

Information Request

Our Reference: STN: 125752/2

Information Request #27

Date: December 6, 2021

To: **Michelle Olsen, Ph.D.**
ModernaTX, Inc.
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From: **Josephine Resnick, Ph.D.**
DVRPA/OVRR/CBER
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Product: COVID-19 Vaccine, mRNA (SPIKEVAX)

Subject: Datasets

Our review of your August 24, 2021 submission (STN 125752/2) is ongoing.

Please refer to amendment #18 (seq 0020), submitted in response to the teleconference held between Moderna and CBER on October 29, 2021. We have the following comments/responses:

We acknowledge your response to the clinical IR (#24) dated November 30, 2021 regarding the analyses of asymptomatic and SARS-CoV-2 infection, submitted in amendment 28, on December 03, 2021. In your response, corrections were made for 2 subjects for asymptomatic infection and 3 subjects for SARS-CoV-2 infection. However, these corrections do not appear to fully address the issues related to mis-labelled samples. Specifically, we note the following 29 discrepancies for asymptomatic infection as presented in Table 6-9 of the P301 CSR:

Table 1. Asymptomatic infection starting 14 days post Dose 2

USUBJID	ADTTEB.PAR AMCD	ADTTEB. CNSR	Date of first positive N- serology or PCR	Date of PDV or unblinding	Infected on or prior to PDV?

mRNA-1273-P301-US303-2145	TASYCRB1	1	9-Jan-21	9-Jan-21	Yes
mRNA-1273-P301-US303-2331	TASYCRB1	0	4-Feb-21	29-Jan-21	No
mRNA-1273-P301-US313-2115	TASYCRB1	0	12-Mar-21	5-Feb-21	No
mRNA-1273-P301-US314-2275	TASYCRB1	0	8-Mar-21	25-Jan-21	No
mRNA-1273-P301-US319-2534	TASYCRB1	0	4-Feb-21	21-Dec-20	No
mRNA-1273-P301-US320-2076	TASYCRB1	0	17-Feb-21	3-Feb-21	No
mRNA-1273-P301-US321-2148	TASYCRB1	1	4-Mar-21	4-Mar-21	Yes
mRNA-1273-P301-US321-2191	TASYCRB1	1	5-Mar-21	5-Mar-21	Yes
mRNA-1273-P301-US322-2380	TASYCRB1	0	2-Feb-21	29-Jan-21	No
mRNA-1273-P301-US322-2594	TASYCRB1	0	12-Mar-21	17-Dec-20	No
mRNA-1273-P301-US331-2221	TASYCRB1	0	26-Mar-21	13-Jan-21	No
mRNA-1273-P301-US334-2338	TASYCRB1	0	25-Jan-21	21-Jan-21	No
mRNA-1273-P301-US339-2064	TASYCRB1	0	6-Jan-21	31-Dec-20	No
mRNA-1273-P301-US340-2036	TASYCRB1	1	9-Feb-21	9-Feb-21	Yes
mRNA-1273-P301-US340-2240	TASYCRB1	0	9-Mar-21	5-Feb-21	No

mRNA-1273-P301-US344-2062	TASYCRB1	0	5-Mar-21	28-Dec-20	No
mRNA-1273-P301-US344-2182	TASYCRB1	0	10-Feb-21	28-Jan-21	No
mRNA-1273-P301-US346-2090	TASYCRB1	0	12-Jan-21	17-Dec-20	No
mRNA-1273-P301-US352-2168	TASYCRB1	0	23-Feb-21	23-Dec-20	No
mRNA-1273-P301-US352-2657	TASYCRB1	0	10-Feb-21	4-Jan-21	No
mRNA-1273-P301-US364-2130	TASYCRB1	0	20-Jan-21	8-Jan-21	No
mRNA-1273-P301-US364-2147	TASYCRB1	0	21-Jan-21	8-Jan-21	No
mRNA-1273-P301-US364-2162	TASYCRB1	0	20-Jan-21	8-Jan-21	No
mRNA-1273-P301-US381-2078	TASYCRB1	0	22-Jan-21	22-Dec-20	No
mRNA-1273-P301-US381-2086	TASYCRB1	0	22-Feb-21	28-Jan-21	No
mRNA-1273-P301-US382-2040	TASYCRB1	0	21-Jan-21	4-Jan-21	No
mRNA-1273-P301-US382-2174	TASYCRB1	0	20-Jan-21	19-Jan-21	No
mRNA-1273-P301-US382-2191	TASYCRB1	0	26-Feb-21	18-Jan-21	No
mRNA-1273-P301-US398-2163	TASYCRB1	0	8-Jan-21	7-Jan-21	No

Similarly, we note the following 39 discrepancies for SARS-CoV-2 infection as presented in Table 6-6 of the P301 CSR:

