**Supplemental Table 1. Age group specific percentages of participants with hemagglutination inhibition antibody titers ≥1:40 and corresponding geometric mean titers for WHO-recommended influenza strains contained in trivalent study vaccines among participants seronegative at baseline for the particular strain**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | TIV |  |  | aTIV |  |  |
|  |  | **6 through 11 months** | **12 through 35 months** | **36 through 71 months** | **6 through 11 months** | **12 through 35 months** | **36 through 71 months** |
|  | **HA dose (volume)** | **15 µg (0.5 ml)** | **15 µg (0.5 ml)** | **15 µg (0.5 ml)** | **7.5 µg + MF59 (0.25 ml)** | **7.5 µg + MF59 (0.25 ml)** | **15 µg + MF59 (0.5 ml)** |
| A/California (H1N1) |  | **N=26** | **N=31** | **N=16** | **N=26** | **N=28** | **N=15** |
| HI Ab titer ≥40 % (95% CI) | 28d post dose 1 | 3.9% (0.10-19.6) | 6.5% (0.8-21.4) | 25.0% (7.3-52.4) | 73.1% (52.2-88.4) | 85.7% (67.3-96.0) | 80.0% (51.9-95.7) |
|  | 28d post dose 2 | 73.1% (52.2-88.4) | 93.6% (78.6-99.2) | 93.8% (69.8-99.8) | 100.0% (86.8-100.0) | 100.0% (87.7-100.0) | 100.0% (78.2-100.0) |
| GMT (95% CI) | 28d post dose 1 | 8.1 (6.3-10.4) | 12.6 (9.9-16.0) | 20.6 (10.8-39.2) | 49.6 (36.9-66.6) | 56.6 (41.7-76.8) | 77.5 (41.1-146.2) |
|  | 28d post dose 2 | 49.2 (33.3-72.9) | 95.6 (73.7-124.1) | 87.2 (59.8-127.0) | 196.3 (146.4-263.2) | 175.2 (138.9-220.9) | 181.1 (118.5-276.7) |
| A/Victoria (H3N2) |  | **N=20** | **N=8** | **N=7** | **N=17** | **N=13** | **N=4** |
| HI Ab titer ≥40% (95% CI) | 28d post dose 1 | 35.0% (15.4-59.2) | 75.0% (34.9-96.8) | 71.4% (29.0-96.3) | 82.4% (56.6-96.2) | 84.6% (54.6-98.1) | 100.0% (39.8-100.0) |
|  | 28d post dose 2 | 95.0% (75.1-99.9) | 100.0% (63.1-100.0) | 100.0% (59.0-100.0) | 100.0% (80.5-100.0) | 100.0% (75.3-100.0) | 100.0% (39.8-100.0) |
| GMT (95% CI) | 28d post dose 1 | 18.0 (12.1-26.8) | 50.4 (12.1-209.2) | 77.3 (12.1-492.9) | 73.6 (38.4-141.2) | 53.2(31.1-90.8) | 56.6 (29.9-106.9) |
|  | 28d post dose 2 | 117.1 (82.0-167.3) | 320.0 (126.4-810.4) | 237.8 114.9-491.8) | 408.7 (274.7-608.0) | 320.0 (238.0-430.3) | 452.6 (109.0-1879.6) |
| B/Wisconsin (Yamagata lineage) |  | **N=7** | **N=9** | **N=12** | **N=9** | **N=9** | **N=8** |
| HI Ab titer ≥40% (95% CI) | 28d post dose 1 | 42.9% (9.9-81.6) | 55.6% (21.2-86.3) | 50.0% (21.1-78.9)  | 44.4% (13.7-78.8) | 55.6% (21.2-86.3) | 75.0% (34.9-96.8) |
|  | 28d post dose 2 | 57.1% (18.4-90.1) | 100.0% (66.4-100.0) | 100.0% (73.5-100.0) | 100.0% (66.4-100.0) | 100.0% (66.4-100.0) | 100.0% (63.1-100.0) |
| GMT (95% CI) | 28d post dose 1 | 22.1 (11.1-43.8) | 27.2 (12.7-58.1) | 24.7 (13.9-44.1) | 31.8 (20.0-50.4)  | 35.3 (20.5-60.8)  | 43.6 (24.6-77.5)  |
|  | 28d post dose 2 | 50.5 (22.1-115.2) | 164.2 (76.7-351.4) | 145.3 (91.2-231.6) | 383.1 (250.8-585.1)  | 435.4 (276.9-684.8)  | 277.0 (207.1-370.4)  |

