

**RESPONSE TO CBER COMMUNICATION REGARDING CLINICAL TOPICS (IR #20)
RECEIVED ON DECEMBER 14, 2020**

The Sponsor acknowledges CBER's communication regarding Clinical topics (IR #20).

This document provides the Sponsor's responses to CBER's requests (in **Bold**).

Item 1:

Please provide the median follow-up time (days) post-dose 2 (include N for each age group with available median follow-up post dose 2) for the safety set and per-protocol set by age: 18-64 years and ≥65 years for both data-cut time points (interim data-cut time & primary data-cut). Please provide this information in the following shell-table:

MEDIAN FOLLOW-UP TIME POST-DOSE 2 (days)

Sponsor Response:

	Interim 18-64y N=	Interim ≥65y N=	Primary 18-64y N=	Primary ≥65 years N=
Safety Set				
PerProtocol Set				

Sponsor Response:

As requested, below is the median follow-up time post dose 2 by age group at the First Interim Analysis (IA1, 11-Nov-2020) and the Primary Analysis (25-Nov-2020). The follow-up time is similar between the two age groups at both IA1 and the Primary Analysis, both in the Per-Protocol Set and in the Safety Set

Median Follow-Up Time Post Dose 2 by Age Group in Days

	Interim 18-64 years	Interim ≥65 years	Primary 18-64 years	Primary ≥65 years
Safety Set	N= 22830 48	N= 7520 51	N = 22831 62	N= 7520 65
Per Protocol Set	N= 20791 49	N= 7026 51	N = 21072 63	N=7135 65

Subjects who did not receive dose 2 is considered to have 0 day in follow-up after dose 2