moderna

200 Technology Square • Cambridge, MA 02139
phone 617-714-6500 • fax 617-649-3744

BLA Number 125752
Sequence No. 0027

November 30, 2021

Marion Gruber, PhD
Director, Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
Document Control Center
10903 New Hampshire Avenue
WO71, G112
Silver Spring, MD 20993-0002

Submission Type: SDTM Datasets for IR#23

Dear Dr. Gruber:

Reference is made to BLA 125752 for the initial Biologics License Application (BLA) for mRNA-1273, a novel lipid nanoparticle (LNP)-encapsulated messenger RNA (mRNA)-based vaccine against the 2019 novel coronavirus (CoV; SARS-CoV-2) currently under review with the agency.

The purpose of this submission is to resubmit the following SDTM domains with application of the updated Solicited Symptom "lookup table" (pre-specified Preferred Terms (PT) that corresponds to symptoms for SAR):

- CE/SUPPCE
- FACE/SUPPFACE
- FAAE/SUPPFAAE
- AE/SUPPAE

The datasets in this submission have been updated to align with the discussion at the October 29, 2021 teleconference and information included in IR#23.

Below is a summary of the updates implemented in the above domains:

1. Solicited Symptom "lookup table" update: Dictionary-Derived Term (AEDECOD) map to pre-specified symptoms (updated lookup table is included in this submission)
2. Add AESCAT if AECAT = "REACTOGENICITY"
3. CE Updates:
   - CE data source
     Both a solicited event captured in e-DIARY and a solicited event captured in Adverse Event where AECAT = "REACTONECITY" AESCAT <> "WRONG CATEGORY" are included
   - Add CECAT = "IMMEDIATE REACTION" row for a solicited event occurred within 30 mins after each dose

- CESTDTC – earliest event date time (CETOXGR > 0) by Participator, Dose #, and Symptom
- CEENDTC – latest event date time (CETOXGR > 0) by Participator, Dose #, and Symptom
- CEENRTPT = "ONGOING" and CEENTPT = "DAY 7" if an event was last beyond day 7

The analysis of duration of SAR using CBER's definition of last day-first day+1 (Table 14.3.1.4.1.4.1 and Table 14.3.1.4.1.4.2 provided in response to IR #5) will be updated and the analysis results (tables) will be provided as soon as they are available.

If FDA has any questions, please do not hesitate to contact me directly at (617) 417-4428 or at michelle.olsen@modernatx.com.

This eCTD submission has been prepared by PPD Development, Inc. in full compliance with ICH and FDA guidance. The eCTD has been verified and confirmed to be virus and spyware free. PPD utilizes Palo Alto Traps v4.2.2. All technical questions should be directed to (b) (6) at PPD (b) (6) or email at (b) (6)

Yours Sincerely,

Michelle Olsen

Digitally signed by Michelle Olsen
Date: 2021.11.30 12:56:22 -05'00'

Michelle Olsen
Associate Director, Regulatory Affairs Strategy
ModernaTX, Inc.
200 Technology Square
Cambridge, MA 02139
Tel.: (617) 417-4428; Fax: (b) (6)
Email: michelle.olsen@modernatx.com