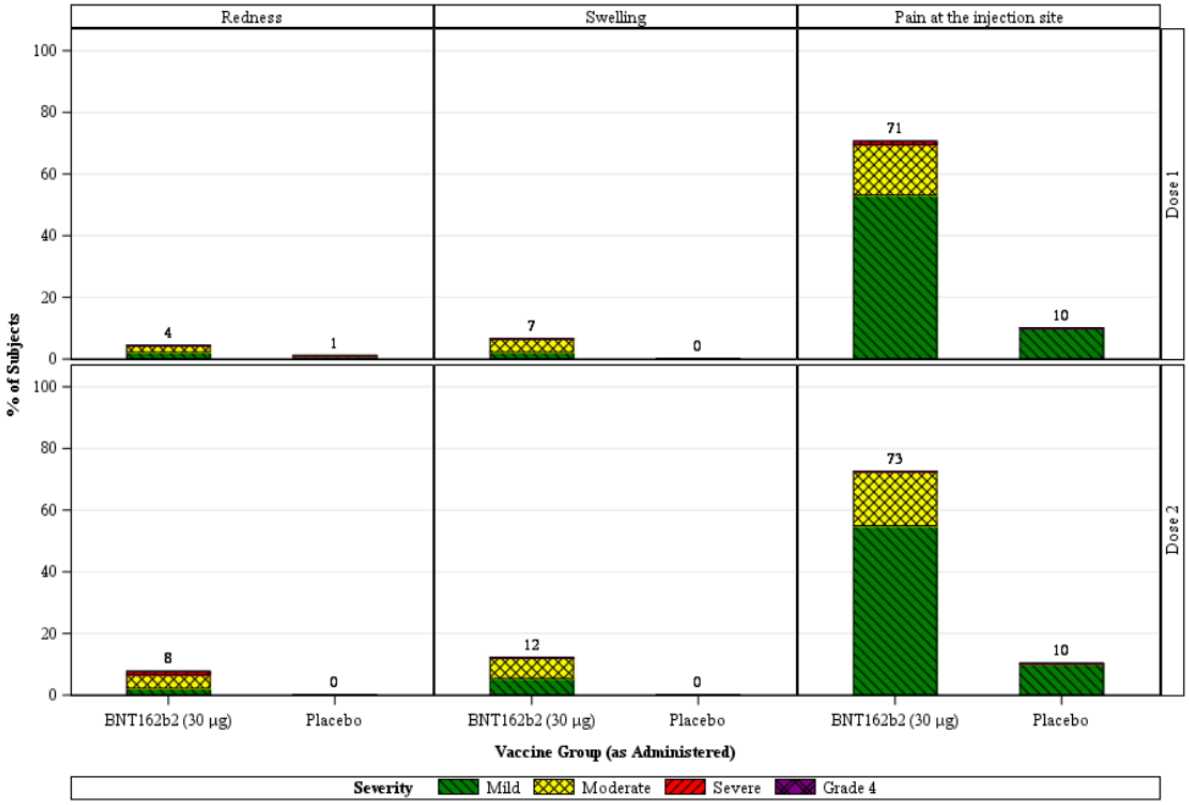
Note: Number above each bar denotes percentage of participants reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 11SEP2020 (17:39)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: /nda2_unblinded/C4591001_IA_P2/adce_f001_lr_maxsev_p2

Figure 10. Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, Phase 2 - Age Group: 18-55 Years – Safety Population



Note: Number above each bar denotes percentage of participants reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 09OCT2020 (04:30)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: /nda2_unblinded/C4591001_IA_P2_2/adce_f001_lr_max_age_p2

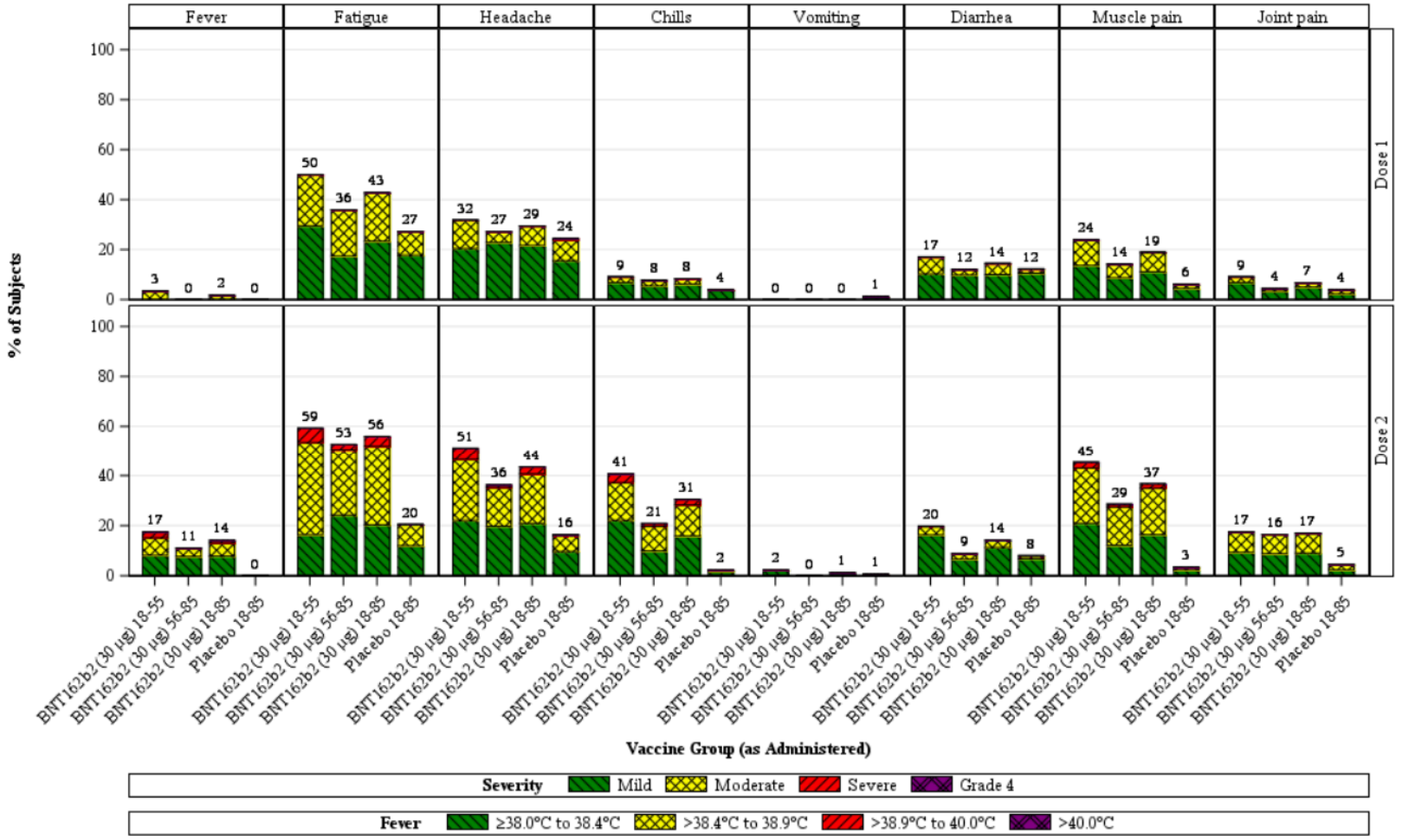
Figure 11. Subjects Reporting Local Reactions, by Maximum Severity, Within 7 Days After Each Dose, Phase 2 – Age Group: 56-85 Years – Safety Population



Note: Number above each bar denotes percentage of participants reporting the reaction with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 09OCT2020 (04:30)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2_2/adce_f001_lr_max_age_p2

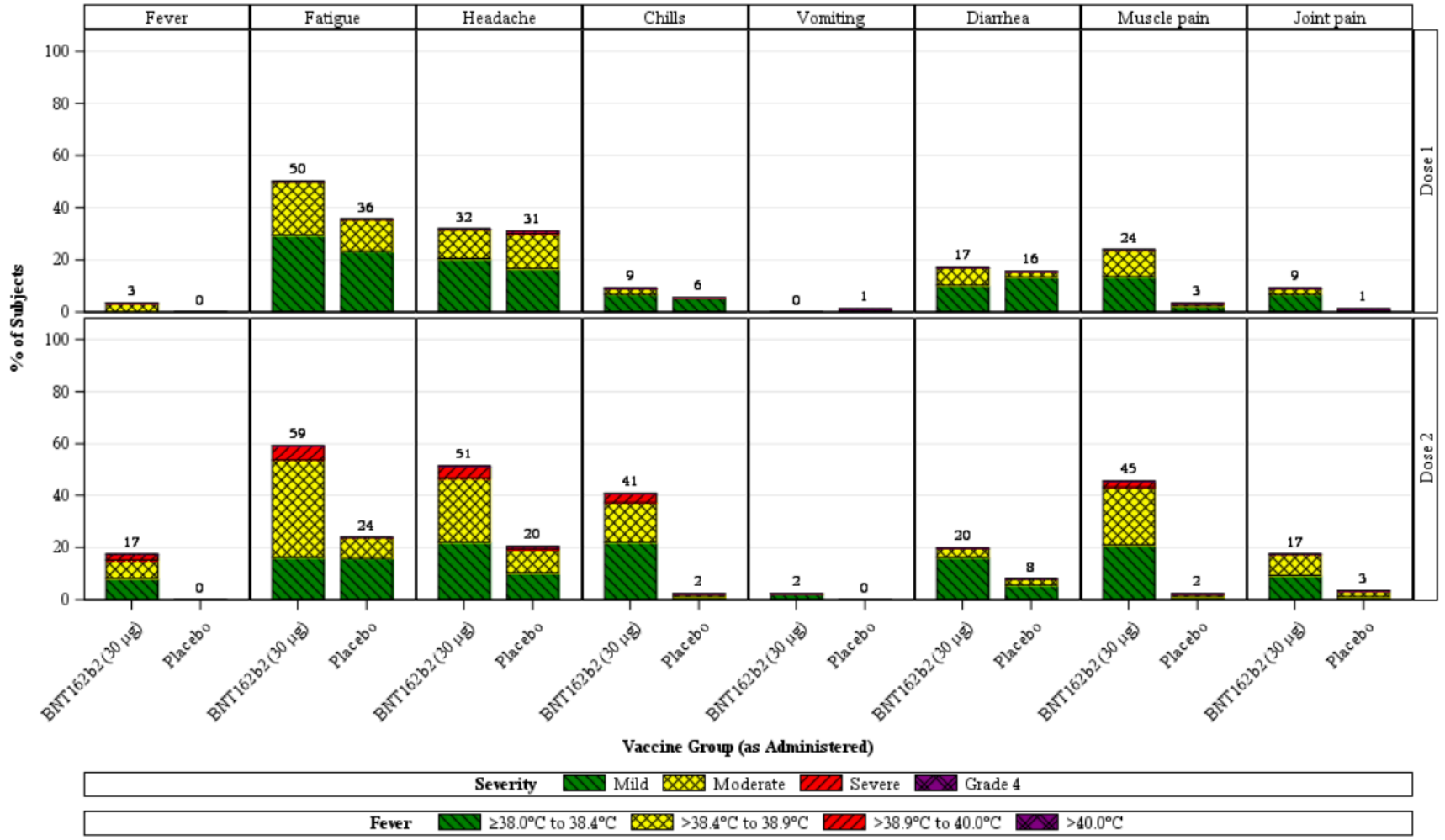
2.7.4.6.3.1.2. Systemic Events (Phase 2, Study C4591001, Post-text Tables and Figures)

