

Resnick, Josephine

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From: Resnick, Josephine  
Sent: Tuesday, October 26, 2021 9:24 AM  
To: 'Michelle Olsen'; Kulinski, Joseph  
Cc: Agnihothram, Sudhakar  
Subject: RE: [EXTERNAL] RE: STN 125752: Information Request #12

Dear Dr. Olsen,

Please find below a clarified request:

Please submit a sensitivity analysis for the rates of solicited adverse reactions by including all relevant events (occurring within the 7 days post vaccination) reported in the COVID-19 symptom logs from subjects that were ultimately negative for SARS-CoV-2. Please perform a similar sensitivity analysis for unsolicited AEs for those events reported in the COVID-19 symptom logs from subjects that were ultimately negative for SARS-CoV-2 but which are not included in the first sensitivity analysis for solicited reactions.

Let us know if you have any additional questions regarding this request.

Warm regards,

Jo Resnick

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From: Michelle Olsen <Michelle.Olsen@modernatx.com>  
Sent: Monday, October 25, 2021 4:10 PM  
To: Kulinski, Joseph <Joseph.Kulinski@fda.hhs.gov>  
Cc: Resnick, Josephine <Josephine.Resnick@fda.hhs.gov>; Agnihothram, Sudhakar <Sudhakar.Agnihothram@fda.hhs.gov>  
Subject: [EXTERNAL] RE: STN 125752: Information Request #12

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Dear Dr. Kulinski,

We are currently having a team meeting to discuss the below IR#12 and we have a few different interpretations of the question that could lead to different answers. If you could request a follow-up clarification from the review team, we'd appreciate it:

The Sponsor would like to ask for further clarifications on the reviewers' request on "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". Are the reviewers referring to the "Symptom Log" reported by participants? Is the request for sensitivity analysis of SAR(solicited adverse reactions), to include the following symptoms reported on "Symptom Log" within 7 days post vaccination in those participants reported such symptoms on "Symptom Log" and later had a negative RT-PCR result? Symptoms reported on "Symptom Log":

- Fever based on Temperature reported

- Chills
- Fatigue
- Muscle Aches (Myalgia) or Body Aches
- Headache
- Nausea or Vomiting

If the team could please re-state the question keeping in mind our questions above, we would greatly appreciate that.

Best regards,  
Michelle

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

EXTERNAL

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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  
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[Josephine.Resnick@fda.hhs.gov](mailto:Josephine.Resnick@fda.hhs.gov)



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