CBER Requested Tables
mRNA-1273

BLA Application #125752

CONFIDENTIAL

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1 Clinical Trial Overview

Table 1: (Table A) Clinical Trials Submitted in Support of Efficacy and Safety Determinations of the Moderna COVID-19 Vaccine mRNA-1273

Study Number	Type of Study (Efficacy, Safety, Nonclinical)	Population (N)	Study Design and Type of Control	Test Product(s); Dosing Regimens; Dosage Forms; Routes of Administration; Duration	Study Status
DMID 20-0003	Safety Immunogenicity	Men and nonpregnant women at least 18 years of age, in good health (120)	Open-label, dose-ranging	10[a], 25, 50, 100, and 250 µg IM injection mRNA-1273 2 doses, 28 days apart	Ongoing
mRNA-1273-P201	Safety Immunogenicity	Men and nonpregnant women at least 18 years of age, in good health (600)	Randomized, observer-blind, placebo-controlled	50 or 100 µg IM injection mRNA-1273 2 doses, 28 days apart	Ongoing
mRNA-1273-P301	Safety Efficacy	**Part A** Men and nonpregnant women at least 18 years of age, at appreciable risk of SARS-CoV-2 infection, with a negative history for SARS-CoV-2 infection (30,346)	Case-driven, randomized, stratified, observer-blind, placebo-controlled	100 µg of mRNA-1273 or placebo 2 doses, 28 days apart	Ongoing

		Part B Men and nonpregnant women at least 18 years of age (28,964) Must have previously enrolled in mRNA-1273-P301 (Part A participants who had received 1 dose of 100 µg mRNA-1273 or placebo)	Open-label, observational	100 µg of mRNA-1273 2 doses, 28 days apart[b]	

Abbreviations: IM=intramuscular; N=number of participants; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2.

[a] The 10 µg cohort was not enrolled.

[b] One dose in some participants: participants who were unblinded at the participant decision visit and who received ONLY 1 dose of mRNA-1273 100 µg in Part A, were eligible to receive a second dose of mRNA-1273 in Part B if they met certain criteria.

Source: Adapted from STN 125752.1_ Module 5.2.

2 Disposition

Table 2: (Table B) Study Disposition (Safety Set)

Table 3: (Table C) Study Disposition, Efficacy Analysis Populations

	mRNA-1273 n (%)	Placebo n (%)	Total n (%)
Randomized	N=15209	N=15206	N=30415
Full Analysis Set	N=15180	N=15166	N=30346
mITT Set	N=14746	N=14745	N=29491
PP Set[a]	N=14297	N=14164	N=28451
Excluded from PP Set	459 (3.0)	581 (3.8)	1040 (3.4)
Reason for exclusion[b]			
Received incorrect study vaccination	6 (<0.1)	7 (<0.1)	13 (<0.1)
Discontinued study or study vaccination before receiving second injection	334 (2.2)	425 (2.8)	759 (2.5)
Received second injection out of window for PP Set	102 (0.7)	119 (0.8)	221 (0.7)
Not received second injection and passed the window for PP Set	0	0	0
Other major protocol deviation impacting critical data	17 (0.1)	30 (0.2)	47 (0.2)
PP Immunogenicity Subset[a]	N=1185	N=272	N=1457
Excluded from PP Immunogenicity Subset	71 (5.7)	63 (18.8)	134 (8.4)
Reason for exclusion[b]			
Received incorrect vaccination	0	1 (0.3)	1 (<0.1)
Received dose 2 out of window for PP Set	5 (0.4)	3 (0.9)	8 (0.5)
Did not receive dose 2 per schedule	44 (3.5)	52 (15.5)	96 (6.0)
Human Immunodeficiency Virus Infection	21 (1.7)	4 (1.2)	25 (1.6)
Had other major protocol deviations	1 (<0.1)	3 (0.9)	4 (0.3)

Abbreviations: IP=investigational product; mITT=modified intent-to-treat; N=number of participants in the analysis set; PP=per-protocol.

Notes: The randomized set consists of all participants who were randomized, regardless of the participant's treatment status in the study.

The full analysis set consists of all randomized participants who received at least 1 dose of IP.

The mITT set consists of all participants in the full analysis set who had no immunologic or virologic evidence of prior COVID-19 (negative SARS-CoV-2 status, ie, negative NP swab test and negative bAb against SARS CoV-2 N-protein as measured by Roche Elecsys) at Day 1 before the first dose of IP.

The PP set consisted of all participants in the mITT Set who received planned doses of IP per schedule and had no major protocol deviations, as determined and documented by the Sponsor prior to database lock and unblinding, which impacted critical or key study data. The PP set was the primary analysis population for efficacy analyses, unless otherwise specified.

The PP immunogenicity subset consisted of of participants in the FAS who were sampled into the random subcohort and a) received both planned doses (ie, received the treatment as the participant was randomized to) with Dose 2 received within [21, 42] days after Dose 1, and b) no major protocol deviation that impacted critical or key data.

[a] Percentages are based on the number of participants in the analysis set.

[b] A participant who has multiple reasons for exclusion is listed under the reason that appears earliest.

Source: Adapted from STN 125752.1_ P301 Clinical Study Report, Table 14.1.2.3, Table 14.1.2.4, Table 14.1.2.5.

Table 4: (Table D) Follow-up (Add Analysis Set)

3 Background Characteristics

Table 5: (Table E) Demographics and Other Baseline Characteristics (Safety Set)

Characteristic	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)	Total (N=30346) n (%)
Sex			
Female	7266 (47.9)	7106 (46.9)	14372 (47.4)
Male	7918 (52.1)	8056 (53.1)	15974 (52.6)
Age (years)			
Mean [SD]	51.4 [15.51]	51.3 [15.60]	51.4 [15.55]
Median	53.0	52.0	52.0
Min, Max	18, 95	18, 95	18, 95
Age subgroups (years)			
≥18 to <65	11415 (75.2)	11411 (75.3)	22826 (75.2)
≥65 and older	3769 (24.8)	3751 (24.7)	7520 (24.8)
Race			
American Indian or Alaska Native	113 (0.7)	121 (0.8)	234 (0.8)
Asian	656 (4.3)	739 (4.9)	1395 (4.6)
Black or African American	1567 (10.3)	1531 (10.1)	3098 (10.2)
Native Hawaiian or other Pacific Islander	36 (0.2)	32 (0.2)	68 (0.2)
White	12034 (79.3)	11998 (79.1)	24032 (79.2)
Multiracial	320 (2.1)	318 (2.1)	638 (2.1)
Other	299 (2.0)	294 (1.9)	593 (2.0)
Not reported	97 (0.6)	74 (0.5)	171 (0.6)
Unknown	62 (0.4)	55 (0.4)	117 (0.4)
Ethnicity			
Hispanic or Latino	3122 (20.6)	3108 (20.5)	6230 (20.5)
Not Hispanic or Latino	11920 (78.5)	11918 (78.6)	23838 (78.6)
Not reported	105 (0.7)	83 (0.5)	188 (0.6)
Unknown	37 (0.2)	53 (0.3)	90 (0.3)
Occupational risk			
Healthcare worker	3809 (25.1)	3840 (25.3)	7649 (25.2)
High risk conditions			
One high risk condition present	2791 (18.4)	2815 (18.6)	5606 (18.5)
Two or more high risk conditions present	657 (4.3)	642 (4.2)	1299 (4.3)
No high risk condition	11736 (77.3)	11705 (77.2)	23441 (77.2)
BMI: <30 kg/m^2	9276 (61.1)	9300 (61.3)	18576 (61.2)
BMI: ≥30 kg/m^2	5820 (38.3)	5777 (38.1)	11597 (38.2)
Age and health risk for severe COVID-19[a]			
≥18 to <65 years and not at risk	8890 (58.5)	8880 (58.6)	17770 (58.6)
≥18 to <65 years and at risk	2530 (16.7)	2535 (16.7)	5065 (16.7)
≥65 years	3764 (24.8)	3747 (24.7)	7511 (24.8)

Characteristic	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)	Total (N=30346) n (%)
Baseline SARS-CoV-2 status[b]			
Negative	14750 (97.1)	14741 (97.2)	29491 (97.2)
Positive	347 (2.3)	337 (2.2)	684 (2.3)
Missing	87 (0.6)	84 (0.6)	171 (0.6)

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; IRT=Interactive Response Technology; Max=maximum; Min=minimum; N=number of participants in the safety set; n=number of participants in the category; RT-PCR=reverse transcriptase polymerase chain reaction; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2; SD=standard deviation.

Note: The safety set consists of all randomized participants who received at least 1 dose of IP.

[a] Based on stratification factor from IRT, participants who are <65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.

[b] Baseline SARS-CoV-2 status: positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RT-PCR test and negative Elecsys result at Day 1.

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table 14.1.3.2.3.

Table 6: (Table E) Demographics and Other Baseline Characteristics (Per-Protocol Set)

Characteristic	mRNA-1273 (N=14287) n (%)	Placebo (N=14164) n (%)	Total (N=28451) n (%)
Sex			
Female	6848 (47.9)	6670 (47.1)	13518 (47.5)
Male	7439 (52.1)	7494 (52.9)	14933 (52.5)
Age (years)			
Mean [SD]	51.6 [15.44]	51.6 [15.55]	51.6 [15.49]
Median	53.0	52.0	53.0
Min, Max	18, 95	18, 95	18, 95
Age subgroups			
≥18 to <65 years	10661 (74.6)	10569 (74.6)	21230 (74.6)
≥65 years	3626 (25.4)	3595 (25.4)	7221 (25.4)
Race			
American Indian or Alaska Native	109 (0.8)	113 (0.8)	222 (0.8)
Asian	628 (4.4)	700 (4.9)	1328 (4.7)
Black or African American	1395 (9.8)	1352 (9.5)	2747 (9.7)
Native Hawaiian or other Pacific Islander	36 (0.3)	31 (0.2)	67 (0.2)
White	11391 (79.7)	11273 (79.6)	22664 (79.7)
Multiracial	300 (2.1)	304 (2.1)	604 (2.1)
Other	282 (2.0)	274 (1.9)	556 (2.0)
Not reported	90 (0.6)	65 (0.5)	155 (0.5)
Unknown	56 (0.4)	52 (0.4)	108 (0.4)

Characteristic	mRNA-1273 (N=14287) n (%)	Placebo (N=14164) n (%)	Total (N=28451) n (%)
Ethnicity			
Hispanic or Latino	2831 (19.8)	2787 (19.7)	5618 (19.7)
Not Hispanic or Latino	11322 (79.2)	11249 (79.4)	22571 (79.3)
Not reported	99 (0.7)	76 (0.5)	175 (0.6)
Unknown	35 (0.2)	52 (0.4)	87 (0.3)
Occupational risk			
Healthcare worker	3631 (25.4)	3621 (25.6)	7252 (25.5)
High risk conditions			
One high risk condition present	2660 (18.6)	2610 (18.4)	5270 (18.5)
Two or more high risk conditions present	623 (4.4)	602 (4.3)	1225 (4.3)
No high risk condition	11004 (77.0)	10952 (77.3)	21956 (77.2)
BMI: <30 kg/m^2	8741 (61.2)	8719 (61.6)	17460 (61.4)
BMI: ≥30 kg/m^2	5460 (38.2)	5365 (37.9)	10825 (38.0)
Age and health risk for severe COVID-19[a]			
≥18 to <65 years and not at risk	8271 (57.9)	8242 (58.2)	16513 (58.0)
≥18 to <65 years and at risk	2395 (16.8)	2331 (16.5)	4726 (16.6)
≥65 years	3621 (25.3)	3591 (25.4)	7212 (25.3)
Baseline SARS-CoV-2 status[b]			
Negative	14287 (100.0)	14164 (100.0)	28451 (100.0)
Positive	0	0	0

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; Max=maximum; Min=minimum; N=number of participants in the per-protocol set; n= n=number of participants in the category; RT-PCR=reverse transcriptase polymerase chain reaction; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2; SD=standard deviation.

Note: The per-protocol set consisted of all participants in the mITT Set who received planned doses of IP per schedule and had no major protocol deviations, as determined and documented by the Sponsor prior to database lock and unblinding, which impacted critical or key study data.

[a] Based on stratification factor from IRT, participants who are <65 years old are categorized as at risk for severe COVID-19 illness if they have at least 1 of the risk factors specified in the study protocol at Screening.

[b] Baseline SARS-CoV-2 status: positive if there is immunologic or virologic evidence of prior COVID-19, defined as positive RT-PCR test or positive Elecsys result at Day 1. Negative is defined as negative RTPCR test and negative Elecsys result at Day 1.

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table 14.1.3.4.3.

Table 7: (Table F) Protocol-Defined Risk for Severe COVID-19 Disease (Safety Set)

Risk category	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)	Total (N=30346) n (%)
Without any protocol risk for severe COVID-19	11736 (77.3)	11705 (77.2)	23441 (77.2)
With any protocol risk for severe COVID-19[a]	3448 (22.7)	3457 (22.8)	6905 (22.8)
Chronic lung disease	712 (4.7)	749 (4.9)	1461 (4.8)
Significant cardiac disease	762 (5.0)	742 (4.9)	1504 (5.0)
Severe obesity	1070 (7.0)	1058 (7.0)	2128 (7.0)
Diabetes	1460 (9.6)	1457 (9.6)	2917 (9.6)
Liver disease	104 (0.7)	96 (0.6)	200 (0.7)
HIV infection	94 (0.6)	91 (0.6)	185 (0.6)

Abbreviations: COVID-19=coronavirus disease 2019; HIV=human immunodeficiency virus; IP=investigational product; N=number of participants in the safety set; n=number of participants in the category.

Note, the safety set consists of all randomized participants who received at least 1 dose of IP.

[a] Participants could be under one or more categories, and are counted once at each category.

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table 14.1.3.2.3.

Table 8: (Table F) Protocol-Defined Risk for Severe COVID-19 Disease (Per-Protocol Set)

Risk category	mRNA-1273 (N=14287) n (%)	Placebo (N=14164) n (%)	Total (N=28451) n (%)
Without any protocol risk for severe COVID-19	11004 (77.0)	10952 (77.3)	21956 (77.2)
With any protocol risk for severe COVID-19[a]	3283 (23.0)	3212 (22.7)	6495 (22.8)
Chronic lung disease	675 (4.7)	692 (4.9)	1367 (4.8)
Significant cardiac disease	726 (5.1)	696 (4.9)	1422 (5.0)
Severe obesity	1009 (7.1)	980 (6.9)	1989 (7.0)
Diabetes	1402 (9.8)	1363 (9.6)	2765 (9.7)
Liver disease	100 (0.7)	90 (0.6)	190 (0.7)
HIV infection	85 (0.6)	82 (0.6)	167 (0.6)

Abbreviations: COVID-19=coronavirus disease 2019; HIV=human immunodeficiency virus; IP=investigational product; N=number of participants in per-protocol set; n=number of participants in the category.

Note: The per-protocol set consisted of all participants in the mITT Set who received planned doses of IP per schedule and had no major protocol deviations, as determined and documented by the Sponsor prior to database lock and unblinding, which impacted critical or key study data.

[a] Participants could be under one or more categories, and are counted once at each category.

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table 14.1.3.4.3.

4 Efficacy Analysis

Table 9: (Table G) Final Blinded Efficacy Analysis of Primary Endpoint, COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After the 2nd Dose (Based on Data Cutoff for the BLA For the Blinded Phase) (Per-Protocol Set)

Primary Endpoint: COVID-19 (per adjudication committee assessment)	mRNA-1273 N=14287; Cases /n (%); Incidence rate per 1,000 person-years	Placebo N=14164; Cases /n (%); Incidence rate per 1,000 person-years	Vaccine Efficacy % (95% CI)
All participants	55/14287 (0.4); 9.599	744/14164 (5.3); 136.633	0.932 (0.910, 0.948)
≥18 to <65 years	46/10661 (0.4); 10.742	644/10569 (6.1); 158.958	0.934 (0.911, 0.951)
≥65 years	9/3626 (0.2); 6.217	100/3595 (2.8); 71.744	0.915 (0.832, 0.957)

Abbreviations: BLA=biologics license application; CI=confidence interval; COVID-19=coronavirus disease 2019; N=number of participants in the per-protocol set; n=number participants in the subgroup.

Notes: Incidence rate is defined as the number of participants with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years. Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table 14.2.2.1.3.1.1, 14.2.2.1.3.6.1.1.

Table 10: (Table H) Subgroup Analysis of Final Efficacy Analysis, COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After the 2nd Dose (Based on Data Cutoff for the BLA For the Blinded Phase) (Per-Protocol Set)

	mRNA-1273 N=14287; Cases /n (%); Incidence rate per 1,000 person-years	Placebo N=14164 Cases /n (%); Incidence rate per 1,000 person-years	Vaccine Efficacy % (95% CI)
Age			
≥18 to <65 years	46/10661 (0.4); 10.742	644/10569 (6.1); 158.958	0.934 (0.911, 0.951)
≥65 to <75 years	9/2990 (0.3); 7.546	81/2898 (2.8); 71.980	0.897 (0.796, 0.949)
≥75 years	0/636; 0.000	19/697 (2.7); 70.755	1.000 (NE, 1.000)
Age and risk for severe COVID-19			
≥18 to <65 years and not at risk	35/8464 (0.4); 10.320	501/8428 (5.9); 155.593	0.935 (0.909, 0.954)
≥18 to <65 years and at risk	11/2197 (0.5); 12.346	143/2141 (6.7); 171.991	0.930 (0.870, 0.962)
≥65 years and not at risk	4/2540 (0.2); 3.960	66/2524 (2.6); 67.598	0.943 (0.843, 0.979)
≥65 years and at risk	5/1086 (0.5); 11.428	34/1071 (3.2); 81.439	0.864 (0.653, 0.947)
Sex			

	mRNA-1273 N=14287; Cases /n (%); Incidence rate per 1,000 person-years	**Placebo N=14164 Cases /n (%); Incidence rate per 1,000 person-years**	**Vaccine Efficacy % (95% CI)**
Female	25/6848 (0.4); 9.078	366/6670 (5.5); 142.186	0.938 (0.907, 0.959)
Male	30/7439 (0.4); 10.081	378/7494 (5.0); 131.656	0.925 (0.891, 0.948)
Race			
American Indian or Alaska Native	0/109; 0.000	5/113 (4.4); 122.198	1.000 (NE, 1.000)
Asian	1/628 (0.2); 4.312	29/700 (4.1); 118.005	0.965 (0.742, 0.995)
Black or African American	4/1395 (0.3); 7.505	41/1352 (3.0), 82.452	0.911 (0.752, 0.968)
Native Hawaiian or other Pacific Islander	0/36; 0.000	0/31; 0.000	NE (NE, NE)
White	48/11391 (0.4); 10.345	631/11273 (5.6); 143.155	0.930 (0.906, 0.947)
Multiracial	1/300 (0.3); 8.960	8/304 (2.6); 73.736	0.881 (0.046, 0.985)
Other	1/282 (0.4); 9.677	19/274 (6.9); 203.829	0.958 (0.686, 0.994)
Not reported	0/90; 0.000	5/65 (7.7); 211.396	1.000 (NE, 1.000)
Unknown	0/56; 0.000	6/52 (11.5); 364.097	1.000 (NE, 1.000)
Ethnicity			
Hispanic or Latino	10/2831 (0.4); 9.202	177/2787 (6.4); 174.817	0.948 (0.902, 0.973)
Not Hispanic or Latino	45/11322 (0.4); 9.807	563/11249 (5.0); 128.417	0.926 (0.900, 0.945)
Not reported	0/99; 0.000	2/76 (2.6); 66.725	1.000 (NE, 1.000)
Unknown	0/35; 0.000	2/52 (3.8); 107.537	1.000 (NE, 1.000)

Abbreviations: BLA=biologics license application; CI=confidence interval; COVID-19=coronavirus disease 2019; N=number of participants in the per-protocol set; n=number participants in the subgroup.

Notes: Incidence rate is defined as the number of participants with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years. Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table 14.2.2.1.3.6.2.1, 14.2.2.1.3.6.4.1, 14.2.2.1.3.6.11.1, 14.2.2.2.3.6.5.1, 14.2.2.2.3.6.6.1.

Table 11: (Table I) Demographic Characteristics of Participants with COVID-19 Based on Adjudication Committee Assessments Starting 14 days after Dose 2, Based on Final Efficacy Analysis (Based on Data Cutoff for the BLA For the Blinded Phase) (Per-Protocol Set)

	mRNA-1273 N=55; n (%)	Placebo N=744; n (%)	Total N=799; n (%)
Age			
≥18 to <65 years	46 (83.6)	644 (86.6)	690 (86.4)
≥65 to <75 years	9 (16.4)	81 (10.9)	90 (11.3)
≥75 to <85 years	0	15 (2.0)	15 (1.9)
≥85 years	0	4 (0.5)	4 (0.5)
Age and risk for severe COVID-19[a]			
≥18 to <65 years and not at risk	35 (63.6)	501 (67.3)	536 (67.1)
≥18 to <65 years and at risk	11 (20.0)	143 (19.2)	154 (19.3)
≥65 years and not at risk	4 (7.3)	66 (8.9)	70 (8.8)
≥65 years and at risk	5 (9.1)	34 (4.6)	39 (4.9)
Sex			
Female	25 (45.5)	366 (49.2)	391 (48.9)
Male	30 (54.5)	378 (50.8)	408 (51.1)
Race			
American Indian or Alaska Native	0	5 (0.7)	5 (0.6)
Asian	1 (1.8)	29 (3.9)	30 (3.8)
Black or African American	4 (7.3)	41 (5.5)	45 (5.6)
Native Hawaiian or other Pacific Islander	0	0	0
White	48 (87.3)	631 (84.8)	679 (85.0)
Multiracial	1 (1.8)	8 (1.1)	9 (1.1)
Other	1 (1.8)	19 (2.6)	20 (2.5)
Not reported	0	5 (0.7)	5 (0.6)
Unknown	0	6 (0.8)	6 (0.8)
Ethnicity			
Hispanic or Latino	10 (18.2)	177 (23.8)	187 (23.4)
Not Hispanic or Latino	45 (81.8)	563 (75.7)	608 (76.1)
Not reported	0	2 (0.3)	2 (0.3)
Unknown	0	2 (0.3)	2 (0.3)
High risk condition			
Yes	16 (29.1)	177 (23.8)	193 (24.2)
No	39 (70.9)	567 (76.2)	606 (75.8)
BMI ≥30	29 (52.7)	326 (43.8)	355 (44.4)
BMI <30	26 (47.3)	415 (55.8)	441 (55.2)

Abbreviations: BLA=biologics license application; BMI=body mass index; COVID-19=coronavirus disease 2019; N=number of participants in the per-protocol set who had COVID-19 starting 14 days after dose 2; n=number participants in the subgroup.

* with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a participant had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the participant is censored at the date with positive RT-PCR or Elecsys.

Percentages are based on the number of participants in Per-Protocol Set with COVID-19 based on adjudication committee assessments starting 14 days after second injection.

[a] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table 14.1.3.4.4.

Table 12: (Table J) Subgroup Analysis of Final Blinded Efficacy Analysis by Risk Factor, COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After the 2nd Dose (Based on Data Cutoff for the BLA For the Blinded Phase) (Per-Protocol Set)

	mRNA-1273 N=14287; Cases /n (%); Incidence rate per 1,000 person-years	**Placebo N=14164; Cases /n (%); Incidence rate per 1,000 person-years**	**Vaccine Efficacy % (95% CI)**
High risk condition			
Yes	16/3283 (0.5); 12.044	177/3212 (5.5); 141.721	0.917 (0.862, 0.950)
No	39/11004 (0.4); 8.861	567/10952 (5.2); 135.119	0.936 (0.912, 0.954)
Risk Factor			
Chronic lung disease	4/675 (0.6); 14.393	30/692 (4.3); 109.173	0.872 (0.638, 0.955)
Significant cardiac disease	4/726 (0.6); 13.666	30/696 (4.3); 110.007	0.880 (0.659, 0.958)
Severe obesity	7/1009 (0.7); 17.010	75/980 (7.7); 196.938	0.914 (0.814, 0.960)
Diabetes	3/1402 (0.2); 5.313	72/1363 (5.3); 135.672	0.962 (0.879, 0.988)
Liver disease	1/100 (1.0); 24.677	5/90 (5.6); 143.213	0.810 (-0.648, 0.978)
HIV infection	0/85; 0.000	4/82 (4.9); 145.445	1.000 (NE, 1.000)
BMI: <30 kg/m^2	26/8741 (0.3); 7.465	415/8719 (4.8); 124.605	0.942 (0.913, 0.961)
BMI: ≥ 30 kg/m^2	29/5460 (0.5); 13.102	326/5365 (6.1); 156.487	0.918 (0.881, 0.944)

Abbreviations: BLA=biologics license application; BMI=body mass index; CI=confidence interval; COVID-19=coronavirus disease 2019; HIV=human immunodeficiency virus; N=number of participants in per-protocol set; NE=not estimable; n=number participants in the subgroup; RT-PCR=reverse-transcription polymerase chain reaction.

Notes: Censoring rules are applied as for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a participant had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms within 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the participant is censored at the date with positive RT-PCR or Elecsys. Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier. Incidence rate is defined as the number of participants with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years. Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table 14.2.2.1.3.6.7.1 and Table 14.2.2.1.3.6.12.1.

Table 13: (Table K) Subgroup Analysis of Final Efficacy Analysis by Baseline SARS-CoV-2 Status, COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After the 2nd Dose (Based on Data Cutoff for the BLA For the Blinded Phase) (Full Analysis Set)

Baseline SARS-CoV-2	mRNA-1273 N=15180; Cases /n (%); Incidence rate per 1,000 person-years	Placebo N=15166; Cases /n (%); Incidence rate per 1,000 person-years	Vaccine Efficacy % (95% CI)
Regardless of baseline SARS-CoV-2 status	58/15180 (0.4); 9.622	754/15166 (5.0); 130.721	0.928 (0.906, 0.945)
Positive	0/347; 0.000	0/337; 0.000	NE (NE, NE)
Negative	58/14746 (0.4); 9.892	751/14745 (5.1); 133.999	0.928 (0.906, 0.945)
Missing	0/87; 0.000	3/84 (3.6); 86.723	1.000 (NE, 1.000)

Abbreviations: BLA=biologics license application; CI=confidence interval; COVID-19=coronavirus disease 2019; N=number of participants in the full analysis set; n=number participants in the subgroup.

Notes: Incidence rate is defined as the number of participants with an event divided by the number of subjects at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years; Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table 14.2.2.7.3.1 and Table 14.2.2.7.3.6.10.

