



Information Request # 8

Subject: Clinical

EUA 27073

Date: Dec 6, 2020, 1:00 PM EST

(b) (6)

Priority

Priority (turnaround requested within 24 h)

1. We acknowledge that given time restraints, it would not be possible to provide narratives for all SAEs from the Phase 3 study. As part of our review, we will need to independently assess causality for all SAEs, which is also difficult to do without narratives. Please provide a summary table including all SAEs from the study, with information of the time of the dose and time to onset for the cases and why the investigator and/or Moderna concluded the event was unrelated (eg, biological implausibility, alternative diagnosis) as well as other elements or comments regarding the case which may help in our assessment of these events. Please respond with a proposal for this summary table within 24 hours.
2. Based on our review of Phase 2 Study (mRNA-1273-P201) Primary Analysis (Extraction Date: 06Nov2020), we note the following:
 - a. 1 SAE (PT: Pneumonia) in the 50ug group and none in the 100 ug [Source 14.3.1.13.2]
 - b. 1 participant in the 50ug group who was SARS-CoV-2 RT-PCR positive between the Day 29 and Day 57 visit. No participants in the 100ug group were tested positive through Day 57. [Source Table 14.2.3.1]

Please confirm the above information; clarify if these participants (one with SAE, one with +RT-PCR) are the same participant or two separate participants; and provide case narratives or any additional information pertaining to these events.

Please also comment if any new data subsequent to the Nov 6th data extraction (post-Day 57) are available for review with regard to Phase 2 SAE data and SARS-CoV-2 test results.

Non-priority (turnaround within 48 hours)

3. As a follow up to your response to Item D from IR EUA #0001, please provide the following additional information on subject US3772037:
 - a. Please indicate any interventions received by the subject during hospitalization (eg ICU admission, mechanical ventilation, treatment specifically for COVID-19)
 - b. Please comment if this case will be eligible to be counted as a severe COVID-19 case and sent to the adjudication committee in future efficacy analyses

4. Please provide a table similar to the one you provided for response to Item A in IR EUA #0001 for severe COVID-19 cases (i.e., Vaccine efficacy of mRNA-1273 to prevent **severe** COVID-19 in subjects who only received one dose—mITT set).

5. Please provide for the safety set:

Baseline SARS-CoV-2 status****	mRNA vaccine	Placebo	overall
Negative			
Positive			
Missing			

Please provide a response to the this information request as an amendment to the EUA. Please acknowledge the receipt of this Information request.