

Information Request

Our Reference: STN: 125752/1

Information Request #44

Date: January 12, 2022

To: **Michelle Olsen, Ph.D.**
ModernaTX, Inc.
Email: Michelle.Olsen@modernatx.com

From: **Josephine Resnick, Ph.D.**
DVRPA/OVRR/CBER
Email: Josephine.Resnick@fda.hhs.gov

Product: COVID-19 Vaccine, mRNA (SPIKEVAX)

Subject: Clinical follow-up to IR #39

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

1. This follow-up Information Request pertains to the tables you had submitted for Items 3 and 4 in response to IR #39 (Amendment #40, submitted December 21, 2021). We have included copies of the tables from your previous response below for reference (Tables 3-1 and 4-1 below).

We are having difficulty matching numbers in your response with the numbers we have obtained from our review of case narratives. To further clarify what information is needed, we have provided Table A with sample pregnancy cases to illustrate how we define timing intervals between last dose relative to LMP (study vaccine dates relative to LMPs) to categorize the observed pregnancy events. We request that you update Tables 3-1 and 4-1 based on further review of the case narratives and the clarifications provided in Table A below.

Table A: Sample pregnancy cases from Part A

Timing of last dose relative to LMP	Arm	Subject ID	Dose 1	Dose 2	LMP
Prior to LMP	Placebo	3002122	8/7/20	9/4/20	10/19/20
Within 30 days after LMP	Placebo	3172349	8/26/20	Not given	8/25/20

>30 days after LMP	Placebo	3252009	8/3/20	Not given	6/10/20
Within 30 days after LMP	mRNA-1273	3092099	8/10/20	Not given	7/25/20
Prior to LMP	mRNA-1273	3302345	8/24/20	9/21/20	10/27/20
LMP unknown	mRNA-1273	3042177	8/13/20	9/10/20	Unknown

Tables from Response to IR #39 Items 3-4:**Table 3-1 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	0	0
Within 30 days after LMP	5	8
>30 days after LMP	8	3
LMP unknown	3	0

Table 4-1 Pregnancies Reported in Part B, Safety Set

	Placebo-mRNA-1273 N=12,648
Total number of pregnancies	19
Timing of last dose of mRNA-1273 relative to LMP	
Prior to LMP	9
Within 30 days after LMP	7
>30 days after LMP	1
LMP unknown	2

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 January 13, 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.