

From: [Michelle Olsen](#)
To: [Kulinski, Joseph](#)
Cc: [Resnick, Josephine](#); [Agnihothram, Sudhakar](#)
Subject: [EXTERNAL] RE: STN 125752: Information Request #12
Date: Friday, October 22, 2021 5:30:50 PM
Attachments: [image001.png](#)

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I acknowledge receipt. We will provided by 10/28.

Best,
Michelle

From: Kulinski, Joseph <Joseph.Kulinski@fda.hhs.gov>
Sent: Friday, October 22, 2021 5:13 PM
To: Michelle Olsen <Michelle.Olsen@modernatx.com>
Cc: Resnick, Josephine <Josephine.Resnick@fda.hhs.gov>; Agnihothram, Sudhakar <Sudhakar.Agnihothram@fda.hhs.gov>
Subject: STN 125752: Information Request #12

EXTERNAL

Dear Dr. Olsen,

Our review of your August 24, 2021 submission (STN 125752) is ongoing. Please find attached an information request regarding clinical dataset analyses.

Please acknowledge receipt of this email and let me know if you have any questions.

Best,

Joe Kulinski

Joseph Kulinski, PhD

Biologist / Primary Reviewer

Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
U.S. Food and Drug Administration
Tel: 301-796-2640
Josephine.Resnick@fda.hhs.gov



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Information Request

Our Reference: STN: 125752/2

Information Request #12

Date: October 22, 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: Datasets

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

1. Please submit a sensitivity analysis for the rates of solicited adverse reactions by including all relevant events (occurring within the 7 days post vaccination) from the e-diary captured as COVID-19 symptoms that were negative for SARS-CoV-2.
2. Please perform a similar sensitivity analysis for unsolicited AEs for those events that occurred beyond 7 days of vaccination.

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 2, 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.