**Supplemental Table 2a. Age group specific percentages of participants with hemagglutination inhibition antibody titers ≥40 and corresponding geometric mean titers for the WHO-recommended influenza B lineage strain not contained in trivalent study vaccines.**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | TIV |  |  | aTIV |  |  |
|  |  | **6 through 11 months** | **12 through 35 months** | **36 through 71 months** | **6 through 11 months** | **12 through 35 months** | **36 through 71 months** |
|  | **HA dose (volume)** | **15 µg** **(0.5 ml)** | **15 µg** **(0.5 ml)** | **15 µg** **(0.5 ml)** | **7.5 µg + MF59****(0.25 ml)** | **7.5 µg + MF59****(0.25 ml)** | **15 µg + MF59** **(0.5 ml)** |
|  |  | **N=26** | **N=34** | **N=33** | **N=30** | **N=31** | **N=38** |
| B/Brisbane (Victoria lineage) |  |  |  |  |  |  |  |
| HI Ab titer ≥40% (95% CI) | Baseline | 15.4% (4.4-34.9) | 29.4% (15.1-47.5) | 45.5% (28.1-63.7) | 33.3% (17.3-52.8) | 19.4% (7.5-37.5) | 55.3% (38.3-71.4) |
|  | 28d post dose 1 | 15.4% (4.4-34.9) | 35.3% (19.8-53.5) | 48.5% (30.8-66.5) | 36.7% (19.9-56.1) | 19.4% (7.5-37.5) | 68.4% (51.4-82.5) |
|  | 28d post dose 2 | 19.2% (6.6-39.4) | 41.2% (24.7-59.3) | 54.5% (36.4-71.9) | 50.0% (31.3-68.7) | 35.5% (19.2-54.6) | 73.7% (56.9-86.6) |
|  |  |  |  |  |  |  |  |
| Seroconversion from baseline | 28d post dose 1 | 0.0% (0.0-13.2) | 5.9% (0.7-19.7) | 3.0% (0.08-15.8) | 3.3% (0.08-17.2) | 3.2% (0.08-16.7) | 13.2% (4.4-28.1) |
|  | 28d post dose 2 | 3.9% (0.1-19.6) | 8.8% (1.9-23.7) | 3.0% (0.08-15.8) | 23.3% (9.9-42.3) | 19.4% (7.5-37.5) | 7.9% (1.7-21.4) |
|  |  |  |  |  |  |  |  |
| GMT (95% CI) | Baseline | 9.6 (6.1-15.1) | 13.7 (8.4-22.3) | 20.4 (12.6-33.1) | 16.6 (9.4-29.5) | 9.8 (6.5-14.6) | 26.3 (16.7-41.4) |
|  | 28d post dose 1 | 10.7 (6.7-16.9) | 15.2 (9.4-24.7) | 24.5 (15.3-39.3) | 18.2 (10.1-33.0) | 11.4 (6.6-19.6) | 39.6 (25.1-62.3) |
|  | 28d post dose 2 | 13.9 (8.5-22.6) | 23.8 (14.6-38.6) | 40.0 (27.6-58.0) | 39.4 (25.2-61.6) | 30.0 (19.8-45.4) | 56.2 (37.6-83.9) |
|  |  |  |  |  |  |  |  |
| GMT ratio from baseline | 28d post dose 1 | 1.1 (0.9-1.4) | 1.1 (0.8-1.5) | 1.2 (1.0-1.5) | 1.1 (0.8-1.5) | 1.2 (0.9-1.5) | 1.5 (1.1-2.0) |
|  | 28d post dose 2 | 1.5 (1.1-1.9) | 1.7 (1.3-2.3) | 2.0 (1.5-2.5) | 2.4 (1.7-3.4) | 3.1 (2.5-3.7) | 2.1 (1.6-2.9) |

**Supplemental Table 2b. Age group specific percentages of participants with hemagglutination inhibition antibody titers ≥40 and corresponding geometric mean titers for the WHO-recommended influenza B lineage strain not contained in trivalent study vaccines among participants seronegative at baseline.**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | TIV |  |  | aTIV |  |  |
|  |  | **6 through 11 months** | **12 through 35 months** | **36 through 71 months** | **6 through 11 months** | **12 through 35 months** | **36 through 71 months** |
