

From: Smith, Michael (CBER)
Sent: Friday, August 13, 2021 3:40 PM
To: Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Subject: RE: [EXTERNAL] RE: STN 125742.0: Three questions from the clinical team

Neda,

The clinical team has the below response to your clarification question.

No, that doesn't address our question #3. Please provide a breakdown of the subjects by age cohorts (young adults and older adults) who have ≥ 6 months of follow-up from Dose 2 to the earlier of discontinuation or the cutoff date, separately for the Safety and Evaluable Efficacy Populations.

Regards,

Mike

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

From: Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>
Sent: Friday, August 13, 2021 2:22 PM
To: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Subject: RE: [EXTERNAL] RE: STN 125742.0: Three questions from the clinical team

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Dear Mike,

Thank you, I really appreciate it.

Kind regards,
Neda

From: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Sent: Friday, August 13, 2021 2:18 PM
To: Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Subject: RE: [EXTERNAL] RE: STN 125742.0: Three questions from the clinical team

Neda,

I confirm receipt of your e-mail and I will get back to you with a response after the clinical team discusses the clarification question.

Regards,

Mike

From: Aghajani Memar, Neda <Neda.AghajaniMemar@pfizer.com>
Sent: Friday, August 13, 2021 2:03 PM
To: Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Devlin, Carmel M <Carmel.Devlin@pfizer.com>
Subject: [EXTERNAL] RE: STN 125742.0: Three questions from the clinical team

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Dear Mike,

We are working on the responses to CBER's clinical information request and have the below clarification question regarding question 3.

Clarification question on #3:

Table 9 (shown below) of the 6-month interim CSR presented summary of follow-up time after Dose 2 for the safety population with age cohort data presented in Tables 14.26 and 14.27. The yellow-highlighted row represents subjects who have ≥ 6 months of follow-up from Dose 2 to the earlier of discontinuation or the cutoff date combining the blinded placebo-controlled follow-up period and open label follow-up period. By definition, subjects in this cohort received 2 doses of BNT162b2 and the follow up time after last dose (Dose 2) is ≥ 6 months. The blue highlighted row shows subjects who have ≥ 6 months of follow-up from Dose 2 to the earlier of unblinding, discontinuation or the cutoff date (blinded follow-up period only). Similarly, such subjects received 2 doses and had ≥ 6 months follow-up after the last dose.

Please advise if Table 9 and Tables 14.26 and 14.27 in the interim CSR addressed the request.

Follow-up Time After Dose 2 – Phase 2/3 Subjects \geq16 Years of Age – Safety Population			
	Vaccine Group (as Administered)		
	BNT162b2 (30 μg) (N^a=22026) n^b (%)	Placebo (N^a=22021) n^b (%)	Total (N^a=44047) n^b (%)
Subjects (%) with length of follow-up of:			
Original blinded placebo-controlled follow-up period			
<2 Months	1251 (5.7)	1331 (6.0)	2582 (5.9)
\geq 2 Months to <4 months	7744 (35.2)	8070 (36.6)	15814 (35.9)
\geq 4 Months to <6 months	11253 (51.1)	11316 (51.4)	22569 (51.2)
\geq6 Months	1778 (8.1)	1304 (5.9)	3082 (7.0)
Total exposure from Dose 2 to cutoff date			
<2 Months	390 (1.8)		
\geq 2 Months to <4 months	679 (3.1)		
\geq 4 Months to <6 months	8951 (40.6)		
\geq6 Months	12006 (54.5)		
Note: Human immunodeficiency virus (HIV)-positive subjects are included in this summary but analyzed and reported separately.			
a. N = number of subjects in the specified group, or the total sample. This value is the denominator for the percentage calculations.			
b. n = Number of subjects with the specified characteristic.			
PFIZER CONFIDENTIAL SDTM Creation: 25MAR2021 (23:24) Source Data: a dsl Table Generation: 27MAR2021 (01:37)			
(CutoffDate: 13MAR2021, SnapshotDate: 25MAR2021) Output			
File: ./nda2_unblinded/C4591001_BLA/adsl_fu_d2_p3_saf			

Kind regards,
Neda