Figure 12. Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose – Phase 2 – Safety Population



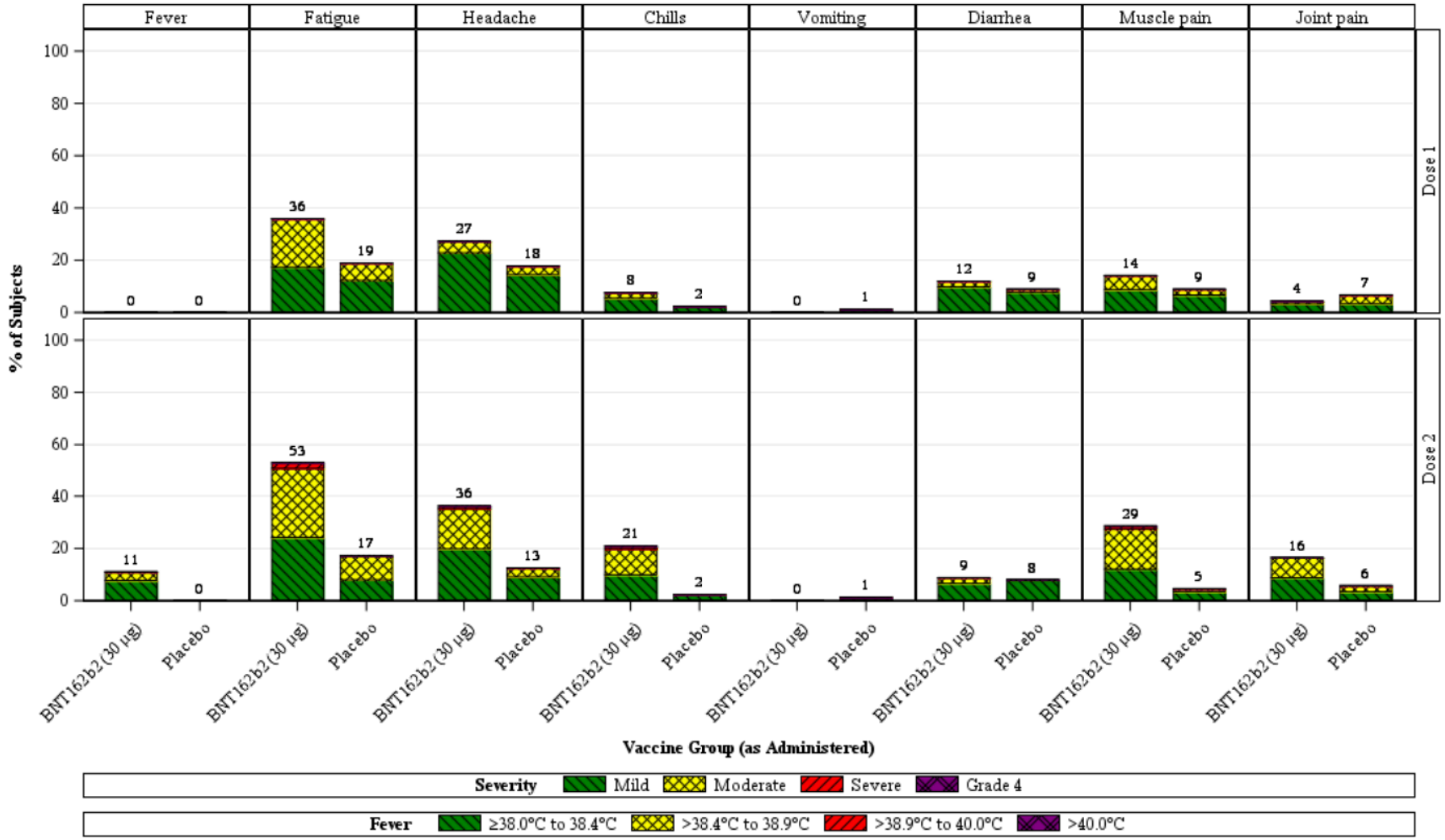
Note: Number above each bar denotes percentage of participants reporting the event with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 11SEP2020 (17:39)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2/adce_f001_se_maxsev_p2

Figure 13. Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, Phase 2 – Age Group: 18-55 Years – Safety Population



Note: Number above each bar denotes percentage of participants reporting the event with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 09OCT2020 (04:30)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2_2/adce_f001_se_max_age_p2

Figure 14. Subjects Reporting Systemic Events, by Maximum Severity, Within 7 Days After Each Dose, Phase 2 – Age Group: 56-85 Years – Phase 2 – Safety Population



Note: Number above each bar denotes percentage of participants reporting the event with any severity.
PFIZER CONFIDENTIAL SDTM Creation: 05SEP2020 (13:09) Source Data: adfacevd Table Generation: 09OCT2020 (04:30)
(Cutoff Date: 02SEP2020, Snapshot Date: 04SEP2020) Output File: ./nda2_unblinded/C4591001_IA_P2_2/adce_f001_se_max_age_p2

2.7.4.6.4. Appendix D: Phase 3 Study C4591001 Post-text Tables

2.7.4.6.4.1. Exposure, Disposition, and Study Population Characteristics (Phase 3, Study C4591001, Post-text Tables)

Table 31. Disposition of All Randomized Subjects – Phase 2/3 Subjects ⩾16 Years of Age

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=22085) n[b] (%)	Placebo (N[a]=22080) n[b] (%)	Total (N[a]=44165) n[b] (%)
Randomized	22085 (100.0)	22080 (100.0)	44165 (100.0)
Not vaccinated	55 (0.2)	50 (0.2)	105 (0.2)
Original blinded placebo-controlled follow-up period			
Vaccinated	22030 (99.8)	22030 (99.8)	44060 (99.8)
Dose 1	22030 (99.8)	22030 (99.8)	44060 (99.8)
Dose 2	21675 (98.1)	21650 (98.1)	43325 (98.1)
Discontinued from original blinded placebo-controlled vaccination period[c]	352 (1.6)	528 (2.4)	880 (2.0)
Reason for discontinuation			
Lost to follow-up	151 (0.7)	153 (0.7)	304 (0.7)
Withdrawal by subject	109 (0.5)	181 (0.8)	290 (0.7)
No longer meets eligibility criteria	26 (0.1)	120 (0.5)	146 (0.3)
Adverse event	27 (0.1)	26 (0.1)	53 (0.1)
Physician decision	5 (0.0)	8 (0.0)	13 (0.0)
Pregnancy	6 (0.0)	6 (0.0)	12 (0.0)
Protocol deviation	3 (0.0)	8 (0.0)	11 (0.0)
Death	3 (0.0)	4 (0.0)	7 (0.0)
Medication error without associated adverse event	3 (0.0)	2 (0.0)	5 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	18 (0.1)	20 (0.1)	38 (0.1)
Unblinded before 1-month post–Dose 2 visit	253 (1.1)	240 (1.1)	493 (1.1)
Completed 1-month post–Dose 2 visit	21382 (96.8)	21293 (96.4)	42675 (96.6)
Withdrawn from the study	343 (1.6)	484 (2.2)	827 (1.9)
Withdrawn after Dose 1 and before Dose 2	176 (0.8)	211 (1.0)	387 (0.9)
Withdrawn after Dose 2 and before 1-month post–Dose 2 visit	100 (0.5)	139 (0.6)	239 (0.5)
Withdrawn after 1-month post–Dose 2 visit	67 (0.3)	134 (0.6)	201 (0.5)
Reason for withdrawal from the study			
Lost to follow-up	174 (0.8)	191 (0.9)	365 (0.8)
Withdrawal by subject	122 (0.6)	226 (1.0)	348 (0.8)
Protocol deviation	11 (0.0)	24 (0.1)	35 (0.1)
Death	16 (0.1)	15 (0.1)	31 (0.1)
Adverse event	9 (0.0)	8 (0.0)	17 (0.0)
Physician decision	3 (0.0)	6 (0.0)	9 (0.0)

Table 31. Disposition of All Randomized Subjects – Phase 2/3 Subjects ⩾16 Years of Age

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=22085) n[b] (%)	Placebo (N[a]=22080) n[b] (%)	Total (N[a]=44165) n[b] (%)
No longer meets eligibility criteria	1 (0.0)	4 (0.0)	5 (0.0)
Pregnancy	0	1 (0.0)	1 (0.0)
Medication error without associated adverse event	1 (0.0)	0	1 (0.0)
Withdrawal by parent/guardian	1 (0.0)	0	1 (0.0)
Other	5 (0.0)	9 (0.0)	14 (0.0)
Open-label follow-up period			
Originally randomized to BNT162b2	20404 (92.4)		
Received Dose 2/unplanned dose	87 (0.4)		
Completed 1-month post–Dose 2 visit	210 (1.0)		
Completed 6-month post–Dose 2 visit	6414 (29.0)		
Withdrawn from the study	105 (0.5)		
Withdrawn before 6-month post–Dose 2 visit	103 (0.5)		
Withdrawn after 6-month post–Dose 2 visit	2 (0.0)		
Reason for withdrawal from the study			
Withdrawal by subject	56 (0.3)		
Protocol deviation	35 (0.2)		
Lost to follow-up	4 (0.0)		
Death	3 (0.0)		
Physician decision	2 (0.0)		
Adverse event	1 (0.0)		
No longer meets eligibility criteria	1 (0.0)		
Other	3 (0.0)		
Originally randomized to placebo		20948 (94.9)	
Withdrawn from the study after unblinding and before Dose 3		497 (2.3)	
Received Dose 3 (first dose of BNT162b2 [30 µg])		19612 (88.8)	
Received Dose 4 (second dose of BNT162b2 [30 µg])		15986 (72.4)	
Discontinued from open-label vaccination period[d]		24 (0.1)	
Reason for discontinuation from open-label vaccination period			
Protocol deviation		6 (0.0)	
Adverse event		5 (0.0)	
Withdrawal by subject		5 (0.0)	
Pregnancy		4 (0.0)	
Death		2 (0.0)	
Lost to follow-up		2 (0.0)	
Completed 1-month post–Dose 4 visit		7209 (32.6)	
Withdrawn from the study		14 (0.1)	
Withdrawn after Dose 3 and before Dose 4		11 (0.0)	

