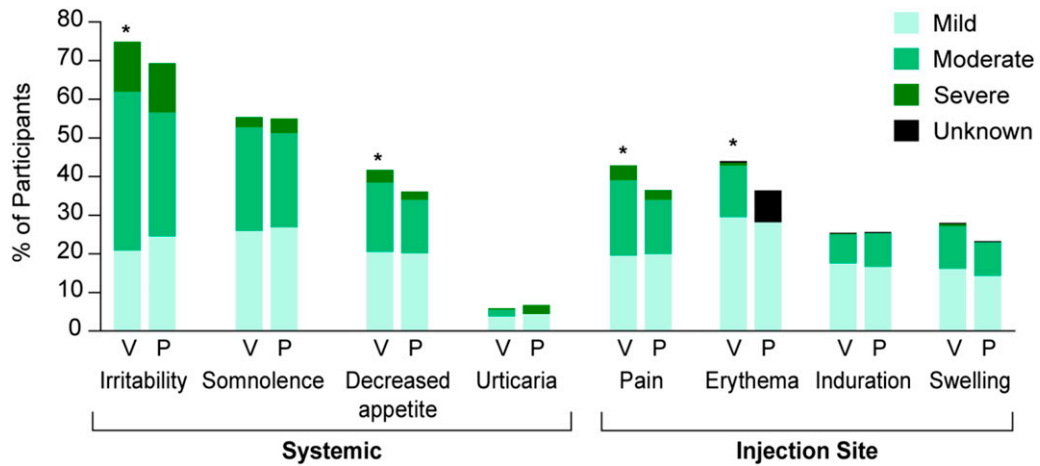


Supplemental Information



SUPPLEMENTAL FIGURE 3

Assessment of AEs. The proportion of participants reporting solicited AEs within 14 days of any vaccination with V114 (V) or PCV13 (P) are shown. Stacked bar colors show AE severity. $*P < .05$ comparing V114 to PCV13.

SUPPLEMENTAL TABLE 4 Participant Enrollment by Study Location

| Study Site | Participants Randomized |
|---------------|-------------------------|
| United States | 533 |
| 20 sites | |
| Thailand | 391 |
| 5 sites | |
| Canada | 309 |
| 8 sites | |
| Malaysia | 291 |
| 5 sites | |
| Finland | 221 |
| 10 sites | |
| Germany | 215 |
| 9 sites | |
| Peru | 183 |
| 3 sites | |
| Taiwan | 135 |
| 4 sites | |
| Israel | 97 |
| 5 sites | |
| Australia | 34 |
| 3 sites | |
| Total | 2409 |

SUPPLEMENTAL TABLE 5 Adverse Event Summary by PCV Dose

| After Dose 1 | V114, n (%) (n = 1965) | PCV13, n (%) (n = 433) | After Dose 2 | V114, n (%) (n = 1930) | PCV13, n (%) (n = 419) |
|----------------------------------|---------------------------|---------------------------|----------------------------------|---------------------------|---------------------------|
| ≥1 AE | 1603 (81.6) | 337 (77.8) | ≥1 AE | 1461 (75.7) | 311 (74.2) |
| Injection-site AEs | 907 (46.2) | 159 (36.7) | Injection-site AEs | 744 (38.5) | 151 (36.0) |
| Systemic AEs | 1487 (75.7) | 324 (74.8) | Systemic AEs | 1347 (69.8) | 282 (67.3) |
| Vaccine-related AEs ^a | 1513 (77.0) | 304 (70.2) | Vaccine-related AEs ^a | 1343 (69.6) | 284 (67.8) |
| Injection-site AEs | 907 (46.2) | 159 (36.7) | Injection-site AEs | 744 (38.5) | 151 (36.0) |
| Systemic AEs | 1335 (67.9) | 282 (65.1) | Systemic AEs | 1172 (60.7) | 245 (58.5) |
| Serious AEs | 41 (2.1) | 11 (2.5) | Serious AEs | 33 (1.7) | 13 (3.1) |
| Serious vaccine-related AEs | 1 (0.1) | 0 (0.0) | Serious vaccine-related AEs | 0 (0.0) | 0 (0.0) |
| Deaths | 0 (0.0) | 1 (0.2) | Deaths | 0 (0.0) | 0 (0.0) |
| After Dose 3 | V114, n (%) (n = 1911) | PCV13, n (%) (n = 414) | After Dose 4 | V114, n (%) (n = 1854) | PCV13, n (%) (n = 398) |
| ≥1 AE | 1349 (70.6) | 280 (67.6) | ≥1 AE | 1295 (69.8) | 275 (69.1) |
| Injection-site AEs | 655 (34.3) | 136 (32.9) | Injection-site AEs | 722 (38.9) | 129 (32.4) |
| Systemic AEs | 1248 (65.3) | 250 (60.4) | Systemic AEs | 1175 (63.4) | 254 (63.8) |
| Vaccine-related AEs ^a | 1182 (61.9) | 248 (59.9) | Vaccine-related AEs ^a | 1140 (61.5) | 228 (57.3) |
| Injection-site AEs | 655 (34.3) | 136 (32.9) | Injection-site AEs | 722 (38.9) | 129 (32.4) |
| Systemic AEs | 1020 (53.4) | 208 (50.2) | Systemic AEs | 954 (51.5) | 188 (47.2) |
| Serious AEs | 100 (5.2) | 18 (4.3) | Serious AEs | 44 (2.4) | 6 (1.5) |
| Serious vaccine-related AEs | 1 (0.1) | 0 (0.0) | Serious vaccine-related AEs | 0 (0.0) | 0 (0.0) |
| Deaths | 0 (0.0) | 0 (0.0) | Deaths | 1 (0.1) | 0 (0.0) |

