

From: Smith, Michael (CBER)

Sent: Tuesday, August 3, 2021 6:08 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/stats IR

Elisa,

The review team has two clinical/stats questions and they requested a response by Friday, August 6, 2021.

1. In your response submitted in STN 125742/0.17 dated July 26, 2021 (to CBER's comment 4 sent on July 22, 2021), you clarified that Episodes B and C were merged into one single COVID-19 case for Subject C4591001 1001 10031167 because this subject had the severe symptom of hospitalization from 22 November 2020 to 23 December 2020. While hospitalization is a criterion for severe COVID-19 according to the CDC definition, it is not a symptom or criterion defined in the study protocol for COVID-19 case definition. In addition, the first positive PCR result was obtained on 19 December 2020, which was ~1 month after the hospitalization, making it difficult to corroborate that the hospitalization was due to COVID-19. Therefore, we disagree with the mergence of these two episodes based on hospitalization. Please provide updated efficacy analyses accordingly, to exclude this subject, and participants 12 through 15 years of age for the shell tables requested.
2. Please submit the SAS programs used to generate efficacy analyses according to the CDC-definition, i.e., adc19ef-ve-sev-7pd2-cdc-wo-eval and adc19ef-ve-sev-7pd2-cdc-eval.

Regards,

Mike

- Please confirm receipt of this e-mail and let us know if you have any questions.

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Captain, USPHS

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