Table 14: (Table L) Final Blinded Efficacy Analysis of Secondary Efficacy Endpoints, COVID-19 Starting 14 Days After the 2nd Dose (Based on Data Cutoff for the BLA For the Blinded Phase) (Per-Protocol Set)

Table 15: (Table M) Updated Demographics Characteristics of Participants with Severe COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After the 2nd Dose (Based on Data Cutoff for the BLA For the Blinded Phase) (Per-Protocol Set)

Characteristic	mRNA-1273 (N=2) n (%)	Placebo (N=106) n (%)	Total (N=108) n (%)
Sex			
Female	1 (50.0)	56 (52.8)	57 (52.8)
Male	1 (50.0)	50 (47.2)	51 (47.2)
Age			
18 to <65	1 (50.0)	76 (71.7)	77 (71.3)
65 to <75	1 (50.0)	23 (21.7)	24 (22.2)
70 to <75	1 (50.0)	10 (9.4)	11 (10.2)
75 to <80	0	5 (4.7)	5 (4.6)

Characteristic	mRNA-1273 (N=2) n (%)	Placebo (N=106) n (%)	Total (N=108) n (%)
≥80	0	2 (1.9)	2 (1.9)
Race			
American Indian or Alaska Native	0	0	0
Asian	0	4 (3.8)	4 (3.7)
Black or African American	0	6 (5.7)	6 (5.6)
Native Hawaiian or Other Pacific Islander	0	0	0
White	2 (100)	86 (81.1)	88 (81.5)
Multiracial	0	3 (2.8)	3 (2.8)
Other	0	4 (3.8)	4 (3.7)
Not reported	0	2 (1.9)	2 (1.9)
Unknown	0	1 (0.9)	1 (0.9)
Ethnicity			
Hispanic or Latino	1 (50.0)	21 (19.8)	22 (20.4)
Not Hispanic or Latino	1 (50.0)	84 (79.2)	85 (78.7)
Not reported	0	0	0
Unknown	0	1 (0.9)	1 (0.9)
High risk conditions			
One high risk condition present	1 (50.0)	32 (30.2)	33 (30.6)
Two or more high risk conditions present	0	12 (11.3)	12 (11.1)
No high risk condition	1 (50.0)	62 (58.5)	63 (58.3)
BMI: <30 kg/m^2	1 (50.0)	45 (42.5)	46 (42.6)
BMI: ≥30 kg/m^2	1 (50.0)	60 (56.6)	61 (56.5)

Abbreviations: BLA=biologics license application; BMI=body mass index; CI=confidence interval; COVID-19=coronavirus disease 2019; N=number of participants in per-protocol set who had severe COVID-19 starting 14 days after dose 2; n=number participants in the subgroup.

Notes: * with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a participant had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the participant is censored at the date with positive RT-PCR or Elecsys. Percentages are based on the number of participants in Per-Protocol Set with severe COVID-19 based on adjudication committee assessments starting 14 days after second injection (N).

[a] Age and health risk for severe COVID-19 are derived from age and risk factors collected on case report form (CRF).

Source: Adapted from Table 14.1.3.4.5.

Table 16: (Table N) Final Blinded Subgroup Analysis of Efficacy Against Severe COVID-19 Based on Adjudication Committee Assessments Starting 14 Days After the 2nd Dose (Based on Data Cutoff for the BLA For the Blinded Phase) (Per-Protocol Set)

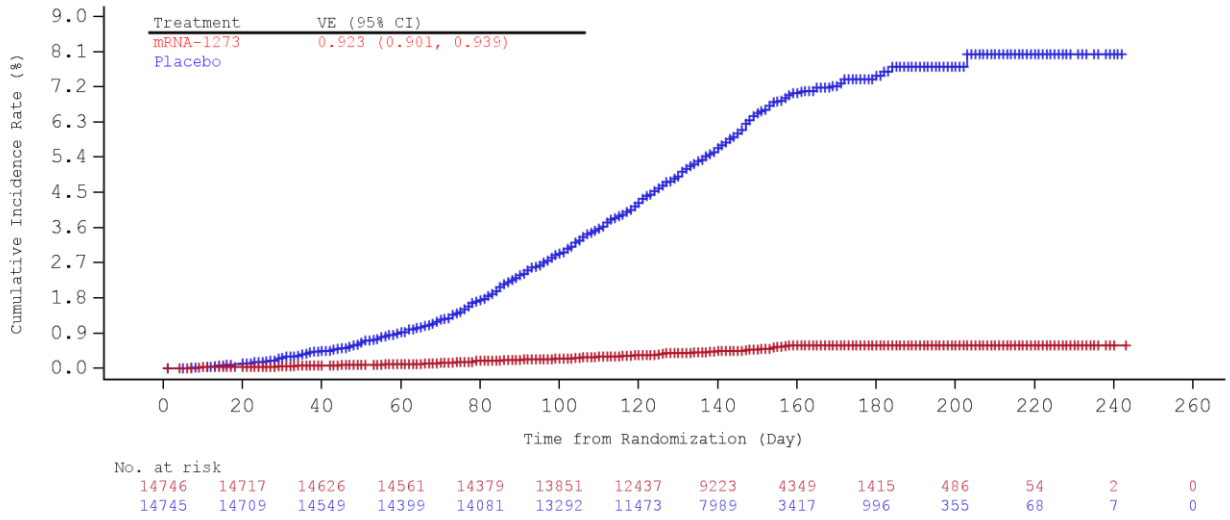
	mRNA-1273 n/N (%); Incidence rate per 1,000 person-years	Placebo n/N (%); Incidence rate per 1,000 person-years	Vaccine Efficacy % (95% CI)
Sex			
Female	1/6848 (<0.1); 0.363	56/6670 (0.8); 21.343	0.983 (0.880, 0.998)
Male	1/7439 (<0.1); 0.336	50/7494 (0.7); 17.109	0.981 (0.860, 0.997)
Age			
≥18 to <65 years	1/10661 (<0.1); 0.233	76/10569 (0.7); 18.351	0.987 (0.910, 0.998)
≥65 to <75 years	1/2990 (<0.1); 0.837	23/2898 (0.8); 20.282	0.960 (0.705, 0.995)
≥75 to <85 years	0/599; 0.000	6/651 (0.9); 23.741	1.000 (NE, 1.000)
≥85 years	0/37; 0.000	1/46 (2.2); 55.849	1.000 (NE, 1.000)
Race			
American Indian or Alaska Native	0/109; 0.000	0/113; 0.000	NE (NE, NE)
Asian	0/628; 0.000	4/700 (0.6); 16.064	1.000 (NE, 1.000)
Black or African American	0/1395; 0.000	6/1352 (0.4); 11.919	1.000 (NE, 1.000)
Native Hawaiian or other Pacific Islander	0/36; 0.000	0/31; 0.000	NE (NE, NE)
White	2/11391 (<0.1); 0.430	86/11273 (0.8); 19.132	0.978 (0.911, 0.995)
Multiracial	0/300; 0.000	3/304 (1.0); 27.494	1.000 (NE, 1.000)
Other	0/282; 0.000	4/274 (1.5); 41.955	1.000 (NE, 1.000)
Not reported	0/90; 0.000	2/65 (3.1); 82.945	1.000 (NE, 1.000)
Unknown	0/56; 0.000	1/52 (1.9); 58.883	1.000 (NE, 1.000)
Ethnicity			
Hispanic or Latino	1/2831 (<0.1); 0.919	21/2787 (0.8); 20.274	0.955 (0.664, 0.994)
Not Hispanic or Latino	1/11322 (<0.1); 0.218	84/11249 (0.7); 18.829	0.989 (0.919, 0.998)
Not reported	0/99; 0.000	0/76; 0.000	NE (NE, NE)
Unknown	0/35; 0.000	1/52 (1.9); 53.066	1.000 (NE, 1.000)
High risk conditions			
Yes	1/3283 (<0.1); 0.752	44/3212 (1.4); 34.638	0.979 (0.846, 0.997)
No	1/11004 (<0.1); 0.227	62/10952 (0.6); 14.500	0.985 (0.889, 0.998)
BMI: ≥40 kg/m^2	0/1009; 0.000	15/980 (1.5); 38.401	1.000 (NE, 1.000)

Abbreviations: BLA=biologics license application; BMI=body mass index; CI=confidence interval; COVID-19=coronavirus disease 2019; N=number of participants in per-protocol set; n=number of participants in the subgroup; NE=not estimable; RT-PCR=reverse-transcription polymerase chain reaction.

Notes: Censoring rules are applied as for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a participant had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms within 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the participant is censored at the date with positive RT-PCR or Elecsys. Person-years is defined as the total years from randomization date to the date of COVID-19, the date of earliest positive RT-PCR or Elecsys at scheduled visits, last date of study participation, or efficacy data cutoff date, whichever is earlier. Incidence rate is defined as the number of participants with an event divided by the number of participants at risk and adjusted by person-years (total time at risk) in each treatment group. The 95% CI is calculated using the exact method (Poisson distribution) and adjusted by person-years; Vaccine efficacy (VE), defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor if applicable.

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table 14.2.2.2.3.6.4, Table 14.2.2.2.3.6.5, Table 14.2.2.2.3.6.6, Table 14.2.2.2.3.6.7, and Table 14.2.2.2.3.6.8.

Figure 1: Cumulative Incidence Curve of COVID-19* Cases Over Time Based on Adjudication Committee Assessments Starting 14 Days after Randomization (Vaccine vs Placebo) (Based on Data Cutoff for the BLA) (mITT Set)



Abbreviations: BLA= biologics license application; CI=confidence interval; COVID-19=coronavirus disease 2019; mITT=modified intent-to-treat; RT-PCR=reverse transcriptase polymerase chain reaction; VE=vaccine efficacy.

Notes: * with the censoring rules for efficacy analyses. COVID-19 case is based on eligible symptoms and positive RT-PCR within 14 days. If a participant had positive RT-PCR at pre-dose 2 visit (Day 29) without eligible symptoms with 14 days, or positive Elecsys at scheduled visits prior to becoming a COVID-19 case, the participant is censored at the date with positive RT-PCR or Elecsys. Vaccine efficacy, defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.

Source: Adapted from STN 125752.1_ P301Clinical Study Report, Figure 14.2.2.1.3.1.4.

Table 17: (Table O) Final Blinded Analysis of COVID-19 Cases Based on Adjudication Committee Assessments From Randomization by Time Period (Based on Data Cutoff for the BLA For the Blinded Phase) (mITT Set)

First COVID-19 occurrence	mRNA-1273 N=14746; n/N (%); Incidence rate per 1,000 person-years	Placebo N=14745; n/N (%); Incidence rate per 1,000 person-years	Vaccine Efficacy % (95% CI)
Any time after dose 1	69/14746 (0.5) 11.8	834/14745 (5.7) 148.8	92.1 (89.9, 93.9)
Any time after dose 1 to before dose 2	10/14746 (0.1) 8.5	59/14745 (0.4) 49.7	83.0 (66.5, 92.2)
14 days after dose 1 to before 14 days after dose 2	5/14725 (<0.1) 4.2	72/14721 (0.5) 61.0	93.0 (83.0, 97.8)
Any time after dose 2	59/14412 (0.4) 12.8	775/14317 (5.4) 177.9	92.8 (90.6, 94.6)
Dose 2 to before 14 days after dose 2	1/14412 (<0.1) 1.8	24/14317 (0.2) 43.8	95.9 (74.6, 99.9)
14 days after dose 2 to <2 months after dose 2	20/14403 (0.1) 12.1	230/14279 (1.6) 141.9	91.4 (86.5, 94.9)
2 months after dose 2 to <4 months after dose 2	30/14102 (0.2) 15.8	437/13684 (3.2) 246.5	93.6 (90.7, 95.7)
≥4 months after dose 2	8/8482 (0.1) 15.3	84/7261 (1.2) 203.0	92.5 (84.4, 96.8)
First severe COVID-19 occurrence			
Any time after dose 1	4/14746 (<0.1) 0.7	114/14745 (0.8) 19.9	96.6 (91.0, 99.1)
Any time after dose 1 to before dose 2	2/14746 (<0.1) 1.7	6/14745 (<0.1) 5.1	66.6 (-86.8, 96.7)
14 days after dose 1 to before 14 days after dose 2	2/14731 (<0.1) 1.7	7/14732 (<0.1) 5.9	71.4 (-50.2, 97.1)
Any time after dose 2	2/14412 (<0.1) 0.4	108/14320 (0.8) 24.2	98.2 (93.4, 99.8)
Dose 2 to before 14 days after dose 2	0/14412 0	1/14320 (<0.1) 1.8	100
14 days after dose 2 to <2 months after dose 2	0/14405 0	33/14306 (0.2) 20.2	100 (88.3, -)
2 months after dose 2 to <4 months after dose 2	2/14123 (<0.1) 1.0	61/13907 (0.4) 33.4	96.9 (88.2, 99.6)
≥4 months after dose 2	0/8517 0	13/7669 (0.2) 29.0	100 (72.0. -)

Abbreviations: BLA=biologics license application; CI=confidence interval; COVID-19=coronavirus disease 2019; mITT=modified intent-to-treat; N=number of participants in analysis set; n=number of participants in the subgroup.
Notes: Incidence rate is defined as the number of participants with an event divided by the number of participants at risk and adjusted by person-years (total time at risk) in each treatment group within a given time period. Person-years for each time period is defined as the total years from the start of each time period to the date of COVID-19, the end of each time period, last date of study participation, efficacy data cutoff date, end date of the blinded phase, whichever is the earliest. Vaccine efficacy (VE) is defined as 1 - ratio of incidence rates (mRNA-1273 vs. placebo). The 95% CI of the ratio is calculated using the exact method conditional upon the total number of cases, adjusting for person-years. 1 month = 28 days.

Table 18: (Table P) Final Blinded Analysis of All Cause Mortality From After Randomization (Based on Data Cutoff for the BLA For the Blinded Phase) (Per-Protocol Set)

	mRNA-1273 N=14287	Placebo N=14164	Vaccine Efficacy % (95% CI)
All participants, cases, n (%)	12 (<0.1)	12 (<0.1)	7.2 (-106.8, 58.3)

Abbreviations: BLA=Biologics License Application; CI=confidence interval; N= number of participants in per protocol set; n=number of participants in the subgroup.
Note: Vaccine efficacy, defined as 1 - hazard ratio (mRNA-1273 vs. placebo), and 95% CI are estimated using a stratified Cox proportional hazard model with Efron's method of tie handling and with the treatment group as a covariate, adjusting for stratification factor.
Source: Adapted from STN 125752.1_ P301Clinical Study Report, Table 14.2.2.8.1.1.

Table 19: (Table Q) Deaths From COVID-19 (Based on Data Cutoff for the BLA) (Add Analysis Set)

Table 20: (Table R) Participants with Multiple, Separate, Symptomatic Confirmed COVID-19 (Based on Data Cutoff for the BLA) (Add Analysis Set)

Table 21: (Table S) Summary of SARS-CoV-2 Variants of Concern or Variants of Interest for First COVID-19 Occurrence from 14 Days After Dose 2 in Cases that were Sequenced (Based on Data Cutoff for the BLA) (Per-Protocol Set)

5 Safety Analysis

5.1 Overall Safety

Table 22: (Table T) Safety Overview (Safety Set and Solicited Safety Set)

Participants reporting at least one	mRNA-1273	Placebo
Immediate unsolicited AE within 30 minutes after vaccination	**n/N (%)**	**n/N (%)**
Dose 1	74/15184 (0.5)	68/15162 (0.4)
Dose 2	47/14631 (0.3)	41/14631 (0.3)
Solicited local AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	12765/15162 (84.2)	3009/15147 (19.9)
Dose 2	13029/14688 (88.7)	2757/14577 (18.9)
Grade 3 or 4 solicited local AR (any dose)	1420/15179 (9.4)	148/15158 (1.0)
Solicited systemic AR within 7 days	**n/N1 (%)**	**n/N1 (%)**
Dose 1	8316/15166 (54.8)	6397/15151 (42.2)
Dose 2	11678/14690 (79.5)	5343/14577 (36.7)
Grade 3 or 4 systemic AR (any dose)	2640/15178 (17.4)	571/15159 (3.8)
Unsolicited AE	**n/N (%)**	**n/N (%)**
Unsolicited AE up to 28 days after any injection	4752/15184 (31.3)	4338/15162 (28.6)
Non-serious unsolicited AE	4716/15184 (31.1)	4294/15162 (28.3)
Related non-serious unsolicited AE	2062/15184 (13.6)	1234/15162 (8.1)
Severe non-serious unsolicited AE	225/15184 (1.5)	186/15162 (1.2)
Related severe non-serious unsolicited AE	82/15184 (0.5)	30/15162 (0.2)
MAAE up to 28 days after any injection	1819/15184 (12.0)	1940/15162 (12.8)
Related MAAE	198/15184 (1.3)	95/15162 (0.6)
SAE	98/15184 (0.6)	104/15162 (0.7)
Related SAE	8/15184 (<0.1)	3/15162 (<0.1)
Deaths up to 28 days after any injection	2/15184 (<0.1)	2/15162 (<0.1)
AE leading to discontinuation of the vaccine up to 28 days after any injection	61/15184 (0.4)	92/15162 (0.6)

Abbreviations: AE=adverse event; AR=adverse reaction; IP=investigational product; MAAE=medically attended adverse events; SAE=serious adverse event; TEAE=treatment-emergent adverse event.

Notes: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages for unsolicited AEs are based on the number of safety participants (N) who received the first injection (Dose 1), second injection (Dose 2), or any injection (any injection).

The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days. Percentages for solicited ARs are based on the number of exposed participants who submitted any data for the event (N1).

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.1.1, Table 14.3.1.1.1.2, Table 14.3.1.1.1.3, Table 14.3.1.7.1.1, Table 14.3.1.19.5.1, Table 14.3.1.19.5.2, Table 14.3.1.23.1.1.

5.2 Solicited Adverse Reactions

5.2.1 Local Adverse Reactions

5.2.1.1 Onset Within 7 Days

Table 29: (Table U) Frequency of Solicited Local Adverse Reactions Within 7 Days After Each Dose, by Maximum Severity (First [Second] Injection Solicited Safety Set)

Event	mRNA-1273 Dose 1 N=15166 n (%)	Placebo Dose 1 N=15151 n (%)	mRNA-1273 Dose 2 N=14691 n (%)	Placebo Dose 2 N=14578 n (%)
Any local AR	N1=15162	N1=15147	N1=14688	N1=14577
Any	12765 (84.2)	3009 (19.9)	13029 (88.7)	2757 (18.9)
Grade 1	10725 (70.7)	2842 (18.8)	8789 (59.8)	2594 (17.8)
Grade 2	1511 (10.0)	89 (0.6)	3217 (21.9)	88 (0.6)
Grade 3	529 (3.5)	78 (0.5)	1023 (7.0)	75 (0.5)
Grade 4	0	0	0	0
Pain	N1=15162	N1=15147	N1=14688	N1=14577
Any	12688 (83.7)	2665 (17.6)	12964 (88.3)	2486 (17.1)
Grade 1	10985 (72.5)	2551 (16.8)	9508 (64.7)	2384 (16.4)
Grade 2	1287 (8.5)	59 (0.4)	2850 (19.4)	61 (0.4)
Grade 3[a]	416 (2.7)	55 (0.4)	606 (4.1)	41 (0.3)
Grade 4[a]	0	0	0	0
Erythema (redness)[b]	N1=15162	N1=15147	N1=14687	N1=14577
Any	445 (2.9)	77 (0.5)	1274 (8.7)	68 (0.5)
Grade 1	281 (1.9)	57 (0.4)	456 (3.1)	48 (0.3)
Grade 2	122 (0.8)	7 (<0.1)	531 (3.6)	5 (<0.1)
Grade 3	42 (0.3)	13 (<0.1)	287 (2.0)	15 (0.1)
Grade 4	0	0	0	0
Swelling (hardness)	N1=15162	N1=15147	N1=14687	N1=14577
Any	935 (6.2)	65 (0.4)	1807 (12.3)	60 (0.4)
Grade 1	608 (4.0)	50 (0.3)	900 (6.1)	38 (0.3)
Grade 2	245 (1.6)	9 (<0.1)	652 (4.4)	10 (<0.1)
Grade 3[c]	82 (0.5)	6 (<0.1)	255 (1.7)	12 (<0.1)
Grade 4[c]	0	0	0	0
Axillary swelling or tenderness	N1=15162	N1=15147	N1=14687	N1=14577
Any	1553 (10.2)	722 (4.8)	2092 (14.2)	571 (3.9)
Grade 1	1394 (9.2)	668 (4.4)	1735 (11.8)	523 (3.6)
Grade 2	110 (0.7)	27 (0.2)	289 (2.0)	28 (0.2)
Grade 3[d]	49 (0.3)	27 (0.2)	68 (0.5)	20 (0.1)
Grade 4[d]	0	0	0	0

Abbreviations: AR=adverse reaction; IP=investigational product.

Notes: Any=Grade 1 or higher. The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days. Percentages for solicited ARs are based on the number of exposed participants who submitted any data for the event (N1).

[a] Pain Grade 3: any use of prescription pain reliever or prevents daily activity; Grade 4: requires emergency room visit or hospitalization.

[b] Erythema (redness) is defined as: Grade 1=25 to 50 mm; Grade 2=51 to 100 mg; Grade 3= >100mm; Grade 4: necrosis or exfoliative dermatitis (erythema).

[c] Swelling: Grade 3 = > 100mm; Grade 4 = necrosis or exfoliative dermatitis.

[d] Axillary swelling or tenderness Grade 3: any use of prescription (narcotic) pain reliever or prevents daily activity; Grade 4: emergency room visit or hospitalization.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.1.1, Table 14.3.1.1.1.2.

Table 30: (Table U) Frequency of Solicited Local Adverse Reactions Within 7 Days After Each Dose, by Maximum Severity, by Baseline SARS-CoV-2 Status (First [Second] Injection Solicited Safety Set)

Event	mRNA-1273 Dose 1 n (%)	Placebo Dose 1 n (%)	mRNA-1273 Dose 2 n (%)	Placebo Dose 2 n (%)
Baseline SARS-CoV-2 Status Positive				
	N=346	**N=337**	**N=232**	**N=233**
Any local AR	N1=346	N1=337	N1=232	N1=232
Any	250 (72.3)	60 (17.8)	172 (74.1)	42 (18.1)
Grade 1	180 (52.0)	56 (16.6)	125 (53.9)	35 (15.1)
Grade 2	56 (16.2)	1 (0.3)	36 (15.5)	5 (2.2)
Grade 3	14 (4.0)	3 (0.9)	11 (4.7)	2 (0.9)
Grade 4	0	0	0	0
Pain	N1=346	N1=337	N1=232	N1=232
Any	247 (71.4)	56 (16.6)	169 (72.8)	36 (15.5)
Grade 1	184 (53.2)	54 (16.0)	126 (54.3)	32 (13.8)
Grade 2	52 (15.0)	1 (0.3)	36 (15.5)	3 (1.3)
Grade 3[a]	11 (3.2)	1 (0.3)	7 (3.0)	1 (0.4)
Grade 4[a]	0	0	0	0
Erythema (redness)[b]	N1=346	N1=337	N1=232	N1=232
Any	10 (2.9)	3 (0.9)	9 (3.9)	1 (0.4)
Grade 1	6 (1.7)	1 (0.3)	2 (0.9)	0
Grade 2	2 (0.6)	0	4 (1.7)	0
Grade 3	2 (0.6)	2 (0.6)	3 (1.3)	1 (0.4)
Grade 4	0	0	0	0
Swelling (hardness)	N1=346	N1=337	N1=232	N1=232
Any	19 (5.5)	2 (0.6)	11 (4.7)	1 (0.4)
Grade 1	10 (2.9)	2 (0.6)	4 (1.7)	0
Grade 2	8 (2.3)	0	5 (2.2)	1 (0.4)
Grade 3[c]	1 (0.3)	0	2 (0.9)	0
Grade 4[c]	0	0	0	0
Axillary swelling or tenderness	N1=346	N1=337	N1=232	N1=232
Any	56 (16.2)	18 (5.3)	32 (13.8)	11 (4.7)
Grade 1	40 (11.6)	17 (5.0)	22 (9.5)	8 (3.4)
Grade 2	12 (3.5)	0	8 (3.4)	3 (1.3)
Grade 3[d]	4 (1.2)	1 (0.3)	2 (0.9)	0
Grade 4[d]	0	0	0	0

Event	mRNA-1273 Dose 1 n (%)	Placebo Dose 1 n (%)	mRNA-1273 Dose 2 n (%)	Placebo Dose 2 n (%)
Baseline SARS-CoV-2 Status Negative				
	N=14733	**N=14730**	**N=14378**	**N=14267**
Any local AR	N1=14729	N1=14726	N1=14375	N1=14267
Any	12442 (84.5)	2934 (19.9)	12783 (88.9)	2699 (18.9)
Grade 1	10481 (71.2)	2771 (18.8)	8620 (60.0)	2543 (17.8)
Grade 2	1449 (9.8)	88 (0.6)	3160 (22.0)	83 (0.6)
Grade 3	512 (3.5)	75 (0.5)	1003 (7.0)	73 (0.5)
Grade 4	0	0	0	0
Pain	N1=14729	N1=14726	N1=14375	N1=14267
Any	12369 (84.0)	2596 (17.6)	12722 (88.5)	2435 (17.1)
Grade 1	10735 (72.9)	2484 (16.9)	9330 (64.9)	2337 (16.4)
Grade 2	1232 (8.4)	58 (0.4)	2797 (19.5)	58 (0.4)
Grade 3[a]	402 (2.7)	54 (0.4)	595 (4.1)	40 (0.3)
Grade 4[a]	0	0	0	0
Erythema (redness)[b]	N1=14729	N1=14726	N1=14374	N1=14267
Any	429 (2.9)	74 (0.5)	1259 (8.8)	66 (0.5)
Grade 1	272 (1.8)	56 (0.4)	452 (3.1)	47 (0.3)
Grade 2	117 (0.8)	7 (<0.1)	527 (3.7)	5 (<0.1)
Grade 3	40 (0.3)	11 (<0.1)	280 (1.9)	14 (<0.1)
Grade 4	0	0	0	0
Swelling (hardness)	N1=14729	N1=14726	N1=14374	N1=14267
Any	910 (6.2)	63 (0.4)	1783 (12.4)	59 (0.4)
Grade 1	593 (4.0)	48 (0.3)	890 (6.2)	38 (0.3)
Grade 2	236 (1.6)	9 (<0.1)	642 (4.5)	9 (<0.1)
Grade 3[c]	81 (0.5)	6 (<0.1)	251 (1.7)	12 (<0.1)
Grade 4[c]	0	0	0	0
Axillary swelling or tenderness	N1=14729	N1=14726	N1=14374	N1=14267
Any	1487 (10.1)	701 (4.8)	2047 (14.2)	557 (3.9)
Grade 1	1344 (9.1)	648 (4.4)	1704 (11.9)	512 (3.6)
Grade 2	98 (0.7)	27 (0.2)	277 (1.9)	25 (0.2)
Grade 3[d]	45 (0.3)	26 (0.2)	66 (0.5)	20 (0.1)
Grade 4[d]	0	0	0	0

Abbreviations: AR=adverse reaction; IP=investigational product.

Notes: Any=Grade 1 or higher. The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days. Percentages for solicited ARs are based on the number of exposed participants who submitted any data for the event (N1).

[a] Pain Grade 3: any use of prescription pain reliever or prevents daily activity; Grade 4: requires emergency room visit or hospitalization.

[b] Erythema (redness) is defined as: Grade 1=25 to 50 mm; Grade 2=51 to 100 mg; Grade 3= >100mm; Grade 4: necrosis or exfoliative dermatitis (erythema).

