BNT162b2

BLA STN 125742/0

Response to CBER 29 June 2021 Clinical Information Request

July 2021

1. INTRODUCTION

On 29 June 2021, Pfizer/BioNTech received the following Clinical Information Request from the FDA regarding Study C4591001 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

Please provide the maximum date (latest date) of randomization for participants included in the reactogenicity subset for Study C4591001. Our evaluation of the datasets indicates that the maximum date of randomization (RANDDT) and vaccination date 01 (VAX101DT) for participants included in the reactogenicity subset is January 8, 2021. If based on your analyses, this date should be different, please provide guidance to the datasets and the appropriate flags we can use to confirm your results within the datasets.

Response

Based on the eSub data submitted for BLA, in Study C4591001, the maximum date of randomization (RANDDT) and vaccination date 01 (VAX101DT) for participants included in the reactogenicity subset is:

VAX101DT =08JAN2021 and RANDDT=08JAN2021 for participants ≥16 years of age.

VAX101DT =01FEB2021 and RANDDT=12JAN2021 for participants 12 through 15 years of age.

Document Approval Record

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