

Supplementary Table 3. Summary of exclusions^a from the per-protocol immunogenicity populations for A) qHPV vaccine; and B) Tdap-IPV vaccine.

| | Concomitant administration (Group A) ^b N = 526 | Non-concomitant administration (Group B) ^b N = 528 |
|---|--|--|
| A. Summary of exclusions from the per-protocol immunogenicity populations for the qHPV vaccine | | |
| Number randomized who received at least one injection | 525 | 528 |
| Number excluded from the per-protocol immunogenicity analyses for: | n (%) | n (%) |
| HPV6/11 | 46 (8.8) | 66 (12.5) |
| HPV16 | 36 (6.9) | 49 (9.3) |
| HPV18 | 39 (7.4) | 53 (10.0) |
| HPV31 | 40 (7.6) | 55 (10.4) |
| HPV33 | 38 (7.2) | 50 (9.5) |
| HPV45 | 36 (6.9) | 50 (9.5) |
| HPV52 | 35 (6.7) | 49 (9.3) |
| HPV58 | 41 (7.8) | 59 (11.2) |
| Reasons for exclusion | | |
| Did not receive Tdap-IPV vaccine | 0 (0.0) | 8 (1.5) |
| Received incorrect clinical material | 0 (0.0) | 1 (0.2) |
| Received non-study vaccination ^c | 1 (0.2) | 3 (0.6) |
| Received corticosteroids prior to Month 7 | 0 (0.0) | 1 (0.2) |
| Received immune globulin or blood products | 1 (0.2) | 0 (0.0) |
| Incorrectly randomized | 4 (0.8) | 1 (0.2) |
| With history of immune disorder | 5 (1.0) | 3 (0.6) |
| Did not complete the 3-dose regimen of 9vHPV Vaccine | 4 (0.8) | 11 (2.1) |
| Received at least one dose of 9vHPV vaccine outside the acceptable day range | 5 (1.0) | 10 (1.9) |
| Serum sample or results missing at Day 1 | 1 (0.2) | 1 (0.2) |
| Serum sample or results missing at Month 7 | 20 (3.8) | 34 (6.4) |
| Day 1 seropositive ^d | | |
| HPV6/11 ^e | 11 (2.1) | 20 (3.8) |
| HPV16 | 1 (0.2) | 0 (0.0) |

| | Concomitant administration (Group A) ^b N = 526 | Non-concomitant administration (Group B) ^b N = 528 |
|-------|---|---|
| HPV18 | 6 (1.1) | 5 (0.9) |
| HPV31 | 5 (1.0) | 6 (1.1) |
| HPV33 | 3 (0.6) | 1 (0.2) |
| HPV45 | 1 (0.2) | 1 (0.2) |
| HPV52 | 0 (0.0) | 0 (0.0) |
| HPV58 | 7 (1.3) | 10 (1.9) |

B. Summary of exclusions from the per-protocol immunogenicity populations for the Tdap-IPV vaccine

| | | |
|---|----------|-----------|
| Number randomized who received at least one injection | 525 | 528 |
| | n (%) | n (%) |
| Number excluded from the per-protocol immunogenicity analyses | 20 (3.8) | 55 (10.4) |
| Reason for Exclusion | | |
| Did not receive Tdap-IPV vaccine | 0 (0.0) | 8 (1.5) |
| Received incorrect clinical material | 0 (0.0) | 1 (0.2) |
| Received non-study vaccination ^c | 1 (0.2) | 0 (0.0) |
| Received corticosteroids prior to Month 7 | 0 (0.0) | 1 (0.2) |
| Received immune globulin or blood products | 1 (0.2) | 0 (0.0) |
| Incorrectly randomized | 4 (0.8) | 1 (0.2) |
| With history of immune disorder | 5 (1.0) | 3 (0.6) |
| Received Tdap-IPV vaccine outside the acceptable day range | 0 (0.0) | 23 (4.4) |
| Serum sample or results missing at 4 weeks post injection of Tdap-IPV vaccine | 9 (1.7) | 29 (5.5) |

^aA subject may appear in more than one category.

^bGroup A (concomitant administration) received a 0.5 mL dose of 9vHPV vaccine at day 1, month 2, and month 6 and a 0.5 mL dose of Tdap-IPV vaccine on day 1; Group B (non-concomitant administration) received 9vHPV vaccine as above and Tdap-IPV vaccine at month 1.

^cIncludes (1) any live vaccine received 21 days prior to or 14 days following study vaccine, or (2) any inactivated or recombinant vaccine received within 14 days of study vaccine.

^dSeropositive at Day 1 to the relevant HPV type(s) applies to the per protocol population for the relevant HPV type(s) only.

^eBecause the L1 proteins for HPV6 and HPV11 are 92% homologous at the amino acid level, all participants were required to be seronegative to both HPV6 and HPV11 to be included in either of the HPV6 and HPV11 per-protocol immunogenicity populations.