BNT162b2 (COMIRNATY)

BLA STN 125742/0

Response to CBER 19 August 2021 Information Request Regarding Postmarketing Requirement/Postmarketing Commitment Studies

19 August 2021

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1. INTRODUCTION

Reference is made to BLA STN 125742/0 for COVID-19 mRNA Vaccine (COMIRNATY), for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals ≥16 years of age and to CBER's Information Request received via email on 19 August 2021.

CBER requests are presented in ***bold italics*** followed by Pfizer-BioNTech response in plain text.

2. CBER REQUESTS AND SPONSOR RESPONSES

We have the below comments regarding the August 16, 2021, amendment containing your PMR and PMC commitments.

2.1. CBER Request 1 - Study C4591021

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.

Sponsor Response

Pfizer/BioNTech confirm the Final Report Submission Date for Study C4591021, 30 September 2024, is correct.

Pfizer/BioNTech acknowledge that the Study Completion Date for Study C4591021 is incorrect. This date will be revised to 31 March 2024 in the next version of the Pharmacovigilance Plan. Submission of the updated Pharmacovigilance Plan is anticipated to be post-approval given our understanding of the imminence of approval of the BLA.

2.2. CBER Request 2 - Substudy C4591021

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.

Sponsor Response

Pfizer/BioNTech confirm the Final Report Submission Date for Study C4591021 substudy, 30 September 2024, is correct.

Pfizer/BioNTech acknowledge that the Study Completion Date for Study C4591021 substudy is incorrect. This date will be revised to 31 March 2024 in the next version of the Pharmacovigilance Plan. Submission of the updated Pharmacovigilance Plan is anticipated to be post-approval given our understanding of the imminence of approval of the BLA.

2.3. CBER Request 3 - Prospective Assessment of Subclinical Myocarditis

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.

Sponsor Response

The protocol amendment will be submitted by 30 September 2021.

2.4. CBER Request 4 - Prospective Cohort Study for Potential Long-term Sequelae of Myocarditis

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.

Sponsor Response

Pfizer/BioNTech agree to change the Study Completion Date and Final Report Submission to the last day of the month, 31 December 2026 and 31 May 2027, respectively. These changes will be reflected in the next version of the Pharmacovigilance Plan. Submission of the updated Pharmacovigilance Plan is anticipated to be post-approval given our understanding of the imminence of approval of the BLA.

This study has been assigned study number C4591036.

2.5. CBER Request 5 - Study C4591022

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.

Sponsor Response

Pfizer/BioNTech agree to change the Study Completion Date and Final Report Submission to the last day of the month, 30 June 2025 and 31 December 2025, respectively. These changes will be reflected in the next version of the Pharmacovigilance Plan. Submission of the updated Pharmacovigilance Plan is anticipated to be post-approval given our understanding of the imminence of approval of the BLA.

2.6. CBER Request 6 - Study C4591012

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

Sponsor Response

Pfizer/BioNTech agree to change the Study Completion Date to the last day of the month, 30 June 2023. This change will be reflected in the next version of the Pharmacovigilance Plan. Submission of the updated Pharmacovigilance Plan is anticipated to be post-approval given our understanding of the imminence of approval of the BLA.

2.7. CBER Request 7 - Study C4591014

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.

Sponsor Response

The Study Completion Date is 30 June 2023.

Document Approval Record

Document Name:	COVID-19 Vaccine Response to FDA IR 19-Aug-2021 - PMR_PMC Studies
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Signed By:	Date(GMT)	Signing Capacity
Harkins Tull, Elisa	19-Aug-2021 19:38:58	Regulatory Affairs Approval