From: Smith, Michael (CBER)

Sent: Friday, June 25, 2021 6:09 PM

To: Harkins Tull, Elisa < Elisa. Harkins Tull@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 "bnt162-01interim3-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	BNT162b230 ug
	Dose 1	Dose 2
	Nª=	N ^a =
	ո ^ь (%)	ո ^ь (%)
Redness	1	
Any (>2.0 cm)		
Mild		
Moderate		
Severe		
Swelling	ı	
Any (>2.0 cm)		
Mild		

	BNT162b2 30 ug	BNT162b2 30 ug
	Dose 1	Dose 2
	N ^a =	N ^a =
	ո ^ь (%)	ո ^ь (%)
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	BNT162b230 ug
	Dose 1	Dose 2
	N ^a =	N ^a =
	n ^b (%)	n ^ь (%)
Fever	1	1
≥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		

Dose 1 Nº= Nº= Nº= nº (%) nº (%) Mild		BNT162b2 30 ug	BNT162b2 30 ug
Mild Moderate Severe Headache Any Mild Moderate Severe Chills Any Mild Moderate Severe Vomiting Any Mild Moderate Severe Vomiting Any Mild Moderate Severe Diarrhea Any		Dose 1	Dose 2
Mild Moderate Severe Headache Any Mild Moderate Severe Chills Any Mild Moderate Severe Vomiting Any Mild Moderate Severe Vomiting Any Mild Any Moderate Severe		Nª=	Nª=
Moderate Severe Headache Any Mild Moderate Severe Chills Any Mild Moderate Severe Vomiting Any Mild Moderate Severe Diarrhea Any		n ^b (%)	n ^b (%)
Severe Headache Any Mild Moderate Severe Chills Any Mild Moderate Severe Vomiting Any Mild Moderate Severe Diarrhea Any	Mild		
Headache Any Mild Moderate Severe Chills Any Mild Moderate Severe Vomiting Any Mild Moderate Severe Diarrhea Any	Moderate		
Any Mild Moderate Severe Chills Any Mild Moderate Severe Vomiting Any Mild Moderate Severe Diarrhea Any	Severe		
Mild Moderate Severe Chills Any Mild Moderate Severe Vomiting Any Mild Moderate Severe Diarrhea Any	Headache		
Moderate Severe Chills Any Mild Moderate Severe Vomiting Any Mild Moderate Severe Diarrhea Any	Any		
Severe Chills Any Mild Moderate Severe Vomiting Any Mild Moderate Severe Diarrhea Any	Mild		
Chills Any Mild Moderate Severe Vomiting Any Mild Moderate Severe Diarrhea Any	Moderate		
Any Mild Moderate Severe Vomiting Any Mild Moderate Severe Diarrhea Any	Severe		
Mild Moderate Severe Vomiting Any Mild Moderate Severe Diarrhea Any	Chills		
Moderate Severe Vomiting Any Mild Moderate Severe Diarrhea Any	Any		
Severe Vomiting Any Mild Moderate Severe Diarrhea Any	Mild		
Vomiting Any Mild Moderate Severe Diarrhea Any	Moderate		
Any Mild Moderate Severe Diarrhea Any	Severe		
Mild Moderate Severe Diarrhea Any	Vomiting		
Moderate Severe Diarrhea Any	Any		
Severe Diarrhea Any	Mild		
Diarrhea Any	Moderate		
Any	Severe		
	Diarrhea	1	
	Any		
Mild	Mild		
Moderate	Moderate		
Severe	Severe		

	BNT162b230 ug	BNT162b2 30 ug
	Dose 1	Dose 2
	N ^a =	N ^a =
	n ^b (%)	ո ^ь (%)
New or worsened muscle pain	1	
Any		
Mild		
Moderate		
Severe		
New or worsened joint pain		
Any		
Mild		
Moderate		
Severe		
Use of antipyretic or pain medication ^f		