Table 31. Disposition of All Randomized Subjects – Phase 2/3 Subjects ⩾16 Years of Age

	Vaccine Group (as Randomized)		
	BNT162b2 (30 µg) (N[a]=22085) n[b] (%)	Placebo (N[a]=22080) n[b] (%)	Total (N[a]=44165) n[b] (%)
Withdrawn after Dose 4 and before 1-month post–Dose 4 visit		2 (0.0)	
Withdrawn after 1-month post–Dose 4 visit		1 (0.0)	
Reason for withdrawal from the study			
Withdrawal by subject		7 (0.0)	
Protocol deviation		3 (0.0)	
Death		2 (0.0)	
Adverse event		1 (0.0)	
Lost to follow-up		1 (0.0)	

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
Note: Subjects randomized but did not sign informed consent or had a significant quality event due to lack of PI oversight are not included in any analysis population.
Note: Because of a dosing error, Subjects C4591001 1081 10811053, C4591001 1088 10881077, C4591001 1177 11771089 and C4591001 1231 12311057 received an additional dose of BNT162b2 (30 µg) at an unscheduled visit after receiving 1 dose of BNT162b2 (30 µg) and 1 dose of placebo.
a. N = number of randomized subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Original blinded placebo-controlled vaccination period is defined as the time period from Dose 1 to 1 month post–Dose 2.
d. Open-label vaccination period is defined as the time period from Dose 3 (first dose of BNT162b2 [30 µg]) to 1 month post–Dose 4 (second dose of BNT162b2 [30 µg]).
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (19:20) Source Data: adds Table Generation: 27MAR2021 (16:34)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adds s002 all p3 rand

Table 32. Vaccine as Administered by Vaccine Group – Phase 2/3 Subjects ⩾16 Years of Age – All Randomized Subjects

Vaccine (as Administered)	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=22085) n[b] (%)	Placebo (N[a]=22080) n[b] (%)
Vaccinated	22030 (99.8)	22030 (99.8)
Not vaccinated	55 (0.2)	50 (0.2)
Dose 1		
BNT162b2 (30 µg)	22026 (99.7)	4 (0.0)
Placebo	2 (0.0)	22025 (99.8)
Indeterminate vaccine[c]	2 (0.0)	1 (0.0)
Dose 2		
BNT162b2 (30 µg)	21756 (98.5)	5 (0.0)
Placebo	3 (0.0)	21645 (98.0)
Indeterminate vaccine[c]	0	0
Dose 3		
First dose BNT162b2 (30 µg)		19612 (88.8)
Indeterminate vaccine[c]		0
Dose 4		
Second dose BNT162b2 (30 µg)		15986 (72.4)
Indeterminate vaccine[c]		0

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. "Indeterminate vaccine" refers to subjects whose vaccine (as administered) could not be determined.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (01:28)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/advx_s002_adm_p3_rand

Table 33. Vaccine Administration Timing – Phase 2/3 Subjects ⩾16 Years of Age – All Randomized Subjects

	Vaccine Group (as Randomized)	
	BNT162b2 (30 µg) (N[a]=22085) n[b] (%)	Placebo (N[a]=22080) n[b] (%)
Randomized	22085 (100.0)	22080 (100.0)
Not vaccinated	55 (0.2)	50 (0.2)
Dose 1	22030 (99.8)	22030 (99.8)
Dose 2[c]	21759 (98.5)	21650 (98.1)
<14 Days	0	2 (0.0)
14 to 20 Days	7374 (33.4)	7283 (33.0)
21 to 27 Days	13823 (62.6)	13850 (62.7)
28 to 34 Days	249 (1.1)	300 (1.4)
35 to 41 Days	96 (0.4)	90 (0.4)
42 to 48 Days	59 (0.3)	47 (0.2)
49 to 55 Days	43 (0.2)	38 (0.2)
>55 Days	115 (0.5)	40 (0.2)
Dose 3 (first dose of BNT162b2 [30 µg])		19612 (88.8)
Dose 4 (second dose of BNT162b2 [30 µg])[d]		15986 (72.4)
<14 Days		2 (0.0)
14 to 20 Days		4980 (22.6)
21 to 27 Days		10617 (48.1)
28 to 34 Days		247 (1.1)
35 to 41 Days		92 (0.4)
42 to 48 Days		34 (0.2)
49 to 55 Days		12 (0.1)
>55 Days		2 (0.0)

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Days calculated since Dose 1.
d. Days calculated since Dose 3.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (01:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/advx s002 time p3 rand

Table 34. Safety Population – Phase 2/3 Subjects ⩾16 Years of Age

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) n[a]	Placebo n[a]	Total n[a] (%)
Randomized[b]			44165
Vaccinated	22032	22025	44060 (99.8)
Safety population	22026	22021	44050 (99.7)
HIV-positive	100	100	200 (0.5)
Indeterminate vaccine[c]			3 (0.0)
Excluded from safety population			115 (0.3)
Reason for exclusion			
Subject did not receive study vaccine			105 (0.2)
Unreliable data due to lack of PI oversight			10 (0.0)

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. n = Number of subjects with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
c. "Indeterminate vaccine" refers to subjects whose vaccine group (as administered) could not be determined. These subjects were not included in the safety analysis but their safety data is listed separately.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (01:42)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adsl s003 pop all p3

Table 35. Follow-up Time After Dose 2 – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)		
	BNT162b2 (30 µg) (N[a]=22026) n[b] (%)	Placebo (N[a]=22021) n[b] (%)	Total (N[a]=44047) n[b] (%)
Subjects (%) with length of follow-up of:			
Original blinded placebo-controlled follow-up period			
<2 Months	1251 (5.7)	1331 (6.0)	2582 (5.9)
≥2 Months to <4 months	7744 (35.2)	8070 (36.6)	15814 (35.9)
≥4 Months to <6 months	11253 (51.1)	11316 (51.4)	22569 (51.2)
≥6 Months	1778 (8.1)	1304 (5.9)	3082 (7.0)
Total exposure from Dose 2 to cutoff date			
<2 Months	390 (1.8)		
≥2 Months to <4 months	679 (3.1)		
≥4 Months to <6 months	8951 (40.6)		
≥6 Months	12006 (54.5)		

Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (01:37)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_fu_d2_p3_saf

Table 36. Demographic Characteristics – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ≥16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=12006) n[b] (%)
Sex	
Male	6040 (50.3)
Female	5966 (49.7)
Race	
White	10370 (86.4)
Black or African American	851 (7.1)
American Indian or Alaska Native	55 (0.5)
Asian	452 (3.8)
Native Hawaiian or other Pacific Islander	31 (0.3)
Multiracial	195 (1.6)
Not reported	52 (0.4)
Racial designation	
Japanese	44 (0.4)
Ethnicity	
Hispanic/Latino	3339 (27.8)
Non-Hispanic/non-Latino	8604 (71.7)
Not reported	63 (0.5)
Country	
Argentina	2118 (17.6)
Brazil	596 (5.0)
USA	9292 (77.4)
Age group (at vaccination)	
16-55 Years	6666 (55.5)
>55 Years	5340 (44.5)
Age at vaccination (years)	
Mean (SD)	51.4 (15.44)
Median	53.0
Min, max	(18, 85)
Baseline SARS-CoV-2 status	
Positive[c]	250 (2.1)
Negative[d]	11678 (97.3)
Missing	78 (0.6)
Body mass index (BMI)	
Underweight (<18.5 kg/m^2)	136 (1.1)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	3527 (29.4)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	4232 (35.2)

Table 36. Demographic Characteristics – Subjects With at Least 6 Months of Follow-up Time After Dose 2 – Phase 2/3 Subjects ⩾16 Years of Age (Subjects Who Originally Received BNT162b2) – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=12006) n[b] (%)
Obese (≥30.0 kg/m^2)	4107 (34.2)
Missing	4 (0.0)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (15:19)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File: ./nda2_unblinded/C4591001_BLA/adsl_s005_demo_6m_p3_saf

Table 37. Demographic Characteristics – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=19611) n[b] (%)
Sex	
Male	9841 (50.2)
Female	9770 (49.8)
Race	
White	16299 (83.1)
Black or African American	1636 (8.3)
American Indian or Alaska Native	189 (1.0)
Asian	849 (4.3)
Native Hawaiian or other Pacific Islander	28 (0.1)
Multiracial	509 (2.6)
Not reported	101 (0.5)
Racial designation	
Japanese	77 (0.4)
Ethnicity	
Hispanic/Latino	5002 (25.5)
Non-Hispanic/non-Latino	14499 (73.9)
Not reported	110 (0.6)
Country	
Argentina	2612 (13.3)
Brazil	1428 (7.3)
Germany	241 (1.2)
South Africa	362 (1.8)
Turkey	242 (1.2)
USA	14726 (75.1)
Age group (at vaccination)	
16-55 Years	11404 (58.2)
>55 Years	8207 (41.8)
Age at vaccination (years)	
Mean (SD)	50.1 (15.91)
Median	51.0
Min, max	(16, 91)
Baseline SARS-CoV-2 status	
Positive[c]	590 (3.0)
Negative[d]	18909 (96.4)
Missing	112 (0.6)
Body mass index (BMI)	

Table 37. Demographic Characteristics – Subjects Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Phase 2/3 Subjects ⩾16 Years of Age – Safety Population

	Vaccine Group (as Administered)
	BNT162b2 (30 µg) (N[a]=19611) n[b] (%)
Underweight (<18.5 kg/m^2)	258 (1.3)
Normal weight (≥18.5 kg/m^2 - 24.9 kg/m^2)	5805 (29.6)
Overweight (≥25.0 kg/m^2 - 29.9 kg/m^2)	6790 (34.6)
Obese (≥30.0 kg/m^2)	6753 (34.4)
Missing	5 (0.0)

Abbreviation: SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.
a. N = number of subjects in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of subjects with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: adsl Table Generation: 27MAR2021 (15:20)
(Cutoff Date: 13MAR2021, Snapshot Date: 25MAR2021) Output File:
./nda2 unblinded/C4591001 BLA/adsl s005 demo cr p3 saf

2.7.4.7. REFERENCES

1 US Food and Drug Administration, Guidance for Industry Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trial. Rockville, MD: Center for Biologics Evaluation and Research; September 2007. Available: Available at: https://www.fda.gov/media/73679/download. Accessed: 30 November 2020.

