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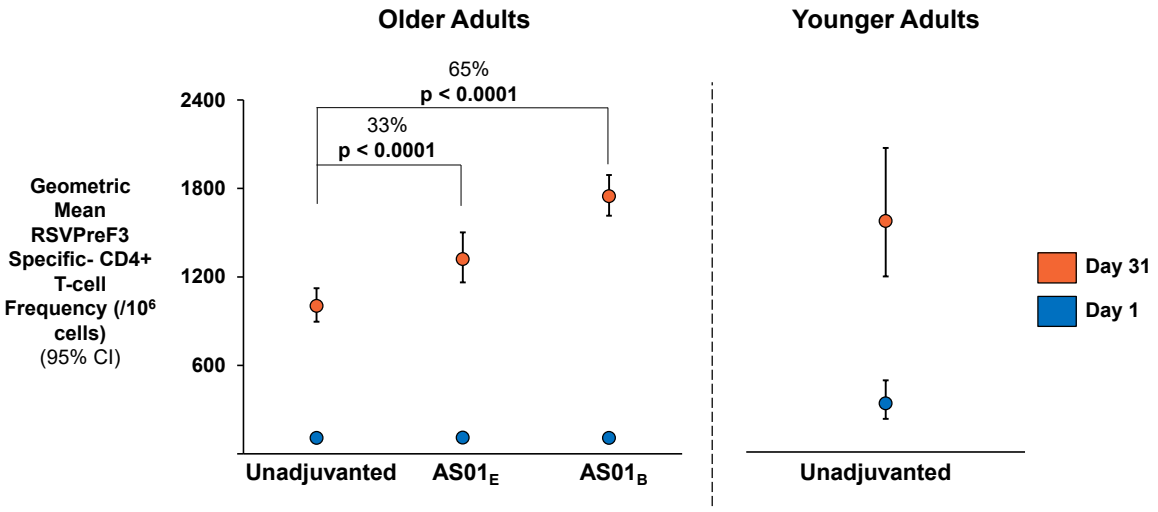
Errata to the GSK Briefing Document for March 1, 2023 Vaccines and Related Biological Products Committee Meeting

Corrections:

- On page 53, the labelling of the y axis of the graph in Figure 7.2 should read Geometric Mean RSVPreF3 CD4+ T-cell Frequency (/10^6 cells) instead of Median, with addition of the mention that the frequency was calculated per 10^6 cells.

The corrected figure is shown below.

Figure 7.2 Study 002: Comparisons of the RSVPreF3-specific CD4+ T cell responses among $AS01_E$, $AS01_B$, and unadjuvanted formulations of RSVPreF3 at 1 month post-Dose 1 – Part A and Part B PPSi



$AS01_B$ = Adjuvant System containing MPL, QS-21 and liposome (50 µg MPL and 50 µg QS-21); $AS01_E$ = Adjuvant System containing MPL, QS-21 and liposome (25 µg MPL and 25 µg QS-21); CI = confidence interval; PPSi = Per-Protocol Set for immunogenicity.
Older adults: participants receiving 30, 60 or 120 µg RSVPreF3 OA unadjuvanted (plain), or adjuvanted with $AS01_E$ or $AS01_B$ in Part B. Younger adults: participants receiving unadjuvanted 30, 60 or 120 µg RSVPreF3 OA in Part A.
Day 1 = pre-vaccination on Day 1; Day 31 = 30 days post-Dose.

- On page 63, the median age of participants at study entry should read 69.0 years instead of 69.5 years. The corrected text is: *Overall, participants in the ES had a median age at study entry of **69.0** years, with participants with various geographic ancestries, which facilitated diversification of participant population.*

- On page 64, in Table 8.2, the number of participants in category 'not Hispanic or Latino' should read 11,780 instead of 11,799. The corrected part of the table is shown below.

Table 8.2 Study 006: Summary of demographic and baseline characteristics — ES

Parameter	RSVPreF3 OA N=12,467 Value or n(%)	Placebo N=12,499 Value or n(%)
Ethnicity		
Hispanic or Latino	682 (5.5)	682 (5.5)
Not Hispanic or Latino	**11,780** (94.5)	11,811 (94.5)
Unknown	5 (<0.1)	6 (<0.1)

- On page 109, the percentage of Grade 3 events in both groups should read as ≤1.2% instead of ≤1%. The corrected text is: *Grade 3 events were infrequent (≤**1.2%**) in both treatment groups.*