[c] Swelling: Grade 3 = >100mm; Grade 4 = necrosis or exfoliative dermatitis.
[d] Axillary swelling or tenderness Grade 3: any use of prescription (narcotic) pain reliever or prevents daily activity; Grade 4: emergency room visit or hospitalization.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.3.1, Table 14.3.1.1.3.2.

Table 31: (Table U) Frequency of Solicited Local Adverse Reactions Within 7 Days After Each Dose, by Maximum Severity, by Age Group (First [Second] Injection Solicited Safety Set)

Event	mRNA-1273 Dose 1 n (%)	Placebo Dose 1 n (%)	mRNA-1273 Dose 2 n (%)	Placebo Dose 2 n (%)
Age ≥18 to <65				
	N=11406	**N=11402**	**N=11000**	**N=10929**
Any local AR	N1=11402	N1=11400	N1=10999	N1=10928
Any	9961 (87.4)	2436 (21.4)	9936 (90.3)	2262 (20.7)
Grade 1	8151 (71.5)	2334 (20.5)	6424 (58.4)	2145 (19.6)
Grade 2	1358 (11.9)	63 (0.6)	2709 (24.6)	73 (0.7)
Grade 3	452 (4.0)	39 (0.3)	803 (7.3)	44 (0.4)
Grade 4	0	0	0	0
Pain	N1=11402	N1=11400	N1=10999	N1=10928
Any	9908 (86.9)	2183 (19.1)	9893 (89.9)	2048 (18.7)
Grade 1	8360 (73.3)	2116 (18.6)	6933 (63.0)	1978 (18.1)
Grade 2	1182 (10.4)	44 (0.4)	2454 (22.3)	48 (0.4)
Grade 3[a]	366 (3.2)	23 (0.2)	506 (4.6)	22 (0.2)
Grade 4[a]	0	0	0	0
Erythema (redness)[b]	N1=11402	N1=11400	N1=10998	N1=10928
Any	354 (3.1)	54 (0.5)	989 (9.0)	53 (0.5)
Grade 1	222 (1.9)	39 (0.3)	358 (3.3)	36 (0.3)
Grade 2	98 (0.9)	4 (<0.1)	421 (3.8)	5 (<0.1)
Grade 3	34 (0.3)	11 (<0.1)	210 (1.9)	12 (0.1)
Grade 4	0	0	0	0
Swelling (hardness)	N1=11402	N1=11400	N1=10998	N1=10928
Any	766 (6.7)	42 (0.4)	1399 (12.7)	46 (0.4)
Grade 1	499 (4.4)	35 (0.3)	706 (6.4)	32 (0.3)
Grade 2	205 (1.8)	4 (<0.1)	510 (4.6)	9 (<0.1)
Grade 3[c]	62 (0.5)	3 (<0.1)	183 (1.7)	5 (<0.1)
Grade 4[c]	0	0	0	0
Axillary swelling or tenderness	N1=11402	N1=11400	N1=10998	N1=10928
Any	1322 (11.6)	567 (5.0)	1777 (16.2)	474 (4.3)
Grade 1	1180 (10.3)	534 (4.7)	1468 (13.3)	435 (4.0)
Grade 2	105 (0.9)	20 (0.2)	262 (2.4)	27 (0.2)
Grade 3[d]	37 (0.3)	13 (0.1)	47 (0.4)	12 (0.1)
Grade 4[d]	0	0	0	0

Event	mRNA-1273 Dose 1 n (%)	Placebo Dose 1 n (%)	mRNA-1273 Dose 2 n (%)	Placebo Dose 2 n (%)
Age ≥ 65				
	N=3760	**N=3749**	**N=3691**	**N=3649**
Any local AR	N1=3760	N1=3747	N1=3689	N1=3649
Any	2804 (74.6)	573 (15.3)	3093 (83.8)	495 (13.6)
Grade 1	2574 (68.5)	508 (13.6)	2365 (64.1)	449 (12.3)
Grade 2	153 (4.1)	26 (0.7)	508 (13.8)	15 (0.4)
Grade 3	77 (2.0)	39 (1.0)	220 (6.0)	31 (0.8)
Grade 4	0	0	0	0
Pain	N1=3760	N1=3747	N1=3689	N1=3649
Any	2780 (73.9)	482 (12.9)	3071 (83.2)	438 (12.0)
Grade 1	2625 (69.8)	435 (11.6)	2575 (69.8)	406 (11.1)
Grade 2	105 (2.8)	15 (0.4)	396 (10.7)	13 (0.4)
Grade 3[a]	50 (1.3)	32 (0.9)	100 (2.7)	19 (0.5)
Grade 4[a]	0	0	0	0
Erythema (redness)[b]	N1=3760	N1=3747	N1=3689	N1=3649
Any	91 (2.4)	23 (0.6)	285 (7.7)	15 (0.4)
Grade 1	59 (1.6)	18 (0.5)	98 (2.7)	12 (0.3)
Grade 2	24 (0.6)	3 (<0.1)	110 (3.0)	0
Grade 3	8 (0.2)	2 (<0.1)	77 (2.1)	3 (<0.1)
Grade 4	0	0	0	0
Swelling (hardness)	N1=3760	N1=3747	N1=3689	N1=3649
Any	169 (4.5)	23 (0.6)	408 (11.1)	14 (0.4)
Grade 1	109 (2.9)	15 (0.4)	194 (5.3)	6 (0.2)
Grade 2	40 (1.1)	5 (0.1)	142 (3.8)	1 (<0.1)
Grade 3[c]	20 (0.5)	3 (<0.1)	72 (2.0)	7 (0.2)
Grade 4[c]	0	0	0	0
Axillary swelling or tenderness	N1=3760	N1=3747	N1=3689	N1=3649
Any	231 (6.1)	155 (4.1)	315 (8.5)	97 (2.7)
Grade 1	214 (5.7)	134 (3.6)	267 (7.2)	88 (2.4)
Grade 2	5 (0.1)	7 (0.2)	27 (0.7)	1 (<0.1)
Grade 3[d]	12 (0.3)	14 (0.4)	21 (0.6)	8 (0.2)
Grade 4[d]	0	0	0	0

Abbreviations: AR=adverse reaction; IP=investigational product.

Notes: Any=Grade 1 or higher. The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days. Percentages for solicited ARs are based on the number of exposed participants who submitted any data for the event (N1).

[a] Pain Grade 3: any use of prescription pain reliever or prevents daily activity; Grade 4: requires emergency room visit or hospitalization.

[b] Erythema (redness) is defined as: Grade 1=25 to 50 mm; Grade 2=51 to 100 mg; Grade 3= >100mm; Grade 4: necrosis or exfoliative dermatitis (erythema).
[c] Swelling: Grade 3 = >100mm; Grade 4 = necrosis or exfoliative dermatitis.
[d] Axillary swelling or tenderness Grade 3: any use of prescription (narcotic) pain reliever or prevents daily activity; Grade 4: emergency room visit or hospitalization.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.2.1.1, Table 14.3.1.1.2.1.2.

5.2.1.2 Onset After 7 Days

Table 32: (Table V) Frequency of Delayed Solicited Local Injection Site Reactions (Onset After 7 Days) (Safety Set – Dose 1 and Dose 2)

Table 33: (Table V) Frequency of Delayed Solicited Local Injection Site Reactions, by Baseline SARS-CoV-2 Status (Onset After 7 Days) (First [Second] Injection Solicited Safety Set)

Table 34: (Table V) Frequency of Delayed Solicited Local Injection Site Reactions, by Age Group (Onset After 7 Days) (Safety Set – Dose 1 and Dose 2)

5.2.1.3 Overall Characteristics

Table 35: (Table X) Characteristics of Solicited Local Adverse Reactions (First [Second] Injection Solicited Safety Set)

Table 36: (Table X) Characteristics of Solicited Local Adverse Reactions, by Baseline SARS-CoV-2 Status (First [Second] Injection Solicited Safety Set)

Table 37: (Table X) Characteristics of Solicited Local Adverse Reactions, by Age Group (First [Second] Injection Solicited Safety Set)

5.2.2 Systemic Adverse Reactions

5.2.2.1 Onset Within 7 Days

Table 38: (Table W) Frequency of Solicited Systemic Adverse Reactions Within 7 Days After Each Dose, by Maximum Severity (First [Second] Injection Solicited Safety Set)

Event	mRNA-1273 N=15166 Dose 1 n (%)	Placebo N=15151 Dose 1 n (%)	mRNA-1273 N=14691 Dose 2 n (%)	Placebo N=14578 Dose 2 n (%)
Any systemic AR	N1=15166	N1=15151	N1=14690	N1=14577
Any	8316 (54.8)	6397 (42.2)	11678 (79.5)	5343 (36.7)
Grade 1	5358 (35.3)	4334 (28.6)	3717 (25.3)	3519 (24.1)
Grade 2	2504 (16.5)	1746 (11.5)	5611 (38.2)	1535 (10.5)
Grade 3	449 (3.0)	311 (2.1)	2336 (15.9)	286 (2.0)
Grade 4	5 (<0.1)	6 (<0.1)	14 (<0.1)	3 (<0.1)
Fever[a]	N1=15163	N1=15149	N1=14682	N1=14573
≥38.0°C	112 (0.7)	44 (0.3)	2276 (15.5)	43 (0.3)
38.0°C to 38.4°C	73 (0.5)	28 (0.2)	1363 (9.3)	33 (0.2)
38.5°C to 38.9°C	24 (0.2)	8 (<0.1)	697 (4.7)	5 (<0.1)
39°C to 40.0°C	11 (<0.1)	2 (<0.1)	203 (1.4)	2 (<0.1)
>40.0°C	4 (<0.1)	6 (<0.1)	13 (<0.1)	3 (<0.1)
Headache	N1=15162	N1=15146	N1=14687	N1=14575
Any	4950 (32.6)	4026 (26.6)	8637 (58.8)	3427 (23.5)
Grade 1	3947 (26.0)	3297 (21.8)	4815 (32.8)	2740 (18.8)
Grade 2	730 (4.8)	532 (3.5)	3156 (21.5)	522 (3.6)
Grade 3[b]	273 (1.8)	197 (1.3)	666 (4.5)	165 (1.1)
Grade 4[b]	0	0	0	0
Fatigue	N1=15162	N1=15146	N1=14687	N1=14575
Any	5636 (37.2)	4133 (27.3)	9607 (65.4)	3418 (23.5)
Grade 1	3585 (23.6)	2705 (17.9)	3431 (23.4)	2181 (15.0)
Grade 2	1899 (12.5)	1323 (8.7)	4743 (32.3)	1129 (7.7)
Grade 3[c]	151 (1.0)	105 (0.7)	1433 (9.8)	108 (0.7)
Grade 4[c]	1 (<0.1)	0	0	0
Myalgia	N1=15162	N1=15146	N1=14687	N1=14575
Any	3442 (22.7)	2069 (13.7)	8529 (58.1)	1824 (12.5)
Grade 1	2442 (16.1)	1560 (10.3)	3242 (22.1)	1307 (9.0)
Grade 2	909 (6.0)	462 (3.1)	3966 (27.0)	465 (3.2)
Grade 3[c]	91 (0.6)	47 (0.3)	1321 (9.0)	52 (0.4)
Grade 4[c]	0	0	0	0

Event	mRNA-1273 N=15166 Dose 1 n (%)	Placebo N=15151 Dose 1 n (%)	mRNA-1273 N=14691 Dose 2 n (%)	Placebo N=14578 Dose 2 n (%)
Arthralgia	N1=15162	N1=15146	N1=14687	N1=14575
Any	2510 (16.6)	1784 (11.8)	6303 (42.9)	1579 (10.8)
Grade 1	1842 (12.1)	1333 (8.8)	2809 (19.1)	1143 (7.8)
Grade 2	607 (4.0)	413 (2.7)	2719 (18.5)	392 (2.7)
Grade 3[c]	60 (0.4)	38 (0.3)	775 (5.3)	44 (0.3)
Grade 4[c]	1 (<0.1)	0	0	0
Nausea/vomiting	N1=15162	N1=15146	N1=14687	N1=14575
Any	1262 (8.3)	1075 (7.1)	2794 (19.0)	941 (6.5)
Grade 1	1047 (6.9)	887 (5.9)	2094 (14.3)	761 (5.2)
Grade 2	205 (1.4)	175 (1.2)	678 (4.6)	169 (1.2)
Grade 3[d]	10 (<0.1)	13 (<0.1)	21 (0.1)	11 (<0.1)
Grade 4[d]	0	0	1 (<0.1)	0
Chills	N1=15162	N1=15146	N1=14687	N1=14575
Any	1251 (8.3)	878 (5.8)	6500 (44.3)	813 (5.6)
Grade 1	938 (6.2)	706 (4.7)	2907 (19.8)	629 (4.3)
Grade 2	289 (1.9)	158 (1.0)	3402 (23.2)	167 (1.1)
Grade 3[e]	24 (0.2)	14 (<0.1)	191 (1.3)	17 (0.1)
Grade 4[e]	0	0	0	0
Use of antipyretic or pain medication	3329 (22.0)	2000 (13.2)	7855 (53.5)	1585 (10.9)

Abbreviations: AR=adverse reaction; IP=investigational product.

Notes: Any=Grade 1 or higher. The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days. Percentages for solicited ARs are based on the number of exposed participants who submitted any data for the event (N1). Medications were collected on the eDiary.

[a] Fever is defined as: Grade 1=38°C to 38.4°C; Grade 2=38.5°C to 38.9°C; Grade 3=39°C to 40°C; Grade 4=greater than 40°C.

[b] Headache: Grade 3: significant, any use of prescription pain reliever or prevents daily activity; Grade 4: requires emergency room visit or hospitalization.

[c] Fatigue, myalgia, arthralgia: Grade 3: significant, prevents daily activity; Grade 4: requires emergency room visit or hospitalization.

[d] Nausea/vomiting: Grade 3: prevents daily activity, requires outpatient intravenous hydration; Grade 4: requires emergency room visit or hospitalization for hypotensive shock.

[e] Chills: Grade 3: prevents daily activity and requires medical intervention; Grade 4: requires emergency room visit or hospitalization.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.1.1, Table 14.3.1.1.1.2, Table 14.1.5.5.1, Table 14.1.5.5.2.

Table 39: (Table W) Frequency of Solicited Systemic Adverse Reactions Within 7 Days After Each Dose, by Maximum Severity, by Baseline SARS-CoV-2 Status (First [Second] Injection Solicited Safety Set)

Event	mRNA-1273 Dose 1 n (%)	Placebo Dose 1 n (%)	mRNA-1273 Dose 2 n (%)	Placebo Dose 2 n (%)
Baseline SARS-CoV-2 Status Positive				
	N=346	**N=337**	**N=232**	**N=233**
Any systemic AR	N1=346	N1=337	N1=232	N1=233
Any	214 (61.8)	122 (36.2)	152 (65.5)	73 (31.3)
Grade 1	108 (31.2)	70 (20.8)	61 (26.3)	44 (18.9)
Grade 2	82 (23.7)	40 (11.9)	70 (30.2)	28 (12.0)
Grade 3	23 (6.6)	11 (3.3)	21 (9.1)	1 (0.4)
Grade 4	1 (0.3)	1 (0.3)	0	0
Fever[a]	N1=346	N1=336	N1=232	N1=232
≥38.0°C	33 (9.5)	6 (1.8)	31 (13.4)	1 (0.4)
38.0°C to 38.4°C	20 (5.8)	3 (0.9)	20 (8.6)	1 (0.4)
38.5°C to 38.9°C	10 (2.9)	2 (0.6)	9 (3.9)	0
39°C to 40.0°C	2 (0.6)	0	2 (0.9)	0
>40.0°C	1 (0.3)	1 (0.3)	0	0
Headache	N1=346	N1=337	N1=232	N1=232
Any	134 (38.7)	83 (24.6)	98 (42.2)	43 (18.5)
Grade 1	89 (25.7)	60 (17.8)	61 (26.3)	35 (15.1)
Grade 2	33 (9.5)	16 (4.7)	31 (13.4)	8 (3.4)
Grade 3[b]	12 (3.5)	7 (2.1)	6 (2.6)	0
Grade 4[b]	0	0	0	0
Fatigue	N1=346	N1=337	N1=232	N1=232
Any	138 (39.9)	72 (21.4)	106 (45.7)	54 (23.3)
Grade 1	71 (20.5)	40 (11.9)	42 (18.1)	31 (13.4)
Grade 2	57 (16.5)	28 (8.3)	52 (22.4)	22 (9.5)
Grade 3[c]	10 (2.9)	4 (1.2)	12 (5.2)	1 (0.4)
Grade 4[c]	0	0	0	0
Myalgia	N1=346	N1=337	N1=232	N1=232
Any	128 (37.0)	47 (13.9)	117 (50.4)	34 (14.7)
Grade 1	71 (20.5)	27 (8.0)	60 (25.9)	22 (9.5)
Grade 2	50 (14.5)	18 (5.3)	46 (19.8)	12 (5.2)
Grade 3[c]	7 (2.0)	2 (0.6)	11 (4.7)	0
Grade 4[c]	0	0	0	0
Arthralgia	N1=346	N1=337	N1=232	N1=232
Any	88 (25.4)	40 (11.9)	77 (33.2)	26 (11.2)
Grade 1	54 (15.6)	21 (6.2)	37 (15.9)	19 (8.2)
Grade 2	29 (8.4)	17 (5.0)	36 (15.5)	7 (3.0)
Grade 3[c]	5 (1.4)	2 (0.6)	4 (1.7)	0
Grade 4[c]	0	0	0	0

Event	mRNA-1273 Dose 1 n (%)	Placebo Dose 1 n (%)	mRNA-1273 Dose 2 n (%)	Placebo Dose 2 n (%)
Nausea/vomiting	N1=346	N1=337	N1=232	N1=232
Any	43 (12.4)	25 (7.4)	33 (14.2)	13 (5.6)
Grade 1	30 (8.7)	17 (5.0)	25 (10.8)	10 (4.3)
Grade 2	13 (3.8)	8 (2.4)	7 (3.0)	3 (1.3)
Grade 3[d]	0	0	1 (0.4)	0
Grade 4[d]	0	0	0	0
Chills	N1=346	N1=337	N1=232	N1=232
Any	81 (23.4)	27 (8.0)	80 (34.5)	19 (8.2)
Grade 1	43 (12.4)	17 (5.0)	40 (17.2)	16 (6.9)
Grade 2	35 (10.1)	9 (2.7)	40 (17.2)	3 (1.3)
Grade 3[e]	3 (0.9)	1 (0.3)	0	0
Grade 4[e]	0	0	0	0
Baseline SARS-CoV-2 Status Negative				
	N=14733	**N=14730**	**N=14378**	**N=14267**
Any systemic AR	N1=14733	N1=14730	N1=14377	N1=14266
Any	8053 (54.7)	6239 (42.4)	5241 (36.7)	11459 (79.7)
Grade 1	5214 (35.4)	4234 (28.7)	3642 (25.3)	3453 (24.2)
Grade 2	2412 (16.4)	1701 (11.5)	5498 (38.2)	1500 (10.5)
Grade 3	423 (2.9)	299 (2.0)	2305 (16.0)	285 (2.0)
Grade 4	4 (<0.1)	5 (<0.1)	14 (<0.1)	3 (<0.1)
Fever[a]	N1=14731	N1=14729	N1=14370	N1=14263
≥38.0°C	78 (0.5)	38 (0.3)	2235 (15.6)	42 (0.3)
38.0°C to 38.4°C	52 (0.4)	25 (0.2)	1340 (9.3)	32 (0.2)
38.5°C to 38.9°C	14 (<0.1)	6 (<0.1)	682 (4.7)	5 (<0.1)
39°C to 40.0°C	9 (<0.1)	2 (<0.1)	200 (1.4)	2 (<0.1)
>40.0°C	3 (<0.1)	5 (<0.1)	13 (<0.1)	3 (<0.1)
Headache	N1=14729	N1=14725	N1=14374	N1=14265
Any	4787 (32.5)	3917 (26.6)	8488 (59.1)	3363 (23.6)
Grade 1	3833 (26.0)	3214 (21.8)	4725 (32.9)	2688 (18.8)
Grade 2	695 (4.7)	514 (3.5)	3105 (21.6)	510 (3.6)
Grade 3[b]	259 (1.8)	189 (1.3)	658 (4.6)	165 (1.2)
Grade 4[b]	0	0	0	0
Fatigue	N1=14729	N1=14725	N1=14374	N1=14265
Any	5466 (37.1)	4038 (27.4)	9446 (65.7)	3344 (23.4)
Grade 1	3490 (23.7)	2646 (18.0)	3375 (23.5)	2134 (15.0)
Grade 2	1834 (12.5)	1292 (8.8)	4655 (32.4)	1103 (7.7)
Grade 3[c]	141 (1.0)	100 (0.7)	1416 (9.9)	107 (0.8)
Grade 4[c]	1 (<0.1)	0	0	0
Myalgia	N1=14729	N1=14725	N1=14374	N1=14265
Any	3295 (22.4)	2011 (13.7)	8357 (58.1)	1775 (12.4)
Grade 1	2355 (16.0)	1524 (10.3)	3166 (22.0)	1271 (8.9)

Event	mRNA-1273 Dose 1 n (%)	Placebo Dose 1 n (%)	mRNA-1273 Dose 2 n (%)	Placebo Dose 2 n (%)
Grade 2	857 (5.8)	443 (3.0)	3886 (27.0)	452 (3.2)
Grade 3[c]	83 (0.6)	44 (0.3)	1305 (9.1)	52 (0.4)
Grade 4[c]	0	0	0	0
Arthralgia	N1=14729	N1=14725	N1=14374	N1=14265
Any	2406 (16.3)	1735 (11.8)	6181 (43.0)	1543 (10.8)
Grade 1	1776 (12.1)	1305 (8.9)	2758 (19.2)	1115 (7.8)
Grade 2	574 (3.9)	395 (2.7)	2655 (18.5)	384 (2.7)
Grade 3[c]	55 (0.4)	35 (0.2)	768 (5.3)	44 (0.3)
Grade 4[c]	1 (<0.1)	0	0	0
Nausea/vomiting	N1=14729	N1=14725	N1=14374	N1=14265
Any	1210 (8.2)	1044 (7.1)	2741 (19.1)	922 (6.5)
Grade 1	1009 (6.9)	866 (5.9)	2052 (14.3)	747 (5.2)
Grade 2	191 (1.3)	165 (1.1)	668 (4.6)	164 (1.1)
Grade 3[d]	10 (<0.1)	13 (<0.1)	20 (0.1)	11 (<0.1)
Grade 4[d]	0	0	1 (<0.1)	0
Chills	N1=14729	N1=14725	N1=14374	N1=14265
Any	1162 (7.9)	846 (5.7)	6384 (44.4)	790 (5.5)
Grade 1	891 (6.0)	684 (4.6)	2854 (19.9)	610 (4.3)
Grade 2	250 (1.7)	149 (1.0)	3340 (23.2)	163 (1.1)
Grade 3[e]	21 (0.1)	13 (<0.1)	190 (1.3)	17 (0.1)
Grade 4[e]	0	0	0	0

Abbreviations: AR=adverse reaction; IP=investigational product.

Notes: Any=Grade 1 or higher. The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days. Percentages for solicited ARs are based on the number of exposed participants who submitted any data for the event (N1).

[a] Fever is defined as: Grade 1=38 to 38.4°C; Grade 2=38.5 to 38.9°C; Grade 3=39 to 40°C; Grade 4=greater than 40°C.

[b] Headache: Grade 3: significant, any use of prescription pain reliever or prevents daily activity; Grade 4: requires emergency room visit or hospitalization.

[c] Fatigue, myalgia, arthralgia: Grade 3: significant, prevents daily activity; Grade 4: requires emergency room visit or hospitalization.

[d] Nausea/vomiting: Grade 3: prevents daily activity, requires outpatient intravenous hydration; Grade 4: requires emergency room visit or hospitalization for hypotensive shock.

[e] Chills: Grade 3: prevents daily activity and requires medical intervention; Grade 4: requires emergency room visit or hospitalization.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.3.1, Table 14.3.1.1.3.2.