2 Miettinen O, Nurminen M. Comparative analysis of two rates. Stat Med 1985;4(2):213-26.

3 Centers for Disease Control and Prevention (CDC). COVID-19 Data Tracker. Available at: https://covid.cdc.gov/covid-data-tracker/#vaccinations. Accessed 23 April 2021.

4 Coronavirus (COVID-19) Vaccinations – Statistics and Research – Our World in Data. Available at: https://ourworldindata.org/covid-vaccinations#which-vaccines-have-been-administered-in-each-country. Accessed 23 April 2021.

Section 1 - 125742/0/0

- 1.3.4 Financial Certification and Disclosure
  - [0001] Financial Certification and Disclosure - Summary Note
  - [0001] Financial Certification and Disclosure - Bias Statement
  - [0001] Financial Certification and Disclosure - FDA Form 3454
  - [0001] Financial Certification and Disclosure - FDA Form 3455
- 1.3.5 Patent and Exclusivity
  - 1.3.5.3 Exclusivity Claim
    - [0001] Exclusivity Claim
- 1.4 References
  - 1.4.3 List of Authorized Persons to Incorporate By Reference
    - [0001] Letter of Authorization to US Agent
- 1.6 Meetings
  - 1.6.3 Correspondence Regarding Meetings
    - [0001] Correspondence Regarding Meetings
- 1.7 Fast Track
  - 1.7.4 Correspondence Regarding Fast Track/Rolling Review
    - [0001] Grant Fast Track Designation Letter
- 1.9 Pediatric Administrative Information
  - 1.9.2 Request for Deferral of Pediatric Studies
    - [0001] Request for Deferral of Pediatric Studies
  - 1.9.4 Proposed Pediatric Study Request and Amendments
    - [0001] Agreed Initial Pediatric Study Plan

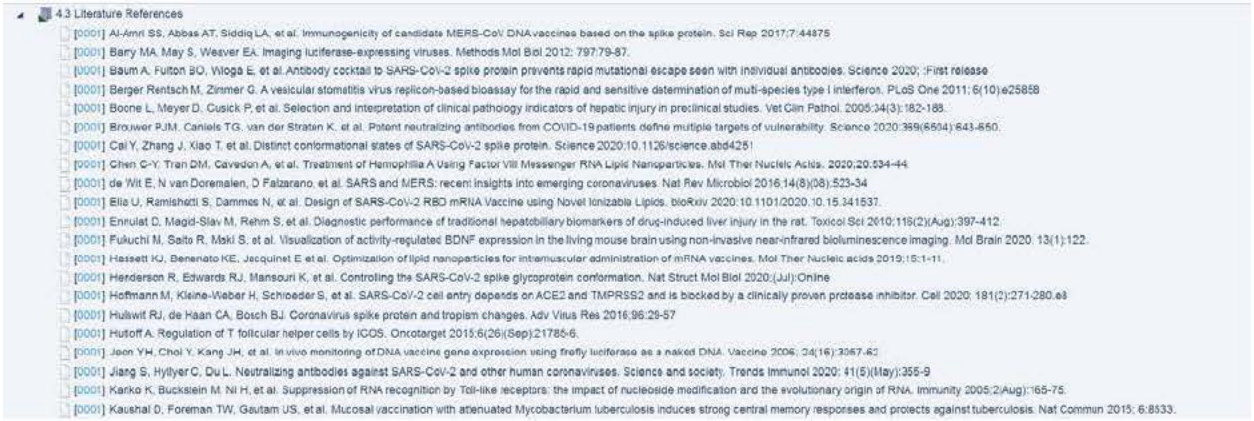
- 1.9.4 Proposed Pediatric Study Request and Amendments
  - [0001] Agreed Initial Pediatric Study Plan

- 1.9.6 Other Correspondence Regarding Pediatric Exclusivity or Study Plans
  - [0001] Agreed iPSP Agreement Letter
- 1.12 Other Correspondence
  - 1.12.5 Request for a Waiver
    - [0001] Waiver Request for FDA Designated Suffix
- 2 Common Technical Document Summaries
- **4 Nonclinical Study Reports**
- 5 Clinical Study Reports

Section 2 - 125742/0/0

- [0001] Pharmacology Tabulated Summary
- 2.6.4 Pharmacokinetics Written Summary
  - [0001] Pharmacokinetics Written Summary
- 2.6.5 Pharmacokinetics Tabulated Summary
  - [0001] Pharmacokinetics Tabulated Summary
- 2.6.6 Toxicology Written Summary
  - [0001] Toxicology Written Summary
- 2.6.7 Toxicology Tabulated Summary
  - [0001] Toxicology Tabulated Summary
- 2.7 Clinical Summary
  - 2.7.1 Summary of Biopharmaceutic Studies and Associated Analytical Methods
    - [0001] Summary of Biopharmaceutic Studies and Associated Analytical Methods
  - 2.7.3 Summary of Clinical Efficacy
    - [0001] Summary of Clinical Efficacy
  - 2.7.4 Summary of Clinical Safety
    - [0001] Summary of Clinical Safety
  - 2.7.5 Literature-References
    - [0001] Literature References
  - 2.7.6 Synopses of Individual Studies
    - [0001] Synopses of Individual Studies
- **4 Nonclinical Study Reports**
- 5 Clinical Study Reports

Section 4 - 125742/0/0

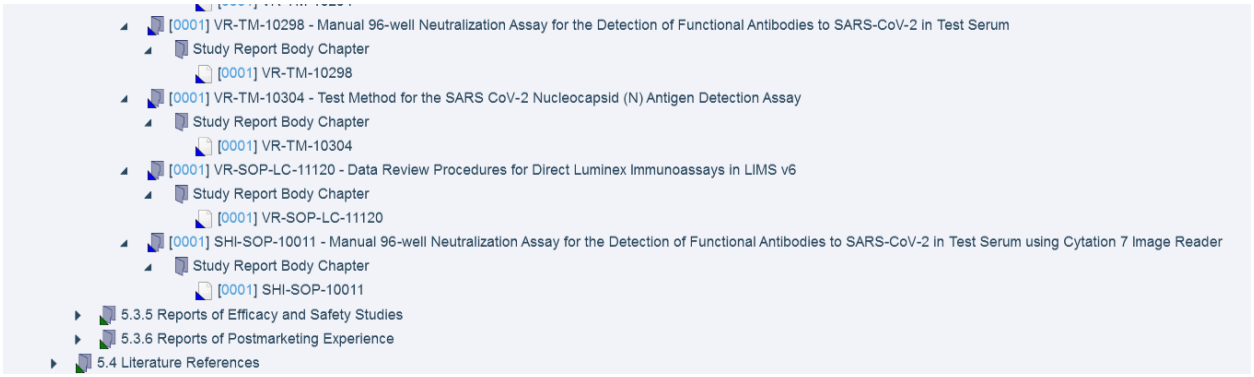


[0001] Kaushal D, Foreman TW, Gautam US, et al. Mucosal vaccination with attenuated Mycobacterium tuberculosis induces strong central memory responses and protects against tuberculosis. Nat Commun 2015; 6:8533.
[0001] Ke Z, Oton J, Qu K, et al. Structures and distributions of SARS-CoV-2 spike proteins on intact virions. Nature 2020;10.1038/s41586-020-2665-2.
[0001] Kim JY, Ko JH, Kim Y, et al. Viral load kinetics of SARS-CoV-2 infection in first two patients in Korea. J Korean Med Sci 2020;35(7)(Feb):e86
[0001] Liu L, Wang P, Nair MS, et al. Potent neutralizing antibodies against multiple epitopes on SARS-CoV-2 spike. Nature 2020;584(7821):450-456.
[0001] Munster JV, Feldmann F, Williamson BN, et al. Respiratory disease in rhesus macaques inoculated with SARS-CoV-2. Nature 2020;(May):Accepted preview.
[0001] Muruato AE, Fontes-Garfias CR, Ren P, et al. A high-throughput neutralizing antibody assay for COVID-19 diagnosis and vaccine evaluation. Nat Commun 2020;11(1):4059.
[0001] Pallesen J, Wang N, Corbett KS, et al. Immunogenicity and structures of a rationally designed prefusion MERS-CoV spike antigen. Proc Natl Acad Sci USA 2017;114(35):E7348-57
[0001] Pardi N, Hogan MJ, Pelc RS, et al. Zika virus protection by a single low-dose nucleoside-modified mRNA vaccination. Nature 2017;543(7644):248-51
[0001] Pardi N, Parkhouse K, Kirkpatrick E, et al. Nucleoside-modified mRNA immunization elicits influenza virus hemagglutinin stalk-specific antibodies. Nat Commun 2018;9(1)(08):3361.
[0001] Sahin U, Kariko K, Tureci O. mRNA-based therapeutics - developing a new class of drugs. Nat Rev Drug Discov 2014;13(10):759-80
[0001] Sedic M, Senn J, Lynn A, et al. Safety evaluation of lipid nanoparticle-formulated modified mRNA in Sprague-Dawley rat and cynomologous monkey. Vet Pathol 2018;55(2):341-54.
[0001] Sellers RS, Nelson K, Bindu Bennet B, et al. Scientific and Regulatory Policy Committee Points to Consider: Approaches to the Conduct and Interpretation of Vaccine Safety Studies for Clinical and Anatomic Pathologists. Toxicol Pathol 2020;48(2):257-
[0001] Singh DK, SR Ganatra, B Singh et al. SARS-CoV-2 infection leads to acute infection with dynamic cellular and inflammatory flux in the lung that varies across nonhuman primate species. bioRxiv 10.1101/2020.06.05.136481 (2020).
[0001] Slansky JE, Rattis FM, Boyd LF, et al. Enhanced antigen-specific antitumor immunity with altered peptide ligands that stabilize the MHC-peptide-TCR complex. Immunity 2000; 13(4):529-38
[0001] Truong B, Allegri G, Liu X-B, et al. Lipid nanoparticle-targeted mRNA therapy as a treatment for the inherited metabolic liver disorder arginase deficiency. Proc Natl Acad Sci USA. 2019;116(42):21150-9.
[0001] US Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research. Development and licensure of vaccines to prevent COVID-19. In: Guidance for Industry. Rockville, MD: Food and Drug Admi
[0001] World Health Organization. Annex 1. WHO guidelines on nonclinical evaluation of vaccines. In: World Health Organization. WHO technical report series, no. 927. Geneva, Switzerland; World Health Organization; 2005: p. 31-63
[0001] World Health Organization. Annex 2. Guidelines on the nonclinical evaluation of vaccine adjuvants and adjuvanted vaccines. In: WHO technical report series no. 987. Geneva, Switzerland: World Health Organization; 2014: p. 59-100
[0001] Wrapp D, Wang N, Corbett KS, et al. Cryo-EM structure of the 2019-nCoV spike in the prefusion conformation. Science 2020;367(6483):1260-3
[0001] Wu Y, Wang F, Shen C, et al. A noncompeting pair of human neutralizing antibodies block COVID-19 virus binding to its receptor ACE2. Science 2020; 368(6496):1274-8
[0001] Xie X, Muruato A, Lokugamage KG, et al. An infectious cDNA clone of SARS-CoV-2. Cell Host Microbe 2020; 27(5):841-848.e3

