



Information Request

Our Reference: STN: 125752/2

Information Request #14

Date: November 1, 2021

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

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

Product: COVID-19 Vaccine, mRNA (SPIKEVAX)

Subject: EU Risk Management Plan

The EU Risk Management Plan submitted in your BLA 125752/2 is under ongoing review. Please submit the protocols or protocol synopses for the following studies to your BLA 125752:

- Study mRNA-1273-P902
- Study mRNA-1273-P903
- Study mRNA-1273-P904
- Study mRNA-1273-P905

Please confirm your receipt of this request, and provide your responses as an amendment to STN 125752 at your earliest convenience but no later than November 3, 2021.

Please contact me if you have questions and include Sudhakar Agnihothram (sudhakar.agnihothram@fda.hhs.gov) and Josephine Resnick (josephine.resnick@fda.hhs.gov) on all communications.