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Submission ID: *STN 125752*

Office: *OVRR*

Product: *COVID-19 Vaccine, mRNA*

Applicant: *ModernaTX Inc*

Telecon Date/Time: *29-OCT-2021 01:00 PM*

Initiated by FDA?: *Yes*

Author: *JOSEPH KULINSKI*

Purpose: Meeting with Moderna to discuss their responses to IR #5 and to inform them as to why responses were not adequate

FDA Participants:
Sudhakar Agnihothram, Ph.D., DVRPA, OVRR
Maria Allende, M.D., DVRPA, OVRR
Brenda Baldwin, Ph.D., DVRPA, OVRR
Timothy Fritz, Ph.D., DVRPA, OVRR
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Joseph Kulinski, Ph.D., DVRPA, OVRR
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Josephine Resnick. Ph.D., DVRPA, OVRR
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Rachel Zhang, M.D., DVRPA, OVRR

Moderna Participants:
Michelle Olsen, AD, Regulatory Strategy
Honghong Zhou, Sr Director, Biostatistics
Shu Han, VP, Biostatistics
Weiping Deng, Director, Biostatistics
Baoyu Ding, Sr Director, Statistical Programming
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Carla Vinals, VP, Regulatory
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Heather Clouting, Clinical Operations P301 Lead
Deborah Manzo, Sr. Director, Clinical Operations
Allison August, VP, Clinical Development, ID
Rituparna Das, VP, Clinical Development, COVID-19 Vaccines
Walter Straus, VP, Clinical Safety Lead, mRNA-1273
Melissa Rossi, Sr. Director, Clinical Safety Sciences

Summary of Discussion:

Moderna was sent 10 discussion items along with 2 corresponding reference spreadsheets on 10/28/2021 and was asked to comment on the impact each item has on the solicited and/or unsolicited safety results as well as update and resubmit the CBER Requested Tables (Batches #1 and #2) after addressing the items that impact the safety results (with particular attention to items 4a, 4d, 5, 6 and 10.

Modera submitted responses to the discussion items prior to the telecon on 10/29/2021 (see attached documents for detailed discussion points). Action items agreed on by Moderna are as follows:

- Discussion Items 2 and 3:

    - Asked Moderna why out of 25 AE records, 3 have been removed by the site personnel.
        - Moderna will provide this information to CBER.
    - In study P301, 6 subjects had AEs with an AEOUT= NOT RECOVERED/NOT RESOLVED, but an end date is provided.
        - Details on the 6 events will be provided by Moderna.
- Discussion Item 4a:
    - Moderna agreed to do a line-by-line review of the 2428 events in P301 in which reactogenicity events reported in CE and lasting longer than the 7-day evaluation period (CERFTDTC + 6) were not reported in the AE dataset, and provide a comprehensive assessment of these discrepancies.
- Discussion Item 4b:
    - Moderna indicated that updating the CE domain adding CENRTPT=”Day 7” and CEENTPT=”ONGOING” for all last beyond Day 7 events would have no impact on analysis.
    - Moderna proposed to implement CBER's suggestion in a future sBLA submission.
- Discussion Item 4C:
    - Moderna agreed that to correct the current dataset, the category “REACTOGENICITY” should be removed, if it is not ongoing and not an SAE. An additional flag will be added in the subAE indicating that the category is changed.
- Discussion Item 4d:
    - Moderna was asked if all cases of lymphadenopathy AE accounted for in SAR regardless if categorized as reactogenicity in AE dataset.
        - This was confirmed by Moderna
    - Moderna agreed to revise and resubmit datasets where events that are reported in the ‘Events’ datasets and ‘Findings About’ datasets but are not connected to provide a combined assessment for the event.
- Discussion Item 5:
    - Moderna agreed to provide scenarios for subcatergorization
- Discussion Item 6:
    - Moderna committed to take a deeper look at events in which there are discrepancies between CE and AE reporting and correct if possible. For those that cannot be corrected, Moderna will provide an impact assessment on the analyses.
- Discussion Item 7:
    - CBER further asked for details on how the communication between the eDiary/participant and the Investigator is handled.
        - Moderna agreed to discuss internally and see if affected dates can be corrected

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