# Clinical trial results:
# A Phase 3, Open-label, Single-Arm Trial to Evaluate the Safety, Tolerability, and Immunogenicity of 2 and 3 Doses of 13-valent Pneumococcal Conjugate Vaccine in Human Immunodeficiency Virus-Infected Subjects 6 Years of Age and Older Who Have Not Been Previously Immunized With Pneumococcal Vaccine

## Summary

| | |
|---|---|
| EudraCT number | 2009-011564-11 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 12 April 2013 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 29 June 2016 |
| First version publication date | 01 August 2015 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | 6115A1-3002-WW |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT00962780 |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | Alias: B1851021 |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | Pfizer Inc. |
| Sponsor organisation address | 235 E 42nd Street, New York, United States, NY 10017 |
| Public contact | Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com |
| Scientific contact | Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com |

Notes:

**Paediatric regulatory details**

| | |
|---|---|
| Is trial part of an agreed paediatric investigation plan (PIP) | Yes |
| EMA paediatric investigation plan number(s) | EMEA-000036-PIP01-07 |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | Yes |

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Final |
| Date of interim/final analysis | 12 September 2013 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 12 April 2013 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

1. To evaluate the immune responses 1 month after 3 doses of 13-valent Pneumococcal Conjugate Vaccine (13vPnC) compared with the immune responses 1 month after 2 doses of 13vPnC as measured by serotype-specific immunoglobulin G (IgG) geometric mean fold rises (GMFRs) in subjects greater than or equal to (>=) 6 years of age.
2. To evaluate the acceptability of the safety profile of 13vPnC as measured by the incidence rates of local reactions, systemic events, and adverse events (AEs).

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 18 March 2010 |
| Long term follow-up planned | Yes |
| Long term follow-up rationale | Safety |
| Long term follow-up duration | 6 Months |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Romania: 16 |
| Country: Number of subjects enrolled | South Africa: 285 |
| Worldwide total number of subjects | 301 |
| EEA total number of subjects | 16 |

Notes:

### Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |

| | |
|---|---|
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 99 |
| Adolescents (12-17 years) | 51 |
| Adults (18-64 years) | 150 |
| From 65 to 84 years | 1 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Study was initiated on 18 March 2010 and completed on 12 April 2013. Subjects were enrolled from 2 countries(Romania and South Africa). Three hundred and three subjects were randomized in study, out of which 301 subjects received the investigational vaccines (2 subjects were withdrawn prior to vaccination for non safety related reasons).

### Period 1

| | |
|---|---|
| Period 1 title | Overall Trial (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | 13vPnC, 23vPS (Pediatric Subjects) |

Arm description:

Subjects older than or equal to [>=] 6 to less than [<] 18 years of age (pediatric subjects) received 3 doses of 13-valent pneumococcal conjugate vaccine (13vPnC) 1 month apart, followed by 1 dose of 23-valent pneumococcal polysaccharide vaccine (23vPS) 1 month after 13vPnC Dose 3 (23vPS Dose).

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | 13-valent pneumococcal conjugate vaccine |
| Investigational medicinal product code | PF-05208760 |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Three doses of 0.5 milliliter (mL) of 13vPnC intramuscularly 1 month apart.

| | |
|---|---|
| Investigational medicinal product name | 23-valent pneumococcal polysaccharide |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

One dose of 0.5 mL of 23vPS intramuscularly 1 month after 13vPnC Dose 3.

| | |
|---|---|
| **Arm title** | 13vPnC, 23vPS (Adult Subjects) |

Arm description:

Subjects >=18 years of age (adult subjects) received 3 doses of 13vPnC 1 month apart, followed by 1 dose of 23vPS 1 month after 13vPnC Dose 3 (23vPS Dose).