[0001] **Xie X, Muruato A, Lokugamage KG, et al. An infectious cDNA clone of SARS-CoV-2. Cell Host Microbe 2020; 27(5):841-848.e3**
[0001] Yong CY, Ong HK, Yeap SK, et al. Recent advances in the vaccine development against middle east respiratory syndrome-coronavirus. Front Microbiol 2019;10:1781
[0001] Yuan M, Wu NC, Zhu X, et al. A highly conserved cryptic epitope in the receptor binding domains of SARS-CoV-2 and SARS-CoV. Science 2020; 368(6491):630-3
[0001] Zakhartchouk AN, Sharon C, Satkunarajah M, et al. Immunogenicity of a receptor-binding domain of SARS coronavirus spike protein in mice: implications for a subunit vaccine. Vaccine 2007;25(1):136-43
[0001] Zhou M, Zhang X, Qu J. Coronavirus disease 2019 (COVID-19): a clinical update. Front Med 2020(Apr):1-10
[0001] Zost Seth J, Gilchuk Pavlo, Chen Rita E, et al. Rapid isolation and profiling of a diverse panel of human monoclonal antibodies targeting the SARS-CoV-2 spike protein Nature Medicine 2020;26 9:1422-1427.
[0001] Zou L, Ruan F, Huang M, et al. SARS-CoV-2 viral load in upper respiratory specimens of infected patients. N Engl J Med 2020;382(12)(03):1177-9.

Section 5.3.1 - 125742/0/0


[0001] VR-MQR-10211 - Qualification Report for a Single-plex Direct Luminex Assay (dLIA) for Quantitation of IgG Antibodies to SARS-CoV-2 S1 Protein in Human Sera
Study Report Body Chapter
[0001] VR-MQR-10211
[0001] VR-MQR-10211-ATT01
[0001] VR-MQR-10212 - Qualification Report for a Single-plex Direct Luminex Assay (dLIA) for Quantitation of IgG Antibodies to SARS-CoV-2 RBD Protein in Human Sera
Study Report Body Chapter
[0001] VR-MQR-10212
[0001] VR-MQR-10212-ATT01
[0001] VR-MQR-10214 - Qualification of the SARS-CoV-2 mNeonGreen Virus Miconeutralization Assay
Study Report Body Chapter
[0001] VR-MQR-10214
[0001] VR-MQR-10214-ATT01
[0001] VR-MQR-10214-ATT02
[0001] VR-MQR-10214-ATT03
[0001] VR-TM-10293 - Single-plex Luminex Assay for Quantitation of IgG Antibodies to SARS-CoV-2 S1 Protein in Human Serum
Study Report Body Chapter
[0001] VR-TM-10293
[0001] VR-TM-10294 - Single-plex Luminex Assay for Quantitation of IgG Antibodies to SARS-CoV-2 RBD Protein in Human Serum
Study Report Body Chapter
[0001] VR-TM-10294
[0001] VR-TM-10298 - Manual 96-well Neutralization Assay for the Detection of Functional Antibodies to SARS-CoV-2 in Test Serum
Study Report Body Chapter


[0001] VR-TM-10298 - Manual 96-well Neutralization Assay for the Detection of Functional Antibodies to SARS-CoV-2 in Test Serum
Study Report Body Chapter
[0001] VR-TM-10298
[0001] VR-TM-10304 - Test Method for the SARS CoV-2 Nucleocapsid (N) Antigen Detection Assay
Study Report Body Chapter
[0001] VR-TM-10304
[0001] VR-SOP-LC-11120 - Data Review Procedures for Direct Luminex Immunoassays in LIMS v6
Study Report Body Chapter
[0001] VR-SOP-LC-11120
[0001] SHI-SOP-10011 - Manual 96-well Neutralization Assay for the Detection of Functional Antibodies to SARS-CoV-2 in Test Serum using Cytation 7 Image Reader
Study Report Body Chapter
[0001] SHI-SOP-10011
5.3.5 Reports of Efficacy and Safety Studies
5.3.6 Reports of Postmarketing Experience
5.4 Literature References

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Order: FDA/Appl, Then Date Ascending

THIS REPORT MAY CONTAIN CONFIDENTIAL INFORMATION

STN: L 125742/0

Applicant: BioNTech Manufacturing GmbH #2229

Product: COVID-19 Vaccine, mRNA

Short Summary: For active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older.

Date	Elec	Post	Description	FDA Recd Date	Login ID
13-MAY-2021	Y		Letter. Acknowledgement Letter - Rolling Review (DICKERSON, DAVID)		
18-MAY-2021	Y		Telecon. Information Request - IR RE datasets. (SMITH, MICHAEL)		
20-MAY-2021	Y		Telecon. Information Request - Four facility questions from DMPQ and a request for a t-con on 5/25/21 or 5/26/21 to discuss production schedules and the shutdown activities planned for the Puurs, Belgium site. (SMITH, MICHAEL)		
03-JUN-2021	Y		Meeting Summary. First Committee Meeting - First Committee Meeting Summary (NAIK, RAMACHANDRA)		
08-JUN-2021	Y		Telecon. Information Request - Three clinical questions. (SMITH, MICHAEL)		
09-JUN-2021	Y		Telecon. Information Request - IR for PREA dates for deferred pediatric studies. (SMITH, MICHAEL)		
17-JUN-2021	Y		Memo. Other - Permission to release License number to applicant prior to approval. (JONECKIS, CHRISTOPHER)		
25-JUN-2021	Y		Telecon. Information Request - IR from DBSQC regarding the lot release protocol (LRP) template and samples & reagents. (SMITH, MICHAEL)		
25-JUN-2021	Y		Telecon. Information Request - IR regarding the document titled ¿bnt162-01-interim3-report-body¿. (SMITH, MICHAEL)		
29-JUN-2021	Y		Meeting Summary. Filing Meeting Summary - Summary of the June 29, 2021 Filing Meeting. The BLA is fileable. (NAIK, RAMACHANDRA)		
29-JUN-2021	Y		Telecon. Information Request - Clinical IR regarding Study C4591001. (SMITH, MICHAEL)		
01-JUL-2021	Y		Memo. Filing Checklist/RPM - RPM Filing Checklist - the application is fileable. (GOTTSCHALK, LAURA)		
02-JUL-2021	Y		Memo. Committee Memo/APLB - PNR COMIRNATY: ACCEPTABLE (ELEKWACHI, OLUCHI)		
02-JUL-2021	Y		Telecon. Advice - Advice: Pfizer¿s assumption as outlined in Elisa Harkins June 29, 2021 e-mail RE the bnt162-01-interim3-report-body are correct. (SMITH, MICHAEL)		
02-JUL-2021	Y		Telecon. Information Request - Comments regarding CMC information and categorical exclusion for an environment analysis (NAIK, RAMACHANDRA)		
06-JUL-2021	Y		Telecon. PNR Acceptance / Advice - The Applicant was informed that their proprietary name "COMIRNATY" is acceptable. (SMITH, MICHAEL)		
06-JUL-2021	Y		Telecon. Information Request - Clinical IR RE the document titled ¿c4591001-interim-mth6-report-body.pdf." (SMITH, MICHAEL)		
09-JUL-2021	Y		Telecon. Information Request - IR RE the validation of the RNA Integrity by capillary gel electrophoresis (CGE) method. (SMITH, MICHAEL)		
13-JUL-2021	Y		Telecon. Information Request - OBE IR RE adding myocarditis and pericarditis to the PVP. (SMITH, MICHAEL)		
13-JUL-2021	Y		Telecon. Information Request - DVP IR regarding exception or alternative to the requirement that products in multiple-dose vials include a preservative (NAIK, RAMACHANDRA)		
15-JUL-2021	Y		Letter. Filing Notification Letter / No Deficiencies Identified - Filing Notification No Deficiencies Identified (SMITH, MICHAEL)		
15-JUL-2021	Y		Telecon. Information Request - IR RE Study C4591007; please provide updated goal dates for final protocol submission. (SMITH, MICHAEL)		
15-JUL-2021	Y		Meeting Summary. Committee Meeting Summary - Summary of the July 15, 2021 Monthly Committee Meeting. (GOTTSCHALK, LAURA)		
15-JUL-2021	Y		Telecon. Information Request - F/U IR RE updated PVP by 7/29/21. (SMITH, MICHAEL)		
16-JUL-2021	Y		Telecon. Information Request - DBSQC IR regarding lot release protocol template and drug substance handling instructions. (GOTTSCHALK, LAURA)		

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STN: L 125742/0

Applicant: BioNTech Manufacturing GmbH #2229

Product: COVID-19 Vaccine, mRNA

Short Summary: For active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older.

