From: Smith, Michael (CBER)
Sent: Friday, August 13, 2021 10:31 AM
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: STN 125742.0: Three questions from the clinical team

Neda,

The clinical team has three questions for Pfizer – see below. Please respond by COB Monday, August 16, 2021.

1. Please complete the following table to describe follow-up time for the efficacy population.

Table. Blinded Follow-up Time after Dose 2, Phase 2/3 Participants 16 Years of Age and Older, Evaluable Efficacy Population

	Vaccine Group (as Randomized)		
	BNT162b2 N[a]=21047 n[b] (%)	Placebo N[a]=21210 n[b] (%)	Total N[a]=42257 n[b] (%)
Evaluable efficacy (7 days) population			
<2 Months			
≥2 Months to <4 Months			
≥4 Months to <6 Months			
≥6 Months			

Note: HIV-positive participants are not included in this summary because they are not included in the efficacy analyses.

a. N = number of participants in the analysis population for the primary efficacy endpoints (evaluable participants with and without evidence of prior infection). This value is the denominator for the percentage calculations

b. n = Number of subjects with the specified characteristic.

2. Please provide the number of participants, by age cohort, who received placebo originally and opted not to receive BNT162b2 after unblinding.

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. Please also provide a breakdown of these subjects, number of doses received and time of follow up after last dose.

Regards,

Mike

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

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