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | 13-valent pneumococcal conjugate vaccine |
| Investigational medicinal product code | PF-05208760 |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Three doses of 0.5 mL of 13vPnC intramuscularly 1 month apart.

| | |
|---|---|
| Investigational medicinal product name | 23-valent pneumococcal polysaccharide |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

One dose of 0.5 mL of 23vPS intramuscularly 1 month after 13vPnC Dose 3.

| **Number of subjects in period 1** | 13vPnC, 23vPS (Pediatric Subjects) | 13vPnC, 23vPS (Adult Subjects) |
|---|---|---|
| Started | 150 | 151 |
| Vaccinated 13vPnC Dose 1 | 150 | 151 |
| Vaccinated 13vPnC Dose 2 | 145 | 145 |
| Vaccinated 13vPnC Dose 3 | 144 | 142 |
| Vaccinated 23vPS Dose | 143 | 139 |
| Completed | 141 | 138 |
| Not completed | 9 | 13 |
| Consent withdrawn by subject | 1 | 7 |
| Death | - | 1 |
| Protocol Violation | 8 | 4 |
| Unspecified | - | 1 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | 13vPnC, 23vPS (Pediatric Subjects) |
| Reporting group description: | |
| Subjects older than or equal to [>=] 6 to less than [<] 18 years of age (pediatric subjects) received 3 doses of 13-valent pneumococcal conjugate vaccine (13vPnC) 1 month apart, followed by 1 dose of 23-valent pneumococcal polysaccharide vaccine (23vPS) 1 month after 13vPnC Dose 3 (23vPS Dose). | |
| Reporting group title | 13vPnC, 23vPS (Adult Subjects) |
| Reporting group description: | |
| Subjects >=18 years of age (adult subjects) received 3 doses of 13vPnC 1 month apart, followed by 1 dose of 23vPS 1 month after 13vPnC Dose 3 (23vPS Dose). | |

| Reporting group values | 13vPnC, 23vPS (Pediatric Subjects) | 13vPnC, 23vPS (Adult Subjects) | Total |
|---|---|---|---|
| Number of subjects | 150 | 151 | 301 |
| Age categorical | | | |
| Units: Subjects | | | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 10.3 | 41.2 | |
| standard deviation | ± 3.04 | ± 8.45 | - |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 76 | 88 | 164 |
| Male | 74 | 63 | 137 |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | 13vPnC, 23vPS (Pediatric Subjects) |

Reporting group description:

Subjects older than or equal to [>=] 6 to less than [<] 18 years of age (pediatric subjects) received 3 doses of 13-valent pneumococcal conjugate vaccine (13vPnC) 1 month apart, followed by 1 dose of 23-valent pneumococcal polysaccharide vaccine (23vPS) 1 month after 13vPnC Dose 3 (23vPS Dose).

| | |
|---|---|
| Reporting group title | 13vPnC, 23vPS (Adult Subjects) |

Reporting group description:

Subjects >=18 years of age (adult subjects) received 3 doses of 13vPnC 1 month apart, followed by 1 dose of 23vPS 1 month after 13vPnC Dose 3 (23vPS Dose).

| | |
|---|---|
| Subject analysis set title | 13vPnC, 23vPS (All Subjects) |
| Subject analysis set type | Per protocol |

Subject analysis set description:

Subjects >=6 years of age (all subjects) received 3 doses of 0.5 mL of 13vPnC intramuscularly 1 month apart, followed by 1 dose of 0.5 mL of 23vPS intramuscularly 1 month after 13vPnC Dose 3 (23vPS Dose).

### Primary: Geometric Mean Fold Rise (GMFR) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody From 1 Month After 13vPnC Dose 2 to 1 Month After 13vPnC Dose 3 in All Subjects

| | |
|---|---|
| End point title | Geometric Mean Fold Rise (GMFR) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody From 1 Month After 13vPnC Dose 2 to 1 Month After 13vPnC Dose 3 in All Subjects[1] |

End point description:

GMFR for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) from 1 month after 13vPnC Dose 2 to 1 month after 13vPnC Dose 3 were computed using the logarithmically transformed assay results. Confidence interval (CI) for GMFR were back transformations of a CI based on the Student t distribution for the mean logarithm of the mean fold rise. GMFRs were calculated using all subjects with available data from both 1 month after 13vPnC Dose 2 and after 13vPnC Dose 3 blood draws. Evaluable immunogenicity population: eligible subjects who received vaccination as assigned; had blood drawn within pre-specified time-frames; had at least 1 valid, determinate assay result; had no major protocol violation. Here, n=subjects evaluable for specified serotype.

| | |
|---|---|
| End point type | Primary |

End point timeframe:

