From: Smith, Michael (CBER)
Sent: Friday, August 13, 2021 6:49 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: STN 125742.0: One clinical question

Neda,

The clinical team has one question for Pfizer - see below. They requested a response as soon as possible and no later than COB Monday, August 16, 2021.

1. Please complete the following table to describe the updated VE at later time points periods, to supplement Table O provided with the VE shell tables in STN 125742.0.32.

Table O. Updated Vaccine Efficacy after Dose 1, Dose 1 All-Available Efficacy Population

Efficacy Endpoint Subgroup	BNT162b2 (N[a]=21909) Cases n1[b] Surveillance Time[c] (n2[d])	Placebo (N[a]=21908) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]
First COVID-19 occurrence after Dose 1	128 8.155 (21385)	998 7.874 (21315)	87.6 (85.1, 89.8)
After Dose 1 to before Dose 2	43 1.273 (21385)	98 1.266 (21315)	56.4 (37.0, 70.3)
Dose 2 to 7 days after Dose 2	3 0.403 (21049)	30 0.401 (20952)	90 (68.0, 98.1)
≥7 Days after Dose 2	82 6.479 (21019)	870 6.207 (20901)	91 (88.7, 92.9)
≥7 Days after Dose 2 to <2 Months after Dose 2			

Efficacy Endpoint Subgroup	BNT162b2 (N[a]=21909) Cases n1[b] Surveillance Time[c] (n2[d])	Placebo (N[a]=21908) Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)[e]
≥2 Months after Dose 2 to 4 Months after Dose 2			
≥4 Months after Dose 2			

Abbreviation: VE = vaccine efficacy.

[a] N = number of subjects in the specified group.

[b] n1 = Number of subjects meeting the endpoint definition.

[c] Total surveillance time in 1000 person-years for the given endpoint across all subjects within each group at risk for the endpoint. Time period for COVID-19 case accrual is from Dose 1 to the end of the surveillance period.

[d] n2 = Number of subjects at risk for the endpoint.

[e] Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted for surveillance time.

Regards,

Mike

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

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