Table 2. SARS-CoV-2 infection starting 14 days post Dose 2

USUBJID	ADTTEB.PAR AMCD	ADTTEB. CNSR	Date of first positive N- serology or PCR	Date of PDV or unblinding	Infected on or prior to PDV?
mRNA-1273- P301-US303- 2145	TTINFB1	1	9-Jan-21	9-Jan-21	Yes
mRNA-1273- P301-US303- 2331	TTINFB1	0	4-Feb-21	29-Jan-21	No
mRNA-1273- P301-US308- 2216	TTINFB1	1	8-Jan-21	9-Feb-21	Yes
mRNA-1273- P301-US313- 2115	TTINFB1	0	12-Mar-21	5-Feb-21	No
mRNA-1273- P301-US314- 2275	TTINFB1	0	8-Mar-21	25-Jan-21	No
mRNA-1273- P301-US315- 2071	TTINFB1	1	27-Jan-21	27-Jan-21	Yes
mRNA-1273- P301-US319- 2534	TTINFB1	0	4-Feb-21	21-Dec-20	No
mRNA-1273- P301-US320- 2076	TTINFB1	0	17-Feb-21	3-Feb-21	No
mRNA-1273- P301-US321- 2148	TTINFB1	1	4-Mar-21	4-Mar-21	Yes
mRNA-1273- P301-US321- 2191	TTINFB1	1	5-Mar-21	5-Mar-21	Yes
mRNA-1273- P301-US322- 2380	TTINFB1	0	2-Feb-21	29-Jan-21	No
mRNA-1273- P301-US322- 2594	TTINFB1	0	12-Mar-21	17-Dec-20	No
mRNA-1273- P301-US328- 2090	TTINFB1	0	20-Jan-21	31-Dec-20	No

mRNA-1273-P301-US331-2221	TTINFB1	0	26-Mar-21	13-Jan-21	No
mRNA-1273-P301-US332-2226	TTINFB1	1	25-Feb-21	25-Feb-21	Yes
mRNA-1273-P301-US334-2338	TTINFB1	0	25-Jan-21	21-Jan-21	No
mRNA-1273-P301-US337-2429	TTINFB1	1	4-Feb-21	4-Feb-21	Yes
mRNA-1273-P301-US339-2064	TTINFB1	0	6-Jan-21	31-Dec-20	No
mRNA-1273-P301-US340-2036	TTINFB1	1	9-Feb-21	9-Feb-21	Yes
mRNA-1273-P301-US340-2240	TTINFB1	0	9-Mar-21	5-Feb-21	No
mRNA-1273-P301-US344-2062	TTINFB1	0	5-Mar-21	28-Dec-20	No
mRNA-1273-P301-US344-2107	TTINFB1	1	6-Jan-21	6-Jan-21	Yes
mRNA-1273-P301-US344-2182	TTINFB1	0	10-Feb-21	28-Jan-21	No
mRNA-1273-P301-US346-2090	TTINFB1	0	12-Jan-21	17-Dec-20	No
mRNA-1273-P301-US348-2302	TTINFB1	1	14-Jan-21	14-Jan-21	Yes
mRNA-1273-P301-US352-2168	TTINFB1	0	23-Feb-21	23-Dec-20	No
mRNA-1273-P301-US352-2657	TTINFB1	0	10-Feb-21	4-Jan-21	No
mRNA-1273-P301-US354-2214	TTINFB1	1	22-Jan-21	22-Jan-21	Yes

mRNA-1273-P301-US354-2215	TTINFB1	1	22-Jan-21	22-Jan-21	Yes
mRNA-1273-P301-US364-2130	TTINFB1	0	20-Jan-21	8-Jan-21	No
mRNA-1273-P301-US364-2147	TTINFB1	0	21-Jan-21	8-Jan-21	No
mRNA-1273-P301-US364-2162	TTINFB1	0	20-Jan-21	8-Jan-21	No
mRNA-1273-P301-US381-2078	TTINFB1	0	22-Jan-21	22-Dec-20	No
mRNA-1273-P301-US381-2086	TTINFB1	0	22-Feb-21	28-Jan-21	No
mRNA-1273-P301-US382-2040	TTINFB1	0	21-Jan-21	4-Jan-21	No
mRNA-1273-P301-US382-2174	TTINFB1	0	20-Jan-21	19-Jan-21	No
mRNA-1273-P301-US382-2191	TTINFB1	0	26-Feb-21	18-Jan-21	No
mRNA-1273-P301-US396-2063	TTINFB1	1	4-Feb-21	4-Mar-21	Yes
mRNA-1273-P301-US398-2163	TTINFB1	0	8-Jan-21	7-Jan-21	No

Please comment on whether each subject was correctly censored in your analysis. Please submit the corrected analyses of asymptomatic and SARS-CoV-2 infection, if applicable, starting 14 days after Dose 2 in the PPS, including the sensitivity analysis of asymptomatic infection excluding those with any documented CDC or protocol-defined COVID-19 symptom at any time during the study.

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 09 , 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.