Table 40: (Table W) Frequency of Solicited Systemic Adverse Reactions Within 7 Days After Each Dose, by Maximum Severity, by Age Group (First [Second] Injection Solicited Safety Set)

Event	mRNA-1273 Dose 1 n (%)	Placebo Dose 1 n (%)	mRNA-1273 Dose 2 n (%)	Placebo Dose 2 n (%)
Age ≥18 to <65				
	N=11406	**N=11402**	**N=11000**	**N=10929**
Any systemic AR	N1=11406	N1=11402	N1=10999	N1=10928
Any	6499 (57.0)	5063 (44.4)	9023 (82.0)	4208 (38.5)
Grade 1	4079 (35.8)	3367 (29.5)	2615 (23.8)	2731 (25.0)
Grade 2	2050 (18.0)	1442 (12.6)	4458 (40.5)	1248 (11.4)
Grade 3	365 (3.2)	250 (2.2)	1938 (17.6)	227 (2.1)
Grade 4	5 (<0.1)	4 (<0.1)	12 (0.1)	2 (<0.1)
Fever[a]	N1=11404	N1=11400	N1=10993	N1=10925
≥38.0°C	102 (0.9)	37 (0.3)	1909 (17.4)	38 (0.3)
38.0°C to 38.4°C	66 (0.6)	25 (0.2)	1112 (10.1)	30 (0.3)
38.5°C to 38.9°C	22 (0.2)	7 (<0.1)	600 (5.5)	4 (<0.1)
39°C to 40.0°C	10 (<0.1)	1 (<0.1)	185 (1.7)	2 (<0.1)
>40.0°C	4 (<0.1)	4 (<0.1)	12 (0.1)	2 (<0.1)
Headache	N1=11402	N1=11400	N1=10998	N1=10926
Any	4028 (35.3)	3303 (29.0)	6929 (63.0)	2775 (25.4)
Grade 1	3168 (27.8)	2668 (23.4)	3669 (33.4)	2182 (20.0)
Grade 2	640 (5.6)	472 (4.1)	2701 (24.6)	461 (4.2)
Grade 3[b]	220 (1.9)	163 (1.4)	559 (5.1)	132 (1.2)
Grade 4[b]	0	0	0	0
Fatigue	N1=11402	N1=11400	N1=10998	N1=10926
Any	4385 (38.5)	3281 (28.8)	7453 (67.8)	2701 (24.7)
Grade 1	2732 (24.0)	2100 (18.4)	2527 (23.0)	1701 (15.6)
Grade 2	1531 (13.4)	1098 (9.6)	3748 (34.1)	912 (8.3)
Grade 3[c]	121 (1.1)	83 (0.7)	1178 (10.7)	88 (0.8)
Grade 4[c]	1 (<0.1)	0	0	0
Myalgia	N1=11402	N1=11400	N1=10998	N1=10926
Any	2700 (23.7)	1625 (14.3)	6789 (61.7)	1425 (13.0)
Grade 1	1874 (16.4)	1200 (10.5)	2415 (22.0)	1002 (9.2)
Grade 2	752 (6.6)	387 (3.4)	3258 (29.6)	381 (3.5)
Grade 3[c]	74 (0.6)	38 (0.3)	1116 (10.1)	42 (0.4)
Grade 4[c]	0	0	0	0
Arthralgia	N1=11402	N1=11400	N1=10998	N1=10926
Any	1892 (16.6)	1327 (11.6)	5010 (45.6)	1180 (10.8)
Grade 1	1368 (12.0)	966 (8.5)	2111 (19.2)	841 (7.7)
Grade 2	476 (4.2)	331 (2.9)	2249 (20.4)	302 (2.8)
Grade 3[c]	47 (0.4)	30 (0.3)	650 (5.9)	37 (0.3)
Grade 4[c]	1 (<0.1)	0	0	0

Event	mRNA-1273 Dose 1 n (%)	Placebo Dose 1 n (%)	mRNA-1273 Dose 2 n (%)	Placebo Dose 2 n (%)
Nausea/vomiting	N1=11402	N1=11400	N1=10998	N1=10926
Any	1068 (9.4)	908 (8.0)	2355 (21.4)	807 (7.4)
Grade 1	889 (7.8)	749 (6.6)	1755 (16.0)	651 (6.0)
Grade 2	173 (1.5)	151 (1.3)	589 (5.4)	148 (1.4)
Grade 3[d]	6 (<0.1)	8 (<0.1)	11 (0.1)	8 (<0.1)
Grade 4[d]	0	0	0	0
Chills	N1=11402	N1=11400	N1=10998	N1=10926
Any	1050 (9.2)	730 (6.4)	5357 (48.7)	662 (6.1)
Grade 1	780 (6.8)	584 (5.1)	2316 (21.1)	505 (4.6)
Grade 2	253 (2.2)	138 (1.2)	2877 (26.2)	142 (1.3)
Grade 3[e]	17 (0.1)	8 (<0.1)	164 (1.5)	15 (0.1)
Grade 4[e]	0	0	0	0
Use of antipyretic or pain medication	2656 (23.3)	1523 (13.4)	6307 (57.3)	1254 (11.5)
Age ≥ 65				
	N=3760	**N=3749**	**N=3691**	**N=3649**
Any systemic AR	N1=3760	N1=3749	N1=3691	N1=3649
Any	1817 (48.3)	1334 (35.6)	2655 (71.9)	1135 (31.1)
Grade 1	1279 (34.0)	967 (25.8)	1102 (29.9)	788 (21.6)
Grade 2	454 (12.1)	304 (8.1)	1153 (31.2)	287 (7.9)
Grade 3	84 (2.2)	61 (1.6)	398 (10.8)	59 (1.6)
Grade 4	0	2 (<0.1)	2 (<0.1)	1 (<0.1)
Fever[a]	N1=3759	N1=3749	N1=3689	N1=3648
≥38.0°C	10 (0.3)	7 (0.2)	367 (9.9)	5 (0.1)
38.0°C to 38.4°C	7 (0.2)	3 (<0.1)	251 (6.8)	3 (<0.1)
38.5°C to 38.9°C	2 (<0.1)	1 (<0.1)	97 (2.6)	1 (<0.1)
39°C to 40.0°C	1 (<0.1)	1 (<0.1)	18 (0.5)	0
>40.0°C	0	2 (<0.1)	1 (<0.1)	1 (<0.1)
Headache	N1=3760	N1=3746	N1=3689	N1=3649
Any	922 (24.5)	723 (19.3)	1708 (46.3)	652 (17.9)
Grade 1	779 (20.7)	629 (16.8)	1146 (31.1)	558 (15.3)
Grade 2	90 (2.4)	60 (1.6)	455 (12.3)	61 (1.7)
Grade 3[b]	53 (1.4)	34 (0.9)	107 (2.9)	33 (0.9)
Grade 4[b]	0	0	0	0
Fatigue	N1=3760	N1=3746	N1=3689	N1=3649
Any	1251 (33.3)	852 (22.7)	2154 (58.4)	717 (19.6)
Grade 1	853 (22.7)	605 (16.2)	904 (24.5)	480 (13.2)
Grade 2	368 (9.8)	225 (6.0)	995 (27.0)	217 (5.9)
Grade 3[c]	30 (0.8)	22 (0.6)	255 (6.9)	20 (0.5)
Grade 4[c]	0	0	0	0
Myalgia	N1=3760	N1=3746	N1=3689	N1=3649
Any	742 (19.7)	444 (11.9)	1740 (47.2)	399 (10.9)
Grade 1	568 (15.1)	360 (9.6)	827 (22.4)	305 (8.4)
Grade 2	157 (4.2)	75 (2.0)	708 (19.2)	84 (2.3)
Grade 3[c]	17 (0.5)	9 (0.2)	205 (5.6)	10 (0.3)
Grade 4[c]	0	0	0	0

Event	mRNA-1273 Dose 1 n (%)	Placebo Dose 1 n (%)	mRNA-1273 Dose 2 n (%)	Placebo Dose 2 n (%)
Arthralgia	N1=3760	N1=3746	N1=3689	N1=3649
Any	618 (16.4)	457 (12.2)	1293 (35.1)	399 (10.9)
Grade 1	474 (12.6)	367 (9.8)	698 (18.9)	302 (8.3)
Grade 2	131 (3.5)	82 (2.2)	470 (12.7)	90 (2.5)
Grade 3[c]	13 (0.3)	8 (0.2)	125 (3.4)	7 (0.2)
Grade 4[c]	0	0	0	0
Nausea/vomiting	N1=3760	N1=3746	N1=3689	N1=3649
Any	194 (5.2)	167 (4.5)	439 (11.9)	134 (3.7)
Grade 1	158 (4.2)	138 (3.7)	339 (9.2)	110 (3.0)
Grade 2	32 (0.9)	24 (0.6)	89 (2.4)	21 (0.6)
Grade 3[d]	4 (0.1)	5 (0.1)	10 (0.3)	3 (<0.1)
Grade 4[d]	0	0	1 (<0.1)	0
Chills	N1=3760	N1=3746	N1=3689	N1=3649
Any	201 (5.3)	148 (4.0)	1143 (31.0)	151 (4.1)
Grade 1	158 (4.2)	122 (3.3)	591 (16.0)	124 (3.4)
Grade 2	36 (1.0)	20 (0.5)	525 (14.2)	25 (0.7)
Grade 3[e]	7 (0.2)	6 (0.2)	27 (0.7)	2 (<0.1)
Grade 4[e]	0	0	0	0
Use of antipyretic or pain medication	673 (17.9)	477 (12.7)	1548 (41.9)	331 (9.1)

Abbreviations: AR=adverse reaction; IP=investigational product.

Notes: Any=Grade 1 or higher. The Solicited Safety Set consists of randomized participants who received at least 1 dose of IP and contributed any solicited AR data, ie, had at least 1 post-baseline solicited safety (eDiary) assessment. The First (Second) Injection Solicited Safety Set consisted of all participants in the Solicited Safety Set who received the first (second) study injection and contributed any solicited AR data (eDiary) from the time of first (second) study injection through the following 6 days. Percentages for solicited ARs are based on the number of exposed participants who submitted any data for the event (N1). Medications were collected on the eDiary.

[a] Fever is defined as: Grade 1=38 to 38.4°C; Grade 2=38.5 to 38.9°C; Grade 3=39 to 40°C; Grade 4=greater than 40°C.

[b] Headache: Grade 3: significant, any use of prescription pain reliever or prevents daily activity; Grade 4: requires emergency room visit or hospitalization.

[c] Fatigue, myalgia, arthralgia: Grade 3: significant, prevents daily activity; Grade 4: requires emergency room visit or hospitalization.

[d] Nausea/vomiting: Grade 3: prevents daily activity, requires outpatient intravenous hydration; Grade 4: requires emergency room visit or hospitalization for hypotensive shock.

[e] Chills: Grade 3: prevents daily activity and requires medical intervention; Grade 4: requires emergency room visit or hospitalization.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.1.2.1.1, Table 14.3.1.1.2.1.2, Table 14.1.5.5.1, Table 14.1.5.5.2.

5.2.2.2 Onset After 7 Days

Table 41: (Table V) Frequency of Delayed Solicited Systemic Reactions (Onset After 7 Days) (Safety Set – Dose 1 and Dose 2)

Table 42: (Table V) Frequency of Delayed Solicited Systemic Reactions, by Baseline SARS-CoV-2 Status (Onset After 7 Days) (First [Second] Injection Solicited Safety Set)

Table 43: (Table V) Frequency of Delayed Solicited Systemic Reactions, by Age Group (Onset After 7 Days) (Safety Set – Dose 1 and Dose 2)

5.2.2.3 Overall Characteristics

Table 44: (Table X) Characteristics of Solicited Systemic Adverse Reactions (First [Second] Injection Solicited Safety Set)

Table 45: (Table X) Characteristics of Solicited Systemic Adverse Reactions, by Baseline SARS-CoV-2 Status (First [Second] Injection Solicited Safety Set)

Table 46: (Table X) Characteristics of Solicited Systemic Adverse Reactions, by Age Group (First [Second] Injection Solicited Safety Set)

5.3 Unsolicited Adverse Events

5.3.1 Overall Adverse Events

Table 47: (Table Y) Frequency of Unsolicited Adverse Events with Occurrence in ≥1% of Participants in Any Treatment Group up to 28 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term (Safety Set)

	mRNA-1273 (N=15184)		Placebo (N=15162)	
Primary System Organ Class Preferred Term	**Any n (%)**	**Severe n (%)**	**Any n (%)**	**Severe n (%)**
Infections and infestations				
Adverse events in any PT[a]	783 (5.2)	20 (0.1)	952 (6.3)	34 (0.2)
COVID-19	22 (0.1)	0	156 (1.0)	7 (<0.1)
Blood and lymphatic system disorders				
Adverse events in any PT[a]	292 (1.9)	3 (<0.1)	148 (1.0)	0
Lymphadenopathy	264 (1.7)	1 (<0.1)	127 (0.8)	0
Nervous system disorders				
Adverse events in any PT[a]	1008 (6.6)	26 (0.2)	881 (5.8)	23 (0.2)
Headache	744 (4.9)	14 (<0.1)	687 (4.5)	11 (<0.1)
Vascular disorders				
Adverse events in any PT[a]	198 (1.3)	33 (0.2)	204 (1.3)	44 (0.3)
Hypertension	153 (1.0)	28 (0.2)	161 (1.1)	34 (0.2)
Respiratory, thoracic and mediastinal disorders				
Adverse events in any PT[a]	603 (4.0)	15 (<0.1)	667 (4.4)	12 (<0.1)
Cough	177 (1.2)	3 (<0.1)	165 (1.1)	1 (<0.1)
Oropharyngeal pain	158 (1.0)	0	232 (1.5)	2 (<0.1)
Nasal congestion	155 (1.0)	2 (<0.1)	165 (1.1)	0
Rhinorrhoea	130 (0.9)	2 (<0.1)	145 (1.0)	0
Gastrointestinal disorders				
Adverse events in any PT[a]	599 (3.9)	21 (0.1)	567 (3.7)	16 (0.1)
Diarrhoea	204 (1.3)	3 (<0.1)	199 (1.3)	1 (<0.1)
Nausea	162 (1.1)	5 (<0.1)	164 (1.1)	1 (<0.1)
Musculoskeletal and connective tissue disorders				
Adverse events in any PT[a]	1007 (6.6)	26 (0.2)	1017 (6.7)	35 (0.2)
Arthralgia	391 (2.6)	7 (<0.1)	389 (2.6)	7 (<0.1)
Myalgia	387 (2.5)	9 (<0.1)	388 (2.6)	4 (<0.1)
General disorders and administration site conditions				
Adverse events in any PT[a]	1606 (10.6)	55 (0.4)	1065 (7.0)	20 (0.1)
Fatigue	752 (5.0)	20 (0.1)	666 (4.4)	9 (<0.1)
Injection site pain	258 (1.7)	4 (<0.1)	118 (0.8)	1 (<0.1)
Injection site erythema	157 (1.0)	8 (<0.1)	39 (0.3)	0

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term; SOC=system organ class; TEAE=treatment-emergent adverse event.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. A TEAE is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on the number of safety participants.

[a] Participant experienced at least 1 TEAE within the SOC regardless of the MedDRA PT.
Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.8.1.1, Table 14.3.1.17.1.1.

5.3.2 Serious Adverse Events

5.3.2.1 Overall Serious Adverse Events

Table 48: (Table Z) Percentage of Participants Reporting Serious Adverse Events up to 28 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number (%) of participants reporting serious adverse events		98 (0.6)	104 (0.7)
Infections and infestations	Adverse events in any PT	13 (<0.1)	19 (0.1)
	Pneumonia	3 (<0.1)	4 (<0.1)
	Appendicitis	1 (<0.1)	3 (<0.1)
	COVID-19	1 (<0.1)	4 (<0.1)
	Cellulitis	1 (<0.1)	0
	Clostridium difficile infection	1 (<0.1)	0
	Hepatitis A	1 (<0.1)	0
	Liver abscess	1 (<0.1)	0
	Lung abscess	1 (<0.1)	0
	Peritonitis	1 (<0.1)	0
	Pneumonia mycoplasmal	1 (<0.1)	0
	Pneumonia staphylococcal	1 (<0.1)	0
	Pyelonephritis acute	1 (<0.1)	1 (<0.1)
	Toxic shock syndrome	1 (<0.1)	0
	Urosepsis	1 (<0.1)	0
	COVID-19 pneumonia	0	1 (<0.1)
	Coccidioidomycosis	0	1 (<0.1)
	Diverticulitis	0	1 (<0.1)
	Osteomyelitis	0	1 (<0.1)
	Pharyngitis streptococcal	0	1 (<0.1)
	Sepsis	0	1 (<0.1)
	Septic shock	0	1 (<0.1)
	Streptococcal sepsis	0	1 (<0.1)
	Urinary tract infection	0	2 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adverse events in any PT	9 (<0.1)	8 (<0.1)
	Prostate cancer	3 (<0.1)	3 (<0.1)
	Colorectal cancer	1 (<0.1)	0
	Malignant melanoma	1 (<0.1)	0
	Metastases to bone	1 (<0.1)	0
	Metastases to lung	1 (<0.1)	0
	Papillary thyroid cancer	1 (<0.1)	0
	Pelvic neoplasm	1 (<0.1)	0
	Splenic marginal zone lymphoma	1 (<0.1)	0
	Throat cancer	1 (<0.1)	0
	Thyroid cancer metastatic	1 (<0.1)	0
	Breast cancer stage I	0	1 (<0.1)
	Intraductal proliferative breast lesion	0	1 (<0.1)
	Lung adenocarcinoma	0	1 (<0.1)
	Prostate cancer metastatic	0	1 (<0.1)
	Renal cell carcinoma	0	1 (<0.1)
Blood and lymphatic system disorders	Adverse events in any PT	1 (<0.1)	1 (<0.1)
	Blood loss anaemia	1 (<0.1)	0
	Anaemia	0	1 (<0.1)
Immune system disorders	Adverse events in any PT	0	1 (<0.1)
	Anaphylactic reaction	0	1 (<0.1)
Endocrine disorders	Adverse events in any PT	1 (<0.1)	0
	Basedow's disease	1 (<0.1)	0
Metabolism and nutrition disorders	Adverse events in any PT	2 (<0.1)	4 (<0.1)
	Dehydration	2 (<0.1)	2 (<0.1)
	Hyperkalaemia	1 (<0.1)	0
	Hypokalaemia	0	1 (<0.1)
	Hyponatraemia	0	1 (<0.1)
	Metabolic acidosis	0	1 (<0.1)
Psychiatric disorders	Adverse events in any PT	5 (<0.1)	7 (<0.1)
	Alcohol withdrawal syndrome	1 (<0.1)	0
	Completed suicide	1 (<0.1)	0
	Drug abuse	1 (<0.1)	0
	Schizoaffective disorder	1 (<0.1)	1 (<0.1)
	Suicidal ideation	1 (<0.1)	0
	Alcoholism	0	1 (<0.1)
	Anxiety	0	1 (<0.1)
	Confusional state	0	1 (<0.1)
	Depression	0	2 (<0.1)
	Major depression	0	1 (<0.1)
	Mental status changes	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Nervous system disorders	Adverse events in any PT	10 (<0.1)	8 (<0.1)
	Cerebrovascular accident	2 (<0.1)	0
	Subarachnoid haemorrhage	2 (<0.1)	0
	Syncope	2 (<0.1)	2 (<0.1)
	Autonomic nervous system imbalance	1 (<0.1)	0
	Carotid artery thrombosis	1 (<0.1)	0
	Cervical radiculopathy	1 (<0.1)	0
	Embolic stroke	1 (<0.1)	0
	Seizure	1 (<0.1)	0
	Transient ischaemic attack	1 (<0.1)	1 (<0.1)
	Basal ganglia haemorrhage	0	1 (<0.1)
	Encephalopathy	0	1 (<0.1)
	Ischaemic stroke	0	1 (<0.1)
	Migraine	0	1 (<0.1)
	Paraesthesia	0	1 (<0.1)
	Speech disorder	0	1 (<0.1)
Eye disorders	Adverse events in any PT	0	1 (<0.1)
	Retinal detachment	0	1 (<0.1)
Cardiac disorders	Adverse events in any PT	14 (<0.1)	17 (0.1)
	Atrial fibrillation	3 (<0.1)	3 (<0.1)
	Cardiac failure congestive	3 (<0.1)	3 (<0.1)
	Myocardial infarction	3 (<0.1)	1 (<0.1)
	Acute myocardial infarction	2 (<0.1)	1 (<0.1)
	Acute coronary syndrome	1 (<0.1)	0
	Acute left ventricular failure	1 (<0.1)	1 (<0.1)
	Atrial flutter	1 (<0.1)	1 (<0.1)
	Cardio-respiratory arrest	1 (<0.1)	1 (<0.1)
	Coronary artery disease	1 (<0.1)	2 (<0.1)
	Cardiac failure	0	2 (<0.1)
	Pericardial effusion	0	1 (<0.1)
	Sinus tachycardia	0	2 (<0.1)
Vascular disorders	Adverse events in any PT	4 (<0.1)	8 (<0.1)
	Hypertension	2 (<0.1)	1 (<0.1)
	Aortic aneurysm	1 (<0.1)	1 (<0.1)
	Hypertensive urgency	1 (<0.1)	1 (<0.1)
	Hypotension	1 (<0.1)	1 (<0.1)
	Aortic stenosis	0	1 (<0.1)
	Fibromuscular dysplasia	0	1 (<0.1)
	Hypertensive emergency	0	2 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Respiratory, thoracic, and mediastinal disorders	Adverse events in any PT	9 (<0.1)	15 (<0.1)
	Pulmonary embolism	3 (<0.1)	3 (<0.1)
	Acute respiratory failure	2 (<0.1)	3 (<0.1)
	Respiratory failure	2 (<0.1)	0
	Atelectasis	1 (<0.1)	0
	Dyspnoea	1 (<0.1)	0
	Pleural effusion	1 (<0.1)	1 (<0.1)
	Chronic obstructive pulmonary disease	0	3 (<0.1)
	Emphysema	0	1 (<0.1)
	Hypoxia	0	1 (<0.1)
	Laryngeal oedema	0	1 (<0.1)
	Pleuritic pain	0	1 (<0.1)
	Pneumonia aspiration	0	1 (<0.1)
	Pulmonary fibrosis	0	1 (<0.1)
	Pulmonary infarction	0	1 (<0.1)
Gastrointestinal disorders	Adverse events in any PT	15 (<0.1)	7 (<0.1)
	Colitis	2 (<0.1)	1 (<0.1)
	Hiatus hernia	2 (<0.1)	0
	Nausea	2 (<0.1)	1 (<0.1)
	Abdominal pain upper	1 (<0.1)	0
	Diarrhoea	1 (<0.1)	0
	Duodenal ulcer	1 (<0.1)	0
	Inguinal hernia	1 (<0.1)	0
	Intestinal obstruction	1 (<0.1)	0
	Large intestine perforation	1 (<0.1)	0
	Pancreatitis acute	1 (<0.1)	0
	Rectal prolapse	1 (<0.1)	0
	Small intestinal obstruction	1 (<0.1)	1 (<0.1)
	Vomiting	1 (<0.1)	1 (<0.1)
	Abdominal pain	0	2 (<0.1)
	Duodenal ulcer haemorrhage	0	1 (<0.1)
	Gastric perforation	0	1 (<0.1)
	Gastritis	0	1 (<0.1)
Hepatobiliary disorders	Adverse events in any PT	3 (<0.1)	0
	Cholecystitis	2 (<0.1)	0
	Bile duct stone	1 (<0.1)	0
Skin and subcutaneous tissue disorders	Adverse events in any PT	2 (<0.1)	2 (<0.1)
	Alopecia areata	1 (<0.1)	0
	Angioedema	1 (<0.1)	1 (<0.1)
	Dermatitis bullous	0	1 (<0.1)

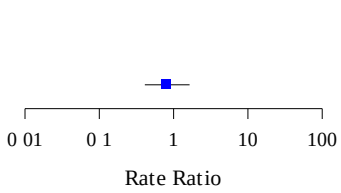
Primary System Organ Class	Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Musculoskeletal and connective tissue disorders	Adverse events in any PT	9 (<0.1)	12 (<0.1)
	Osteoarthritis	2 (<0.1)	6 (<0.1)
	Spinal stenosis	2 (<0.1)	1 (<0.1)
	Back pain	1 (<0.1)	0
	Fracture nonunion	1 (<0.1)	0
	Intervertebral disc protrusion	1 (<0.1)	1 (<0.1)
	Musculoskeletal chest pain	1 (<0.1)	0
	Rheumatoid arthritis	1 (<0.1)	0
	Cervical spinal stenosis	0	1 (<0.1)
	Joint stiffness	0	1 (<0.1)
	Polymyalgia rheumatica	0	1 (<0.1)
	Spinal osteoarthritis	0	1 (<0.1)
Renal and urinary disorders	Adverse events in any PT	5 (<0.1)	2 (<0.1)
	Nephrolithiasis	3 (<0.1)	0
	Acute kidney injury	1 (<0.1)	1 (<0.1)
	Chronic kidney disease	1 (<0.1)	0
	Urinary retention	0	1 (<0.1)
Reproductive system and breast disorders	Adverse events in any PT	3 (<0.1)	1 (<0.1)
	Benign prostatic hyperplasia	1 (<0.1)	0
	Ovarian cyst	1 (<0.1)	0
	Uterine haemorrhage	1 (<0.1)	0
	Breast pain	0	1 (<0.1)
Congenital, familial, and genetic disorders	Adverse events in any PT	0	1 (<0.1)
	Talipes	0	1 (<0.1)
General disorders and administration site conditions	Adverse events in any PT	4 (<0.1)	5 (<0.1)
	Swelling face	2 (<0.1)	1 (<0.1)
	Chest pain	1 (<0.1)	1 (<0.1)
	Non-cardiac chest pain	1 (<0.1)	1 (<0.1)
	Feeling hot	0	1 (<0.1)
	Incarcerated hernia	0	2 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Injury, poisoning, and procedural complications	Adverse events in any PT	10 (<0.1)	11 (<0.1)
	Cervical vertebral fracture	2 (<0.1)	0
	Road traffic accident	2 (<0.1)	0
	Back injury	1 (<0.1)	0
	Craniocerebral injury	1 (<0.1)	0
	Facial bones fracture	1 (<0.1)	0
	Fall	1 (<0.1)	1 (<0.1)
	Femoral neck fracture	1 (<0.1)	0
	Hip fracture	1 (<0.1)	2 (<0.1)
	Overdose	1 (<0.1)	0
	Skin laceration	1 (<0.1)	0
	Subdural haematoma	1 (<0.1)	0
	Tendon rupture	1 (<0.1)	0
	Traumatic liver injury	1 (<0.1)	0
	Upper limb fracture	1 (<0.1)	0
	Wrist fracture	1 (<0.1)	0
	Cartilage injury	0	1 (<0.1)
	Femur fracture	0	1 (<0.1)
	Immunisation anxiety related reaction	0	1 (<0.1)
	Joint injury	0	1 (<0.1)
	Post procedural haematoma	0	1 (<0.1)
	Post procedural haemorrhage	0	1 (<0.1)
	Procedural haemorrhage	0	1 (<0.1)
	Rib fracture	0	1 (<0.1)
Social circumstances	Adverse events in any PT	0	1 (<0.1)
	Sexual abuse	0	1 (<0.1)
Product issues	Adverse events in any PT	0	1 (<0.1)
	Lead dislodgement	0	1 (<0.1)

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term.

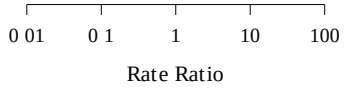
Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.
Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.13.1.1.

Figure 2: (Figure X) Participants with Serious Adverse Events by MedDRA System Organ Class up to 28 Days after Any Injection (Safety Set)

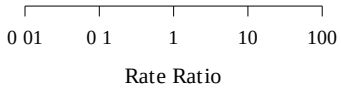


System Organ Class	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)
Infections and infestations	19 (0.1)	13 (<0.1)	0.68 (0.34, 1.36)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8 (<0.1)	9 (<0.1)	1.12 (0.45, 2.82)
Blood and lymphatic system disorders	1 (<0.1)	1 (<0.1)	1.00 (0.10, 9.56)
Immune system disorders	1 (<0.1)	0	
Endocrine disorders	0	1 (<0.1)	
Metabolism and nutrition disorders	4 (<0.1)	2 (<0.1)	0.50 (0.11, 2.33)
Psychiatric disorders	7 (<0.1)	5 (<0.1)	0.71 (0.24, 2.13)
Nervous system disorders	8 (<0.1)	10 (<0.1)	1.25 (0.51, 3.07)
Eye disorders	1 (<0.1)	0	
Cardiac disorders	17 (0.1)	14 (<0.1)	0.82 (0.41, 1.64)

System Organ Class	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)
Vascular disorders	8 (<0.1)	4 (<0.1)	0.50 (0.16, 1.56)
Respiratory, thoracic and mediastinal disorders	15 (<0.1)	9 (<0.1)	0.60 (0.27, 1.34)
Gastrointestinal disorders	7 (<0.1)	15 (<0.1)	2.14 (0.90, 5.10)
Hepatobiliary disorders	0	3 (<0.1)	
Skin and subcutaneous tissue disorders	2 (<0.1)	2 (<0.1)	1.00 (0.18, 5.66)
Musculoskeletal and connective tissue disorders	12 (<0.1)	9 (<0.1)	0.75 (0.32, 1.73)
Renal and urinary disorders	2 (<0.1)	5 (<0.1)	2.50 (0.56, 11.15)
Reproductive system and breast disorders	1 (<0.1)	3 (<0.1)	3.00 (0.43, 20.91)
Congenital, familial and genetic disorders	1 (<0.1)	0	



System Organ Class	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)
General disorders and administration site conditions	5 (<0.1)	4 (<0.1)	0.80 (0.23, 2.75)
Injury, poisoning and procedural complications	11 (<0.1)	10 (<0.1)	0.91 (0.40, 2.09)
Social circumstances	1 (<0.1)	0	
Product issues	1 (<0.1)	0	

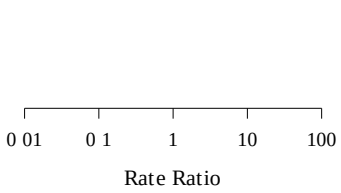


Abbreviations: CI=confidence interval; MedDRA=Medical Dictionary for Regulatory Activities; TEAE=treatment-emergent adverse event.

