Response to CBER 21 August 2021 Information Request Regarding Postmarketing Requirement/Postmarketing Commitment Studies

Final List of Studies

21 August 2021
FINAL LIST OF STUDIES

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: November 30, 2023
   Final Report Submission: May 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.

   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.

   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.

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).

Final Protocol Submission: November 30, 2021

Study Completion Date: December 31, 2026

Final Report Submission: May 31, 2027

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

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.

   Final Protocol Submission: November 30, 2021

   Study Completion Date: June 30, 2022

   Final Report Submission: December 31, 2022


   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


   Final Protocol Submission: January 29, 2021

   Study Completion Date: June 30, 2023

   Final Report Submission: December 31, 2023


   Final Protocol Submission: March 22, 2021

   Study Completion Date: December 31, 2022

   Final Report Submission: June 30, 2023
## Document Approval Record

| Document Name: | Attachment Final List of Studies - COVID-19 Vaccine Response to FDA IR 21-Aug-2021 |
| Document Title: | Attachment Final List of Studies - COVID-19 Vaccine Response to FDA IR 21-Aug-2021 |

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