From: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Sent: Friday, July 2, 2021 11:38 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: Clinical IR RE document titled "bnt162-01-interim3-report-body"

Elisa,

I discussed this with the clinical team and Pfizer's assumption as outlined is correct.

Regards,

Mike

Mike Smith, Ph.D.
Captain, USPHS

Senior Regulatory Review Officer
Food and Drug Administration
Center for Biologics Evaluation & Research
Office of Vaccines Research & Review
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Tel: 301-796-2640
michael.smith2@fda.hhs.gov

From: Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>
Sent: Friday, July 2, 2021 9:01 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: Clinical IR RE document titled "bnt162-01-interim3-report-body"

Good Morning Mike,

I'm writing to check in on CBER's feedback regarding below. Please advise.

Best regards,
Elisa

From: Harkins Tull, Elisa
Sent: Tuesday, June 29, 2021 6:23 PM
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: RE: STN 125742.0: Clinical IR RE document titled "bnt162-01-interim3-report-body"

Hi Mike,

Our colleagues from BioNTech have the following request for clarification/confirmation on this (Study BNT162-01 is conducted by BioNTech). Please advise.

We are providing and seeking clarification to your request in SNT 125742.0 dated 25 June 2021, clinical final IR document, where you commented on the document "bnt162-01-interim3-report-body," tables 14.3.1-1.3-3, pages (1241/2151), titled "Frequency of subjects with solicited local reactions by grade - BNT162b2."

We have re-reviewed all solicited local and systemic reactogenicity data in the tables and have not identified inconsistencies in the results from the older and younger subjects who received 30 mcg dose of BNT162. Our analysis includes every solicited reaction of any severity for each subject, not just the worst grade of solicited reaction per subject. Consequently, there may be more total events per symptom than number of subjects exposed.

Based on your request for clarification of the tables 14.3.1-1.3-3, pages (1241/2151), we are anticipating that CBER wishes us to provide new tables based on worst grade per participant per reactogenicity event (solicited AEs), so as each participant is counted only once per symptom. We will accordingly plan to submit new tables for solicited AEs (local and systemic) for the 7 days following each 30 mcg dose of the investigational vaccine based on the worst grade per symptom per participant by July 2nd, as requested. We would greatly appreciate confirmation or further clarification if our assumptions are correct.

Thank you.

Best regards,
Elisa