|  | **HA dose (volume)** | **15 µg** **(0.5 ml)** | **15 µg** **(0.5 ml)** | **15 µg** **(0.5 ml)** | **7.5 µg + MF59****(0.25 ml)** | **7.5 µg + MF59****(0.25 ml)** | **15 µg + MF59** **(0.5 ml)** |
| B/Brisbane (Victoria lineage) |  | **N=16** | **N=20** | **N=14** | **N=17** | **N=20** | **N=12** |
| HI Ab titer ≥40% (95% CI) | 28d post dose 1 | 0.0% (0.0-20.6) | 5.0% (0.1-24.9) | 0.0% (0.0-23.2) | 5.9% (0.2-28.7) | 0.0% (0.0-16.8) | 16.7% (2.1-48.4) |
|  | 28d post dose 2 | 0.0% (0.0-20.6) | 5.0% (0.1-24.9) | 7.1% (0.2-33.9) | 29.4% (10.3-56.0) | 15.0% (3.2-37.9) | 16.7% (2.1-48.4) |
|  |  |  |  |  |  |  |  |
| GMT (95% CI) | 28d post dose 1 | 7.2 (5.3-9.8) | 7.1 (4.8-10.4) | 7.3 (5.5-9.7) | 6.5 (4.7-8.9) | 5.6 (4.9-6.3) | 9.4 (4.9-18.3) |
|  | 28d post dose 2 | 8.3 (6.0-11.5) | 9.5 (6.4-14.0) | 16.4 (11.9-22.6) | 20.3 (13.5-30.6) | 17.1 (13.7-21.2) | 16.5 (9.9-27.5) |

**Supplemental Table 3a. Children 6 through 35 months of age experiencing solicited systemic events from 30 minutes through 7 days post dose one.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Placebo** |  | **TIV** |  | **aTIV** |  |
|  | **n** | **% (95% CI)** | **n** | **% (95% CI)** | **n** | **% (95% CI)** |
|  | N=39 |  | N=79 |  | N=78 |  |
| Change in Eating Habits |  |  |  |  |  |  |
| Mild | 5 | 12.8 (4.3-27.4) | 4 | 5.1 (1.4-12.5) | 3 | 3.9 (0.8-10.8) |
| Moderate | 0 | 0.0 (0.0-9.0) | 0 | 0.0 (0.0-4.6) | 1 | 1.3 (0.0-6.9) |
| Severe | 0 | 0.0 (0.0-9.0) | 0 | 0.0 (0.0-4.6) | 0 | 0.0 (0.0-4.6) |
| Diarrhea |  |  |  |  |  |  |
| Mild | 5 | 12.8 (4.3-27.4) | 7 | 8.9 (3.6-17.4) | 2 | 2.6 (0.3-9.0) |
| Moderate | 0 | 0.0 (0.0-9.0) | 2 | 2.5 (0.3-8.9) | 1 | 1.3 (0.0-6.9) |
| Severe | 0 | 0.0 (0.0-9.0) | 0 | 0.0 (0.0-4.6) | 1 | 1.3 (0.0-6.9) |
| Irritability |  |  |  |  |  |  |
| Mild | 3 | 7.7 (1.6-20.9) | 4 | 5.1 (1.4-12.5) | 5 | 6.4 (2.1-14.3) |
| Moderate | 0 | 0.0 (0.0-9.0) | 0 | 0.0 (0.0-4.6) | 0 | 0.0 (0.0-4.6) |
| Severe | 0 | 0.0 (0.0-9.0) | 0 | 0.0 (0.0-4.6) | 0 | 0.0 (0.0-4.6) |
| Shivering |  |  |  |  |  |  |
| Mild | 1 | 2.6 (0.1-13.5) | 1 | 1.3 (0.0-6.9) | 1 | 1.3 (0.0-6.9) |
| Moderate | 0 | 0.0 (0.0-9.0) | 0 | 0.0 (0.0-4.6) | 0 | 0.0 (0.0-4.6) |
| Severe | 0 | 0.0 (0.0-9.0) | 0 | 0.0 (0.0-4.6) | 0 | 0.0 (0.0-4.6) |
| Sleepiness |  |  |  |  |  |  |
| Mild | 3 | 7.7 (1.6-20.9) | 3 | 3.8 (0.8-10.7) | 1 | 1.3 (0.0-6.9) |
| Moderate | 0 | 0.0 (0.0-9.0) | 0 | 0.0 (0.0-4.6) | 0 | 0.0 (0.0-4.6) |
| Severe | 0 | 0.0 (0.0-9.0) | 0 | 0.0 (0.0-4.6) | 0 | 0.0 (0.0-4.6) |
| Unusual Crying |  |  |  |  |  |  |
| Mild | 3 | 7.7 (1.6-20.9) | 8 | 10.1 (4.5-19.0) | 7 | 9.0 (3.7-17.6) |
| Moderate | 0 | 0.0 (0.0-9.0) | 0 | 0.0 (0.0-4.6) | 0 | 0.0 (0.0-4.6) |
| Severe | 0 | 0.0 (0.0-9.0) | 0 | 0.0 (0.0-4.6) | 0 | 0.0 (0.0-4.6) |
| Vomiting |  |  |  |  |  |  |
| Mild | 2 | 5.1 (0.6-17.3) | 2 | 2.5 (0.3-8.9) | 3 | 3.9 (0.8-10.8) |
| Moderate | 0 | 0.0 (0.0-9.0) | 0 | 0.0 (0.0-4.6) | 0 | 0.0 (0.0-4.6) |
| Severe | 0 | 0.0 (0.0-9.0) | 0 | 0.0 (0.0-4.6) | 0 | 0.0 (0.0-4.6) |

