From: Smith, Michael (CBER)
Sent: Saturday, August 21, 2021 10:33 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: RE: STN 125742.0: IR RE PMR's and PMC's

Elisa,

Sorry, be we had two minor revisions to our IR after I sent it. We revised the beginning of the first sentence for the second paragraph and we also revised the final protocol submission date for study C4591007.

Regards,

Mike

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

From: Smith, Michael (CBER)
Sent: Saturday, August 21, 2021 10:22 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: STN 125742.0: IR RE PMR's and PMC's

Elisa,

There have been numerous information requests and amendments regarding the PMR's and PMC's for this BLA. I have a generated the below list of PMR's and PMC's that we have received from you. Please review and submit the list of studies and dates in an amendment to the BLA by COB today containing your commitment to conduct all of these studies in the timeframes noted.

Based on our preliminary review, we do not consider the amendment you submitted on August 10, 2021 as adequate for the final protocol for PMC Study C4591007 substudy to evaluate the immunogenicity and safety of lower dose

levels of COMIRNATY in individuals 12 through <30 years of age. Therefore, we are using the future date of September 30, 2021 for Final Protocol Submission. In the coming weeks we will provide comments on the amendment submitted on August 10, 2021. Please acknowledge our revision to the Final Protocol Submission date for this PMC (highlighted in yellow below for #11). Please also propose any revisions that you anticipate may be needed for Study Completion Date and Final Report Submission for this PMC.

1. Deferred pediatric Study C4591001 to evaluate the safety and effectiveness of COMIRNATY in children 12 years through 15 years of age.

   Final Protocol Submission: October 7, 2020

   Study Completion Date: May 31, 2023

   Final Report Submission: October 31, 2023

2. Deferred pediatric Study C4591007 to evaluate the safety and effectiveness of COMIRNATY in infants and children 6 months to <12 years of age.

   Final Protocol Submission: February 8, 2021

   Study Completion: October 31, 2023

   Final Report Submission: March 31, 2024

3. Deferred pediatric Study C4591023 to evaluate the safety and effectiveness of COMIRNATY in infants <6 months of age.

   Final Protocol Submission: January 31, 2022

   Study Completion: July 31, 2024

   Final Report Submission: October 31, 2024

4. Study C4591009, entitled "A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

   We acknowledge the timetable you submitted on August 16, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: August 31, 2021

Monitoring Report Submission: October 31, 2022

Interim Report Submission: October 31, 2023

Study Completion Date: June 30, 2025

Final Report Submission: October 31, 2025

5. Study C4591021, entitled "Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

   We acknowledge the timetable you submitted on August 16, and 19, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: August 11, 2021

   Progress Report Submission: September 30, 2021

   Interim Report 1 Submission: March 31, 2022

   Interim Report 2 Submission: September 30, 2022

   Interim Report 3 Submission: March 31, 2023

   Interim Report 4 Submission: September 30, 2023

   Interim Report 5 Submission: March 31, 2024

   Study Completion Date: March 31, 2024

   Final Report Submission: September 30, 2024

6. Study C4591021 substudy to describe the natural history of myocarditis and pericarditis following administration of COMIRNATY.

   We acknowledge the timetable you submitted on August 16, and 19, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: January 31, 2022

   Study Completion Date: March 31, 2024

   Final Report Submission: September 30, 2024

7. Study C4591036, a 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).

   We acknowledge the timetable you submitted on August 16, and 19, 2021, which states that you will conduct this study according to the following schedule:
   Final Protocol Submission: November 30, 2021

   Study Completion Date: December 31, 2026

   Final Report Submission: May 31, 2027

8. Study C4591007 substudy to prospectively assessthe incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age.

   We acknowledge the timetable you submitted on August 18, and 19, 2021, which states that you will conduct this assessment according to the following schedule:

   Final Protocol Submission: September 30, 2021

   Study Completion Date: November 30, 2023

   Final Report Submission: May 31, 2024

9. Study C4591031 substudy to prospectively assess the incidence of subclinical myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age.

   We acknowledge the timetable you submitted on August 16, 2021, which states that you will conduct this study according to the following schedule:

   Final Protocol Submission: November 30, 2021

   Study Completion Date: June 30, 2022

   Final Report Submission: December 31, 2022

10. Study C4591022, entitled “Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post- Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry.”

    Final Protocol Submission: July 1, 2021

Study Completion Date: June 30, 2025

Final Report Submission: December 31, 2025

11. Study C4591007 substudy to evaluate the immunogenicity and safety of lower dose levels of COMIRNATY in individuals 12 through <30 years of age in.

    Final Protocol Submission: September 30, 2021

    Study Completion Date: November 30, 2023

    Final Report Submission: May 31, 2024

12. Study C4591012, entitled "Post-emergency Use Authorization Active Safety Surveillance Study Among Individuals in the Veteran's Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine."

    Final Protocol Submission: January 29, 2021

    Study Completion Date: June 30, 2023

    Final Report Submission: December 31, 2023

13. Study C4591014, entitled "Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California."

    Final Protocol Submission: March 22, 2021

    Study Completion Date: December 31, 2022

    Final Report Submission: June 30, 2023

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
Office of Vaccines Research & Review
Division of Vaccines and Related Products Applications
Tel: 301-796-2640
michael.smith2@fda.hhs.gov