U.S. FOOD & DRUG ADMINISTRATION

Information Request

Our Reference: STN: 125752/2

Information Request #45

Date: January 13, 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 IR – Safety Data Study P301

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

1. For mRNA-1273 and placebo recipients in Part A who reported PT of chest pain, chest discomfort, myocardial infarction within 28 days of any vaccination, please provide the following information in a table and arrange rows by Dose 1 or 2 and ascending order of day of onset from most recent vaccination:

Group	Sex	Age	MedDRA PT	Onset after Dose 1 or 2	Day of onset after most recent vaccination	Resolution	Grade	Serious	Other risk factors	Causality as assessed by the investigator
mRNA				Dose 1						
mRNA				Dose 2						
Placebo				Dose 1						
Placebo				Dose 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 10 AM EST on January 14, 2022.

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.