From: Smith, Michael (CBER)
Sent: Tuesday, July 27, 2021 10:01 AM
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: IR RE assessment of vaccine effectiveness

Elisa,

The review team has the below Information Request for Pfizer and BioNTech Manufacturing GmbH.

1. Regarding the cumulative incidence rates, please calculate vaccine effectiveness with confidence intervals during the two intervals of interest separately from days 35-91 (i.e., 8 weeks of observation after dose 2) and from days 91-224 (more prolonged follow up post vaccination series).

2. We also request assessment of vaccine effectiveness during a time period that is entirely further out from vaccination (e.g., starting at 4 months post-dose 2). We acknowledge though that at some point unblinding and placebo cross-over started, and there may have been differential loss between the two groups from blinded follow-up that could introduce bias and/or confound the analyses.

Please respond within one week from today.

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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