Notes: A TEAE is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in placebo. The 95% CI is calculated using the Miettinen and Nurminen method. MedDRA version 23.0

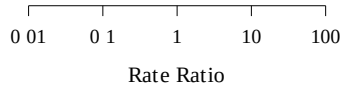
Source: Figure 14.3.1.13.1.

Figure 3: (Figure X) Participants with Serious Adverse Events by MedDRA System Organ Class within 7 Days After Any Injection (Safety Set)



System Organ Class	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)
Infections and infestations	2 (<0.1)	2 (<0.1)	1.00 (0.18, 5.66)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (<0.1)	1 (<0.1)	0.33 (0.05, 2.32)
Metabolism and nutrition disorders	0	1 (<0.1)	
Psychiatric disorders	4 (<0.1)	2 (<0.1)	0.50 (0.11, 2.33)
Nervous system disorders	2 (<0.1)	3 (<0.1)	1.50 (0.30, 7.49)
Cardiac disorders	3 (<0.1)	2 (<0.1)	0.67 (0.13, 3.33)
Vascular disorders	2 (<0.1)	0	
Respiratory, thoracic and mediastinal disorders	1 (<0.1)	0	
Gastrointestinal disorders	0	4 (<0.1)	

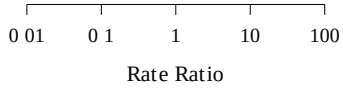
System Organ Class	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)
Skin and subcutaneous tissue disorders	0	1 (<0.1)	
Musculoskeletal and connective tissue disorders	1 (<0.1)	2 (<0.1)	2.00 (0.26, 15.24)
Renal and urinary disorders	0	2 (<0.1)	
Congenital, familial and genetic disorders	1 (<0.1)	0	
General disorders and administration site conditions	1 (<0.1)	3 (<0.1)	3.00 (0.43, 20.91)
Injury, poisoning and procedural complications	3 (<0.1)	2 (<0.1)	0.67 (0.13, 3.33)



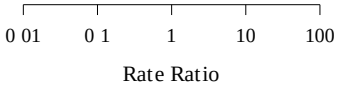
Abbreviations: CI=confidence interval; MedDRA=Medical Dictionary for Regulatory Activities; TEAE=treatment-emergent adverse event.
Notes: A TEAE is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in placebo. The 95% CI is calculated using the Miettinen and Nurminen method. MedDRA version 23.0.
Source: Figure 14.3.1.13.3.

Figure 4: (Figure X) Participants with Serious Adverse Events by MedDRA System Organ Class Through BLA Data Cut (Safety Set)

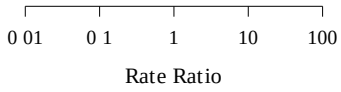
System Organ Class	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)
Infections and infestations	77 (0.5)	48 (0.3)	0.62 (0.44, 0.89)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	24 (0.2)	27 (0.2)	1.12 (0.65, 1.93)
Blood and lymphatic system disorders	7 (<0.1)	3 (<0.1)	0.43 (0.12, 1.52)
Immune system disorders	2 (<0.1)	0	
Endocrine disorders	0	1 (<0.1)	
Metabolism and nutrition disorders	15 (<0.1)	17 (0.1)	1.13 (0.57, 2.24)
Psychiatric disorders	13 (<0.1)	13 (<0.1)	1.00 (0.47, 2.12)
Nervous system disorders	27 (0.2)	31 (0.2)	1.15 (0.69, 1.91)
Eye disorders	1 (<0.1)	0	
Cardiac disorders	43 (0.3)	36 (0.2)	0.84 (0.54, 1.30)



System Organ Class	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)
Vascular disorders	15 (<0.1)	15 (<0.1)	1.00 (0.50, 2.01)
Respiratory, thoracic and mediastinal disorders	35 (0.2)	25 (0.2)	0.71 (0.43, 1.18)
Gastrointestinal disorders	25 (0.2)	36 (0.2)	1.44 (0.87, 2.38)
Hepatobiliary disorders	5 (<0.1)	6 (<0.1)	1.20 (0.39, 3.70)
Skin and subcutaneous tissue disorders	2 (<0.1)	3 (<0.1)	1.50 (0.30, 7.49)
Musculoskeletal and connective tissue disorders	28 (0.2)	24 (0.2)	0.86 (0.50, 1.47)
Renal and urinary disorders	11 (<0.1)	10 (<0.1)	0.91 (0.40, 2.09)
Pregnancy, puerperium and perinatal conditions	2 (<0.1)	1 (<0.1)	0.50 (0.07, 3.81)
Reproductive system and breast disorders	6 (<0.1)	6 (<0.1)	1.00 (0.34, 2.94)



System Organ Class	Placebo (N=15162) n (%)	mRNA-1273 (N=15184) n (%)	Rate Ratio (95% CI)
Congenital, familial and genetic disorders	1 (<0.1)	0	
General disorders and administration site conditions	12 (<0.1)	15 (<0.1)	1.25 (0.59, 2.62)
Investigations	1 (<0.1)	3 (<0.1)	3.00 (0.43, 20.91)
Injury, poisoning and procedural complications	29 (0.2)	27 (0.2)	0.93 (0.55, 1.56)
Social circumstances	1 (<0.1)	0	
Product issues	1 (<0.1)	0	



Abbreviations: CI=confidence interval; MedDRA=Medical Dictionary for Regulatory Activities; TEAE=treatment-emergent adverse event.
Notes: A TEAE is defined as any event not present before exposure to study vaccination or any event already present that worsens in intensity or frequency after exposure. Percentages are based on the number of safety subjects. The rate ratio is calculated as the ratio of percentage of participants reporting the event in mRNA-1273 divided by that in placebo. The 95% CI is calculated using the Miettinen and Nurminen method. MedDRA version 23.0.
Source: Figure 14.3.1.13.2.

5.3.2.2 Participants ≥ 18 to < 65 Years of Age

Table 49: (Table Z) Percentage of Participants Reporting Serious Adverse Events within 7 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 18 to < 65 Years of Age (Safety Set)

Table 50: (Table Z) Percentage of Participants Reporting Serious Adverse Events within 28 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 18 to < 65 Years of Age (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Number (%) of participants reporting serious adverse events		59 (0.5)	54 (0.5)
Infections and infestations	Adverse events in any PT	7 (<0.1)	8 (<0.1)
	COVID-19	1 (<0.1)	3 (<0.1)
	Clostridium difficile infection	1 (<0.1)	0
	Hepatitis A	1 (<0.1)	0
	Liver abscess	1 (<0.1)	0
	Lung abscess	1 (<0.1)	0
	Pneumonia	1 (<0.1)	1 (<0.1)
	Pneumonia mycoplasmal	1 (<0.1)	0
	Toxic shock syndrome	1 (<0.1)	0
	Appendicitis	0	1 (<0.1)
	COVID-19 pneumonia	0	1 (<0.1)
	Coccidioidomycosis	0	1 (<0.1)
	Diverticulitis	0	1 (<0.1)
	Pyelonephritis acute	0	1 (<0.1)
	Sepsis	0	1 (<0.1)
	Septic shock	0	1 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adverse events in any PT	6 (<0.1)	1 (<0.1)
	Colorectal cancer	1 (<0.1)	0
	Malignant melanoma	1 (<0.1)	0
	Metastases to bone	1 (<0.1)	0
	Metastases to lung	1 (<0.1)	0
	Papillary thyroid cancer	1 (<0.1)	0
	Pelvic neoplasm	1 (<0.1)	0
	Prostate cancer	1 (<0.1)	0
	Throat cancer	1 (<0.1)	0
	Thyroid cancer metastatic	1 (<0.1)	0
	Lung adenocarcinoma	0	1 (<0.1)
Blood and lymphatic system disorders	Adverse events in any PT	0	1 (<0.1)
	Anaemia	0	1 (<0.1)
Immune system disorders	Adverse events in any PT	0	1 (<0.1)
	Anaphylactic reaction	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Metabolism and nutrition disorders	Adverse events in any PT	0	3 (<0.1)
	Dehydration	0	1 (<0.1)
	Hypokalaemia	0	1 (<0.1)
	Hyponatraemia	0	1 (<0.1)
	Metabolic acidosis	0	1 (<0.1)
Psychiatric disorders	Adverse events in any PT	5 (<0.1)	6 (<0.1)
	Alcohol withdrawal syndrome	1 (<0.1)	0
	Completed suicide	1 (<0.1)	0
	Drug abuse	1 (<0.1)	0
	Schizoaffective disorder	1 (<0.1)	1 (<0.1)
	Suicidal ideation	1 (<0.1)	0
	Alcoholism	0	1 (<0.1)
	Anxiety	0	1 (<0.1)
	Depression	0	2 (<0.1)
	Major depression	0	1 (<0.1)
	Mental status changes	0	1 (<0.1)
Nervous system disorders	Adverse events in any PT	6 (<0.1)	6 (<0.1)
	Autonomic nervous system imbalance	1 (<0.1)	0
	Cervical radiculopathy	1 (<0.1)	0
	Seizure	1 (<0.1)	0
	Subarachnoid haemorrhage	1 (<0.1)	0
	Syncope	1 (<0.1)	1 (<0.1)
	Transient ischaemic attack	1 (<0.1)	1 (<0.1)
	Basal ganglia haemorrhage	0	1 (<0.1)
	Encephalopathy	0	1 (<0.1)
	Migraine	0	1 (<0.1)
	Paraesthesia	0	1 (<0.1)
Eye disorders	Adverse events in any PT	0	1 (<0.1)
	Retinal detachment	0	1 (<0.1)
Cardiac disorders	Adverse events in any PT	5 (<0.1)	8 (<0.1)
	Myocardial infarction	3 (<0.1)	1 (<0.1)
	Cardiac failure congestive	2 (<0.1)	2 (<0.1)
	Acute left ventricular failure	1 (<0.1)	1 (<0.1)
	Atrial flutter	1 (<0.1)	0
	Atrial fibrillation	0	1 (<0.1)
	Cardio-respiratory arrest	0	1 (<0.1)
	Pericardial effusion	0	1 (<0.1)
	Sinus tachycardia	0	2 (<0.1)
Vascular disorders	Adverse events in any PT	0	5 (<0.1)
	Aortic stenosis	0	1 (<0.1)
	Hypertension	0	1 (<0.1)
	Hypertensive emergency	0	2 (<0.1)
	Hypotension	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Respiratory, thoracic, and mediastinal disorders	Adverse events in any PT	7 (<0.1)	10 (<0.1)
	Acute respiratory failure	2 (<0.1)	2 (<0.1)
	Pulmonary embolism	2 (<0.1)	3 (<0.1)
	Atelectasis	1 (<0.1)	0
	Dyspnoea	1 (<0.1)	0
	Pleural effusion	1 (<0.1)	0
	Respiratory failure	1 (<0.1)	0
	Chronic obstructive pulmonary disease	0	1 (<0.1)
	Hypoxia	0	1 (<0.1)
	Laryngeal oedema	0	1 (<0.1)
	Pleuritic pain	0	1 (<0.1)
	Pneumonia aspiration	0	1 (<0.1)
	Pulmonary fibrosis	0	1 (<0.1)
	Pulmonary infarction	0	1 (<0.1)
Gastrointestinal disorders	Adverse events in any PT	11 (<0.1)	4 (<0.1)
	Colitis	2 (<0.1)	1 (<0.1)
	Hiatus hernia	2 (<0.1)	0
	Abdominal pain upper	1 (<0.1)	0
	Diarrhoea	1 (<0.1)	0
	Duodenal ulcer	1 (<0.1)	0
	Inguinal hernia	1 (<0.1)	0
	Large intestine perforation	1 (<0.1)	0
	Rectal prolapse	1 (<0.1)	0
	Small intestinal obstruction	1 (<0.1)	1 (<0.1)
	Abdominal pain	0	1 (<0.1)
	Gastritis	0	1 (<0.1)
	Nausea	0	1 (<0.1)
	Vomiting	0	1 (<0.1)
Hepatobiliary disorders	Adverse events in any PT	1 (<0.1)	0
	Cholecystitis	1 (<0.1)	0
Skin and subcutaneous tissue disorders	Adverse events in any PT	2 (<0.1)	0
	Alopecia areata	1 (<0.1)	0
	Angioedema	1 (<0.1)	0
Musculoskeletal and connective tissue disorders	Adverse events in any PT	5 (<0.1)	6 (<0.1)
	Back pain	1 (<0.1)	0
	Intervertebral disc protrusion	1 (<0.1)	1 (<0.1)
	Musculoskeletal chest pain	1 (<0.1)	0
	Osteoarthritis	1 (<0.1)	1 (<0.1)
	Rheumatoid arthritis	1 (<0.1)	0
	Cervical spinal stenosis	0	1 (<0.1)
	Joint stiffness	0	1 (<0.1)
	Spinal osteoarthritis	0	1 (<0.1)
	Spinal stenosis	0	1 (<0.1)
Renal and urinary disorders	Adverse events in any PT	3 (<0.1)	0
	Nephrolithiasis	2 (<0.1)	0
	Acute kidney injury	1 (<0.1)	0

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Reproductive system and breast disorders	Adverse events in any PT	2 (<0.1)	1 (<0.1)
	Benign prostatic hyperplasia	1 (<0.1)	0
	Uterine haemorrhage	1 (<0.1)	0
	Breast pain	0	1 (<0.1)
Congenital, familial, and genetic disorders	Adverse events in any PT	0	1 (<0.1)
	Talipes	0	1 (<0.1)
General disorders and administration site conditions	Adverse events in any PT	4 (<0.1)	3 (<0.1)
	Swelling face	2 (<0.1)	1 (<0.1)
	Chest pain	1 (<0.1)	1 (<0.1)
	Non-cardiac chest pain	1 (<0.1)	1 (<0.1)
	Feeling hot	0	1 (<0.1)
Injury, poisoning, and procedural complications	Adverse events in any PT	4 (<0.1)	8 (<0.1)
	Back injury	1 (<0.1)	0
	Road traffic accident	1 (<0.1)	0
	Tendon rupture	1 (<0.1)	0
	Wrist fracture	1 (<0.1)	0
	Cartilage injury	0	1 (<0.1)
	Fall	0	1 (<0.1)
	Femur fracture	0	1 (<0.1)
	Hip fracture	0	1 (<0.1)
	Immunisation anxiety related reaction	0	1 (<0.1)
	Joint injury	0	1 (<0.1)
	Post procedural haemorrhage	0	1 (<0.1)
	Procedural haemorrhage	0	1 (<0.1)
Social circumstances	Adverse events in any PT	0	1 (<0.1)
	Sexual abuse	0	1 (<0.1)

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.
Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.13.2.1.

Table 51: (Table Z) Percentage of Participants Reporting Serious Adverse Events Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 18 to < 65 Years of Age Through BLA Data Cut (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Number (%) of participants reporting serious adverse events		150 (1.3)	168 (1.5)
Infections and infestations	Adverse events in any PT	30 (0.3)	41 (0.4)
	Pneumonia	4 (<0.1)	8 (<0.1)
	Sepsis	3 (<0.1)	3 (<0.1)
	Cellulitis	2 (<0.1)	0
	Abscess limb	1 (<0.1)	0
	Appendicitis	1 (<0.1)	3 (<0.1)
	Appendicitis perforated	1 (<0.1)	0
	Bronchitis	1 (<0.1)	0
	COVID-19	1 (<0.1)	24 (0.2)
	Clostridium difficile infection	1 (<0.1)	0
	Diabetic foot infection	1 (<0.1)	0
	Diverticulitis	1 (<0.1)	1 (<0.1)
	Gastroenteritis viral	1 (<0.1)	0
	Hepatitis A	1 (<0.1)	0
	Liver abscess	1 (<0.1)	0
	Lung abscess	1 (<0.1)	0
	Peritonitis	1 (<0.1)	0
	Pneumonia mycoplasmal	1 (<0.1)	0
	Post procedural infection	1 (<0.1)	0
	Salpingitis	1 (<0.1)	0
	Septic shock	1 (<0.1)	2 (<0.1)
	Spinal cord abscess	1 (<0.1)	0
	Toxic shock syndrome	1 (<0.1)	0
	Upper respiratory tract infection	1 (<0.1)	0
	Urosepsis	1 (<0.1)	0
	Viral infection	1 (<0.1)	0
	Wound infection	1 (<0.1)	0
	COVID-19 pneumonia	0	3 (<0.1)
	Coccidioidomycosis	0	1 (<0.1)
	Enterococcal bacteraemia	0	1 (<0.1)
	Meningitis aseptic	0	1 (<0.1)
	Perirectal abscess	0	1 (<0.1)
	Pneumonia bacterial	0	1 (<0.1)
	Pyelonephritis	0	1 (<0.1)
	Pyelonephritis acute	0	1 (<0.1)
	Tooth abscess	0	1 (<0.1)
	Urinary tract infection	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adverse events in any PT	17 (0.1)	11 (<0.1)
	Benign lung neoplasm	1 (<0.1)	0
	Clear cell renal cell carcinoma	1 (<0.1)	1 (<0.1)
	Colorectal cancer	1 (<0.1)	0
	Gastric cancer	1 (<0.1)	0
	Gastrointestinal stromal tumour	1 (<0.1)	0
	Hepatocellular carcinoma	1 (<0.1)	0
	Invasive lobular breast carcinoma	1 (<0.1)	0
	Malignant melanoma	1 (<0.1)	0
	Metastases to bone	1 (<0.1)	0
	Metastases to lung	1 (<0.1)	0
	Metastatic neoplasm	1 (<0.1)	0
	Non-Hodgkin's lymphoma	1 (<0.1)	0
	Oesophageal carcinoma	1 (<0.1)	0
	Papillary thyroid cancer	1 (<0.1)	1 (<0.1)
	Pelvic neoplasm	1 (<0.1)	0
	Prostate cancer	1 (<0.1)	1 (<0.1)
	Renal cell carcinoma	1 (<0.1)	0
	Throat cancer	1 (<0.1)	0
	Thymoma malignant	1 (<0.1)	0
	Thyroid cancer metastatic	1 (<0.1)	0
	Adenocarcinoma gastric	0	1 (<0.1)
	Colon cancer stage III	0	1 (<0.1)
	Endometrial cancer	0	2 (<0.1)
	Intraductal proliferative breast lesion	0	1 (<0.1)
	Invasive ductal breast carcinoma	0	1 (<0.1)
	Lung adenocarcinoma	0	1 (<0.1)
	Uterine leiomyoma	0	1 (<0.1)
Blood and lymphatic system disorders	Adverse events in any PT	1 (<0.1)	4 (<0.1)
	Anaemia	1 (<0.1)	1 (<0.1)
	Anaemia macrocytic	0	1 (<0.1)
	Iron deficiency anaemia	0	1 (<0.1)
	Thrombocytopenia	0	1 (<0.1)
Immune system disorders	Adverse events in any PT	0	2 (<0.1)
	Anaphylactic reaction	0	1 (<0.1)
	Cytokine storm	0	1 (<0.1)
Metabolism and nutrition disorders	Adverse events in any PT	8 (<0.1)	11 (<0.1)
	Diabetic ketoacidosis	2 (<0.1)	3 (<0.1)
	Hyponatraemia	2 (<0.1)	1 (<0.1)
	Dehydration	1 (<0.1)	2 (<0.1)
	Diabetic complication	1 (<0.1)	0
	Hypoglycaemia	1 (<0.1)	1 (<0.1)
	Type 2 diabetes mellitus	1 (<0.1)	1 (<0.1)
	Diabetes mellitus	0	1 (<0.1)
	Diabetes mellitus inadequate control	0	1 (<0.1)
	Hypokalaemia	0	1 (<0.1)
	Metabolic acidosis	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Psychiatric disorders	Adverse events in any PT	12 (0.1)	11 (<0.1)
	Depression	3 (<0.1)	2 (<0.1)
	Alcohol withdrawal syndrome	2 (<0.1)	0
	Alcohol abuse	1 (<0.1)	0
	Completed suicide	1 (<0.1)	1 (<0.1)
	Drug abuse	1 (<0.1)	0
	Intentional self-injury	1 (<0.1)	0
	Schizoaffective disorder	1 (<0.1)	1 (<0.1)
	Substance-induced mood disorder	1 (<0.1)	0
	Substance-induced psychotic disorder	1 (<0.1)	0
	Suicidal ideation	1 (<0.1)	0
	Suicide attempt	1 (<0.1)	0
	Alcoholism	0	1 (<0.1)
	Anxiety	0	1 (<0.1)
	Anxiety disorder	0	1 (<0.1)
	Depression suicidal	0	1 (<0.1)
	Major depression	0	2 (<0.1)
	Mania	0	1 (<0.1)
	Mental status changes	0	1 (<0.1)
	Schizophrenia	0	1 (<0.1)
Nervous system disorders	Adverse events in any PT	18 (0.2)	19 (0.2)
	Cerebrovascular accident	3 (<0.1)	2 (<0.1)
	Seizure	3 (<0.1)	1 (<0.1)
	Syncope	3 (<0.1)	5 (<0.1)
	Aphasia	1 (<0.1)	0
	Autonomic nervous system imbalance	1 (<0.1)	0
	Cauda equina syndrome	1 (<0.1)	0
	Cervical radiculopathy	1 (<0.1)	0
	Dizziness	1 (<0.1)	0
	Hemiparesis	1 (<0.1)	0
	Multiple sclerosis	1 (<0.1)	1 (<0.1)
	Spinal cord compression	1 (<0.1)	0
	Subarachnoid haemorrhage	1 (<0.1)	0
	Transient ischaemic attack	1 (<0.1)	2 (<0.1)
	Arachnoid cyst	0	1 (<0.1)
	Basal ganglia haemorrhage	0	1 (<0.1)
	Encephalopathy	0	2 (<0.1)
	Hydrocephalus	0	1 (<0.1)
	Loss of consciousness	0	1 (<0.1)
	Migraine	0	1 (<0.1)
	Paraesthesia	0	1 (<0.1)
Eye disorders	Adverse events in any PT	0	1 (<0.1)
	Retinal detachment	0	1 (<0.1)
	Retinal tear	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Cardiac disorders	Adverse events in any PT	11 (<0.1)	18 (0.2)
	Myocardial infarction	4 (<0.1)	6 (<0.1)
	Atrial flutter	2 (<0.1)	0
	Cardiac failure congestive	2 (<0.1)	2 (<0.1)
	Coronary artery disease	2 (<0.1)	0
	Acute coronary syndrome	1 (<0.1)	0
	Acute left ventricular failure	1 (<0.1)	1 (<0.1)
	Acute myocardial infarction	1 (<0.1)	2 (<0.1)
	Atrial fibrillation	1 (<0.1)	1 (<0.1)
	Cardiac failure acute	1 (<0.1)	0
	Pericardial effusion	1 (<0.1)	1 (<0.1)
	Pericarditis	1 (<0.1)	2 (<0.1)
	Angina pectoris	0	1 (<0.1)
	Cardio-respiratory arrest	0	1 (<0.1)
	Paroxysmal arrhythmia	0	1 (<0.1)
	Sinus tachycardia	0	2 (<0.1)
Vascular disorders	Adverse events in any PT	5 (<0.1)	11 (<0.1)
	Deep vein thrombosis	1 (<0.1)	0
	Embolism venous	1 (<0.1)	0
	Haematoma	1 (<0.1)	0
	Polyarteritis nodosa	1 (<0.1)	0
	Venous thrombosis limb	1 (<0.1)	0
	Aortic stenosis	0	1 (<0.1)
	Arterial haemorrhage	0	1 (<0.1)
	Hypertension	0	2 (<0.1)
	Hypertensive emergency	0	2 (<0.1)
	Hypotension	0	2 (<0.1)
	Peripheral artery aneurysm	0	1 (<0.1)
	Peripheral artery occlusion	0	1 (<0.1)
	Thrombophlebitis superficial	0	1 (<0.1)
Respiratory, thoracic, and mediastinal disorders	Adverse events in any PT	15 (0.1)	21 (0.2)
	Dyspnoea	5 (<0.1)	0
	Pulmonary embolism	4 (<0.1)	5 (<0.1)
	Acute respiratory failure	3 (<0.1)	5 (<0.1)
	Pleural effusion	2 (<0.1)	1 (<0.1)
	Atelectasis	1 (<0.1)	0
	Respiratory failure	1 (<0.1)	0
	Acute respiratory distress syndrome	0	1 (<0.1)
	Chronic obstructive pulmonary disease	0	3 (<0.1)
	Epistaxis	0	1 (<0.1)
	Hypoxia	0	3 (<0.1)
	Laryngeal oedema	0	1 (<0.1)
	Pleuritic pain	0	1 (<0.1)
	Pneumonia aspiration	0	1 (<0.1)
	Pneumothorax	0	2 (<0.1)
	Pulmonary fibrosis	0	1 (<0.1)
	Pulmonary infarction	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Gastrointestinal disorders	Adverse events in any PT	18 (0.2)	14 (0.1)
	Colitis	2 (<0.1)	4 (<0.1)
	Hiatus hernia	2 (<0.1)	0
	Abdominal pain	1 (<0.1)	1 (<0.1)
	Abdominal pain upper	1 (<0.1)	0
	Crohn's disease	1 (<0.1)	0
	Diarrhoea	1 (<0.1)	0
	Duodenal ulcer	1 (<0.1)	0
	Gastritis	1 (<0.1)	2 (<0.1)
	Inguinal hernia	1 (<0.1)	0
	Intestinal obstruction	1 (<0.1)	0
	Large intestine perforation	1 (<0.1)	0
	Nausea	1 (<0.1)	2 (<0.1)
	Oesophageal rupture	1 (<0.1)	0
	Rectal prolapse	1 (<0.1)	0
	Retroperitoneal haemorrhage	1 (<0.1)	0
	Small intestinal obstruction	1 (<0.1)	1 (<0.1)
	Vomiting	1 (<0.1)	2 (<0.1)
	Abdominal hernia	0	1 (<0.1)
	Abdominal pain lower	0	2 (<0.1)
	Gastric ulcer haemorrhage	0	1 (<0.1)
	Pancreatitis	0	2 (<0.1)
Hepatobiliary disorders	Adverse events in any PT	4 (<0.1)	3 (<0.1)
	Cholecystitis	2 (<0.1)	2 (<0.1)
	Bile duct stone	1 (<0.1)	0
	Cholelithiasis	1 (<0.1)	0
	Biliary dyskinesia	0	1 (<0.1)
Skin and subcutaneous tissue disorders	Adverse events in any PT	3 (<0.1)	0
	Alopecia areata	1 (<0.1)	0
	Angioedema	1 (<0.1)	0
	Rash	1 (<0.1)	0
	Rash vesicular	1 (<0.1)	0
Musculoskeletal and connective tissue disorders	Adverse events in any PT	11 (<0.1)	15 (0.1)
	Intervertebral disc protrusion	3 (<0.1)	1 (<0.1)
	Osteoarthritis	3 (<0.1)	2 (<0.1)
	Back pain	1 (<0.1)	0
	Musculoskeletal chest pain	1 (<0.1)	1 (<0.1)
	Rheumatoid arthritis	1 (<0.1)	0
	Spinal osteoarthritis	1 (<0.1)	3 (<0.1)
	Vertebral foraminal stenosis	1 (<0.1)	0
	Arthritis	0	1 (<0.1)
	Cervical spinal stenosis	0	1 (<0.1)
	Flank pain	0	1 (<0.1)
	Joint stiffness	0	1 (<0.1)
	Muscular weakness	0	1 (<0.1)
	Rhabdomyolysis	0	1 (<0.1)
	Spinal stenosis	0	2 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Renal and urinary disorders	Adverse events in any PT	5 (<0.1)	3 (<0.1)
	Nephrolithiasis	3 (<0.1)	1 (<0.1)
	Acute kidney injury	2 (<0.1)	2 (<0.1)
Pregnancy, puerperium and perinatal conditions	Adverse events in any PT	1 (<0.1)	2 (<0.1)
	Abortion spontaneous	1 (<0.1)	1 (<0.1)
	Ectopic pregnancy	0	1 (<0.1)
Reproductive system and breast disorders	Adverse events in any PT	5 (<0.1)	4 (<0.1)
	Pelvic pain	2 (<0.1)	0
	Benign prostatic hyperplasia	1 (<0.1)	0
	Dysfunctional uterine bleeding	1 (<0.1)	0
	Uterine haemorrhage	1 (<0.1)	0
	Breast pain	0	1 (<0.1)
	Endometrial hyperplasia	0	1 (<0.1)
	Ovarian cyst	0	2 (<0.1)
Congenital, familial, and genetic disorders	Adverse events in any PT	0	1 (<0.1)
	Talipes	0	1 (<0.1)
General disorders and administration site conditions	Adverse events in any PT	11 (<0.1)	7 (<0.1)
	Death	4 (<0.1)	2 (<0.1)
	Chest pain	2 (<0.1)	2 (<0.1)
	Non-cardiac chest pain	2 (<0.1)	1 (<0.1)
	Swelling face	2 (<0.1)	1 (<0.1)
	Drug withdrawal syndrome	1 (<0.1)	0
	Feeling hot	0	1 (<0.1)
	Systemic inflammatory response syndrome	0	1 (<0.1)
Investigations	Adverse events in any PT	2 (<0.1)	0
	Heart rate irregular	1 (<0.1)	0
	Hepatic enzyme increased	1 (<0.1)	0

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Injury, poisoning, and procedural complications	Adverse events in any PT	13 (0.1)	18 (0.2)
	Back injury	1 (<0.1)	0
	Concussion	1 (<0.1)	0
	Craniocerebral injury	1 (<0.1)	0
	Gastrointestinal procedural complication	1 (<0.1)	0
	Head injury	1 (<0.1)	0
	Incision site pain	1 (<0.1)	0
	Joint injury	1 (<0.1)	1 (<0.1)
	Post procedural haemorrhage	1 (<0.1)	1 (<0.1)
	Road traffic accident	1 (<0.1)	0
	Superficial injury of eye	1 (<0.1)	0
	Tendon rupture	1 (<0.1)	1 (<0.1)
	Wound dehiscence	1 (<0.1)	0
	Wrist fracture	1 (<0.1)	0
	Ankle fracture	0	1 (<0.1)
	Cartilage injury	0	1 (<0.1)
	Fall	0	3 (<0.1)
	Femur fracture	0	1 (<0.1)
	Gun shot wound	0	1 (<0.1)
	Hip fracture	0	1 (<0.1)
	Immunisation anxiety related reaction	0	1 (<0.1)
	Post procedural fever	0	1 (<0.1)
	Procedural haemorrhage	0	1 (<0.1)
	Rib fracture	0	1 (<0.1)
	Skin laceration	0	1 (<0.1)
	Sternal fracture	0	1 (<0.1)
	Tracheal haemorrhage	0	1 (<0.1)
	Traumatic haemothorax	0	1 (<0.1)
Social circumstances	Adverse events in any PT	0	1 (<0.1)
	Sexual abuse	0	1 (<0.1)

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.13.2.3.

