



BNT162b2 (COMIRNATY)

BLA STN 125742/0

**Response to CBER 19 August 2021 Follow-up Information Request Regarding
Postmarketing Commitment Study C4591014**

20 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 REQUEST AND SPONSOR RESPONSE

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.

Sponsor Response

Pfizer/BioNTech confirm the Final Report Submission Date for Study C4591014, 30 June 2023, is correct.

Pfizer/BioNTech acknowledge that the Study Completion Date for Study C4591014 is incorrect. This date will be revised to 31 December 2022 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.

Document Approval Record

Document Name:	COVID-19 Vaccine Response to FDA Follow-up IR 19-Aug-2021 - PM C Study C4591014
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Signed By:	Date(GMT)	Signing Capacity
Harkins Tull, Elisa	20-Aug-2021 12:21:06	Regulatory Affairs Approval