^a Determined by the investigator to be related to the vaccine.

| SUPPLEMENTAL TABLE 6 Participants With Solicited Adverse Events by Maximum Duration After Any Dose | | | | | |
|---|-------------------------------|-------------------------------|-------------------------------|-------------------------------|-------------------------------|
| Solicited Injection-Site AEs | V114, n (%) (n = 1965) | PCV13, n (%) (n = 433) | Solicited Systemic AEs | V114, n (%) (n = 1965) | PCV13, n (%) (n = 433) |
| Erythema | 863 (43.9) | 156 (36.0) | Decreased appetite | 817 (41.6) | 156 (36.0) |
| ≤3 d | 782 (39.8) | 148 (34.2) | ≤3 d | 684 (34.8) | 135 (31.2) |
| >3 d and ≤5 d | 63 (3.2) | 7 (1.6) | >3 d and ≤5 d | 70 (3.6) | 11 (2.5) |
| >5 d and ≤10 d | 17 (0.9) | 1 (0.2) | >5 d and ≤10 d | 50 (2.5) | 5 (1.2) |
| >10 d | 1 (0.1) | 0 (0.0) | >10 d | 13 (0.7) | 5 (1.2) |
| Induration | 497 (25.3) | 111 (25.6) | Irritability | 1472 (74.9) | 300 (69.3) |
| ≤3 d | 314 (16.0) | 70 (16.2) | ≤3 d | 1065 (54.2) | 213 (49.2) |
| >3 d and ≤5 d | 78 (4.0) | 20 (4.6) | >3 d and ≤5 d | 222 (11.3) | 50 (11.5) |
| >5 d and ≤10 d | 71 (3.6) | 16 (3.7) | >5 d and ≤10 d | 136 (6.9) | 30 (6.9) |
| >10 d | 34 (1.7) | 5 (1.2) | >10 d | 49 (2.5) | 7 (1.6) |
| Pain | 843 (42.9) | 158 (36.5) | Somnolence | 1088 (55.4) | 238 (55.0) |
| ≤3 d | 778 (39.6) | 143 (33.0) | ≤3 d | 929 (47.3) | 210 (48.5) |
| >3 d and ≤5 d | 43 (2.2) | 11 (2.5) | >3 d and ≤5 d | 91 (4.6) | 16 (3.7) |
| >5 d and ≤10 d | 20 (1.0) | 4 (0.9) | >5 d and ≤10 d | 50 (2.5) | 10 (2.3) |
| >10 d | 2 (0.1) | 0 (0.0) | >10 d | 18 (0.9) | 2 (0.5) |
| Swelling | 549 (27.9) | 101 (23.3) | Urticaria | 115 (5.9) | 29 (6.7) |
| ≤3 d | 471 (24.0) | 87 (20.1) | ≤3 d | 91 (4.6) | 23 (5.3) |
| >3 d and ≤5 d | 47 (2.4) | 4 (0.9) | >3 d and ≤5 d | 7 (0.4) | 1 (0.2) |
| >5 d and ≤10 d | 27 (1.4) | 9 (2.1) | >5 d and ≤10 d | 13 (0.7) | 4 (0.9) |
| >10 d | 4 (0.2) | 1 (0.2) | >10 d | 4 (0.2) | 1 (0.2) |