5.3.2.3 Participants 65 Years of Age and Older

Table 52: (Table Z) Percentage of Participants Reporting Serious Adverse Events within 7 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 65 Years of Age (Safety Set)

Table 53: (Table Z) Percentage of Participants Reporting Serious Adverse Events within 28 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 65 Years of Age (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Number (%) of participants reporting serious adverse events		39 (1.0)	50 (1.3)
Infections and infestations	Adverse events in any PT	6 (0.2)	11 (0.3)
	Pneumonia	2 (<0.1)	3 (<0.1)
	Appendicitis	1 (<0.1)	2 (<0.1)
	Cellulitis	1 (<0.1)	0
	Peritonitis	1 (<0.1)	0
	Pneumonia staphylococcal	1 (<0.1)	0
	Pyelonephritis acute	1 (<0.1)	0
	Urosepsis	1 (<0.1)	0
	COVID-19	0	1 (<0.1)
	Osteomyelitis	0	1 (<0.1)
	Pharyngitis streptococcal	0	1 (<0.1)
	Streptococcal sepsis	0	1 (<0.1)
	Urinary tract infection	0	2 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adverse events in any PT	3 (<0.1)	7 (0.2)
	Prostate cancer	2 (<0.1)	3 (<0.1)
	Splenic marginal zone lymphoma	1 (<0.1)	0
	Breast cancer stage I	0	1 (<0.1)
	Intraductal proliferative breast lesion	0	1 (<0.1)
	Prostate cancer metastatic	0	1 (<0.1)
	Renal cell carcinoma	0	1 (<0.1)
Blood and lymphatic system disorders	Adverse events in any PT	1 (<0.1)	0
	Blood loss anaemia	1 (<0.1)	0
Endocrine disorders	Adverse events in any PT	1 (<0.1)	0
	Basedow's disease	1 (<0.1)	0
Metabolism and nutrition disorders	Adverse events in any PT	2 (<0.1)	1 (<0.1)
	Dehydration	2 (<0.1)	1 (<0.1)
	Hyperkalaemia	1 (<0.1)	0
Psychiatric disorders	Adverse events in any PT	0	1 (<0.1)
	Confusional state	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Nervous system disorders	Adverse events in any PT	4 (0.1)	2 (<0.1)
	Cerebrovascular accident	2 (<0.1)	0
	Carotid artery thrombosis	1 (<0.1)	0
	Embolic stroke	1 (<0.1)	0
	Subarachnoid haemorrhage	1 (<0.1)	0
	Syncope	1 (<0.1)	1 (<0.1)
	Ischaemic stroke	0	1 (<0.1)
	Speech disorder	0	1 (<0.1)
Cardiac disorders	Adverse events in any PT	9 (0.2)	9 (0.2)
	Atrial fibrillation	3 (<0.1)	2 (<0.1)
	Acute myocardial infarction	2 (<0.1)	1 (<0.1)
	Acute coronary syndrome	1 (<0.1)	0
	Cardiac failure congestive	1 (<0.1)	1 (<0.1)
	Cardio-respiratory arrest	1 (<0.1)	0
	Coronary artery disease	1 (<0.1)	2 (<0.1)
	Atrial flutter	0	1 (<0.1)
	Cardiac failure	0	2 (<0.1)
Vascular disorders	Adverse events in any PT	4 (0.1)	3 (<0.1)
	Hypertension	2 (<0.1)	0
	Aortic aneurysm	1 (<0.1)	1 (<0.1)
	Hypertensive urgency	1 (<0.1)	1 (<0.1)
	Hypotension	1 (<0.1)	0
	Fibromuscular dysplasia	0	1 (<0.1)
Respiratory, thoracic, and mediastinal disorders	Adverse events in any PT	2 (<0.1)	5 (0.1)
	Pulmonary embolism	1 (<0.1)	0
	Respiratory failure	1 (<0.1)	0
	Acute respiratory failure	0	1 (<0.1)
	Chronic obstructive pulmonary disease	0	2 (<0.1)
	Emphysema	0	1 (<0.1)
	Pleural effusion	0	1 (<0.1)
Gastrointestinal disorders	Adverse events in any PT	4 (0.1)	3 (<0.1)
	Nausea	2 (<0.1)	0
	Intestinal obstruction	1 (<0.1)	0
	Pancreatitis acute	1 (<0.1)	0
	Vomiting	1 (<0.1)	0
	Abdominal pain	0	1 (<0.1)
	Duodenal ulcer haemorrhage	0	1 (<0.1)
	Gastric perforation	0	1 (<0.1)
Hepatobiliary disorders	Adverse events in any PT	2 (<0.1)	0
	Bile duct stone	1 (<0.1)	0
	Cholecystitis	1 (<0.1)	0
Skin and subcutaneous tissue disorders	Adverse events in any PT	0	2 (<0.1)
	Angioedema	0	1 (<0.1)
	Dermatitis bullous	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Musculoskeletal and connective tissue disorders	Adverse events in any PT	4 (0.1)	6 (0.2)
	Spinal stenosis	2 (<0.1)	0
	Fracture nonunion	1 (<0.1)	0
	Osteoarthritis	1 (<0.1)	5 (0.1)
	Polymyalgia rheumatica	0	1 (<0.1)
Renal and urinary disorders	Adverse events in any PT	2 (<0.1)	2 (<0.1)
	Chronic kidney disease	1 (<0.1)	0
	Nephrolithiasis	1 (<0.1)	0
	Acute kidney injury	0	1 (<0.1)
	Urinary retention	0	1 (<0.1)
Reproductive system and breast disorders	Adverse events in any PT	1 (<0.1)	0
	Ovarian cyst	1 (<0.1)	0
General disorders and administration site conditions	Adverse events in any PT	0	2 (<0.1)
	Incarcerated hernia	0	2 (<0.1)
Injury, poisoning, and procedural complications	Adverse events in any PT	6 (0.2)	3 (<0.1)
	Cervical vertebral fracture	2 (<0.1)	0
	Craniocerebral injury	1 (<0.1)	0
	Facial bones fracture	1 (<0.1)	0
	Fall	1 (<0.1)	0
	Femoral neck fracture	1 (<0.1)	0
	Hip fracture	1 (<0.1)	1 (<0.1)
	Overdose	1 (<0.1)	0
	Road traffic accident	1 (<0.1)	0
	Skin laceration	1 (<0.1)	0
	Subdural haematoma	1 (<0.1)	0
	Traumatic liver injury	1 (<0.1)	0
	Upper limb fracture	1 (<0.1)	0
	Post procedural haematoma	0	1 (<0.1)
	Rib fracture	0	1 (<0.1)
Product issues	Adverse events in any PT	0	1 (<0.1)
	Lead dislodgement	0	1 (<0.1)

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.13.2.1.

Table 54: (Table Z) Percentage of Participants Reporting Serious Adverse Events Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 65 Years of Age Through BLA Data Cut (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Number (%) of participants reporting serious adverse events		118 (3.1)	124 (3.3)
Infections and infestations	Adverse events in any PT	18 (0.5)	36 (1.0)
	Pneumonia	5 (0.1)	3 (<0.1)
	Appendicitis	3 (<0.1)	2 (<0.1)
	Postoperative abscess	2 (<0.1)	0
	Bronchitis	1 (<0.1)	0
	COVID-19	1 (<0.1)	16 (0.4)
	Cellulitis	1 (<0.1)	0
	Giardiasis	1 (<0.1)	0
	Peritonitis	1 (<0.1)	0
	Pneumonia staphylococcal	1 (<0.1)	0
	Postoperative wound infection	1 (<0.1)	0
	Pyelonephritis acute	1 (<0.1)	0
	Sepsis	1 (<0.1)	0
	Urinary tract infection	1 (<0.1)	4 (0.1)
	Urosepsis	1 (<0.1)	0
	Viral pharyngitis	1 (<0.1)	0
	Appendicitis perforated	0	1 (<0.1)
	COVID-19 pneumonia	0	5 (0.1)
	Clostridium difficile colitis	0	1 (<0.1)
	Diverticulitis	0	2 (<0.1)
	Localised infection	0	1 (<0.1)
	Osteomyelitis	0	1 (<0.1)
	Pharyngitis streptococcal	0	1 (<0.1)
	Pneumonia klebsiella	0	1 (<0.1)
	Pyelonephritis	0	1 (<0.1)
	Septic shock	0	1 (<0.1)
	Streptococcal sepsis	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adverse events in any PT	10 (0.3)	13 (0.3)
	Prostate cancer	4 (0.1)	3 (<0.1)
	B-cell small lymphocytic lymphoma	1 (<0.1)	0
	Cancer pain	1 (<0.1)	0
	Hepatocellular carcinoma	1 (<0.1)	0
	Liposarcoma	1 (<0.1)	0
	Meningioma	1 (<0.1)	0
	Plasma cell myeloma	1 (<0.1)	0
	Splenic marginal zone lymphoma	1 (<0.1)	0
	Breast cancer stage I	0	1 (<0.1)
	Endometrial cancer	0	1 (<0.1)
	Intraductal proliferative breast lesion	0	2 (<0.1)
	Leiomyosarcoma metastatic	0	1 (<0.1)
	Non-small cell lung cancer	0	1 (<0.1)
	Pancreatic carcinoma stage IV	0	1 (<0.1)
	Prostate cancer metastatic	0	1 (<0.1)
	Renal cell carcinoma	0	1 (<0.1)
	Thyroid cancer	0	1 (<0.1)
Blood and lymphatic system disorders	Adverse events in any PT	2 (<0.1)	3 (<0.1)
	Anaemia	1 (<0.1)	1 (<0.1)
	Blood loss anaemia	1 (<0.1)	1 (<0.1)
	Thrombocytopenia	1 (<0.1)	0
	Thrombocytosis	0	1 (<0.1)
Endocrine disorders	Adverse events in any PT	1 (<0.1)	0
	Basedow's disease	1 (<0.1)	0
Metabolism and nutrition disorders	Adverse events in any PT	9 (0.2)	4 (0.1)
	Dehydration	3 (<0.1)	2 (<0.1)
	Diabetic ketoacidosis	1 (<0.1)	0
	Failure to thrive	1 (<0.1)	0
	Gout	1 (<0.1)	1 (<0.1)
	Hyperkalaemia	1 (<0.1)	0
	Hypoglycaemia	1 (<0.1)	0
	Hypokalaemia	1 (<0.1)	0
	Hyponatraemia	1 (<0.1)	0
	Obesity	1 (<0.1)	0
	Type 2 diabetes mellitus	1 (<0.1)	0
	Hypomagnesaemia	0	1 (<0.1)
Psychiatric disorders	Adverse events in any PT	1 (<0.1)	2 (<0.1)
	Mental status changes	1 (<0.1)	0
	Alcohol withdrawal syndrome	0	1 (<0.1)
	Confusional state	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Nervous system disorders	Adverse events in any PT	13 (0.3)	8 (0.2)
	Cerebrovascular accident	3 (<0.1)	2 (<0.1)
	Embolic stroke	2 (<0.1)	0
	Subarachnoid haemorrhage	2 (<0.1)	0
	Syncope	2 (<0.1)	2 (<0.1)
	Carotid artery stenosis	1 (<0.1)	0
	Carotid artery thrombosis	1 (<0.1)	0
	Facial paralysis	1 (<0.1)	0
	Lumbar radiculopathy	1 (<0.1)	0
	Optic neuritis	1 (<0.1)	0
	Transient ischaemic attack	1 (<0.1)	0
	Amyotrophic lateral sclerosis	0	1 (<0.1)
	Dizziness	0	1 (<0.1)
	Ischaemic stroke	0	1 (<0.1)
	Nerve compression	0	1 (<0.1)
	Speech disorder	0	1 (<0.1)
Cardiac disorders	Adverse events in any PT	25 (0.7)	25 (0.7)
	Atrial fibrillation	5 (0.1)	9 (0.2)
	Myocardial infarction	3 (<0.1)	3 (<0.1)
	Acute coronary syndrome	2 (<0.1)	0
	Acute myocardial infarction	2 (<0.1)	4 (0.1)
	Cardiac failure congestive	2 (<0.1)	1 (<0.1)
	Cardio-respiratory arrest	2 (<0.1)	0
	Angina unstable	1 (<0.1)	0
	Bradycardia	1 (<0.1)	0
	Cardiac arrest	1 (<0.1)	0
	Cardiac failure	1 (<0.1)	2 (<0.1)
	Coronary artery disease	1 (<0.1)	3 (<0.1)
	Coronary artery occlusion	1 (<0.1)	0
	Pericarditis	1 (<0.1)	0
	Stress cardiomyopathy	1 (<0.1)	0
	Supraventricular tachycardia	1 (<0.1)	0
	Ventricular extrasystoles	1 (<0.1)	0
	Acute left ventricular failure	0	1 (<0.1)
	Arrhythmia	0	1 (<0.1)
	Atrial flutter	0	2 (<0.1)
	Atrioventricular block complete	0	1 (<0.1)
	Atrioventricular block second degree	0	1 (<0.1)
	Cardiac failure acute	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Vascular disorders	Adverse events in any PT	10 (0.3)	4 (0.1)
	Deep vein thrombosis	3 (<0.1)	1 (<0.1)
	Hypertension	2 (<0.1)	0
	Hypertensive urgency	2 (<0.1)	1 (<0.1)
	Aortic aneurysm	1 (<0.1)	1 (<0.1)
	Arteriosclerosis	1 (<0.1)	0
	Axillary vein thrombosis	1 (<0.1)	0
	Haematoma	1 (<0.1)	0
	Hypotension	1 (<0.1)	0
	Fibromuscular dysplasia	0	1 (<0.1)
Respiratory, thoracic, and mediastinal disorders	Adverse events in any PT	10 (0.3)	14 (0.4)
	Acute respiratory failure	4 (0.1)	5 (0.1)
	Pulmonary embolism	2 (<0.1)	2 (<0.1)
	Chronic obstructive pulmonary disease	1 (<0.1)	5 (0.1)
	Emphysema	1 (<0.1)	1 (<0.1)
	Pneumothorax	1 (<0.1)	0
	Pulmonary mass	1 (<0.1)	0
	Respiratory failure	1 (<0.1)	1 (<0.1)
	Asthma	0	1 (<0.1)
	Organising pneumonia	0	1 (<0.1)
	Pleural effusion	0	1 (<0.1)
Gastrointestinal disorders	Adverse events in any PT	18 (0.5)	11 (0.3)
	Gastrointestinal haemorrhage	3 (<0.1)	2 (<0.1)
	Duodenal ulcer perforation	2 (<0.1)	0
	Nausea	2 (<0.1)	1 (<0.1)
	Small intestinal obstruction	2 (<0.1)	2 (<0.1)
	Abdominal pain	1 (<0.1)	1 (<0.1)
	Abdominal pain upper	1 (<0.1)	0
	Colitis	1 (<0.1)	0
	Diarrhoea	1 (<0.1)	1 (<0.1)
	Diverticular perforation	1 (<0.1)	0
	Gastrooesophageal reflux disease	1 (<0.1)	0
	Intestinal obstruction	1 (<0.1)	0
	Intra-abdominal fluid collection	1 (<0.1)	0
	Oesophageal spasm	1 (<0.1)	0
	Pancreatitis	1 (<0.1)	0
	Pancreatitis acute	1 (<0.1)	0
	Vomiting	1 (<0.1)	0
	Duodenal ulcer haemorrhage	0	1 (<0.1)
	Gastric perforation	0	1 (<0.1)
	Hiatus hernia	0	1 (<0.1)
	Tooth socket haemorrhage	0	1 (<0.1)
Hepatobiliary disorders	Adverse events in any PT	2 (<0.1)	2 (<0.1)
	Bile duct stone	1 (<0.1)	0
	Cholecystitis	1 (<0.1)	1 (<0.1)
	Cholecystitis acute	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Skin and subcutaneous tissue disorders	Adverse events in any PT	0	2 (<0.1)
	Angioedema	0	1 (<0.1)
	Dermatitis bullous	0	1 (<0.1)
Musculoskeletal and connective tissue disorders	Adverse events in any PT	13 (0.3)	13 (0.3)
	Osteoarthritis	5 (0.1)	10 (0.3)
	Spinal stenosis	2 (<0.1)	0
	Back pain	1 (<0.1)	0
	Flank pain	1 (<0.1)	0
	Fracture nonunion	1 (<0.1)	0
	Muscular weakness	1 (<0.1)	0
	Neck pain	1 (<0.1)	0
	Spondylolisthesis	1 (<0.1)	0
	Intervertebral disc protrusion	0	1 (<0.1)
	Osteonecrosis	0	1 (<0.1)
	Polymyalgia rheumatica	0	1 (<0.1)
Renal and urinary disorders	Adverse events in any PT	5 (0.1)	8 (0.2)
	Acute kidney injury	3 (<0.1)	4 (0.1)
	Nephrolithiasis	2 (<0.1)	0
	Chronic kidney disease	1 (<0.1)	2 (<0.1)
	Renal impairment	0	1 (<0.1)
	Urinary retention	0	1 (<0.1)
Reproductive system and breast disorders	Adverse events in any PT	1 (<0.1)	2 (<0.1)
	Ovarian cyst	1 (<0.1)	0
	Benign prostatic hyperplasia	0	1 (<0.1)
	Pelvic prolapse	0	1 (<0.1)
General disorders and administration site conditions	Adverse events in any PT	4 (0.1)	5 (0.1)
	Asthenia	1 (<0.1)	0
	Generalised oedema	1 (<0.1)	0
	Multiple organ dysfunction syndrome	1 (<0.1)	0
	Non-cardiac chest pain	1 (<0.1)	1 (<0.1)
	Oedema peripheral	1 (<0.1)	0
	Incarcerated hernia	0	2 (<0.1)
	Pyrexia	0	1 (<0.1)
	Systemic inflammatory response syndrome	0	1 (<0.1)
Investigations	Adverse events in any PT	1 (<0.1)	1 (<0.1)
	Hepatic enzyme increased	1 (<0.1)	0
	Transaminases increased	0	1 (<0.1)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Injury, poisoning, and procedural complications	Adverse events in any PT	14 (0.4)	11 (0.3)
	Hip fracture	3 (<0.1)	2 (<0.1)
	Cervical vertebral fracture	2 (<0.1)	0
	Fall	2 (<0.1)	2 (<0.1)
	Subdural haematoma	2 (<0.1)	0
	Craniocerebral injury	1 (<0.1)	0
	Facial bones fracture	1 (<0.1)	0
	Femoral neck fracture	1 (<0.1)	0
	Femur fracture	1 (<0.1)	1 (<0.1)
	Humerus fracture	1 (<0.1)	0
	Incarcerated incisional hernia	1 (<0.1)	0
	Overdose	1 (<0.1)	0
	Procedural haemorrhage	1 (<0.1)	0
	Rib fracture	1 (<0.1)	2 (<0.1)
	Road traffic accident	1 (<0.1)	1 (<0.1)
	Skin laceration	1 (<0.1)	0
	Traumatic liver injury	1 (<0.1)	0
	Upper limb fracture	1 (<0.1)	0
	Pelvic fracture	0	1 (<0.1)
	Post procedural haematoma	0	1 (<0.1)
	Post-traumatic pain	0	1 (<0.1)
	Thoracic vertebral fracture	0	1 (<0.1)
	Traumatic haemothorax	0	1 (<0.1)
Product issues	Adverse events in any PT	0	1 (<0.1)
	Lead dislodgement	0	1 (<0.1)

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.13.2.3.

5.3.2.4 Serious Adverse Events Considered Related by Investigator (Safety Set)

Table 55 (Table AA) Serious Adverse Events Considered Related by Investigator (Safety Set)

5.3.3 Unsolicited Adverse Events Leading to Study Withdrawal

5.3.3.1 Participants ≥ 18 to < 65 Years of Age

Table 56: (Table Z) Percentage of Participants with Adverse Events Leading to Study Withdrawal Within 7 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 18 to < 65 Years of Age (Safety Set)

Table 57: (Table Z) Percentage of Participants with Adverse Events Leading to Study Withdrawal within 28 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 18 to < 65 Years of Age (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Number (%) of participants with adverse events leading to study withdrawal		7 (<0.1)	3 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adverse events in any PT	1 (<0.1)	0
	Colorectal cancer	1 (<0.1)	0
Psychiatric disorders	Adverse events in any PT	3 (<0.1)	0
	Completed suicide	1 (<0.1)	0
	Schizoaffective disorder	1 (<0.1)	0
	Substance abuse	1 (<0.1)	0
Cardiac disorders	Adverse events in any PT	0	1 (<0.1)
	Cardio-respiratory arrest	0	1 (<0.1)
Respiratory, thoracic, and mediastinal disorders	Adverse events in any PT	1 (<0.1)	0
	Pulmonary embolism	1 (<0.1)	0
Skin and subcutaneous tissue disorders	Adverse events in any PT	1 (<0.1)	1 (<0.1)
	Urticaria	1 (<0.1)	0
	Dermatitis allergic	0	1 (<0.1)
General disorders and administration site conditions	Adverse events in any PT	1 (<0.1)	0
	Induration	1 (<0.1)	0
Investigations	Adverse events in any PT	1 (<0.1)	0
	Hepatic enzyme increased	1 (<0.1)	0
Injury, poisoning, and procedural complications	Adverse events in any PT	1 (<0.1)	0
	Hip fracture	1 (<0.1)	0

Abbreviations: IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.16.2.1.

Table 58: (Table Z) Percentage of Participants with Adverse Events Leading to Study Withdrawal Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 18 to < 65 Years of Age Through BLA Data Cut (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=11415) n (%)	Placebo (N=11411) n (%)
Number (%) of participants with adverse events leading to study withdrawal		15 (0.1)	15 (0.1)
Infections and infestations	Adverse events in any PT	0	3 (<0.1)
	COVID-19	0	3 (<0.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adverse events in any PT	3 (<0.1)	0
	Colorectal cancer	1 (<0.1)	0
	Gastric cancer	1 (<0.1)	0
	Hepatocellular carcinoma	1 (<0.1)	0
Metabolism and nutrition disorders	Adverse events in any PT	1 (<0.1)	0
	Diabetic complication	1 (<0.1)	0
Psychiatric disorders	Adverse events in any PT	3 (<0.1)	2 (<0.1)
	Completed suicide	1 (<0.1)	1 (<0.1)
	Schizoaffective disorder	1 (<0.1)	0
	Substance abuse	1 (<0.1)	0
	Depression suicidal	0	1 (<0.1)
Nervous system disorders	Adverse events in any PT	0	1 (<0.1)
	Seizure	0	1 (<0.1)
Ear and labyrinth disorders	Adverse events in any PT	0	1 (<0.1)
	Vertigo	0	1 (<0.1)
Cardiac disorders	Adverse events in any PT	1 (<0.1)	3 (<0.1)
	Coronary artery disease	1 (<0.1)	0
	Cardio-respiratory arrest	0	1 (<0.1)
	Myocardial infarction	0	2 (<0.1)
Vascular disorders	Adverse events in any PT	0	1 (<0.1)
	Hypertension	0	1 (<0.1)
Respiratory, thoracic, and mediastinal disorders	Adverse events in any PT	1 (<0.1)	0
	Pulmonary embolism	1 (<0.1)	0
Skin and subcutaneous tissue disorders	Adverse events in any PT	1 (<0.1)	1 (<0.1)
	Urticaria	1 (<0.1)	0
	Dermatitis allergic	0	1 (<0.1)
General disorders and administration site conditions	Adverse events in any PT	5 (<0.1)	2 (<0.1)
	Death	4 (<0.1)	2 (<0.1)
	Induration	1 (<0.1)	0
Investigations	Adverse events in any PT	1 (<0.1)	0
	Hepatic enzyme increased	1 (<0.1)	0
Injury, poisoning, and procedural complications	Adverse events in any PT	1 (<0.1)	1 (<0.1)
	Head injury	1 (<0.1)	0
	Hip fracture	0	1 (<0.1)

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.16.2.3.

