

BNT162b2 (COMIRNATY)

BLA STN 125742/0

**Response to CBER 22 July 2021 Information Request Regarding
Clinical Shell Tables for Study C4591001
Follow-Up #4 (Safety 508 Tables)**

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 22 July 2022 Information Request received via email from Laura Gottshalk, PhD (CBER) regarding clinical shell tables for Study C4591001.

Further reference is made to:

- the [Response to CBER 22 July 2021 Information Request](#) submitted to BLA 125742/0 on 26 July 2021 (Sequence Number 0018)
- the [Response to CBER 22 July 2021 Information Request Follow-up #1](#) submitted to BLA 125549/0 on 28 July 2021 (Sequence Number 0020)
- the [Response to CBER 22 July 2021 Information Request Follow-up #2](#) submitted to BLA 125549/0 on 2 August 2021 (Sequence Number 0028).
- the [Response to CBER 22 July 2021 Information Request Follow-up #3](#) submitted to BLA 125549/0 on 5 August 2021 (Sequence Number 0033).

Please note the following:

- Responses to CBER 22 July 2021 Information Request Items 3, 4, 5, 7, 8 and 9 were submitted to BLA 125549/0 on 26 July 2021.
- Responses to CBER 22 July 2021 Information Request Items 1 and 2 were submitted to BLA 125549/0 on 28 July 2021.
- Further response to CBER 22 July 2021 Information Request Item 5b was submitted to BLA 125549/0 on 2 August 2021.
- Partial Response to CBER 22 July 2021 Information Request Item 6 (508 Efficacy Tables) was submitted to BLA 125549/0 on 5 August 2021.
- The present response addresses the remaining information requested by CBER in the 22 July 2021 Information Request for Item 6: The safety 508 tables are provided herein.

CBER requests are provided below in ***bold italics*** with Sponsor responses in plain text.

2. CBER INFORMATION REQUESTS AND SPONSOR RESPONSES

2.1. CBER Request 6 from 22 July 2021 Information Request

Please complete the following tables, based on the Study C4591001 Phase 2/3 populations, limited to participants 16 years of age and older (please exclude participants 12-15 years of

age) from the March data cutoff, unless otherwise specified. Please add rows, as needed to list additional items.

Sponsor Response

The requested safety 508 tables are provided in [Module 5.3.5.1 C4591001 508 Compliant Safety Tables \(PDF\)](#) and [Module 5.3.5.1 C4591001 508 Compliant Safety Tables \(Word\)](#).

Table C notes:

- Table C is based on the Safety population and vaccine group as administered. Therefore, the numbers are different from Table B (disposition of all randomized subjects), which is based on vaccine group as randomized. Vaccine group as administered is not identical to vaccine group as randomized because some subjects received a study intervention that was different from what they were randomized to.
- The BNT162b2 and placebo columns do not add up to the 'Total' column because the 3 indeterminate subjects were included in the 'total' column but not in BNT162b2 or placebo columns.
- Total vaccinated does not equal to safety population because there were 10 subjects who received vaccination but were excluded from the safety population due to unreliable data (lack of Principal Instigator oversight).

Table T note: The Case Report Form (CRF) collects information only regarding Investigator assessment of relatedness and not Pfizer assessment of relatedness.

The requested efficacy 508 tables were provided on 5 August 2021.

Document Approval Record

Document Name: COVID-19 Vaccine - Follow-up 4 (508 Safety Tables) for CBER 22 Jul 2021 Information Request

Document Title: COVID-19 Vaccine - Follow-up 4 (508 Safety Tables) for CBER 22 Jul 2021 Information Request

Signed By:	Date(GMT)	Signing Capacity
Perez, John	08-Aug-2021 14:35:57	Final Approval