From: Smith, Michael (CBER)
Sent: Friday, June 25, 2021 6:09 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 document titled "bnt162-01-interim3-report-body"

Elisa,

The clinical team has the attached IR regarding the document titled "bnt162-01-interim3-report-body". Please provide a response by July 2, 2021.

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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We have the following comment regarding the document titled "bnt162-01-interim3-report-body":

We note that possible numerical inconsistencies in Table 14.3.1-1.3-3 page (1241/2151) titled "Frequency of subjects with solicited local reactions by grade - BNT162b2" for the older subjects enrolled in BNT162-01 who received 30 mcg dose of the investigational product.

Please clarify and provide summary tables for the cohorts (older and younger subjects) who received 30 mcg dose of BNT162 for both solicited local and systemic adverse reactions. In the table, please present solicited AEs (local and systemic) for the 7 days following each 30 mcg dose of the investigational vaccine.

A suggested format for the summary table is below.

Please provide a response by 2 July 2021.

Table XX: Solicited Local Reactions by Grade in Subjects XX-XX years of age who received BNT162b2 30 **ug (N = 12)**.

	BNT162b2 30 ug Dose 1 N[a]= n[b] (%)	**BNT162b2 30 ug Dose 2 N[a]= n[b] (%)**
Redness		
Any (>2.0 cm)		
Mild		
Moderate		
Severe		
Swelling		
Any (>2.0 cm)		
Mild		

	BNT162b2 30 ug Dose 1 N[a]= n[b] (%)	BNT162b2 30 ug Dose 2 N[a]= n[b] (%)
Moderate		
Severe		
Pain at the injection site		
Any		
Mild		
Moderate		
Severe		

Table YY: Solicited Systemic Reactions by Grade in Subjects XX-XX years of age who received BNT162b2 30 **ug (N = 12)**.

	BNT162b2 30 ug Dose 1 N[a]= n[b] (%)	BNT162b2 30 ug Dose 2 N[a]= n[b] (%)
Fever		
≥38.0°C		
≥38.0°C to 38.4°C		
>38.4°C to 38.9°C		
>38.9°C to 40.0°C		
>40.0°C		
Fatigue		
Any		

	BNT162b2 30 ug Dose 1 N[a]= n[b] (%)	BNT162b2 30 ug Dose 2 N[a]= n[b] (%)
Mild		
Moderate		
Severe		
Headache		
Any		
Mild		
Moderate		
Severe		
Chills		
Any		
Mild		
Moderate		
Severe		
Vomiting		
Any		
Mild		
Moderate		
Severe		
Diarrhea		
Any		
Mild		
Moderate		
Severe		

	BNT162b2 30 ug Dose 1 N[a]= n[b] (%)	BNT162b2 30 ug Dose 2 N[a]= n[b] (%)
New or worsened muscle pain		
Any		
Mild		
Moderate		
Severe		
New or worsened joint pain		
Any		
Mild		
Moderate		
Severe		
Use of antipyretic or pain medication[f]		