Date	Elec	Post	Description	FDA Recd Date	Login ID
16-JUL-2021	Y		Telecon. Information Request - DBSQC IR regarding (b) (4) and (b) (4) test methods (GOTTSCHALK, LAURA)		
19-JUL-2021	Y		Telecon. Advice - US license number 2229 was provided to the applicant prior to approval in response to the request included in the cover letter of the first roll of their BLA on May 6, 2021. (NAIK, RAMACHANDRA)		
20-JUL-2021	Y		Memo. Review - CDISC validation results and discussion (BALDWIN, BRENDA)		
20-JUL-2021	Y		Telecon. Information Request - Clinical IR for a revised pediatric plan to include study C4591007 for subject 6 months to 11 years of age and proposal of another study to enroll infants <6 months of age. (NAIK, RAMACHANDRA)		
22-JUL-2021	Y		Telecon. Information Request - Clinical and stats IR regarding shell tables to include safety and efficacy data from study C4591001 and other clinical comments (GOTTSCHALK, LAURA)		
26-JUL-2021	Y		Telecon. Information Request - Clinical IR regarding the disposition of participants in safety populations who experienced pregnancy. (GOTTSCHALK, LAURA)		
26-JUL-2021	Y		Telecon. Information Request - DMPQ IR regarding manufacturing and equipment (GOTTSCHALK, LAURA)		
27-JUL-2021	Y		Telecon. Information Request - Clinical IR RE vaccine effectiveness (SMITH, MICHAEL)		
27-JUL-2021	Y		Telecon. Information Request - Third clinical IR RE vaccine effectiveness. (SMITH, MICHAEL)		
28-JUL-2021	Y		Telecon. Labeling Target Closure / Labeling via FAX/e-mail - First set of labeling comments regarding the PI (NAIK, RAMACHANDRA)		
28-JUL-2021	Y		Telecon. Information Request - OBE IR regarding postmarketing safety study(ies) (NAIK, RAMACHANDRA)		
29-JUL-2021	Y		Telecon. Information Request - Clinical IR regarding safety analysis for two age groups (GOTTSCHALK, LAURA)		
02-AUG-2021	Y		Telecon. Information Request - Questions regarding the Validation Report VR-MVR-10077 (SMITH, MICHAEL)		
02-AUG-2021	Y		Telecon. Information Request - Five questions regarding validation of assay methods and lot release. (SMITH, MICHAEL)		
03-AUG-2021	Y		Telecon. Information Request - Six CMC-related questions. (SMITH, MICHAEL)		
03-AUG-2021	Y		Telecon. Information Request - Two clinical/stats questions regarding July 26, 2021, submission and SAS programs. (SMITH, MICHAEL)		
04-AUG-2021	Y		Telecon. Information Request - Two questions regarding the potency assay for determination of (b) (4) by (b) (4) . (SMITH, MICHAEL)		
04-AUG-2021	Y		Telecon. Information Request - F/U IR RE the LRP that was submitted to BLA 125742/0.14 on July 20, 2021. (SMITH, MICHAEL)		
04-AUG-2021	Y		Telecon. Information Request - Secondary e-mail with attachment RE 8/4/21 F/U LRP comments. (SMITH, MICHAEL)		
05-AUG-2021	Y		Telecon. Advice - Informed the applicant regarding the PROPER NAME for their product in this BLA. (GOTTSCHALK, LAURA)		
05-AUG-2021	Y		Telecon. Information Request - 11 facility questions. (SMITH, MICHAEL)		
05-AUG-2021	Y		Telecon. Information Request - Four questions regarding the diluent. (SMITH, MICHAEL)		
05-AUG-2021	Y		Telecon. Labeling via FAX/e-mail - 2nd round of PI labeling comments. (SMITH, MICHAEL)		
06-AUG-2021	Y		Letter. UNII Code Notification - Unique Ingredient Identifier (UNII) Code Assignment (SMITH, MICHAEL)		
06-AUG-2021	Y		Memo. Committee Memo/APLB - APLB BLA LR (ELEKWACHI, OLUCHI)		

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Applicant: BioNTech Manufacturing GmbH #2229

Product: COVID-19 Vaccine, mRNA

Short Summary: For active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older.

Date	Elec	Post	Description	FDA Recd Date	Login ID
06-AUG-2021	Y	Y	Memo. Review - OBE/DE Pharmacovigilance Review (THOMPSON, DEBORAH)		
06-AUG-2021	Y		Telecon. Information Request - IR RE two DP documents. (SMITH, MICHAEL)		
06-AUG-2021	Y		Telecon. Information Request - Three DBSQC questions RE measurement of (b) (4) using the (b) (4) procedures. (SMITH, MICHAEL)		
09-AUG-2021	Y		Telecon. Advice - Advice RE submitting samples, LRP and distribution of EUA and BLA labeled product after COMIRNATY is licensed. (SMITH, MICHAEL)		
09-AUG-2021	Y		Telecon. Information Request - Clinical IR RE sequencing data. (SMITH, MICHAEL)		
09-AUG-2021	Y		Telecon. Labeling via FAX/e-mail - Comments on the Carton and Container labels (SMITH, MICHAEL)		
10-AUG-2021	Y		Telecon. Information Request - Second OBE IR regarding safety-related postmarketing studies. (NAIK, RAMACHANDRA)		
10-AUG-2021	Y		Telecon. Information Request - One testing related question from DBSQC. (SMITH, MICHAEL)		
11-AUG-2021	Y		Telecon. Information Request - One question from DMPQ regarding the diluent that is to be provided with the vaccine. (SMITH, MICHAEL)		
11-AUG-2021	Y		Telecon. Other - This teleconference between CBER and Pfizer was to seek clarity on availability of EUA and BLA products and plans for distribution after licensure of COMIRNATY. (SMITH, MICHAEL)		
12-AUG-2021	Y		Memo. Committee Memo/Require Pre-Approval Inspection (CHEUNG, ANISSA)		
12-AUG-2021	Y		Telecon. Other - Teleconference between CBER and Pfizer to receive clarification on how EUA lots and BLA lots will be indentified. (NAIK, RAMACHANDRA)		
13-AUG-2021	Y	Y	Memo. Committee Memo/BIMO - BIMO Discipline Review Memo (CHUN, HAECIN)		
13-AUG-2021	Y		Memo. Request For Compliance Check - Request for Compliance check. (ZUBKOVA, IRYNA)		
13-AUG-2021	Y		Telecon. Information Request - Three clinical questions. (SMITH, MICHAEL)		
13-AUG-2021	Y		Telecon. Information Request - DBQSC IR LRP and testing. (SMITH, MICHAEL)		
13-AUG-2021	Y		Telecon. Information Request - 7 facility questions from the DMPQ team. (SMITH, MICHAEL)		
13-AUG-2021	Y		Telecon. Information Request - A clinical IR was sent on 13AUG21 and Pfizer had a clarification question. This IR t-con was in response to the F/U clarification question. (SMITH, MICHAEL)		
13-AUG-2021	Y		Telecon. Labeling via FAX/e-mail - 3rd set of PI labeling comments. (SMITH, MICHAEL)		
13-AUG-2021	Y		Telecon. Information Request - One clinical question. (SMITH, MICHAEL)		
13-AUG-2021	Y		Telecon. Information Request - IR RE PMR's and PMC's. (SMITH, MICHAEL)		
16-AUG-2021	Y		Telecon. Information Request - DMPQ IR RE (b) (4) (b) (4) . (SMITH, MICHAEL)		
16-AUG-2021	Y		Telecon. Labeling via FAX/e-mail - Second set of comments and questions on the carton and container labels. (SMITH, MICHAEL)		
16-AUG-2021	Y		Telecon. Information Request - Teleconference regarding measurement of (b) (4) . Pfizer commits to implement (b) (4) testing method on (b) (4) . (SMITH, MICHAEL)		

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Product: COVID-19 Vaccine, mRNA

Short Summary: For active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older.

Date	Elec	Post	Description	FDA Recd Date	Login ID
16-AUG-2021	Y		Telecon. Information Request - Please submit this same CMC stability information that was submitted to EUA 27034.260 to your BLA STN 125742 .0 so that we can consider a 9-month shelf-life for the licensed product. (NAIK, RAMACHANDRA)		
17-AUG-2021	Y		Memo. Lot Release Clearance Memo / Lot Release Clearance Request - Lot Release Clearance Request and Lot Release Clearance Memo. (BESHIR, LEYLA)		
17-AUG-2021	Y		Memo. Other; Non-proprietary name does not include a suffix - Justification memo regarding approving non-proprietary name without a suffix (GRUBER, MARION)		
17-AUG-2021	Y		Telecon. Other - The purpose of the teleconference between DMPQ and Pfizer was to discuss items 2b, 2c, 6 and 9c from the FDA form 483 for the Andover site. (SMITH, MICHAEL)		
17-AUG-2021	Y		Telecon. Information Request - Two questions from Xiao Wang regarding drug substance. (SMITH, MICHAEL)		
17-AUG-2021	Y		Telecon. Labeling via FAX/e-mail - 4th set of PI labeling comments. (SMITH, MICHAEL)		
17-AUG-2021	Y		Telecon. Information Request - Follow up IR RE PMR & PMC's commitments that were received in amendment 51 dated August 16, 2021. (NAIK, RAMACHANDRA)		
17-AUG-2021	Y		Telecon. Information Request - DVP IR regarding two questions on shelf life and date of manufacture. (SMITH, MICHAEL)		
18-AUG-2021	Y		Memo. Committee Memo/Review - DBSQC LRP template review memo (ANDERSON, MARIE)		
18-AUG-2021	Y	Y	Memo. Committee Memo/Statistical Non-Clinical - Statistical review memo for non-clinical data (TANG, XINYU)		
18-AUG-2021	Y		Telecon. Advice - Pfizer e-mailed clarification questions on August 18, 2021, to DVP's two DS questions dated August 17, 2021. This e-mail was guidance in response to their clarification questions. (SMITH, MICHAEL)		
18-AUG-2021	Y		Telecon. Information Request - Two DBSQC questions on amendments 54 and 50 RE (b) (4) testing and specific parameters/instructions for (b) (4) (b) (4) test method. (SMITH, MICHAEL)		
18-AUG-2021	Y		Telecon. Information Request - DVP follow-up response to Pfizer August 18, 2021, clarification questions regarding DVP's August 17, 2021, IR on shelf life and date of manufacture. (SMITH, MICHAEL)		
18-AUG-2021	Y		Telecon. Labeling via FAX/e-mail - 5th set of PI labeling comments. (SMITH, MICHAEL)		
18-AUG-2021	Y		Telecon. Labeling via FAX/e-mail - 3rd set of comments on the carton and container labels. (GOTTSCHALK, LAURA)		
18-AUG-2021	Y		Telecon. Information Request - Identification of BLA-compliant lots and Letter to HCP. (NAIK, RAMACHANDRA)		
19-AUG-2021	Y	Y	Memo. Committee Memo/Statistical Clinical - Statistical memo for clinical efficacy data (HUANG, LEI)		
19-AUG-2021	Y	Y	Memo. Committee Memo/Statistical Clinical - Statistical review for safety data. (YANG, YE)		
19-AUG-2021	Y		Memo. Compliance Check Acceptable - Compliance check is acceptable. (DECIERO, DANIEL)		
19-AUG-2021	Y		Telecon. Information Request - IR RE PMR's and PMC's that were listed in amendment 51. (SMITH, MICHAEL)		
19-AUG-2021	Y		Telecon. Labeling via FAX/e-mail - 6th set of PI labeling comments. (GOTTSCHALK, LAURA)		
19-AUG-2021	Y		Telecon. Information Request - IR RE PMC Study Completion Date and Final Report Submission date for PMC Study C4591014. (SMITH, MICHAEL)		
20-AUG-2021	Y		Memo. Committee Memo/Labeling - Review Memo: Containers, Cartons, Sticker, Stamp (STEWART, DAPHNE)		

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Product: COVID-19 Vaccine, mRNA

Short Summary: For active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older.

