**Sensitivity analysis excluding SAEs requiring clinical judgments**

September 9, 2022

As we write in the paper, "decisions about which SAEs to include or exclude as AESIs requires subjective, clinical judgements in the absence of detailed clinical information about the actual SAEs."[1] Accordingly, it is worthwhile to investigate the possible impact that clinical judgements had on the final results. One way to do this is for other parties to replicate the analysis. Another way to is to perform a sensitivity analysis that excluded SAEs for which subjective decisions were made to include them.

We carried out such a sensitivity analysis (see Table) and found the results to be consistent with the original analysis, suggesting subjective decisions were not the major driver of the differences between vaccine and placebo groups.

**Table. Sensitivity analysis excluding SAEs requiring clinical judgments**

| | Total events | | Risk difference per 10,000 participants (95% CI) | Risk ratio (95% CI) |
|---|---|---|---|---|
| **Trial** | **Vaccine** | **Placebo** | | |
| **Serious AESIs[a]** | | | | |
| Pfizer | 52 | 33 | 10.1 (-0.4 to 20.6) | 1.57 (0.98 to 2.54) |
| Moderna | 87 | 64 | 15.1 (-3.6 to 33.8) | 1.36 (0.93 to 1.99) |
| **Serious AESIs excluding SAEs requiring clinical judgments** | | | | |
| Pfizer | 43 | 25 | 9.6 (0.2 to 19.0) | 1.72 (1.00 to 2.95) |
| Moderna | 69 | 48 | 13.8 (-2.7 to 30.2) | 1.44 (0.93 to 2.22) |

[a] From Table 1 in Fraiman et al.[1]
AESI = adverse event of special interest
SAE = serious adverse event

**References**


1. Fraiman J, Erviti J, Jones M, Greenland S, Whelan P, Kaplan RM, Doshi P. Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults. Vaccine. 2022 Aug 30;40(40):5798–805. doi: 10.1016/j.vaccine.2022.08.036. Epub ahead of print. PMID: 36055877; PMCID: PMC9428332. https://doi.org/10.1016/j.vaccine.2022.08.036