

BNT162b2
BLA STN 125742/0
Module 1.11.3 Response to FDA Request for Information



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BLA STN 125742/0

Response to CBER 15 July 2021 Clinical Information Request

July 2021

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1. INTRODUCTION

On 15 July 2021, Pfizer/BioNTech received the following Clinical Information Request from the FDA regarding Study C4591007 submitted to STN 125742/0.

The FDA's request in ***bold italics*** is followed by Pfizer/BioNTech's response below.

2. CLINICAL INFORMATION REQUEST

2.1. FDA Information Request Item 1

The review team has the question below for you regarding Study C4591007. The review team has requested that a response be submitted to the BLA by July 21, 2021.

We note that the goal dates provided for Study C4591007 final protocol submission reflect the date of the first version of the protocol, which did not include all children 11 years of age and younger. Please provide updated goal dates for final protocol submission (that will include participants down to birth), study completion and report submission for Study C4591007.

Response

Reference is made to the email conversation between Dr. Ramachandra Naik, FDA, CBER, OVRP and Ms. Elisa Harkins, Pfizer Inc. within which Pfizer/BioNTech proposed to include a Request for Waiver of Pediatric Studies for infants less than 2 months of age as part of this response. Pfizer/BioNTech acknowledge CBER's response (20 July 2021 email from Dr. Naik to Ms. Harkins), "Currently, you are proposing a deferred study C4591007 to evaluate the safety and effectiveness of COMIRNATY in children 11 years of age and younger. Due to time constraints associated with the BLA review, we cannot consider a new request for a partial waiver without risking delayed approval of the BLA. Please submit a revised pediatric plan to indicate that study C4591007, for which the protocol has already been submitted to the IND, will enroll subjects 6 months to 11 years of age and to propose another study to enroll infants <6 months of age, with submission milestone dates in the future. Following approval of your BLA and pending further information about epidemiology of the disease and safety and effectiveness of your vaccine, we would consider a partial waiver and a release from the corresponding PREA PMR."

The present submission provides the amended Agreed Pediatric Study Plan ([Clean Copy](#) and [Track Changes Copy](#)) and Request for Deferral of Pediatric Studies ([Clean Copy](#) and [Track Changes Copy](#)) as requested by CBER. These documents have been updated to include the addition of study C4591023, a dose-finding safety and effectiveness study in infants less than 6 months of age. They will also be submitted to BB-IND 019736.

Pfizer/BioNTech propose the following goal dates for study C4591007 (children 6 months to <12 years of age):

- Final Protocol Submission: 8 February 2021
- Study Completion: 31 October 2023

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- Final Report Submission: 31 March 2024

Pfizer/BioNTech propose the following goal dates for study C4591023 (infants <6 months of age):

- Final Protocol Submission: 31 January 2022
- Study Completion: 31 July 2024
- Final Report Submission: 31 October 2024

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