From: Smith, Michael (CBER)
Sent: Thursday, August 19, 2021 6:32 PM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Subject: RE: [EXTERNAL] RE: STN 125742.0: IR RE PMR's and PMC's

Elisa,

We received the responses to our August 19, 2021 questions on the PMR and PMC studies and we have another question for you regarding the Study Completion Date and Final Report Submission date for PMC Study C4591014.

The Study Completion Date listed in the amendment received today is June 30, 2023. However, the Final Report Submission date listed in amendment 51 received on August 16, 2021, is also June 30, 2023. Please clarify if this is correct and provide corrections as needed.

Please confirm receipt of this information request and submit the response to this additional question to the BLA as soon as possible and no later than 12:00 PM Friday, August 20, 2021.

Regards,

Mike

From: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Sent: Thursday, August 19, 2021 11:42 AM
To: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Subject: [EXTERNAL] RE: STN 125742.0: IR RE PMR's and PMC's

Hi Mike, I confirm receipt.

Best regards,
Elisa

From: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Sent: Thursday, August 19, 2021 11:35 AM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Subject: [EXTERNAL] STN 125742.0: IR RE PMR's and PMC's

Elisa,

We have the below comments regarding the August 16, 2021, amendment containing your PMR and PMC commitments. Please submit your responses in an amendment to the BLA by COB Thursday, August 19, 2021.

1. Regarding PMR study C4591021: We notice that the Study Completion Date and Final Report Submission have the same dates (September 30, 2024). Please clarify if this is correct and provide corrections as needed.

2. Regarding PMR substudy C4591021: We notice that the Study Completion Date and Final Report Submission have the same dates (September 30, 2024). Please clarify if this is correct and provide corrections as needed.

3. Regarding the PMR for a prospective assessment of the incidence of subclinical myocarditis following administration of the second dose of Comirnaty in a subset of participants 5 through 15 years of age enrolled in Study C4591007, please provide the date for submission of the protocol amendment.

4. Regarding the PMR prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network): Please change the dates for the Study Completion Date and Final Report Submission to the last day of the month, December 31, 2026 and May 31, 2027, respectively. Also, please provide a study number for this study.

5. Regarding PMC study C4591022: Please change the dates for the Study Completion Date and Final Report Submission to the last day of the month, June 30, 2025 and December 31, 2025, respectively.

6. Regarding PMC study C4591012: Please change the date for the Study Completion Date to the last day of the month, June 30, 2023.

7. Regarding PMC study C4591014: We note that there wasn't a Study Completion Date provided, please provide a Study Completion Date for the last day of the month that the study will be completed.

Regards,

Mike

- Please confirm receipt of this e-mail and let us know if you have any questions.

Mike Smith, Ph.D.
Captain, USPHS

Senior Regulatory Review Officer
Food and Drug Administration
Center for Biologics Evaluation & Research
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Division of Vaccines and Related Products Applications
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