From: Smith, Michael (CBER)
Sent: Tuesday, July 6, 2021 6:40 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 IR RE the document titled "c4591001-interim-mth6-report-body.pdf"

Elisa,

We have the following comment regarding the document titled "c4591001-interim-mth6-report-body.pdf":

1. Please provide a description of the nature of the severe AEs and the AEs which lead to withdrawal from the stable HIV cohort at any time during the study. (e.g., in section 12.2.3.1.1.1. Participants with Confirmed Stable HIV Disease – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to 1 Month After Dose 2 and 12.2.3.2.1.1. Participants with Confirmed Stable HIV Disease – Blinded Placebo-Controlled Follow-Up Period From Dose 1 to the Unblinding Date. There were 2 SAEs in the BNT162b2 group (1 severe and 1 life-threatening) and 2 SAEs in the placebo group (1 life-threatening). There were 2 AEs leading to withdrawal in the BNT162b2 group (1 life-threatening) and 1 AE (life-threatening) leading to withdrawal in the placebo group). Or if this information is available in the submission, please provide a reference to the location of the requested information.

Regards,

Mike

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

Mike Smith, Ph.D.
Captain, USPHS

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