

Errata to mRNA-1273 Booster Dose Briefing Document

**SUBMITTED TO THE VACCINES AND RELATED BIOLOGICAL PRODUCTS
ADVISORY COMMITTEE OF THE FOOD & DRUG ADMINISTRATION FOR THE
14 OCTOBER 2021 MEETING**

This document contains errata to the original mRNA-1273 Booster Dose Briefing Document noting 2 additional updates/edits.

1. The document stated that no SAEs had occurred in the DMID 21-0012 study, which was the case when the document was initially written. Moderna has since received an updated report from DMID 21-0012 and would like to update the section to include 1 SAE that has been reported, which was unrelated to study vaccination.

The original text is followed by the correction in bold below.

Page 58, Section 5.2.3

Original text:

In DMID Study 21-0012, no deaths, SAEs, discontinuations from investigational product or study participation, or pregnancies had occurred at the time of the data snapshot.

Corrected to read as:

In DMID Study 21-0012, no deaths, ~~SAEs~~, discontinuations from investigational product or study participation, or pregnancies had occurred at the time of the data snapshot. One SAE was reported in an mRNA-1273 recipient, which was acute renal failure due to rhabdomyolysis after a fall, considered by the investigator as unrelated to study vaccination.

2. The seroresponse rate of participants boosted with 50 µg following a two-dose primary series of 100 µg was unintentionally omitted from the briefing document. Please refer to the respective information below.

Page 38, Section 4.2.1.2.2

The table below shows the difference in seroresponse rate of participants boosted with 50 µg following a two-dose primary series of 100 µg (P201 Part B) compared to P301 two-dose primary series, per the 4-fold definition for SRR.

Seroresponse Rates^{ab} at 28 Days After a 50 µg mRNA-1273 Booster Dose (Day 29) in Study P201B Versus 28 Days After the mRNA-1273 Primary Series (Day 57) in Study P301, Participants ≥ 18 Years of Age, Per-Protocol Immunogenicity Set

Study P301 100 µg Primary Series^c Seroresponse n (%) (95% CI)^d N^e=1050	Study P201B 50 µg Booster After 100 µg Primary Series Seroresponse n (%) (95% CI)^d N^e=149	Difference in Seroresponse Rate (P201B-P301) % (95% CI)^f	Met Immunobridging Success Criterion (Yes/No)
1033 (98.4) (97.4, 99.1)	131 (87.9) (81.6, 92.7)	-10.5 (-16.7, -6.1)	LL of 95% CI ≥ -10% Criterion: No

a. Pseudovirus neutralization antibody ID50 assay; SRR against a pseudovirus expressing the

b. Seroresponse defined as ≥ 4-fold rise of pseudovirus neutralizing antibody titers from baseline (pre-booster dose in Study P201B and pre-dose 1 in Study P301), where baseline titers < LLOQ

c. Day 57 is 28 days after completion of the 2-dose primary series in Study P301. Day 29 in 28

d. 95% CI is calculated using the Clopper-Pearson method.

e. Number of subjects with non-missing data at both baseline and the post-baseline timepoint of interest.

f. 95% CI is calculated using the Miettinen-Nurminen (score) confidence limits.