Note: Systemic events were graded as follows: mild, symptoms causing no or minimal interference with usual social & functional activities; moderate, symptoms causing greater than minimal interference with usual social & functional activities; severe, symptoms causing inability to perform usual social & functional activities.

**Supplemental Table 3b. Children 6 through 35 months of age experiencing solicited systemic events from 30 minutes through 7 days post dose two.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Placebo** |  | **TIV** |  | **aTIV** |  |
|  | **n** | **% (95% CI)** | **n** | **% (95% CI)** | **n** | **% (95% CI)** |
|  | N=35 |  | N=68 |  | N=73 |  |
| Change in Eating Habits |  |  |  |  |  |  |
| Mild | 2 | 5.7 (0.7-19.2) | 4 | 5.9 (1.6-14.4) | 1 | 1.4 (0.0-7.4) |
| Moderate | 0 | 0.0 (0.0-10.0) | 0 | 0.0 (0.0-5.3) | 0 | 0.0 (0.0-4.9) |
| Severe | 0 | 0.0 (0.0-10.0) | 0 | 0.0 (0.0-5.3) | 0 | 0.0 (0.0-4.9) |
| Diarrhea |  |  |  |  |  |  |
| Mild | 1 | 2.9 (0.1-14.9) | 3 | 4.4 (0.9-12.4) | 0 | 0.0 (0.0-4.9) |
| Moderate | 0 | 0.0 (0.0-10.0) | 0 | 0.0 (0.0-5.3) | 1 | 1.4 (0.0-7.4) |
| Severe | 0 | 0.0 (0.0-10.0) | 0 | 0.0 (0.0-5.3) | 0 | 0.0 (0.0-4.9) |
| Irritability |  |  |  |  |  |  |
| Mild | 0 | 0.0 (0.0-10.0) | 3 | 4.4 (0.9-12.4) | 3 | 4.1 (0.9-11.5) |
| Moderate | 0 | 0.0 (0.0-10.0) | 0 | 0.0 (0.0-5.3) | 0 | 0.0 (0.0-4.9) |
| Severe | 0 | 0.0 (0.0-10.0) | 0 | 0.0 (0.0-5.3) | 0 | 0.0 (0.0-4.9) |
| Shivering |  |  |  |  |  |  |
| Mild | 0 | 0.0 (0.0-10.0) | 1 | 1.5 (0.0-7.9) | 0 | 0.0 (0.0-4.9) |
| Moderate | 0 | 0.0 (0.0-10.0) | 0 | 0.0 (0.0-5.3) | 0 | 0.0 (0.0-4.9) |
| Severe | 0 | 0.0 (0.0-10.0) | 0 | 0.0 (0.0-5.3) | 0 | 0.0 (0.0-4.9) |
| Sleepiness |  |  |  |  |  |  |
| Mild | 0 | 0.0 (0.0-10.0) | 1 | 1.5 (0.0-7.9) | 2 | 2.7 (0.3-9.6) |
| Moderate | 0 | 0.0 (0.0-10.0) | 0 | 0.0 (0.0-5.3) | 0 | 0.0 (0.0-4.9) |
| Severe | 0 | 0.0 (0.0-10.0) | 0 | 0.0 (0.0-5.3) | 0 | 0.0 (0.0-4.9) |
| Unusual Crying |  |  |  |  |  |  |
| Mild | 0 | 0.0 (0.0-10.0) | 1 | 1.5 (0.0-7.9) | 3 | 4.1 (0.9-11.5) |
| Moderate | 0 | 0.0 (0.0-10.0) | 0 | 0.0 (0.0-5.3) | 1 | 1.4 (0.0-7.4) |
| Severe | 0 | 0.0 (0.0-10.0) | 0 | 0.0 (0.0-5.3) | 0 | 0.0 (0.0-4.9) |
| Vomiting |  |  |  |  |  |  |
| Mild | 0 | 0.0 (0.0-10.0) | 3 | 4.4 (0.9-12.4) | 3 | 4.1 (0.9-11.5) |
| Moderate | 0 | 0.0 (0.0-10.0) | 0 | 0.0 (0.0-5.3) | 0 | 0.0 (0.0-4.9) |
| Severe | 0 | 0.0 (0.0-10.0) | 0 | 0.0 (0.0-5.3) | 0 | 0.0 (0.0-4.9) |

Note: In the 6 through 35 month age groups, 4, 11, and 5 children did not receive the second dose in the placebo, TIV and aTIV groups, respectively. Systemic events were graded as follows: mild, symptoms causing no or minimal interference with usual social & functional activities; moderate, symptoms causing greater than minimal interference with usual social & functional activities; severe, symptoms causing inability to perform usual social & functional activities.

