From: Smith, Michael (CBER)
Sent: Tuesday, June 8, 2021 2:17 PM
To: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Subject: STN 125742.0: Clinical Information Request

Elisa,

The clinical team has the below questions for Pfizer and they requested that responses be submitted to the BLA as soon as possible.

For Study BNT162-01:

1. In the IS dataset, there is missing immunogenicity data for at least 12 subjects who received the 30 µg dose of BNT162b2. Please submit all immunogenicity data for participants who received 30 µg dose of BNT162b2 to the BLA.
2. Please submit fully functional pdf documents (e.g., that can be searched to locate information) for the following reports that are hyperlinked from the BLA submission (document bnt162-01-interim3-report body):
    a. R&D Report R-20-0253 (28 November 2020)
    b. R&D Report R-20-0235 (27 Nov 2020)
    c. Interim report GA-RB-02201A (19 March 2021)
    d. R-20-0244 (19 March 2021)
    e. Interim Clinical Study Report R-20-0241 (20 March 2021)

For Study C4591001:

1. Please provide a rationale for the differences in the number of participants described in the reactogenicity subset of the safety population as presented in Tables 1 through 4 in (1) the proposed Prescribing Information (PI), submitted in STN 125742/0/1 (dated May 18, 2021) and (2) the most recent version of the Fact Sheet for Healthcare Providers/Full EUA PI, submitted with EUA 27034/181 (dated May 20, 2021). The descriptions for the safety population in Section 6 of each of the PI documents are similar, with an enrollment by date of October 9, 2020 and differing data cut off dates, as expected. However, we would expect that the entire reactogenicity subset would be included in the BLA submission, without a specified "enrollment by date." If this is the rationale for the differences in the number of participants described in the reactogenicity subset, please provide a revised PI to STN 125742 that accurately describes the safety population in Section 6, in tracked changes.

Regards,

Mike

- Please confirm receipt of this e-mail.

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Captain, USPHS

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