Date	Elec	Post	Description	FDA Recd Date	Login ID
20-AUG-2021	Y		Memo. Other - CONFIDENTIAL - DO NOT POST TO THE WEB CBER Laboratory Quality Product Testing Plan (ANDERSON, MARIE)		
20-AUG-2021	Y	Y	Memo. Review - Pharmacovigilance Plan Review; Addendum Memorandum (WELSH, KERRY)		
20-AUG-2021	Y		Memo. Test Results - In-support (b) (4) Test Results (KONG, HYESUK)		
20-AUG-2021	Y		Memo. Test Results - Test memo for (b) (4) (WANG, HSIAOLING)		
20-AUG-2021	Y		Telecon. Labeling via FAX/e-mail - 7th set of PI comments and shell table. (GOTTSCHALK, LAURA)		
20-AUG-2021	Y		Telecon. Information Request / Advice - Lot Numbers for the COVID Launch Lots (NAIK, RAMACHANDRA)		
20-AUG-2021	Y		Telecon. Information Request - CBER comments regarding label for identification of BLA lots and Dear HCP Letter (NAIK, RAMACHANDRA)		
20-AUG-2021	Y		Telecon. Labeling via FAX/e-mail - Comment regarding vial label to include the name of the diluent on vial labels. (GOTTSCHALK, LAURA)		
21-AUG-2021	Y	Y	Memo. Committee Memo/CMC - CMC Product Review Memo (WANG, XIAO)		
21-AUG-2021	Y	Y	Memo. Committee Memo/CMC - DBSQC Analytical Review Memo (YITBAREK, EMNET)		
21-AUG-2021	Y		Telecon. Information Request - IR RE request to resubmit all PMR's and PMC's and a commitment to conduct them in the timeframe noted in an amendment to the BLA. Also, revised study completion date for study C4591007. (SMITH, MICHAEL)		
21-AUG-2021	Y		Telecon. Labeling via FAX/e-mail - 8th set of PI labeling comments (GOTTSCHALK, LAURA)		
21-AUG-2021	Y		Telecon. Labeling via FAX/e-mail - The Applicant was notified that the Carton and Container labels submitted in Amendment 63 dated August 19, 2021, are considered the Final Draft Labels for approval. (GOTTSCHALK, LAURA)		
21-AUG-2021	Y		Telecon. Information Request - CBER comments regarding label for identification of BLA lots and Dear HCP Letter. (NAIK, RAMACHANDRA)		
21-AUG-2021	Y		Telecon. Advice - The Applicant was notified that there are no additional comments on the Dear HCP letter submitted in Amendment 73 submitted August 21, 2021. (NAIK, RAMACHANDRA)		
22-AUG-2021	Y	Y	Memo. Committee Memo/Postmarketing Safety Epidemiological - OBE Real World Evidence Memo (LU, YUN)		
22-AUG-2021	Y	Y	Memo. Committee Memo/Review - DMPQ Review Memo - Recommend approval (JONES, KATHLEEN)		
22-AUG-2021	Y	Y	Memo. Other - Employee/Officer List Memo (GOTTSCHALK, LAURA)		
22-AUG-2021	Y		Telecon. Labeling via FAX/e-mail - The Applicant was notified that the Package Insert submitted in Amendment 74 dated August 21, 2021, is considered the Final Draft Label for approval (GOTTSCHALK, LAURA)		
23-AUG-2021	Y	Y	Letter. Approval - BLA Approval Letter (SMITH, MICHAEL)		
23-AUG-2021	Y	Y	Memo. Committee Memo/SBRA - SBRA - Summary Basis for Regulatory Action (NAIK, RAMACHANDRA)		
23-AUG-2021	Y	Y	Memo. Committee Memo/Toxicology - Committee Memo/Toxicology (AL-HUMADI, NABIL)		
23-AUG-2021	Y		Memo. Other - OCOD Transmittal Memo for web posting (SMITH, MICHAEL)		
23-AUG-2021	Y	Y	Memo. Review - OBE Sentinel Sufficiency Assessment (OBIDI, JOYCE)		

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Product: COVID-19 Vaccine, mRNA

Short Summary: For active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older.

Date	Elec	Post	Description	FDA Recd Date	Login ID
30-AUG-2021	Y		Telecon. Other - Amendment 125742.0.41 was reviewed in the DBSQC memo dated 08/20/2021. Pfizer's responses were acceptable. (WANG, HSIAOLING)		
30-AUG-2021	Y		Telecon. Other - Amendment 125742.0.60 was reviewed in the Andover 483 response memo. Pfizer's responses were acceptable. (JONES, KATHLEEN)		
01-SEP-2021	Y		Memo. Committee Memo/Labeling - RPM Labeling Review Memo (GOTTSCHALK, LAURA)		
02-SEP-2021	Y	Y	Memo. Committee Memo/Clinical Review - Committee Memo/Clinical Review. Ann Schwartz and Lucia Lee contributed to this review memo. (WOLLERSHEIM, SUSAN)		
13-SEP-2021	Y	Y	Memo. Committee Memo/Review / Benefit-Risk assessment - Benefit-Risk assessment review memo; Patrick Funk, Ph.D., and Osman N. Yogurtcu, Ph.D., also contributed to the review memo. (YANG, HONG)		
13-SEP-2021	Y		Memo. Committee Memo/Review - Documentation review memo. (SMITH, MICHAEL)		
30-SEP-2021	Y	Y	Memo. Revised Post Lockdown / Committee Memo/Toxicology - Revised Post Lockdown/ Committee Memo/Toxicology/23-Aug-2021 (AL-HUMADI, NABIL)		
08-NOV-2021	Y	Y	Memo. Revised Post Lockdown / Committee Memo/SBRA - Table 2 header and value for water in the table were changed. (NAIK, RAMACHANDRA)		
06-MAY-2021	Y		Original Application. For active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older.	06-MAY-2021	1067058
18-MAY-2021	Y		Amendment # 1. Second and final rolling piece to start the review clock.	18-MAY-2021	1086158
19-MAY-2021	Y		Amendment # 2. Request for Proprietary Name Review	19-MAY-2021	1087747
19-MAY-2021	Y		Amendment # 3. Response to May 18, 2021, clinical IR RE three dataset questions.	19-MAY-2021	1088844
24-MAY-2021	Y		Amendment # 4. Response to DMPQ¿s May 20, 2021, IR RE four facilities questions and a request for a t-con on 5/25/21 or 5/26/21 to discuss production schedules and the shutdown activities planned for the Puurs, Belgium site.	24-MAY-2021	1094917
07-JUN-2021	Y		Amendment # 5. COVID-19 case strain sequencing data.	07-JUN-2021	1119355
16-JUN-2021	Y		Amendment # 6. Response to June 8, 2021, clinical IR on three clinical questions regarding datasets and the PI.	16-JUN-2021	1137474
17-JUN-2021	Y		Amendment # 7. Response to June 9, 2021, clinical IR requesting dates for PREA deferred studies.	17-JUN-2021	1139420
02-JUL-2021	Y		Amendment # 8. Response to June 29, 2021, clinical IR RE latest date of randomization for participants included in the reactogenicity subset for Study C4591001.	02-JUL-2021	1168170
02-JUL-2021	Y		Amendment # 9. Response to June 25, 2021, clinical IR regarding IR regarding the document titled ¿bnt162-01-interim3-report-body¿	02-JUL-2021	1168177
09-JUL-2021	Y		Amendment # 10. Response to DBSQC¿s June 25, 2021, IR regarding the lot release protocol (LRP) template and samples & reagents.	09-JUL-2021	1183932
15-JUL-2021	Y		Amendment # 11. Response to DVP¿s July 13, 2021, IR regarding exception or alternative to the requirement that products in multiple-dose vials include a preservative.	15-JUL-2021	1199647
16-JUL-2021	Y		Amendment # 12. Response to July 6, 2021, clinical IR regarding IR regarding the document titled ¿c4591001-interim-mth6-report-body.pdf.¿	16-JUL-2021	1201833
19-JUL-2021	Y		Amendment # 13. The applicant waives their rights to the mid- and late-cycle review meetings for BLA 125742.	19-JUL-2021	1204967
20-JUL-2021	Y		Amendment # 14.	20-JUL-2021	1207929

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Product: COVID-19 Vaccine, mRNA

Short Summary: For active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older.