1 month after 13vPnC Dose 2, 1 month after 13vPnC Dose 3

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

| End point values | 13vPnC, 23vPS (All Subjects) | | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | | | |
| Number of subjects analysed | 259[2] | | | |
| Units: fold rise | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 1 (n = 248) | 1.03 (1.01 to 1.08) | | | |
| Serotype 3 (n = 238) | 1.05 (0.99 to 1.07) | | | |
| Serotype 4 (n = 257) | 1.09 (1 to 1.1) | | | |
| Serotype 5 (n = 257) | 1.01 (1.03 to 1.14) | | | |

| | | | | |
|---|---|---|---|---|
| Serotype 6A (n = 249) | 1.02 (0.97 to 1.05) | | | |
| Serotype 6B (n = 257) | 1.04 (0.97 to 1.07) | | | |
| Serotype 7F (n = 259) | 1.1 (1.05 to 1.16) | | | |
| Serotype 9V (n = 259) | 1.05 (1.01 to 1.09) | | | |
| Serotype 14 (n = 259) | 1.04 (1 to 1.09) | | | |
| Serotype 18C (n = 259) | 0.99 (0.96 to 1.02) | | | |
| Serotype 19A (n = 259) | 0.99 (0.96 to 1.03) | | | |
| Serotype 19F (n = 252) | 1.06 (1.01 to 1.11) | | | |
| Serotype 23F (n = 258) | 1.09 (1.03 to 1.15) | | | |

Notes:

[2] - N (number of subjects analyzed)= subjects evaluable for this measure.

### Statistical analyses

No statistical analyses for this end point

## Secondary: Geometric Mean Concentration (GMC) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After 13vPnC Dose 3 Relative to 1 Month After 13vPnC Dose 2 in Pediatric, Adult and All Subjects

| | |
|---|---|
| End point title | Geometric Mean Concentration (GMC) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After 13vPnC Dose 3 Relative to 1 Month After 13vPnC Dose 2 in Pediatric, Adult and All Subjects |

End point description:

Antibody GMC for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) for pediatric, adult and all subjects are presented. GMC (13vPnC) and corresponding 2-sided 95 percent (%) CIs were evaluated. Geometric means were calculated using all subjects with available data for both 1 month after 13vPnC Dose 2 and after 13vPnC Dose 3 blood draws. CI for GMC were back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Evaluable immunogenicity population. Here "n" signifies all subjects who were evaluable for specified serotype for each treatment arm, respectively.

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

1 month after 13vPnC Dose 2, 1 month after 13vPnC Dose 3

| **End point values** | 13vPnC, 23vPS (Pediatric Subjects) | 13vPnC, 23vPS (Adult Subjects) | 13vPnC, 23vPS (All Subjects) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 128[3] | 131[4] | 259[5] | |
| Units: microgram per milliliter (mcg/mL) | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 1: 13vPnC Dose 2 (n = 120, 128, 248) | 3.88 (3.3 to 4.57) | 3.95 (3.23 to 4.85) | 3.92 (3.44 to 4.46) | |
| Serotype 1: 13vPnC Dose 3 (n = 120, 128, 248) | 4.14 (3.56 to 4.83) | 3.92 (3.21 to 4.79) | 4.03 (3.55 to 4.57) | |

