



Information Request # 7

Subject: Clinical

EUA 27073

Date: Dec 5, 2020, 8:15 PM EST

(b) (6)

1. Please provide Overall Summary Tables for Rates of Solicited AEs by Baseline Serostatus, and Grade within 7 days after each dose (for review purposes) in two separate tables based on age. [Source Tables 14.3.1.1.7 and 14.3.1.1.8 submitted as part of EUA data Extraction:11Nov2020.]
 - Frequency Sol AEs (local and systemic) by baseline status and grade, -1st dose, -2nd dose within 7 days after each dose in 18-64 years
 - Table 1: seronegative at baseline
 - Table 2: seropositive at baseline
 - Frequency Sol AEs (local and systemic) by baseline status and grade, -1st dose, 2nd dose within 7 days after each dose in ≥ 65 years of age
 - Table 3: seronegative at baseline
 - Table 4: seropositive at baseline
2. Please also provide an overall table providing the duration of solicited AEs based on source Tables 14.3.1.4.4 –and 14.3.1.4.

Duration of Solicited Adverse Reactions - Median # Days

	Dose 1	Dose 1	Dose 2	Dose 2
Solicited AE	Vaccine Group	Placebo Group	Vaccine Group	Placebo Group
-Local				
- Pain				
- etc				
-Systemic				
-Fever				
-etc				

3. To further clarify IR comment earlier today requesting narratives for all severe COVID-19 cases from the Nov 25 data snapshot, this includes narratives or all severe COVID-19 cases in the safety set, not just for the per-protocol set.

Non-priority (turnaround requested with in 48 hours)

4. Please fill in the following table using data from the final analysis (Nov 25 snapshot):

Table XX: Summary of severe COVID-19 starting after first injection (safety set)

	Vaccine Group n/N (%)	Control Group n/N (%)
Number of subjects with severe COVID-19 starting after first injection, regardless of baseline SARS-CoV-2 status		
Number of subjects with severe COVID-19 starting after first injection, excluding subjects with baseline positive SARS-CoV-2 status		

5. Regarding your response to Items A and B in EUA IR #0001, please present the data regarding vaccine efficacy after dose 1 using the following table:

Vaccine Efficacy—First COVID-19 Occurrence After Dose 1

	Vaccine Group N=	Placebo Group N=	VE (95% CI)
First COVID-19 occurrence after Dose 1	n1; surveillance time (n2)	n1; surveillance time (n2)	
After dose 1 to before dose 2	n1	n1	
After dose 1 to 14 days after dose 1	n1	n1	
14 days after dose 1 to dose 2	n1	n1	
Dose 2 to 14 days after dose 2	n1	n1	
≥14 days after dose 2	n1	n1	

n1=number of subjects meeting endpoint definition

Surveillance time in person years for given endpoint across all subjects within each group at risk for the endpoint

n2=number of subjects at risk for endpoint