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23-JUL-2021	Y		Amendment # 15. Response to July 15, 2021, Clinical IR RE study C4591007 to provide updated goal dates for final protocol submission and July 20, 2021 follow-up Clinical IR for a revised pediatric plan to include study C4591007 for subject 6 months to 11 years of age and proposal of another study to enroll infants <6 months of age.	23-JUL-2021	1217479
23-JUL-2021	Y		Amendment # 16. Response to July 9, 2021 IR RE the validation of the RNA Integrity by capillary gel electrophoresis method.	23-JUL-2021	1217492
26-JUL-2021	Y		Amendment # 17. Responses to questions 3-5 of July 22, 2021 clinical and stats IR regarding shell tables to include safety and efficacy data from study C4591001 and other clinical comments.	26-JUL-2021	1221258
28-JUL-2021	Y		Amendment # 18. Responses to questions 1-2 of July 22, 2021 clinical and stats IR regarding shell tables to include safety and efficacy data from study C4591001 and other clinical comments.	28-JUL-2021	1227088
28-JUL-2021	Y		Amendment # 19. Response to July 2, 2021 DVP IR regarding 18 question on product related issues and categorical exclusion for an environmental assessment.	28-JUL-2021	1227383
30-JUL-2021	Y		Amendment # 22. Response to July 27, 2021 third Clinical IR RE vaccine effectiveness.	30-JUL-2021	1233501
30-JUL-2021	Y		Amendment # 24. Response to July 26, 2021 DMPQ IR regarding manufacturing and equipment.	30-JUL-2021	1236249
02-AUG-2021	Y		Amendment # 25. Response to the observations contained in the FDA form 483 that was issued for the pre-approval inspection of the Pfizer Andover facility.	02-AUG-2021	1236634
02-AUG-2021	Y		Amendment # 26. Response to July 29, 2021 clinical IR regarding safety analysis for two age groups.	02-AUG-2021	1237210
02-AUG-2021	Y		Amendment # 27. Response to 7/28/2021 first set of labeling comments regarding the PI.	02-AUG-2021	1237211
02-AUG-2021	Y		Amendment # 28. Response to comment 5b of July 22, 2021 clinical-statistical IR.	02-AUG-2021	1237740
03-AUG-2021	Y		Amendment # 29. Follow-up response (remaining supporting documents to response 10) to July 26, 2021 DMPQ IR regarding manufacturing and equipment.	03-AUG-2021	1241021
03-AUG-2021	Y		Amendment # 30. Response to OBE¿s July 28, 2021 comments regarding post marketing observational safety study(ies) to assess myocarditis/pericarditis following administration of COMIRNATY as well as providing plans to characterize subclinical cases of myocarditis.	03-AUG-2021	1241533
05-AUG-2021	Y		Amendment # 31. Response to DVP and OBE Questions regarding the Validation Report VR-MVR-10077.	05-AUG-2021	1247205
05-AUG-2021	Y		Amendment # 32. Response to clinical and stats IR¿s fromJuly 22nd and August 4th regarding shell tables and two additional clinical/stats questions regarding July 26, 2021, submission and SAS program.	05-AUG-2021	1247821
06-AUG-2021	Y		Amendment # 33. Responses to DVP¿s six CMC-related questions from August 3, 2021.	06-AUG-2021	1249468
06-AUG-2021	Y		Amendment # 34. Responses to August 4, 2021, IR RE two questions regarding the potency assay for determination of (b) (4) by (b) (4) .	06-AUG-2021	1249503
09-AUG-2021	Y		Amendment # 35. Response to DBSQC and Xiao Wang's August 2, 2021, questions regarding validation of assay methods and lot release.	09-AUG-2021	1252956
09-AUG-2021	Y		Amendment # 36. Response to four questions regarding the diluent dated August 5, 2021.	09-AUG-2021	1252957
09-AUG-2021	Y		Amendment # 37. Response to July 22nd Clinical and stats IR regarding shell tables to include safety and efficacy data from study C4591001.	09-AUG-2021	1252966
09-AUG-2021	Y		Amendment # 38. Revised PI labeling in response to August 5, 2021, second round of labeling comments.	09-AUG-2021	1253712
10-AUG-2021	Y		Amendment # 39. Response to Xiao Wang¿s August 6, 2021, questions regarding two drug product (DP) documents.	10-AUG-2021	1258976

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Product: COVID-19 Vaccine, mRNA

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Date	Elec	Post	Description	FDA Recd Date	Login ID
11-AUG-2021	Y		Amendment # 40. Response to August 4, 2021, F/U IR RE the LRP that was submitted to BLA 125742/0.14 on July 20, 2021.	11-AUG-2021	1271302
11-AUG-2021	Y		Amendment # 41. Response to one testing related question from DBSQC on August 10, 2021.	11-AUG-2021	1271303
11-AUG-2021	Y		Amendment # 42. Response to August 10, 2021, second OBE IR regarding safety-related postmarketing studies.	11-AUG-2021	1271308
11-AUG-2021	Y		Amendment # 43. Responses to DMPQ¿s August 5, 2021 11 facilities questions.	11-AUG-2021	1273180
11-AUG-2021	Y		Amendment # 44. This amendment was skipped by the Applicant.	11-AUG-2021	1273179
12-AUG-2021	Y		Amendment # 45. Response to August 9. 2021, clinical IR RE sequencing data.	12-AUG-2021	1278583
13-AUG-2021	Y		Amendment # 46. Response to August 9, 2021 IR RE Carton and Container labeling comments.	13-AUG-2021	1284081
13-AUG-2021	Y		Amendment # 47. Response to DMPQ¿s August 11, 2021, diluent IR and amended response to Theresa Finn¿s August 5, 2021, IR regarding diluent.	13-AUG-2021	1284082
13-AUG-2021	Y		Amendment # 48. Response to DBSQC¿s August 6, 2021, three questions RE measurement of (b) (4) using (b) (4) (b) (4) procedures.	13-AUG-2021	1284088
16-AUG-2021	Y		Amendment # 49. Response to 3rd set of PI labeling comments that were sent on August 13, 2021.	16-AUG-2021	1310580
16-AUG-2021	Y		Amendment # 50. Response to DBSQC¿s August 13, 2021, IR RE LRP and testing.	16-AUG-2021	1310586
16-AUG-2021	Y		Amendment # 51. Response to August 13, 2021, IR RE Safety-related Postmarketing Requirement/Postmarketing Commitment studies.	16-AUG-2021	1310587
16-AUG-2021	Y		Amendment # 52. Response to three clinical questions dated August 13, 2021, plus an additional clinical question dated August 13, 2021 (four total clinical questions dated August 13, 2021).	16-AUG-2021	1310589
17-AUG-2021	Y		Amendment # 53. Response to August 16, 2021 IR RE Carton and Container labeling comments.	17-AUG-2021	1318912
17-AUG-2021	Y		Amendment # 54. Response to follow-up to August 13, 2021, (b) (4) IR and August 16, 2021, teleconference on this subject containing a commitment to implement (b) (4) method on (b) (4) .	17-AUG-2021	1320863
17-AUG-2021	Y		Amendment # 55. Response to Xiao Wang¿s August 16, 2021, IR to please submit the same CMC stability information that was submitted to EUA 27034.260 to your BLA STN 125742 .0.	17-AUG-2021	1320989
17-AUG-2021	Y		Amendment # 56. Response to DMPQ¿s August 16, 2021, IR to (b) (4) (b) (4) .	17-AUG-2021	1321046
17-AUG-2021	Y		Amendment # 57. Response to DMPQ¿s 7 facility questions dated August 13, 2021.	17-AUG-2021	1321051
18-AUG-2021	Y		Amendment # 58. Response to August 17, 2021, 4th set of PI labeling comments.	18-AUG-2021	1329921
18-AUG-2021	Y		Amendment # 59. Response to August 17, 2021, follow up IR RE PMR & PMC's commitments that were received in amendment 51 dated August 16, 2021.	18-AUG-2021	1329922
18-AUG-2021	Y		Amendment # 60. Updated response to FDA form 483 for the Andover site based off of teleconference with CBER on August 17, 2021.	18-AUG-2021	1331100
19-AUG-2021	Y		Amendment # 61. Responses to DVP¿s August 17, 2021, two questions regarding shelf life and date of manufacture.	19-AUG-2021	1337760
19-AUG-2021	Y		Amendment # 62. Responses to DVP¿s August 17, 2021, two questions regarding the drug substance.	19-AUG-2021	1337762
19-AUG-2021	Y		Amendment # 63. Responses to the third set of comments and questions on the carton and container labels.	19-AUG-2021	1338337
19-AUG-2021	Y		Amendment # 64. Response to August 18, 2021, IR RE Identification of BLA-compliant lots and Letter to HCP.	19-AUG-2021	1338338
19-AUG-2021	Y		Amendment # 65. Responses to DBSQC¿s August 18, 2021, IR.	19-AUG-2021	1338341

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Exclude Inspection Related

Order: FDA/Appl, Then Date Ascending

THIS REPORT MAY CONTAIN CONFIDENTIAL INFORMATION

STN: L 125742/0

Applicant: BioNTech Manufacturing GmbH #2229

Product: COVID-19 Vaccine, mRNA

Short Summary: For active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in individuals 16 years of age and older.

Date	Elec	Post	Description	FDA Recd Date	Login ID
19-AUG-2021	Y		Amendment # 66. Response to August 18, 2021, 5th set of PI labeling comments.	19-AUG-2021	1338872
19-AUG-2021	Y		Amendment # 67. Response August 19, 2021, IR RE PMR¿s and PMC¿s that were submitted in amendment 51.	19-AUG-2021	1339769
20-AUG-2021	Y		Amendment # 68. Response to August 19, 2021, 6th set of PI labeling comments.	20-AUG-2021	1341754
20-AUG-2021	Y		Amendment # 69. Additional Response to August 19, 2021, IR RE PMR¿s and PMC¿s that were submitted in amendment 51.	20-AUG-2021	1341755
20-AUG-2021	Y		Amendment # 70. Letter of authorization for a new U.S. agent. This amendment was not in response to an information request.	20-AUG-2021	1342120
20-AUG-2021	Y		Amendment # 71. Response to August 20, 2021, 7th set of PI comments and shell table.	20-AUG-2021	1344590
20-AUG-2021	Y		Amendment # 72. Response to August 20, 2021, clinical IR regarding the shell table.	20-AUG-2021	1344591
20-AUG-2021	Y		Amendment # 73. Response to August 20, 2021, CBER comments regarding label for identification of BLA lots and Dear HCP Letter	20-AUG-2021	1344771
21-AUG-2021	Y		Amendment # 74. Response to August 21, 2021, 8th set of comments on the PI.	23-AUG-2021	1344786
21-AUG-2021	Y		Amendment # 75. Response to August 21, 2021, IR RE PMR¿s and PMC¿s and final study protocol date for study C4591007	23-AUG-2021	1344787
21-AUG-2021	Y		Amendment # 76. Response to August 21, 2021, IR RE regarding identification of BLA lots/Dear HCP Letter.	23-AUG-2021	1344788
23-AUG-2021	Y		Amendment # 77. Final PI (when compared to the PI received in STN 125.0.74 it was the same EXCEPT Pfizer¿s version number at the very end of the PI was changed from LAB-1448-.9 to LAB-1448-1.0).	23-AUG-2021	1346819
24-AUG-2021	Y		Amendment # 78. Final PI which has been revised to include the license number	24-AUG-2021	1350971
07-MAY-2023	Y		Amendment # 20. Response to July 13, 2021 OBE IR to add myocarditis and pericarditis to the PVP.	29-JUL-2021	1230081
07-JUN-2023	Y		Amendment # 21. Response to July 16, 2021 DBSQC IR regarding (b) (4) (b) (4) test methods.	30-JUL-2021	1232318
07-JUN-2023	Y		Amendment # 23. Response to July 26, 2021 clinical IR regarding the disposition of participants in safety populations who experienced pregnancy.	30-JUL-2021	1235714