

BNT162b2

BLA STN 125742/0

Response to CBER 18 May 2021 Information Request Regarding Datasets

May 2021

090177e19712a0c4\Approved\Approved On: 19-May-2021 18:00 (GMT)

1. INTRODUCTION

Reference is made to Amendment 132 (dated 09 April 2021) to EUA 27034 to extend emergency use authorization of the Pfizer-BioNTech COVID-19 vaccine to individuals 12-15 years of age. Further reference is made to the teleconference held on 08 April 2021, and Roll 1 of BLA STN 125742/0 (dated 06 May 2021). The purpose of the current document is to respond to CBER's 18 May 2021 Information Request regarding datasets that was provided by Captain Michael Smith, PhD (CBER) to Pfizer via email.

2. CBER COMMENTS AND PFIZER-BIONTECH'S RESPONSES

The BLA review committee has the below IR for you regarding datasets.

Reference is made to amendment 132 (dated April 9, 2021) to your EUA 27034, the teleconference held on April 8, 2021, and roll 1 of your BLA STN 125742/0 (dated May 6, 2021).

2.1. CBER Comment 1

Please confirm that the datasets submitted in the EUA 27034-amendment 132 are identical to the datasets submitted to BLA STN 125742/0.

Response

Pfizer/BioNTech confirm that the datasets submitted in the EUA 27034-amendment 132 are identical to the datasets submitted to BLA STN 125742/0.

2.2. CBER Comment 2

Please confirm that the datasets submitted as SDTM-SUPPL and ADaM-SUPPL contain the reactogenicity data changes as requested (including flags) in the teleconference held on April 8, 2021 and nothing additional.

Response

Pfizer/BioNTech confirm that the datasets submitted as SDTM-SUPPL and ADaM-SUPPL contain the reactogenicity data changes as requested (including flags) in the teleconference held on 08 April 2021 and nothing additional.

2.3. CBER Comment 3

Please clarify what data was changed in the supplemental EX and DM datasets.

Response

No data were changed in the supplemental EX and DM datasets. They were included in the supplemental package because these two datasets would be required for pinnacle 21 check in case FDA wants to run its own check.

Document Approval Record

Document Name:	COVID-19 Vaccine May 2021 Response to FDA Information Request - Datasets
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Signed By:	Date(GMT)	Signing Capacity
Harkins Tull, Elisa	19-May-2021 16:51:33	Regulatory Affairs Approval