From: Smith, Michael (CBER)
Sent: Tuesday, July 27, 2021 10:44 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: RE: [EXTERNAL] RE: STN 125742.0: IR RE assessment of vaccine effectiveness

Elisa,

Sorry, but the below question was inadvertently omitted from the earlier IR. Additionally, the review team has requested a response to this question by Friday, July 30, 2021.

Please calculate the cumulative incidence rates of vaccine and placebo arms at Day 57 and Day 224 and estimate the Risk Difference and Risk Ratio with their 95% CI.

Regards,

Mike

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

From: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Sent: Tuesday, July 27, 2021 10:11 AM
To: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; 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: [EXTERNAL] RE: STN 125742.0: IR RE assessment of vaccine effectiveness

Hi Mike,

I confirm receipt.

Best regards,

Elisa

From: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
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: [EXTERNAL] 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

Senior Regulatory Review Officer
Food and Drug Administration
Center for Biologics Evaluation & Research
Office of Vaccines Research & Review
Division of Vaccines and Related Products Applications
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