| | | | | |
|---|---|---|---|---|
| Serotype 3: 13vPnC Dose 2 (n = 118, 120, 238) | 1.47 (1.25 to 1.74) | 0.97 (0.81 to 1.16) | 1.19 (1.05 to 1.35) | |
| Serotype 3: 13vPnC Dose 3 (n = 118, 120, 238) | 1.49 (1.26 to 1.76) | 1.06 (0.88 to 1.27) | 1.25 (1.11 to 1.42) | |
| Serotype 4: 13vPnC Dose 2 (n = 127, 130, 257) | 3.06 (2.54 to 3.69) | 2.97 (2.4 to 3.67) | 3.01 (2.62 to 3.47) | |
| Serotype 4: 13vPnC Dose 3 (n = 127, 130, 257) | 3.36 (2.84 to 3.97) | 3.19 (2.59 to 3.91) | 3.27 (2.87 to 3.73) | |
| Serotype 5: 13vPnC Dose 2 (n = 126, 131, 257) | 4.52 (3.78 to 5.39) | 5.77 (4.83 to 6.89) | 5.12 (4.51 to 5.8) | |
| Serotype 5: 13vPnC Dose 3 (n = 126, 131, 257) | 4.84 (4.12 to 5.7) | 5.53 (4.63 to 6.61) | 5.18 (4.6 to 5.85) | |
| Serotype 6A: 13vPnC Dose 2 (n = 119, 130, 249) | 7.66 (6.46 to 9.08) | 7.03 (5.71 to 8.67) | 7.33 (6.4 to 8.39) | |
| Serotype 6A: 13vPnC Dose 3 (n = 119, 130, 249) | 7.97 (6.81 to 9.33) | 7.04 (5.74 to 8.64) | 7.47 (6.56 to 8.51) | |
| Serotype 6B: 13vPnC Dose 2 (n = 127, 130, 257) | 11.43 (9.45 to 13.84) | 7.93 (6.51 to 9.65) | 9.5 (8.28 to 10.91) | |
| Serotype 6B: 13vPnC Dose 3 (n = 127, 130, 257) | 11.94 (10.01 to 14.24) | 8.28 (6.78 to 10.11) | 9.92 (8.67 to 11.35) | |
| Serotype 7F: 13vPnC Dose 2 (n = 128, 131, 259) | 4.25 (3.67 to 4.92) | 5.78 (4.81 to 6.95) | 4.96 (4.41 to 5.59) | |
| Serotype 7F: 13vPnC Dose 3 (n = 128, 131, 259) | 5.05 (4.38 to 5.82) | 5.9 (4.95 to 7.04) | 5.46 (4.88 to 6.12) | |
| Serotype 9V: 13vPnC Dose 2 (n = 128, 131, 259) | 4.81 (4.18 to 5.54) | 5.14 (4.27 to 6.19) | 4.98 (4.43 to 5.59) | |
| Serotype 9V: 13vPnC Dose 3 (n = 128, 131, 259) | 4.98 (4.35 to 5.7) | 5.48 (4.59 to 6.55) | 5.23 (4.67 to 5.84) | |
| Serotype 14: 13vPnC Dose 2 (n = 128, 131, 259) | 11.6 (8.76 to 15.35) | 15.14 (11.64 to 19.71) | 13.27 (10.96 to 16.08) | |
| Serotype 14: 13vPnC Dose 3 (n = 128, 131, 259) | 12.62 (9.75 to 16.33) | 15.13 (11.8 to 19.4) | 13.83 (11.57 to 16.53) | |
| Serotype 18C: 13vPnC Dose 2 (n = 128, 131, 259) | 3.79 (3.12 to 4.6) | 5.33 (4.34 to 6.54) | 4.5 (3.91 to 5.19) | |
| Serotype 18C: 13vPnC Dose 3 (n = 128, 131, 259) | 3.83 (3.19 to 4.6) | 5.18 (4.27 to 6.28) | 4.46 (3.9 to 5.1) | |
| Serotype 19A: 13vPnC Dose 2 (n = 128, 131, 259) | 14.38 (12.2 to 16.96) | 13.19 (11.06 to 15.75) | 13.77 (12.21 to 15.53) | |
| Serotype 19A: 13vPnC Dose 3 (n = 128, 131, 259) | 14.19 (12.17 to 16.54) | 13.18 (11.11 to 15.62) | 13.67 (12.2 to 15.32) | |
| Serotype 19F: 13vPnC Dose 2 (n = 124, 128, 252) | 5.78 (4.63 to 7.21) | 5.34 (4.17 to 6.84) | 5.55 (4.71 to 6.55) | |
| Serotype 19F: 13vPnC Dose 3 (n = 124, 128, 252) | 6.09 (4.98 to 7.44) | 5.67 (4.47 to 7.18) | 5.87 (5.03 to 6.85) | |
| Serotype 23F: 13vPnC Dose 2 (n = 127, 131, 258) | 6.45 (5.3 to 7.85) | 6.1 (4.86 to 7.66) | 6.27 (5.4 to 7.28) | |
| Serotype 23F: 13vPnC Dose 3 (n = 127, 131, 258) | 6.64 (5.55 to 7.94) | 7.06 (5.65 to 8.82) | 6.85 (5.94 to 7.9) | |

Notes:

[3] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[4] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[5] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

### Statistical analyses

No statistical analyses for this end point

## Secondary: Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMT) 1 Month After 13vPnC Dose 3 Relative to 1 Month After 13vPnC Dose 2 in Pediatric, Adult and All Subjects

| End point title | Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMT) 1 Month After 13vPnC Dose 3 Relative to 1 Month After 13vPnC Dose 2 in Pediatric, Adult and All Subjects |
|---|---|

End point description:

Serotype-specific OPA GMTs for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) were determined in the blood samples of pediatric, adult and all subjects using a microcolony OPA (mcOPA) assay. GMT (13vPnC) and corresponding 2-sided 95% CIs were evaluated. Geometric means were calculated using all subjects with available data for both 1 month after 13vPnC Dose 2 and after 13vPnC Dose 3 blood draws. CI for GMT were back transformations of a CI based on the Student t distribution for the mean logarithm of the titers. Evaluable immunogenicity population. Here "n" signifies subjects with valid and determinate assay results for specified serotype at both 1 month after 13vPnC Dose 2 and after 13vPnC Dose 3 blood draws for each treatment arm, respectively.

| End point type | Secondary |
|---|---|

End point timeframe:

1 month after 13vPnC Dose 2, 1 month after 13vPnC Dose 3

| **End point values** | 13vPnC, 23vPS (Pediatric Subjects) | 13vPnC, 23vPS (Adult Subjects) | 13vPnC, 23vPS (All Subjects) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 127[6] | 129[7] | 256[8] | |
| Units: titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 1: 13vPnC Dose 2 (n = 126, 127, 253) | 51 (37.2 to 70) | 54 (38.7 to 74.2) | 52 (41.8 to 65.5) | |
| Serotype 1: 13vPnC Dose 3 (n = 126, 127, 253) | 69 (51.6 to 91.4) | 69 (51.3 to 92) | 69 (56.1 to 84.1) | |
| Serotype 3: 13vPnC Dose 2 (n = 127, 129, 256) | 81 (64.1 to 102) | 48 (37.9 to 61.5) | 62 (52.6 to 73.9) | |
| Serotype 3: 13vPnC Dose 3 (n = 127, 129, 256) | 114 (94.5 to 137.8) | 79 (62.1 to 99.9) | 95 (81.3 to 110.3) | |
| Serotype 4: 13vPnC Dose 2 (n = 117, 126, 243) | 2509 (1922.3 to 3274.2) | 1620 (1211.2 to 2167.4) | 2000 (1639.8 to 2439.1) | |
| Serotype 4: 13vPnC Dose 3 (n = 117, 126, 243) | 3246 (2697.1 to 3906.3) | 1944 (1465.3 to 2579.7) | 2488 (2092.1 to 2959.8) | |
| Serotype 5: 13vPnC Dose 2 (n = 122, 124, 246) | 159 (109.2 to 232.2) | 104 (69.1 to 156.9) | 129 (97.3 to 169.7) | |
| Serotype 5: 13vPnC Dose 3 (n = 122, 124, 246) | 267 (191.3 to 371.5) | 142 (97.5 to 206.7) | 194 (150.8 to 249.7) | |
| Serotype 6A: 13vPnC Dose 2 (n = 125, 124, 249) | 5560 (4378.4 to 7060.9) | 2425 (1790.7 to 3284.5) | 3678 (3016.2 to 4485.6) | |
| Serotype 6A: 13vPnC Dose 3 (n = 125, 124, 249) | 7758 (6314.2 to 9531.2) | 3239 (2488.5 to 4215.9) | 5022 (4216.8 to 5979.9) | |
| Serotype 6B: 13vPnC Dose 2 (n = 121, 128, 249) | 5449 (4365.1 to 6801.1) | 2724 (2004.8 to 3701) | 3815 (3140.9 to 4634.1) | |
| Serotype 6B: 13vPnC Dose 3 (n = 121, 128, 249) | 7151 (5828.2 to 8773.9) | 3723 (2771.1 to 5002.5) | 5113 (4250.1 to 6150.5) | |
| Serotype 7F: 13vPnC Dose 2 (n = 125, 127, 252) | 3494 (2772.8 to 4403.3) | 2255 (1739.6 to 2923.6) | 2802 (2352.6 to 3338) | |
| Serotype 7F: 13vPnC Dose 3 (n = 125, 127, 252) | 4638 (3889.7 to 5529.4) | 2702 (2130.3 to 3428.2) | 3533 (3037.4 to 4108.5) | |
| Serotype 9V: 13vPnC Dose 2 (n = 118, 127, 245) | 3339 (2461.4 to 4530.3) | 1432 (998.6 to 2054.9) | 2153 (1690.3 to 2743.3) | |