| SUPPLEMENTAL TABLE 7 System Organ Classes of Serious AEs After Any PCV Dose | | |
|--|-------------------------------|-------------------------------|
| | V114, n (%) (n = 1965) | PCV13, n (%) (n = 433) |
| With ≥1 serious AEs | 192 (9.8) | 45 (10.4) |
| Blood and lymphatic system disorders | 2 (0.1) | 0 (0.0) |
| Cardiac disorders | 0 (0.0) | 2 (0.5) |
| Congenital, familial, and genetic disorders | 0 (0.0) | 1 (0.2) |
| Gastrointestinal disorders ^a | 12 (0.6) | 1 (0.2) |
| General disorders and administration-site conditions | 8 (0.4) | 1 (0.2) |
| Hepatobiliary disorders | 0 (0.0) | 1 (0.2) |
| Immune system disorders | 1 (0.1) | 0 (0.0) |
| Infections and infestations | 148 (7.5) | 32 (7.4) |
| Injury, poisoning, and procedural complications | 7 (0.4) | 4 (0.9) |
| Metabolism and nutrition disorders | 1 (0.1) | 1 (0.2) |
| Musculoskeletal and connective tissue disorders | 1 (0.1) | 1 (0.2) |
| Neoplasms benign, malignant, and unspecified | 1 (0.1) | 0 (0.0) |
| Nervous system disorders | 8 (0.4) | 2 (0.5) |
| Psychiatric disorders | 1 (0.1) | 0 (0.0) |
| Respiratory, thoracic, and mediastinal disorders | 6 (0.3) | 2 (0.5) |
| Skin and subcutaneous tissue disorders | 3 (0.2) | 0 (0.0) |
| Vascular disorders | 1 (0.1) | 0 (0.0) |

^a The most common gastrointestinal disorders reported were diarrhea, vomiting, and enterocolitis.

| SUPPLEMENTAL TABLE 8 Study Investigator List | |
|---|--|
| Location | Investigator Name (Last, First) |
| United States | Weiner, Leonard B. |
| | Zissman, Edward Neal |
| | Klein, Nicola P. |
| | Chambers, Christopher V. |
| | Cordero, Hector Jesus |
| | Husseman, Michael Patrick |
| | Zomcik, Anne |
| | Amisola, Rogelio |
| | Jeanfreau, Robert J |
| | Yudovich, Martin |
| | Cruz, Marilou Gegare |
| | De La Mora, Oscar Manuel |
| | Duffy, Cheryl A. |
| | Eberhard, Brent K. |
| | Ervin, John E. |
| | Hurley, Donald |
| | Navarro Holguin, Marcela |
| | Pruitt, Anthony Gene |
| | Wald, Ellen R. |
| Finland | Seppa, Ilkka |
| | Karhusaari, Hanna Inkeri |
| | Laajalahti, Outi |
| | Paavola, Pauliina |
| | Kokko, Satu |
| | Sipila, Marjaana |
| | Koski, Susanna |
| | Sirnela-Rif, Elina |
| | Ukkonen, Benita |
| | Ahonen, Anitta |
| Germany | Koellges, Ralph |
| | Petri, Andreas |
| | Westerholt, Soeren |
| | Horn, Michael Rudy |
| | Kaiser, Friedrich Karl |
| | Donner, Matthias |
| | Muehlschlegel, Michael |
| | Adelt, Thomas |
| | Sandner, Bernhard |
| Canada | Bonin, Pierre |
| | Dionne, Marc |
| | Halperin, Scott A. |
| | Rubin, Earl |
| | Sadarangani, Manish |
| | Tapiero, Bruce |
| | Kellner, James |
| | Tytus, Richard |
| Malaysia | Chan, Lee Gaik |
| | Jalaludin, Muhammad Yazid |
| | Hasim, Ruziaton |
| | Toh, Teck Hock |
| | Vengadasalam P |
| | Paranthaman V |
| Thailand | Lapphra, Keswadee |

| SUPPLEMENTAL TABLE 8 Continued | |
|---------------------------------------|--|
| Location | Investigator Name (Last, First) |
| | Puthanakit, Thanyawee |
| | Oberdorfer, Peninnah |
| | Kosalaraksa, Pope |
| | Laoprasopwattana, Kamolwish |
| Taiwan | Chiu, Nan Chang |
| | Chen, Po-Yen |
| | Huang, Li-Min |
| | Chiu, Cheng-Hsun |
| Australia | Richmond, Peter |
| | Buttery, Jim Peter |
| | Marshall, Helen |
| Peru | Campos, Francisco Eduardo |
| | Herrera Acuna, Teobaldo |
| | Ruiz, Carlos |
| Israel | Greenberg, David |
| | Kassis, Imad |