**Information Request**

**Our Reference: STN: 125752/2**

**Information Request #39**

**Date:** December 17, 2021

**To:** **Michelle Olsen, Ph.D.**
ModernaTX, Inc.
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**From:** **Josephine Resnick, Ph.D.**
DVRPA/OVRR/CBER
Email: Josephine.Resnick@fda.hhs.gov

**Product:** COVID-19 Vaccine, mRNA (SPIKEVAX)

**Subject:** Clinical: Safety Data for Study P301 submitted to module 5 of BLA.

Our review of your August 24, 2021 submission (STN 125752/2) is ongoing. We have the following request for additional information:

1. For cases of dyspnea and syncope that occurred within 7 days after any vaccination dose across study groups, please provide:
    a. (Excel doc) A line listing by participant ID number and study group (different Excel sheets for each group) that provides additional information on each reported case of dyspnea and syncope including but not limited to, day of onset following each dose (dose 1 and dose 2), duration (in days), concomitant medications, concomitant AEs, other underlying conditions.
    b. (Excel and Word doc) Two separate summary tables for dyspnea following dose 1 and dose 2 across study groups, that provide the following information based on events that occurred following the most recent dose only
        i. Median day of onset and range (days)
        ii. Median duration and range (days) of dyspnea and syncope
    c. (Excel and Word doc) Two separate summary tables for syncope following dose 1 and dose 2 across study groups based on events that occurred following the most recent dose only
        i. Median day of onset and range (days)
        ii. Median duration and range (days) of dyspnea and syncope

2. For subjects with deep vein thrombosis in Part A of the study, please provide:
    a. (Excel doc) A line listing by participant ID number and study group (different Excel sheets for each group) that provides additional information on each reported case of deep vein thrombosis including but not limited to, day of onset following each dose (dose 1 and dose 2), duration (in days), concomitant medications, concomitant AEs, other underlying conditions

3. Please complete the following table for pregnancies reported in Part A

**Table. Pregnancies Reported in Part A, Safety Set**

| | **mRNA-1273 N=15184 n** | **Placebo N=15162 n** |
|---|---|---|
| **Total number of pregnancies** | 16 | 11 |
| **Timing of last dose relative to LMP** | | |
| Prior to LMP | | |
| Within 30 days after LMP | | |
| >30 days after LMP | | |
| LMP unknown | | |

4. Please complete the following table above for Part B, for participants who were in the original placebo group who crossed over to receive mRNA-1273.

**Table. Pregnancies Reported in Part B, Safety Set**

| | **Placebp-mRNA-1273 N=** |
|---|---|
| **Total number of pregnancies** | 19 |
| **Timing of last dose of mRNA-1273 relative to LMP** | |
| Prior to LMP | |
| Within 30 days after LMP | |
| >30 days after LMP | |
| LMP unknown | |

Please confirm your receipt of this request and submit your response as an amendment to STN 125752 as soon as possible but no later than December 29, 2021.

Please contact me if you have questions and include Sudhakar Agnihothram (sudhakar.agnihothram@fda.hhs.gov) and Joseph Kulinski (joseph.kulinski@fda.hhs.gov) on all communications.