**Supplemental Table 4a. Children 36 through 71 months of age experiencing solicited systemic events from 30 minutes through 7 days post dose one.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Placebo** |  | **TIV** |  | **aTIV** |  |
|  | **n** | **% (95% CI)** | **n** | **% (95% CI)** | **n** | **% (95% CI)** |
|  | N=20 |  | N=40 |  | N=40 |  |
| Muscle/Joint pain |  |  |  |  |  |  |
| Mild | 1 | 5.0 (0.1-24.9) | 1 | 2.5 (0.1-13.2) | 0 | 0.0 (0.0-8.8) |
| Moderate | 0 | 0.0 (0.0-16.8) | 0 | 0.0 (0.0-8.8) | 0 | 0.0 (0.0-8.8) |
| Severe | 0 | 0.0 (0.0-16.8) | 0 | 0.0 (0.0-8.8) | 0 | 0.0 (0.0-8.8) |
| Chills |  |  |  |  |  |  |
| Mild | 0 | 0.0 (0.0-16.8) | 2 | 5.0 (0.6-16.9) | 1 | 2.5 (0.1-13.2) |
| Moderate | 0 | 0.0 (0.0-16.8) | 0 | 0.0 (0.0-8.8) | 0 | 0.0 (0.0-8.8) |
| Severe | 0 | 0.0 (0.0-16.8) | 0 | 0.0 (0.0-8.8) | 0 | 0.0 (0.0-8.8) |
| Diarrhea |  |  |  |  |  |  |
| Mild | 0 | 0.0 (0.0-16.8) | 1 | 2.5 (0.1-13.2) | 2 | 5.0 (0.6-16.9) |
| Moderate | 0 | 0.0 (0.0-16.8) | 0 | 0.0 (0.0-8.8) | 0 | 0.0 (0.0-8.8) |
| Severe | 0 | 0.0 (0.0-16.8) | 0 | 0.0 (0.0-8.8) | 0 | 0.0 (0.0-8.8) |
| Fatigue |  |  |  |  |  |  |
| Mild | 1 | 5.0 (0.1-24.9) | 4 | 10.0 (2.8-23.7) | 2 | 5.0 (0.6-16.9) |
| Moderate | 0 | 0.0 (0.0-16.8) | 0 | 0.0 (0.0-8.8) | 0 | 0.0 (0.0-8.8) |
| Severe | 0 | 0.0 (0.0-16.8) | 0 | 0.0 (0.0-8.8) | 0 | 0.0 (0.0-8.8) |
| Headache |  |  |  |  |  |  |
| Mild | 1 | 5.0 (0.1-24.9) | 5 | 12.5 (4.2-26.8) | 7 | 17.5 (7.3-32.8) |
| Moderate | 0 | 0.0 (0.0-16.8) | 0 | 0.0 (0.0-8.8) | 0 | 0.0 (0.0-8.8) |
| Severe | 0 | 0.0 (0.0-16.8) | 0 | 0.0 (0.0-8.8) | 0 | 0.0 (0.0-8.8) |
| Malaise |  |  |  |  |  |  |
| Mild | 0 | 0.0 (0.0-16.8) | 2 | 5.0 (0.6-16.9) | 2 | 5.0 (0.6-16.9) |
| Moderate | 0 | 0.0 (0.0-16.8) | 0 | 0.0 (0.0-8.8) | 0 | 0.0 (0.0-8.8) |
| Severe | 0 | 0.0 (0.0-16.8) | 0 | 0.0 (0.0-8.8) | 0 | 0.0 (0.0-8.8) |
| Sleepiness |  |  |  |  |  |  |
| Mild | 1 | 5.0 (0.1-24.9) | 2 | 5.0 (0.6-16.9) | 1 | 2.5 (0.1-13.2) |
| Moderate | 0 | 0.0 (0.0-16.8) | 0 | 0.0 (0.0-8.8) | 0 | 0.0 (0.0-8.8) |
| Severe | 0 | 0.0 (0.0-16.8) | 0 | 0.0 (0.0-8.8) | 0 | 0.0 (0.0-8.8) |
| Sweating |  |  |  |  |  |  |
| Mild | 0 | 0.0 (0.0-16.8) | 1 | 2.5 (0.1-13.2) | 0 | 0.0 (0.0-8.8) |
| Moderate | 0 | 0.0 (0.0-16.8) | 0 | 0.0 (0.0-8.8) | 0 | 0.0 (0.0-8.8) |
| Severe | 0 | 0.0 (0.0-16.8) | 0 | 0.0 (0.0-8.8) | 0 | 0.0 (0.0-8.8) |
| Vomiting |  |  |  |  |  |  |
| Mild | 0 | 0.0 (0.0-16.8) | 2 | 5.0 (0.6-16.9) | 0 | 0.0 (0.0-8.8) |
| Moderate | 0 | 0.0 (0.0-16.8) | 0 | 0.0 (0.0-8.8) | 0 | 0.0 (0.0-8.8) |
| Severe | 0 | 0.0 (0.0-16.8) | 0 | 0.0 (0.0-8.8) | 0 | 0.0 (0.0-8.8) |

Note: Systemic events were graded as follows: mild, symptoms causing no or minimal interference with usual social & functional activities; moderate, symptoms causing greater than minimal interference with usual social & functional activities; severe, symptoms causing inability to perform usual social & functional activities.