5.3.3.2 Participants 65 Years of Age and Older

Table 59: (Table Z) Percentage of Participants with Adverse Events Leading to Study Withdrawal within 7 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 65 Years of Age (Safety Set)

Table 60: (Table Z) Percentage of Participants with Adverse Events Leading to Study Withdrawal within 28 Days After Any Injection Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 65 Years of Age (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Number (%) of participants with adverse events leading to study withdrawal		2 (<0.1)	3 (<0.1)
Cardiac disorders	Adverse events in any PT	1 (<0.1)	0
	Cardio-respiratory arrest	1 (<0.1)	0
Gastrointestinal disorders	Adverse events in any PT	1 (<0.1)	2 (<0.1)
	Pancreatitis acute	1 (<0.1)	0
	Duodenal ulcer haemorrhage	0	1 (<0.1)
	Gastric perforation	0	1 (<0.1)
General disorders and administration site conditions	Adverse events in any PT	0	1 (<0.1)
	Incarcerated hernia	0	1 (<0.1)

Abbreviations: IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.16.2.1.

Table 61: (Table Z) Percentage of Participants with Adverse Events Leading to Study Withdrawal Classified by MedDRA Primary System Organ Class and Preferred Term in Participants ≥ 65 Years of Age Through BLA Data Cut (Safety Set)

Primary System Organ Class	Preferred Term	mRNA-1273 (N=3769) n (%)	Placebo (N=3751) n (%)
Number (%) of participants with adverse events leading to study withdrawal		11 (0.3)	8 (0.2)
Infections and infestations	Adverse events in any PT	1 (<0.1)	0
	COVID-19	1 (<0.1)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adverse events in any PT	0	1 (<0.1)
	Hepatic cancer	0	1 (<0.1)
	Pancreatic carcinoma stage IV	0	1 (<0.1)
Nervous system disorders	Adverse events in any PT	0	1 (<0.1)
	Amyotrophic lateral sclerosis	0	1 (<0.1)
Cardiac disorders	Adverse events in any PT	6 (0.2)	2 (<0.1)
	Cardio-respiratory arrest	2 (<0.1)	0
	Myocardial infarction	2 (<0.1)	2 (<0.1)
	Cardiac arrest	1 (<0.1)	0
	Cardiac failure congestive	1 (<0.1)	0
Respiratory, thoracic, and mediastinal disorders	Adverse events in any PT	3 (<0.1)	0
	Acute respiratory failure	1 (<0.1)	0
	Dyspnoea	1 (<0.1)	0
	Pulmonary mass	1 (<0.1)	0
Gastrointestinal disorders	Adverse events in any PT	2 (<0.1)	2 (<0.1)
	Gastrointestinal haemorrhage	1 (<0.1)	0
	Pancreatitis acute	1 (<0.1)	0
	Duodenal ulcer haemorrhage	0	1 (<0.1)
	Gastric perforation	0	1 (<0.1)
General disorders and administration site conditions	Adverse events in any PT	1 (<0.1)	2 (<0.1)
	Multiple organ dysfunction syndrome	1 (<0.1)	0
	Incarcerated hernia	0	1 (<0.1)
	Systemic inflammatory response syndrome	0	1 (<0.1)

Abbreviations: COVID-19=coronavirus disease 2019; IP=investigational product; MedDRA=Medical Dictionary for Regulatory Activities; PT=preferred term.

Note: The Safety Set consists of all randomized participants who received at least 1 dose of IP. Percentages are based on the number of safety participants.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.16.2.3.

5.4 Deaths

Table 62: (Table CC) Deaths (Safety Set)

5.5 Pregnancies

Table 63: (Table CC) Pregnancies in Part A, Based on Original Randomization (Safety Set)

Table 64: (Table CC) Pregnancies in Cross-Over Participants (Participants who were Originally Randomized to Placebo and Crossed Over to mRNA-1273 After Unblinding)

5.6 SMQ Analysis

5.6.1 Embolic and Thrombotic Events

Table 65: Participant Incidence of Embolic and Thrombotic Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting embolic and thrombotic events	47 (0.3)	43 (0.3)
Number of embolic and thrombotic events	54	45
Acute myocardial infarction	4 (<0.1)	6 (<0.1)
Arterial occlusive disease	1 (<0.1)	0
Axillary vein thrombosis	1 (<0.1)	0
Blindness transient	1 (<0.1)	0
Carotid artery thrombosis	1 (<0.1)	0
Cerebrovascular accident	7 (<0.1)	4 (<0.1)
Coronary artery occlusion	2 (<0.1)	0
Deep vein thrombosis	8 (<0.1)	6 (<0.1)
Deep vein thrombosis postoperative	1 (<0.1)	0
Embolic stroke	2 (<0.1)	0
Embolism venous	1 (<0.1)	0
Hemiparesis	1 (<0.1)	0
Ischaemic stroke	0	1 (<0.1)
Myocardial infarction	7 (<0.1)	9 (<0.1)
Peripheral arterial occlusive disease	1 (<0.1)	0
Peripheral artery occlusion	1 (<0.1)	1 (<0.1)
Pulmonary embolism	6 (<0.1)	7 (<0.1)
Pulmonary infarction	0	1 (<0.1)
Retinal infarction	0	1 (<0.1)
Stress cardiomyopathy	1 (<0.1)	0
Thrombophlebitis	1 (<0.1)	0
Thrombophlebitis superficial	2 (<0.1)	4 (<0.1)
Transient ischaemic attack	3 (<0.1)	4 (<0.1)
Venous thrombosis limb	1 (<0.1)	0
Vertebral artery occlusion	0	1 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Embolic and thrombotic events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.12.4.

Table 66: Participant Incidence of Embolic and Thrombotic Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting embolic and thrombotic events	47 (0.3)	43 (0.3)
Number of embolic and thrombotic events	54	45
Acute myocardial infarction	4 (<0.1)	6 (<0.1)
Arterial occlusive disease	1 (<0.1)	0
Axillary vein thrombosis	1 (<0.1)	0
Blindness transient	1 (<0.1)	0
Carotid artery thrombosis	1 (<0.1)	0
Cerebrovascular accident	7 (<0.1)	4 (<0.1)
Coronary artery occlusion	2 (<0.1)	0
Deep vein thrombosis	8 (<0.1)	6 (<0.1)
Deep vein thrombosis postoperative	1 (<0.1)	0
Embolic stroke	2 (<0.1)	0
Embolism venous	1 (<0.1)	0
Hemiparesis	1 (<0.1)	0
Ischaemic stroke	0	1 (<0.1)
Myocardial infarction	7 (<0.1)	9 (<0.1)
Peripheral arterial occlusive disease	1 (<0.1)	0
Peripheral artery occlusion	1 (<0.1)	1 (<0.1)
Pulmonary embolism	6 (<0.1)	7 (<0.1)
Pulmonary infarction	0	1 (<0.1)
Retinal infarction	0	1 (<0.1)
Stress cardiomyopathy	1 (<0.1)	0
Thrombophlebitis	1 (<0.1)	0
Thrombophlebitis superficial	2 (<0.1)	4 (<0.1)
Transient ischaemic attack	3 (<0.1)	4 (<0.1)
Venous thrombosis limb	1 (<0.1)	0
Vertebral artery occlusion	0	1 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Embolic and thrombotic events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.12.

5.6.2 Hearing and Vestibular Disorder Events

Table 67: Participant Incidence of Hearing and Vestibular Disorder Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting hearing and vestibular disorder events	192 (1.3)	171 (1.1)
Number of hearing and vestibular disorder events	203	186
Balance disorder	1 (<0.1)	2 (<0.1)
Deafness neurosensory	2 (<0.1)	0
Deafness unilateral	3 (<0.1)	2 (<0.1)
Diplacusis	0	1 (<0.1)
Dizziness	97 (0.6)	88 (0.6)
Eustachian tube dysfunction	2 (<0.1)	4 (<0.1)
Facial paralysis	8 (<0.1)	3 (<0.1)
Hyperacusis	0	1 (<0.1)
Hypoacusis	1 (<0.1)	1 (<0.1)
Labyrinthitis	1 (<0.1)	1 (<0.1)
Meniere's disease	6 (<0.1)	2 (<0.1)
Middle ear effusion	1 (<0.1)	3 (<0.1)
Motion sickness	2 (<0.1)	0
Tinnitus	20 (0.1)	22 (0.1)
Tympanic membrane disorder	0	1 (<0.1)
Tympanic membrane perforation	2 (<0.1)	9 (<0.1)
Vertigo	46 (0.3)	34 (0.2)
Vertigo positional	8 (<0.1)	4 (<0.1)
Vestibular migraine	1 (<0.1)	0
Vestibular neuronitis	0	1 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Hearing and vestibular disorder events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.13.4.

Table 68: Participant Incidence of Hearing and Vestibular Disorder Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting hearing and vestibular disorder events	88 (0.6)	81 (0.5)
Number of hearing and vestibular disorder events	92	88
Deafness neurosensory	2 (<0.1)	0
Deafness unilateral	3 (<0.1)	2 (<0.1)
Diplacusis	0	1 (<0.1)
Eustachian tube dysfunction	2 (<0.1)	4 (<0.1)
Hyperacusis	0	1 (<0.1)
Hypoacusis	1 (<0.1)	1 (<0.1)
Meniere's disease	6 (<0.1)	2 (<0.1)
Middle ear effusion	1 (<0.1)	3 (<0.1)
Tinnitus	20 (0.1)	22 (0.1)
Tympanic membrane disorder	0	1 (<0.1)
Tympanic membrane perforation	2 (<0.1)	9 (<0.1)
Vertigo	46 (0.3)	34 (0.2)
Vertigo positional	8 (<0.1)	4 (<0.1)
Vestibular migraine	1 (<0.1)	0
Vestibular neuronitis	0	1 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Hearing and vestibular disorder events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.13.

5.6.3 Angioedema Events

Table 69: Participant Incidence of Angioedema Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting angioedema events	142 (0.9)	133 (0.9)
Number of angioedema events	155	145
Angioedema	3 (<0.1)	3 (<0.1)
Breast swelling	1 (<0.1)	0
Choking sensation	1 (<0.1)	0
Drug hypersensitivity	12 (<0.1)	8 (<0.1)
Eye swelling	2 (<0.1)	5 (<0.1)
Generalised oedema	1 (<0.1)	0
Hypersensitivity	9 (<0.1)	9 (<0.1)
Idiopathic urticaria	0	1 (<0.1)
Laryngeal oedema	1 (<0.1)	1 (<0.1)
Lip oedema	1 (<0.1)	0
Lip swelling	6 (<0.1)	2 (<0.1)
Oedema	0	1 (<0.1)
Oedema peripheral	14 (<0.1)	17 (0.1)
Orbital oedema	0	1 (<0.1)
Palatal oedema	0	1 (<0.1)
Periorbital oedema	1 (<0.1)	1 (<0.1)
Periorbital swelling	0	3 (<0.1)
Peripheral swelling	19 (0.1)	14 (<0.1)
Pharyngeal swelling	1 (<0.1)	0
Swelling	1 (<0.1)	2 (<0.1)
Swelling face	6 (<0.1)	4 (<0.1)
Swelling of eyelid	4 (<0.1)	1 (<0.1)
Swollen tongue	2 (<0.1)	1 (<0.1)
Throat tightness	0	2 (<0.1)
Urticaria	55 (0.4)	46 (0.3)
Urticaria papular	3 (<0.1)	5 (<0.1)
Wheezing	5 (<0.1)	11 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Angioedema events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.4.4.

Table 70: Participant Incidence of Angioedema Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting angioedema events	82 (0.5)	71 (0.5)
Number of angioedema events	91	79
Angioedema	3 (<0.1)	3 (<0.1)
Eye swelling	2 (<0.1)	5 (<0.1)
Idiopathic urticaria	0	1 (<0.1)
Laryngeal oedema	1 (<0.1)	1 (<0.1)
Lip oedema	1 (<0.1)	0
Lip swelling	6 (<0.1)	2 (<0.1)
Palatal oedema	0	1 (<0.1)
Periorbital oedema	1 (<0.1)	1 (<0.1)
Periorbital swelling	0	3 (<0.1)
Pharyngeal swelling	1 (<0.1)	0
Swelling face	6 (<0.1)	4 (<0.1)
Swelling of eyelid	4 (<0.1)	1 (<0.1)
Swollen tongue	2 (<0.1)	1 (<0.1)
Urticaria	55 (0.4)	46 (0.3)
Urticaria papular	3 (<0.1)	5 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Angioedema events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.4.

5.6.4 Arthritis Events

Table 71: Participant Incidence of Arthritis Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting arthritis events	648 (4.3)	635 (4.2)
Number of arthritis events	724	706
Arthralgia	443 (2.9)	436 (2.9)
Arthritis	14 (<0.1)	12 (<0.1)
Chondrocalcinosis pyrophosphate	1 (<0.1)	0
Facet joint syndrome	2 (<0.1)	0
Gout	13 (<0.1)	17 (0.1)
Injection site joint pain	5 (<0.1)	2 (<0.1)
Joint abscess	1 (<0.1)	0
Joint effusion	0	1 (<0.1)
Joint noise	1 (<0.1)	1 (<0.1)
Joint range of motion decreased	5 (<0.1)	1 (<0.1)
Joint stiffness	2 (<0.1)	3 (<0.1)
Joint swelling	10 (<0.1)	11 (<0.1)
Musculoskeletal stiffness	15 (<0.1)	16 (0.1)
Neck pain	62 (0.4)	54 (0.4)
Osteoarthritis	61 (0.4)	75 (0.5)
Palindromic rheumatism	1 (<0.1)	0
Periarthritis	7 (<0.1)	4 (<0.1)
Polyarthritis	2 (<0.1)	2 (<0.1)
Psoriatic arthropathy	0	1 (<0.1)
Rheumatic disorder	0	1 (<0.1)
Rheumatoid arthritis	2 (<0.1)	3 (<0.1)
Sacroiliitis	1 (<0.1)	0
Spinal osteoarthritis	9 (<0.1)	9 (<0.1)
Spinal pain	5 (<0.1)	5 (<0.1)
Spondylitis	2 (<0.1)	0
Synovitis	0	2 (<0.1)
Temporomandibular joint syndrome	5 (<0.1)	2 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Arthritis events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.3.4.

Table 72: Participant Incidence of Arthritis Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting arthritis events	118 (0.8)	125 (0.8)
Number of arthritis events	124	132
Arthritis	14 (<0.1)	12 (<0.1)
Chondrocalcinosis pyrophosphate	1 (<0.1)	0
Facet joint syndrome	2 (<0.1)	0
Gout	13 (<0.1)	17 (0.1)
Osteoarthritis	61 (0.4)	75 (0.5)
Palindromic rheumatism	1 (<0.1)	0
Periarthritis	7 (<0.1)	4 (<0.1)
Polyarthritis	2 (<0.1)	2 (<0.1)
Rheumatic disorder	0	1 (<0.1)
Rheumatoid arthritis	2 (<0.1)	3 (<0.1)
Sacroiliitis	1 (<0.1)	0
Spinal osteoarthritis	9 (<0.1)	9 (<0.1)
Spondylitis	2 (<0.1)	0
Synovitis	0	2 (<0.1)
Temporomandibular joint syndrome	5 (<0.1)	2 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Arthritis events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.3.

5.6.5 Convulsion Events

Table 73: Participant Incidence of Convulsion Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting convulsion events	6 (<0.1)	6 (<0.1)
Number of convulsion events	7	6
Aura	1 (<0.1)	0
Seizure	5 (<0.1)	6 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Convulsion events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.7.4.

Table 74: Participant Incidence of Convulsion Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting convulsion events	5 (<0.1)	6 (<0.1)
Number of convulsion events	6	6
Seizure	5 (<0.1)	6 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Convulsion events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.7.

5.6.6 Central Nervous System Vascular Disorder Events

Table 75: Participant Incidence of Central Nervous System Vascular Disorder Events, Narrow and Broad (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting CNS vascular disorder events	22 (0.1)	12 (<0.1)
Number of CNS vascular disorder events	25	13
Aphasia	1 (<0.1)	1 (<0.1)
Basal ganglia haemorrhage	0	1 (<0.1)
Carotid artery stenosis	2 (<0.1)	0
Carotid artery thrombosis	1 (<0.1)	0
Cerebral small vessel ischaemic disease	1 (<0.1)	0
Cerebrovascular accident	7 (<0.1)	4 (<0.1)
Embolic stroke	2 (<0.1)	0
Hemiparesis	1 (<0.1)	0
Ischaemic stroke	0	1 (<0.1)
Right hemisphere deficit syndrome	0	1 (<0.1)
Subarachnoid haemorrhage	4 (<0.1)	0
Subdural haematoma	3 (<0.1)	0
Transient ischaemic attack	3 (<0.1)	4 (<0.1)
Vertebral artery occlusion	0	1 (<0.1)

Abbreviations: CNS=central nervous system; MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. CNS vascular disorder events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.10.4.

Table 76: Participant Incidence of Central Nervous System Vascular Disorder Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting CNS vascular disorder events	21 (0.1)	11 (<0.1)
Number of CNS vascular disorder events	24	11
Basal ganglia haemorrhage	0	1 (<0.1)
Carotid artery stenosis	2 (<0.1)	0
Carotid artery thrombosis	1 (<0.1)	0
Cerebral small vessel ischaemic disease	1 (<0.1)	0
Cerebrovascular accident	7 (<0.1)	4 (<0.1)
Embolic stroke	2 (<0.1)	0
Hemiparesis	1 (<0.1)	0
Ischaemic stroke	0	1 (<0.1)
Subarachnoid haemorrhage	4 (<0.1)	0
Subdural haematoma	3 (<0.1)	0
Transient ischaemic attack	3 (<0.1)	4 (<0.1)
Vertebral artery occlusion	0	1 (<0.1)

Abbreviations: CNS=central nervous system; MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. CNS vascular disorder events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.10.

5.6.7 Hypersensitivity Events

Table 77: Participant Incidence of Hypersensitivity Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting hypersensitivity events	533 (3.5)	505 (3.3)
Number of hypersensitivity events	611	563
Acute respiratory failure	7 (<0.1)	14 (<0.1)
Allergic cough	2 (<0.1)	0
Allergic sinusitis	2 (<0.1)	2 (<0.1)
Allergy to chemicals	1 (<0.1)	1 (<0.1)
Anaphylactic reaction	2 (<0.1)	2 (<0.1)
Angioedema	3 (<0.1)	3 (<0.1)
Asthma	32 (0.2)	39 (0.3)
Blister	3 (<0.1)	3 (<0.1)
Bronchial hyperreactivity	0	1 (<0.1)
Bronchospasm	3 (<0.1)	1 (<0.1)
Bullous impetigo	0	1 (<0.1)
Choking sensation	1 (<0.1)	0
Conjunctivitis	20 (0.1)	24 (0.2)
Conjunctivitis allergic	2 (<0.1)	2 (<0.1)
Cytokine storm	0	1 (<0.1)
Dermatitis	10 (<0.1)	14 (<0.1)
Dermatitis allergic	3 (<0.1)	5 (<0.1)
Dermatitis atopic	6 (<0.1)	9 (<0.1)
Dermatitis bullous	0	2 (<0.1)
Dermatitis contact	34 (0.2)	41 (0.3)
Drug hypersensitivity	12 (<0.1)	8 (<0.1)
Eczema	18 (0.1)	11 (<0.1)
Eczema nummular	3 (<0.1)	1 (<0.1)
Eosinophilia	1 (<0.1)	0
Eosinophilic oesophagitis	0	1 (<0.1)
Erythema	17 (0.1)	8 (<0.1)
Exfoliative rash	1 (<0.1)	0
Eye swelling	2 (<0.1)	5 (<0.1)
Flushing	7 (<0.1)	5 (<0.1)
Generalised oedema	1 (<0.1)	0
Hand dermatitis	2 (<0.1)	1 (<0.1)
Hypersensitivity	9 (<0.1)	9 (<0.1)
Idiopathic urticaria	0	1 (<0.1)
Incision site rash	1 (<0.1)	0
Injection related reaction	1 (<0.1)	1 (<0.1)
Injection site rash	25 (0.2)	1 (<0.1)
Injection site urticaria	38 (0.3)	1 (<0.1)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Laryngeal oedema	1 (<0.1)	1 (<0.1)
Lip oedema	1 (<0.1)	0
Lip swelling	6 (<0.1)	2 (<0.1)
Mechanical urticaria	1 (<0.1)	0
Mouth ulceration	2 (<0.1)	4 (<0.1)
Neurodermatitis	3 (<0.1)	0
Noninfective conjunctivitis	1 (<0.1)	0
Orbital oedema	0	1 (<0.1)
Oropharyngeal blistering	1 (<0.1)	0
Palatal oedema	0	1 (<0.1)
Perineal rash	1 (<0.1)	0
Perioral dermatitis	1 (<0.1)	3 (<0.1)
Periorbital oedema	1 (<0.1)	1 (<0.1)
Periorbital swelling	0	3 (<0.1)
Pharyngeal swelling	1 (<0.1)	0
Photosensitivity reaction	0	1 (<0.1)
Pneumonitis	0	1 (<0.1)
Pruritus	28 (0.2)	29 (0.2)
Rash	44 (0.3)	47 (0.3)
Rash erythematous	3 (<0.1)	4 (<0.1)
Rash follicular	0	1 (<0.1)
Rash macular	8 (<0.1)	6 (<0.1)
Rash maculo-papular	9 (<0.1)	4 (<0.1)
Rash pruritic	6 (<0.1)	11 (<0.1)
Rash pustular	1 (<0.1)	0
Rash vesicular	2 (<0.1)	1 (<0.1)
Respiratory distress	1 (<0.1)	0
Respiratory failure	2 (<0.1)	1 (<0.1)
Rhinitis allergic	21 (0.1)	26 (0.2)
Seasonal allergy	59 (0.4)	72 (0.5)
Serum sickness	0	1 (<0.1)
Skin exfoliation	1 (<0.1)	1 (<0.1)
Sneezing	22 (0.1)	22 (0.1)
Stomatitis	3 (<0.1)	5 (<0.1)
Swelling face	6 (<0.1)	4 (<0.1)
Swelling of eyelid	4 (<0.1)	1 (<0.1)
Swollen tongue	2 (<0.1)	1 (<0.1)
Throat tightness	0	2 (<0.1)
Type IV hypersensitivity reaction	1 (<0.1)	0
Urticaria	55 (0.4)	46 (0.3)
Urticaria papular	3 (<0.1)	5 (<0.1)
Vaccination site rash	2 (<0.1)	0
Wheezing	5 (<0.1)	11 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.
Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Hypersensitivity events are identified through selected narrow and broad SMQ.
Source: Table 14.3.1.22.2.4.

Table 78: Participant Incidence of Hypersensitivity Events, Narrow Scope, (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting hypersensitivity events	336 (2.2)	278 (1.8)
Number of hypersensitivity events	382	301
Allergic cough	2 (<0.1)	0
Allergic sinusitis	2 (<0.1)	2 (<0.1)
Anaphylactic reaction	2 (<0.1)	2 (<0.1)
Angioedema	3 (<0.1)	3 (<0.1)
Bronchospasm	3 (<0.1)	1 (<0.1)
Conjunctivitis allergic	2 (<0.1)	2 (<0.1)
Dermatitis	10 (<0.1)	14 (<0.1)
Dermatitis allergic	3 (<0.1)	5 (<0.1)
Dermatitis atopic	6 (<0.1)	9 (<0.1)
Dermatitis bullous	0	2 (<0.1)
Dermatitis contact	34 (0.2)	41 (0.3)
Drug hypersensitivity	12 (<0.1)	8 (<0.1)
Eczema	18 (0.1)	11 (<0.1)
Eczema nummular	3 (<0.1)	1 (<0.1)
Exfoliative rash	1 (<0.1)	0
Eye swelling	2 (<0.1)	5 (<0.1)
Hand dermatitis	2 (<0.1)	1 (<0.1)
Hypersensitivity	9 (<0.1)	9 (<0.1)
Idiopathic urticaria	0	1 (<0.1)
Incision site rash	1 (<0.1)	0
Injection related reaction	1 (<0.1)	1 (<0.1)
Injection site rash	25 (0.2)	1 (<0.1)
Injection site urticaria	38 (0.3)	1 (<0.1)
Laryngeal oedema	1 (<0.1)	1 (<0.1)
Lip oedema	1 (<0.1)	0
Lip swelling	6 (<0.1)	2 (<0.1)
Oropharyngeal blistering	1 (<0.1)	0
Palatal oedema	0	1 (<0.1)
Perioral dermatitis	1 (<0.1)	3 (<0.1)
Periorbital oedema	1 (<0.1)	1 (<0.1)
Periorbital swelling	0	3 (<0.1)
Pharyngeal swelling	1 (<0.1)	0
Rash	44 (0.3)	47 (0.3)
Rash erythematous	3 (<0.1)	4 (<0.1)
Rash follicular	0	1 (<0.1)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Rash macular	8 (<0.1)	6 (<0.1)
Rash maculo-papular	9 (<0.1)	4 (<0.1)
Rash pruritic	6 (<0.1)	11 (<0.1)
Rash pustular	1 (<0.1)	0
Rash vesicular	2 (<0.1)	1 (<0.1)
Rhinitis allergic	21 (0.1)	26 (0.2)
Serum sickness	0	1 (<0.1)
Swelling face	6 (<0.1)	4 (<0.1)
Swelling of eyelid	4 (<0.1)	1 (<0.1)
Swollen tongue	2 (<0.1)	1 (<0.1)
Type IV hypersensitivity reaction	1 (<0.1)	0
Urticaria	55 (0.4)	46 (0.3)
Urticaria papular	3 (<0.1)	5 (<0.1)
Vaccination site rash	2 (<0.1)	0

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Hypersensitivity events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.2.

5.6.8 Peripheral Neuropathy Events

Table 79: Participant Incidence of Peripheral Neuropathy Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting peripheral neuropathy events	82 (0.5)	68 (0.4)
Number of peripheral neuropathy events	98	85
Burning sensation	6 (<0.1)	1 (<0.1)
Dysaesthesia	0	3 (<0.1)
Gait disturbance	0	2 (<0.1)
Hypoaesthesia	17 (0.1)	14 (<0.1)
Muscular weakness	9 (<0.1)	8 (<0.1)
Nerve conduction studies abnormal	1 (<0.1)	0
Neuralgia	3 (<0.1)	5 (<0.1)
Neuropathy peripheral	3 (<0.1)	5 (<0.1)
Paraesthesia	43 (0.3)	31 (0.2)
Peripheral sensory neuropathy	4 (<0.1)	3 (<0.1)
Peroneal nerve palsy	0	2 (<0.1)
Skin burning sensation	3 (<0.1)	1 (<0.1)
Small fibre neuropathy	1 (<0.1)	0

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Peripheral neuropathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.5.4.

