BNT162b2

BLA STN 125742/0

Response to CBER 25 June 2021 Clinical Information Request

July 2021

1. INTRODUCTION

On 25 June 2021, Pfizer/BioNTech received the following Clinical Information Request from the FDA regarding Study BNT162-01 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

We have the following comment regarding the document titled "bnt162-01-interim3-report-body":

We note that possible numerical inconsistencies in Table 14.3.1-1.3-3 page (1241/2151) titled "Frequency of subjects with solicited local reactions by grade - BNT162b2" for the older subjects enrolled in BNT162-01 who received 30 mcg dose of the investigational product.

Please clarify and provide summary tables for the cohorts (older and younger subjects) who received 30 mcg dose of BNT162 for both solicited local and systemic adverse reactions. In the table, please present solicited AEs (local and systemic) for the 7 days following each 30 mcg dose of the investigational vaccine.

A suggested format for the summary table is below.

Please provide a response by 2 July 2021.

Response

We have re-reviewed all solicited local and systemic reactogenicity data in the tables and have not identified inconsistencies in the results from the older and younger subjects who received 30 µg dose of BNT162. Our analysis includes every solicited reaction of any severity for each subject, not just the worst grade of solicited reaction per subject. Consequently, there may be more total events per symptom than number of subjects exposed.

Based on your request for clarification of the Tables 14.3.1-1.3-3, pages (1241/2151), we anticipate that CBER wishes us to provide new tables based on worst grade per participant per reactogenicity event (solicited AEs), so as each participant is counted only once per symptom.

We are accordingly submitting new tables for solicited AEs (local and systemic) for the seven days following each 30 µg dose of the investigational vaccine summarizing: 1) the frequency of subjects with solicited local reactions by worst grade and 2) the frequency of subjects with solicited systemic reactions by worst grade for younger (n=12) and older (n=12 subjects) (Appendix 1).

The data in these tables is consistent with the previously supplied tables "bnt162-01-interim3-report-body," Tables 14.3.1-1.3-3, pages (1241/2151), titled "Frequency of subjects with solicited local reactions by grade - BNT162b2."

There were 3 severe systemic reactions after the 1st (prime) injection and 2 severe systemic reactions after the second (boost) injection as previously shown in tables which included all reactogenicity events post both first and second injections without selecting for worst grade.

3. APPENDIX

Appendix 1. BNT162-01 Local and Systemic Solicited AEs Summary Table

Document Approval Record

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Signed By:	Date(GMT)	Signing Capacity
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