**Supplemental Table 4b. Children 36 through 71 months of age experiencing solicited systemic events from 30 minutes through 7 days post dose two.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Placebo** |  | **TIV** |  | **aTIV** |  |
|  | **n** | **% (95% CI)** | **n** | **% (95% CI)** | **n** | **% (95% CI)** |
|  | N=18 |  | N=37 |  | N=39 |  |
| Muscle/Joint pain |  |  |  |  |  |  |
| Mild | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Moderate | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Severe | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Chills |  |  |  |  |  |  |
| Mild | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Moderate | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Severe | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Diarrhea |  |  |  |  |  |  |
| Mild | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 1 | 2.6 (0.1-13.5) |
| Moderate | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Severe | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Fatigue |  |  |  |  |  |  |
| Mild | 0 | 0.0 (0.0-18.5) | 1 | 2.7 (0.1-14.2) | 1 | 2.6 (0.1-13.5) |
| Moderate | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Severe | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Headache |  |  |  |  |  |  |
| Mild | 0 | 0.0 (0.0-18.5) | 1 | 2.7 (0.1-14.2) | 5 | 12.8 (4.3-27.4) |
| Moderate | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Severe | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Malaise |  |  |  |  |  |  |
| Mild | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Moderate | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Severe | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Sleepiness |  |  |  |  |  |  |
| Mild | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Moderate | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Severe | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Sweating |  |  |  |  |  |  |
| Mild | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Moderate | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Severe | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Vomiting |  |  |  |  |  |  |
| Mild | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 1 | 2.6 (0.1-13.5) |
| Moderate | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |
| Severe | 0 | 0.0 (0.0-18.5) | 0 | 0.0 (0.0-9.5) | 0 | 0.0 (0.0-9.0) |

Note: In the 36 through 71 month age group, 2, 3 and 1 children did not receive the second dose in the placebo, TIV and aTIV groups, respectively. Systemic events were graded as follows: mild, symptoms causing no or minimal interference with usual social & functional activities; moderate, symptoms causing greater than minimal interference with usual social & functional activities; severe, symptoms causing inability to perform usual social & functional activities.