Table 80: Participant Incidence of Peripheral Neuropathy Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting peripheral neuropathy events	12 (<0.1)	13 (<0.1)
Number of peripheral neuropathy events	12	14
Nerve conduction studies abnormal	1 (<0.1)	0
Neuralgia	3 (<0.1)	5 (<0.1)
Neuropathy peripheral	3 (<0.1)	5 (<0.1)
Peripheral sensory neuropathy	4 (<0.1)	3 (<0.1)
Small fibre neuropathy	1 (<0.1)	0

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Peripheral neuropathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.5.

5.6.9 Demyelination Events

Table 81: Participant Incidence of Demyelination Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting demyelination events	4 (<0.1)	4 (<0.1)
Number of demyelination events	5	4
Hypergammaglobulinaemia benign monoclonal	1 (<0.1)	0
Multiple sclerosis	1 (<0.1)	1 (<0.1)
Optic neuritis	2 (<0.1)	0
Trigeminal neuralgia	1 (<0.1)	3 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Demyelination events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.6.4.

Table 82: Participant Incidence of Demyelination Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting demyelination events	3 (<0.1)	1 (<0.1)
Number of demyelination events	4	1
Hypergammaglobulinaemia benign monoclonal	1 (<0.1)	0
Multiple sclerosis	1 (<0.1)	1 (<0.1)
Optic neuritis	2 (<0.1)	0

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Demyelination events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.6.

5.6.10 Thrombophlebitis Events

Table 83: Participant Incidence of Thrombophlebitis Events, Narrow and Broad Scope (Safety Set))

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting thrombophlebitis events	13 (<0.1)	12 (<0.1)
Number of thrombophlebitis events	13	12
Deep vein thrombosis	8 (<0.1)	6 (<0.1)
Deep vein thrombosis postoperative	1 (<0.1)	0
Phlebitis	1 (<0.1)	2 (<0.1)
Thrombophlebitis	1 (<0.1)	0
Thrombophlebitis superficial	2 (<0.1)	4 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Thrombophlebitis events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.14.4.

Table 84: Participant Incidence of Thrombophlebitis Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting thrombophlebitis events	3 (<0.1)	4 (<0.1)
Number of thrombophlebitis events	3	4
Thrombophlebitis	1 (<0.1)	0
Thrombophlebitis superficial	2 (<0.1)	4 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Thrombophlebitis events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.14.

5.6.11 Vasculitis Events

Table 85: Participant Incidence of Vasculitis Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting vasculitis events	1 (<0.1)	1 (<0.1)
Number of vasculitis events	1	1
Polyarteritis nodosa	1 (<0.1)	0
Polymyalgia rheumatica	0	1 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Vasculitis events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.1.4.

Table 86: Participant Incidence of Vasculitis Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting vasculitis events	1 (<0.1)	1 (<0.1)
Number of vasculitis events	1	1
Polyarteritis nodosa	1 (<0.1)	0
Polymyalgia rheumatica	0	1 (<0.1)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Vasculitis events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.1.

5.6.12 Hematopoietic Cytopenia Events

Table 87: Participant Incidence of Hematopoietic Cytopenia Events, Narrow and Broad Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting hematopoietic cytopenia events	32 (0.2)	20 (0.1)
Number of hematopoietic cytopenia events	33	20
Anaemia	21 (0.1)	17 (0.1)
Anaemia macrocytic	0	1 (<0.1)
Haemoglobin decreased	1 (<0.1)	0
Leukopenia	2 (<0.1)	0
Lymphocyte count decreased	1 (<0.1)	0
Normocytic anaemia	2 (<0.1)	1 (<0.1)
Thrombocytopenia	5 (<0.1)	1 (<0.1)
White blood cell count decreased	1 (<0.1)	0

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Hematopoietic cytopenia events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.15.4.

Table 88: Participant Incidence of Hematopoietic Cytopenia Events, Narrow Scope (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting hematopoietic cytopenia events	9 (<0.1)	2 (<0.1)
Number of hematopoietic cytopenia events	9	2
Anaemia macrocytic	0	1 (<0.1)
Leukopenia	2 (<0.1)	0
Lymphocyte count decreased	1 (<0.1)	0
Thrombocytopenia	5 (<0.1)	1 (<0.1)
White blood cell count decreased	1 (<0.1)	0

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Hematopoietic cytopenia events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.15.

5.6.13 Cardiomyopathy Events

5.6.13.1 Overall and by Age Group

5.6.13.1.1 Overall

Table 89: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Participants Overall (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting cardiomyopathy events	207 (1.4%)	208 (1.4%)
Number of cardiomyopathy events	238	254
Acute left ventricular failure	2 (<0.1%)	2 (<0.1%)
Arrhythmia	5 (<0.1%)	8 (0.1%)
Ascites	0 (0.00%)	2 (<0.1%)
Atrial enlargement	1 (<0.1%)	1 (<0.1%)
Blood pressure diastolic decreased	0 (0.00%)	2 (<0.1%)
Blood pressure diastolic increased	13 (0.1%)	10 (0.1%)
Blood pressure systolic abnormal	1(<0.1%)	1 (<0.1%)
Blood pressure systolic decreased	1 (<0.1%)	0 (0.00%)
Blood pressure systolic increase	21 (0.1%)	21 (0.1%)
Cardiac arrest	1 (<0.1%)	0 (0.00%)
Cardiac failure	4 (<0.1%)	4 (<0.1%)
Cardiac failure acute	1 (<0.1%)	1 (<0.1%)
Cardiac failure congestive	6 (<0.1%)	9 (0.1%)
Cardiomegaly	0 (0.00%)	2 (<0.1%)
Cardiomyopathy	2 (<0.1%)	1 (<0.1%)
Chest pain	15 (0.1%)	11 (0.1%)
Diastolic dysfunction	0 (0.00%)	1 (<0.1%)
Dyspnoea	92 (0.6%)	86 (0.6%)
Left atrial enlargement	0 (0.00%)	1 (<0.1%)
Lung opacity	0 (0.00%)	2 (<0.1%)
Mental status changes	1 (<0.1%)	4 (<0.1%)
Nocturia	4 (<0.1%)	1 (<0.1%)
Oedema	0 (0.00%)	1 (<0.1%)
Orthostatic hypotension	6 (<0.1%)	1 (<0.1%)
Palpitations	22 (0.1%)	13 (0.1%)
Stress cardiomyopathy	1 (<0.1%)	0 (0.00%)
Syncope	25 (0.2%)	40 (0.3%)
Ventricular arrhythmia	0 (0.00%)	1 (<0.1%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4.

Table 90: Participant Incidence of Cardiomyopathy Events, Narrow Scope, All Participants Overall (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting cardiomyopathy events	3 (<0.1%)	1 (<0.1%)
Number of cardiomyopathy events	3	1
Cardiomyopathy	2 (<0.1%)	1 (<0.1%)
Stress cardiomyopathy	1 (<0.1%)	0 (0.0%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.16.

5.6.13.1.2 Overall Males

Table 91: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Participants Overall Males (Safety Set)

Preferred Term	mRNA-1273 (N=7918) n (%)	Placebo (N=8056) n (%)
Number of participants reporting cardiomyopathy events	107 (1.4%)	100 (1.2%)
Number of cardiomyopathy events	122	121
Acute left ventricular failure	2 (<0.1%)	1 (<0.1%)
Arrhythmia	5 (0.1%)	6 (0.1%)
Ascites	0 (0.0%)	2 (<0.1%)
Atrial enlargement	1 (<0.1%)	0 (<0.1%)
Blood pressure diastolic decreased	0 (0.0%)	1 (<0.1%)
Blood pressure diastolic increased	8 (0.1%)	4 (<0.1%)
Blood pressure systolic abnormal	0 (0.0%)	1 (<0.1%)
Blood pressure systolic increase	8 (0.1%)	10 (0.1%)
Cardiac arrest	1 (<0.1%)	0 (0.0%)
Cardiac failure	2 (<0.1%)	3 (<0.1%)
Cardiac failure acute	1 (<0.1%)	1 (<0.1%)
Cardiac failure congestive	2 (<0.1%)	5 (0.1%)
Cardiomegaly	0 (0.0%)	1 (<0.1%)
Cardiomyopathy	2 (<0.1%)	0 (0.0%)
Chest pain	10 (0.1%)	5 (0.1%)
Diastolic dysfunction	0 (0.0%)	1 (<0.1%)
Dyspnoea	41 (0.5%)	37 (0.5%)
Left atrial enlargement	0 (0.0%)	1 (<0.1%)
Lung opacity	0 (0.0%)	2 (<0.1%)
Mental status changes	1 (<0.1%)	4 (<0.1%)
Nocturia	4 (0.1%)	1 (<0.1%)
Orthostatic hypotension	3 (<0.1%)	1 (<0.1%)
Palpitations	14 (0.2%)	4 (<0.1%)
Syncope	15 (0.2%)	23 (0.3%)
Ventricular arrhythmia	0 (0.0%)	1 (<0.1%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

5.6.13.1.3 Overall Females

Table 92: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Participants Overall Females (Safety Set)

Preferred Term	mRNA-1273 (N=15184) n (%)	Placebo (N=15162) n (%)
Number of participants reporting cardiomyopathy events	100 (1.4%)	108 (1.5%)
Number of cardiomyopathy events	116	134
Acute left ventricular failure	0 (0.0%)	1 (<0.1%)
Arrhythmia	3 (<0.1%)	6 (0.1%)
Atrial enlargement	0 (0.0%)	0 (<0.1%)
Blood pressure diastolic decreased	0 (0.0%)	1 (<0.1%)
Blood pressure diastolic increased	5 (0.1%)	4 (0.1%)
Blood pressure systolic abnormal	1 (<0.1%)	1 (<0.1%)
Blood pressure systolic decreased	1 (<0.1%)	0 (0.00%)
Blood pressure systolic increase	13 (0.2%)	11 (0.2%)
Cardiac failure	2 (<0.1%)	1 (<0.1%)
Cardiac failure congestive	4 (0.1%)	4 (0.1%)
Cardiomegaly	0 (0.0%)	1 (<0.1%)
Cardiomyopathy	0 (0.0%)	1 (<0.1%)
Chest pain	5 (0.1%)	6 (0.1%)
Diastolic dysfunction	0 (0.0%)	1 (<0.1%)
Dyspnoea	51 (0.7%)	48 (0.7%)
Left atrial enlargement	0 (0.0%)	1 (<0.1%)
Lung opacity	0 (0.0%)	2 (<0.1%)
Mental status changes	0 (0.0%)	4 (0.1%)
Oedema	0 (0.0%)	1 (<0.1%)
Orthostatic hypotension	3 (<0.1%)	1 (<0.1%)
Palpitations	8 (0.1%)	9 (0.1%)
Stress cardiomyopathy	1 (<0.1%)	0 (0.0%)
Syncope	10 (0.1%)	17 (0.2%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

5.6.13.1.4 Ages 18 to 30 Years

Table 93: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Participants 18 to 30 Years (Safety Set)

Preferred Term	mRNA-1273 (N=1759) n (%)	Placebo (N=1755) n (%)
Number of participants reporting cardiomyopathy events	18 (1.0%)	24 (1.4%)
Number of cardiomyopathy events	21	26
Blood pressure diastolic decreased	0 (0.0%)	1 (0.1%)
Blood pressure diastolic increased	0 (0.0%)	2 (0.1%)
Chest pain	2 (0.1%)	3 (0.2%)
Dyspnoea	8 (0.5%)	8 (0.5%)
Orthostatic hypotension	1 (0.1%)	0 (0.0%)
Palpitations	2 (0.1%)	2 (0.1%)
Syncope	5 (0.3%)	8 (0.5%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

Table 94: Participant Incidence of Cardiomyopathy Events, Narrow Scope, Participants 18 to 30 Years (Safety Set)

Preferred Term	mRNA-1273 (N=1759) n (%)	Placebo (N=1755) n (%)
Number of participants reporting cardiomyopathy events	0 (0 %)	0 (0 %)
Number of cardiomyopathy events	0	0

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.16 (please also refer to the data packages included in Module 5).

5.6.13.1.5 Ages > 30 to < 60 Years

Table 95: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Participants > 30 to < 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=8069) n (%)	Placebo (N=15162) n (%)
Number of participants reporting cardiomyopathy events	104 (1.3%)	96 (1.2%)
Number of cardiomyopathy events	121	120
Acute left ventricular failure	1 (<0.1%)	0 (0.0%)
Arrhythmia	1 (<0.1%)	4 (<0.1%)
Ascites	0 (0.0%)	2 (<0.1%)
Blood pressure diastolic increased	10 (0.1%)	6 (0.1%)
Blood pressure systolic abnormal	0 (0.0%)	1 (<0.1%)
Blood pressure systolic increase	9 (0.1%)	8 (0.1%)
Cardiac failure	1 (<0.1%)	0 (0.0%)
Cardiac failure acute	1 (<0.1%)	0 (0.0%)
Cardiac failure congestive	0 (0.0%)	3 (<0.1%)
Cardiomegaly	0 (0.0%)	1 (<0.1%)
Cardiomyopathy	1 (<0.1%)	1 (<0.1%)
Chest pain	8 (0.1%)	5 (0.1%)
Diastolic dysfunction	0 (0.0%)	1 (<0.1%)
Dyspnoea	57 (0.7%)	46 (0.6%)
Lung opacity	0 (0.0%)	2 (<0.1%)
Mental status changes	0 (0.0%)	2 (<0.1%)
Nocturia	1 (<0.1%)	0 (0.0%)
Orthostatic hypotension	1 (<0.1%)	0 (0.0%)
Palpitations	12 (0.1%)	9 (0.1%)
Syncope	9 (0.1%)	13 (0.2%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

Table 96: Participant Incidence of Cardiomyopathy Events, Narrow Scope, Participants > 30 to < 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=8069) n (%)	Placebo (N=8065) n (%)
Number of participants reporting cardiomyopathy events	1 (<0.1%)	1 (<0.1%)
Number of cardiomyopathy events	1	1
Cardiomyopathy	1 (<0.1%)	1 (<0.1%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.16 (please also refer to the data packages included in Module 5).

5.6.13.1.6 Ages ≥ 60 Years

Table 97: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Participants ≥ 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=5356) n (%)	Placebo (N=5342) n (%)
Number of participants reporting cardiomyopathy events	85 (1.6%)	88 (1.6%)
Number of cardiomyopathy events	96	109
Acute left ventricular failure	1 (<0.1%)	2 (<0.1%)
Arrhythmia	4 (0.1%)	4 (0.1%)
Atrial enlargement	1 (<0.1%)	1 (<0.1%)
Blood pressure diastolic decreased	0 (0.0%)	1 (<0.1%)
Blood pressure diastolic increased	3 (0.1%)	2 (<0.1%)
Blood pressure systolic abnormal	1 (<0.1%)	0 (0.0%)
Blood pressure systolic decreased	1 (<0.1%)	0 (0.0%)
Blood pressure systolic increase	12 (0.2%)	13 (0.2%)
Cardiac arrest	1 (<0.1%)	0 (0.0%)
Cardiac failure	3 (0.1%)	4 (0.1%)
Cardiac failure acute	0 (0.0%)	1 (<0.1%)
Cardiac failure congestive	6 (0.1%)	6 (0.1%)
Cardiomegaly	0 (0.0%)	1 (<0.1%)
Cardiomyopathy	1 (<0.1%)	0 (0.0%)
Chest pain	5 (0.1%)	3 (0.1%)
Dyspnoea	26 (0.5%)	32 (0.6%)
Left atrial enlargement	0 (0.0%)	1 (<0.1%)
Mental status changes	1 (<0.1%)	2 (<0.1%)
Nocturia	3 (0.1%)	1 (<0.1%)
Oedema	0 (0.0%)	1 (<0.1%)
Orthostatic hypotension	4 (0.1%)	1 (<0.1%)
Palpitations	7 (0.1%)	2 (<0.1%)
Stress cardiomyopathy	1 (<0.1%)	0 (0.0%)
Syncope	11 (0.2%)	19 (0.4%)
Ventricular arrhythmia	0 (0.0%)	1 (<0.1%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

Table 98: Participant Incidence of Cardiomyopathy Events, Narrow Scope, Participants ≥ 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=5356) n (%)	Placebo (N=5342) n (%)
Number of participants reporting cardiomyopathy events	2 (<0.1%)	0 (0%)
Number of cardiomyopathy events	2	0
Cardiomyopathy	1 (<0.1%)	0 (0%)
Stress cardiomyopathy	1 (<0.1%)	0 (0%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.16 (please also refer to the data packages included in Module 5).

5.6.13.2 By Gender and Age Group

5.6.13.2.1 Male Participants

5.6.13.2.1.1 Males Ages 18 to 30 Years

Table 99: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Male Participants 18 to 30 Years (Safety Set)

Preferred Term	mRNA-1273 (N=875) n (%)	Placebo (N=911) n (%)
Number of participants reporting cardiomyopathy events	7 (0.8%)	10 (1.1%)
Number of cardiomyopathy events	7	12
Chest pain	2 (0.2%)	2 (0.2%)
Dyspnoea	2 (0.2%)	4 (0.4%)
Orthostatic hypotension	1 (0.1%)	0 (0.0%)
Palpitations	1 (0.1%)	0 (0.0%)
Syncope	1 (0.1%)	4 (0.4%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

Table 100: Participant Incidence of Cardiomyopathy Events, Narrow Scope, Male Participants 18 to 30 Years (Safety Set)

Preferred Term	mRNA-1273 (N=875) n (%)	Placebo (N=911) n (%)
Number of participants reporting cardiomyopathy events	0 (0 %)	0 (0 %)
Number of cardiomyopathy events	0	0

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.16 (please also refer to the data packages included in Module 5).

5.6.13.2.1.2 Males Ages > 30 to < 60 Years

Table 101: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Male Participants > 30 to < 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=3930) n (%)	Placebo (N=4206) n (%)
Number of participants reporting cardiomyopathy events	60 (1.5%)	47 (1.1%)
Number of cardiomyopathy events	68	57
Acute left ventricular failure	1 (<0.1%)	0 (0.0%)
Arrhythmia	0 (0.0%)	3 (0.1%)
Ascites	0 (0.0%)	2 (<0.1%)
Blood pressure diastolic increased	7 (0.2%)	2 (<0.1%)
Blood pressure systolic abnormal	0 (0.0%)	1 (<0.1%)
Blood pressure systolic increase	5 (0.1%)	4 (0.1%)
Cardiac failure	1 (<0.1%)	0 (0.0%)
Cardiac failure acute	1 (<0.1%)	0 (0.0%)
Cardiac failure congestive	0 (0.0%)	2 (<0.1%)
Cardiomegaly	0 (0.0%)	1 (<0.1%)
Cardiomyopathy	1 (<0.1%)	0 (0.0%)
Chest pain	7 (0.2%)	3 (0.1%)
Diastolic dysfunction	0 (0.0%)	1 (<0.1%)
Dyspnoea	26 (0.7%)	21 (0.5%)
Nocturia	1 (<0.1%)	0 (0.0%)
Orthostatic hypotension	1 (<0.1%)	0 (0.0%)
Palpitations	9 (0.2%)	3 (0.1%)
Syncope	6 (0.2%)	8 (0.2%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

Table 102: Participant Incidence of Cardiomyopathy Events, Narrow Scope, Male Participants > 30 to < 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=3930) n (%)	Placebo (N=4206) n (%)
Number of participants reporting cardiomyopathy events	1 (<0.1%)	0 (0 %)
Number of cardiomyopathy events	1	0
Cardiomyopathy	1 (<0.1%)	0 (0%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.16 (please also refer to the data packages included in Module 5).

5.6.13.2.1.3 Males Ages ≥ 60 Years

Table 103: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Male Participants ≥ 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=2904) n (%)	Placebo (N=2939) n (%)
Number of participants reporting cardiomyopathy events	40 (1.4%)	44 (1.5%)
Number of cardiomyopathy events	47	53
Acute left ventricular failure	1 (<0.1%)	1 (<0.1%)
Arrhythmia	2 (0.1%)	3 (0.1%)
Atrial enlargement	1 (<0.1%)	0 (0.0%)
Blood pressure diastolic decreased	0 (0.0%)	1 (<0.1%)
Blood pressure diastolic increased	1 (<0.1%)	2 (0.1%)
Blood pressure systolic increase	3 (0.1%)	6 (0.2%)
Cardiac arrest	1 (<0.1%)	0 (0.0%)
Cardiac failure	1 (<0.1%)	3 (0.1%)
Cardiac failure acute	0 (0.0%)	1 (<0.1%)
Cardiac failure congestive	2 (0.1%)	3 (0.1%)
Cardiomyopathy	1 (<0.1%)	0 (0.0%)
Chest pain	1 (<0.1%)	1 (<0.1%)
Dyspnoea	13 (0.4%)	12 (0.4%)
Mental status changes	1 (<0.1%)	0 (0.0%)
Nocturia	2 (0.1%)	1 (<0.1%)
Orthostatic hypotension	1 (<0.1%)	1 (<0.1%)
Palpitations	4 (0.1%)	1 (<0.1%)
Syncope	8 (0.3%)	11 (0.4%)
Ventricular arrhythmia	0 (0.0%)	1 (<0.1%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

Table 104: Participant Incidence of Cardiomyopathy Events, Narrow Scope, Male Participants ≥ 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=2904) n (%)	Placebo (N=2939) n (%)
Number of participants reporting cardiomyopathy events	1 (<0.1%)	0 (0 %)
Number of cardiomyopathy events	1	0
Cardiomyopathy	1 (<0.1%)	0 (0%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.16 (please also refer to the data packages included in Module 5).

5.6.13.2.2 Female Participants

5.6.13.2.2.1 Females Ages 18 to 30 Years

Table 105: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Female Participants 18 to 30 Years (Safety Set)

Preferred Term	mRNA-1273 (N=884) n (%)	Placebo (N=844) n (%)
Number of participants reporting cardiomyopathy events	10 (1.1%)	14 (1.7%)
Number of cardiomyopathy events	14	14
Blood pressure diastolic decreased	0 (0.0%)	1 (0.1%)
Blood pressure diastolic increased	0 (0.0%)	2 (0.2%)
Chest pain	0 (0.0%)	1 (0.1%)
Dyspnoea	7 (0.8%)	4 (0.5%)
Palpitations	1 (0.1%)	2 (0.2%)
Syncope	4 (0.5%)	4 (0.5%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

Table 106: Participant Incidence of Cardiomyopathy Events, Narrow Scope, Female Participants 18 to 30 Years (Safety Set)

Preferred Term	mRNA-1273 (N=884) n (%)	Placebo (N=844) n (%)
Number of participants reporting cardiomyopathy events	0 (0 %)	0 (0 %)
Number of cardiomyopathy events	0	0

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.16 (please also refer to the data packages included in Module 5).

5.6.13.2.2.2 Females Ages > 30 to < 60 Years

Table 107: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Female Participants > 30 to < 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=3930) n (%)	Placebo (N=3859) n (%)
Number of participants reporting cardiomyopathy events	44 (1.1%)	50 (1.3%)
Number of cardiomyopathy events	53	64
Arrhythmia	1 (<0.1%)	1 (<0.1%)
Blood pressure diastolic increased	3 (0.1%)	4 (0.1%)
Blood pressure systolic increase	4 (0.1%)	4 (0.1%)
Cardiac failure congestive	0 (0.0%)	1 (<0.1%)
Cardiomyopathy	0 (0.0%)	1 (<0.1%)
Chest pain	1 (<0.1%)	3 (0.1%)
Dyspnoea	31 (0.8%)	25 (0.6%)
Lung opacity	0 (0.0%)	1 (<0.1%)
Mental status changes	0 (0.0%)	1 (<0.1%)
Palpitations	4 (0.1%)	3 (0.1%)
Syncope	3 (0.1%)	5 (0.1%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

Table 108: Participant Incidence of Cardiomyopathy Events, Narrow Scope, Female Participants > 30 to < 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=3930) n (%)	Placebo (N=3859) n (%)
Number of participants reporting cardiomyopathy events	1 (<0.1%)	0 (0 %)
Number of cardiomyopathy events	1	0
Cardiomyopathy	1 (<0.1%)	0 (0%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.16 (please also refer to the data packages included in Module 5).

5.6.13.2.2.3 Females Ages ≥ 60 Years

Table 109: Participant Incidence of Cardiomyopathy Events, Narrow and Broad Scope, Female Participants ≥ 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=2452) n (%)	Placebo (N=2403) n (%)
Number of participants reporting cardiomyopathy events	45 (1.8%)	44 (1.8%)
Number of cardiomyopathy events	49	56
Acute left ventricular failure	0 (0.0%)	1 (<0.1%)
Arrhythmia	2 (0.1%)	1 (<0.1%)
Atrial enlargement	0 (0.0%)	1 (<0.1%)
Blood pressure diastolic increased	2 (0.1%)	0 (0.0%)
Blood pressure systolic abnormal	1 (<0.1%)	0 (0.0%)
Blood pressure systolic decreased	1 (<0.1%)	0 (0.0%)
Blood pressure systolic increase	9 (0.4%)	7 (0.3%)
Cardiac failure	2 (0.1%)	1 (<0.1%)
Cardiac failure congestive	4 (0.2%)	3 (0.1%)
Cardiomegaly	0 (0.0%)	1 (<0.1%)
Chest pain	4 (0.2%)	2 (0.1%)
Dyspnoea	13 (0.5%)	19 (0.8%)
Left atrial enlargement	0 (0.0%)	1 (<0.1%)
Mental status changes	0 (0.0%)	2 (0.1%)
Oedema	0 (0.0%)	1 (<0.1%)
Orthostatic hypotension	3 (0.1%)	0 (0.0%)
Palpitations	3 (0.1%)	1 (<0.1%)
Stress cardiomyopathy	1 (<0.1%)	0 (0.0%)
Syncope	3 (0.1%)	8 (0.3%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow and broad SMQ.

Source: Table 14.3.1.22.16.4 (please also refer to the data packages included in Module 5).

Table 110: Participant Incidence of Cardiomyopathy Events, Narrow Scope, Female Participants ≥ 60 Years (Safety Set)

Preferred Term	mRNA-1273 (N=2452) n (%)	Placebo (N=2403) n (%)
Number of participants reporting cardiomyopathy events	1 (<0.1%)	0 (0 %)
Number of cardiomyopathy events	1	0
Stress cardiomyopathy	1 (<0.1%)	0 (0%)

Abbreviations: MedDRA=Medical Dictionary for Regulatory Activities; SMQ=standardized MedDRA queries.

Note: Percentages are based on the number of safety participants. MedDRA and SMQ version 23.0. Cardiomyopathy events are identified through selected narrow SMQ.

Source: Adapted from mRNA-1273-P301 Clinical Study Report Table 14.3.1.22.16 (please also refer to the data packages included in Module 5).