| | | | | |
|---|---|---|---|---|
| Serotype 9V: 13vPnC Dose 3 (n = 118, 127, 245) | 4714 (3731.5 to 5955.4) | 2004 (1416.5 to 2836.1) | 3026 (2434.3 to 3761.4) | |
| Serotype 14: 13vPnC Dose 2 (n = 117, 127, 244) | 3704 (2906.5 to 4719.5) | 1342 (1010.1 to 1782.1) | 2183 (1792.2 to 2659.6) | |
| Serotype 14: 13vPnC Dose 3 (n = 117, 127, 244) | 3963 (3195.8 to 4914.2) | 1480 (1150.3 to 1903.9) | 2373 (1988.4 to 2832.8) | |
| Serotype 18C: 13vPnC Dose 2 (n = 117, 121, 238) | 4635 (3609.7 to 5951.8) | 1349 (947 to 1921.5) | 2475 (1965.7 to 3115.4) | |
| Serotype 18C: 13vPnC Dose 3 (n = 117, 121, 238) | 5579 (4423.7 to 7036.9) | 1787 (1272.8 to 2508.5) | 3127 (2515.2 to 3888.6) | |
| Serotype 19A: 13vPnC Dose 2 (n = 125, 127, 252) | 684 (519.2 to 902.1) | 458 (332.5 to 631.2) | 559 (452.3 to 690.9) | |
| Serotype 19A: 13vPnC Dose 3 (n = 125, 127, 252) | 1002 (814.5 to 1232.3) | 613 (465.6 to 806.4) | 782 (657.2 to 930.5) | |
| Serotype 19F: 13vPnC Dose 2 (n = 122, 118, 240) | 717 (495.6 to 1036.7) | 315 (196.7 to 506) | 479 (354.4 to 646.9) | |
| Serotype 19F: 13vPnC Dose 3 (n = 122, 118, 240) | 1152 (864.2 to 1535) | 597 (397.9 to 897.1) | 834 (650.1 to 1070.2) | |
| Serotype 23F: 13vPnC Dose 2 (n = 120, 126, 246) | 1477 (1086.2 to 2008.2) | 409 (271.9 to 614) | 765 (585.2 to 999.4) | |
| Serotype 23F: 13vPnC Dose 3 (n = 120, 126, 246) | 2327 (1844.2 to 2935.9) | 671 (449.8 to 1000.3) | 1231 (963 to 1572.5) | |

Notes:

[6] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[7] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[8] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

## Statistical analyses

No statistical analyses for this end point

## Secondary: Geometric Mean Fold Rise (GMFR) for Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) From 1 Month After 13vPnC Dose 2 to 1 Month After 13vPnC Dose 3 in Pediatric, Adult and All Subjects

| | |
|---|---|
| End point title | Geometric Mean Fold Rise (GMFR) for Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) From 1 Month After 13vPnC Dose 2 to 1 Month After 13vPnC Dose 3 in Pediatric, Adult and All Subjects |

End point description:

GMFR for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) from 1 month after 13vPnC Dose 2 to 1 month after 13vPnC Dose 3 were computed using the logarithmically transformed assay results. CI for GMFR were back transformations of a CI based on the Student t distribution for the mean logarithm of the mean fold rise. GMFRs were calculated using all subjects with available data from both 1 month after 13vPnC Dose 2 and after 13vPnC Dose 3 blood draws. Evaluable immunogenicity population. Here "n" signifies subjects with valid and determinate assay results for specified serotype at both 1 month after 13vPnC Dose 2 and after 13vPnC Dose 3 blood draws for each treatment arm, respectively.

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

1 month after 13vPnC Dose 2, 1 month after 13vPnC Dose 3

| End point values | 13vPnC, 23vPS (Pediatric Subjects) | 13vPnC, 23vPS (Adult Subjects) | 13vPnC, 23vPS (All Subjects) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 127[9] | 129[10] | 256[11] | |
| Units: fold rise | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 1 (n = 126, 127, 253) | 1.3 (1.13 to 1.61) | 1.3 (1.09 to 1.51) | 1.3 (1.16 to 1.48) | |
| Serotype 3 (n = 127, 129, 256) | 1.4 (1.25 to 1.59) | 1.6 (1.45 to 1.83) | 1.5 (1.4 to 1.65) | |
| Serotype 4 (n = 117, 126, 243) | 1.3 (1.1 to 1.52) | 1.2 (1.07 to 1.34) | 1.2 (1.13 to 1.37) | |
| Serotype 5 (n = 122, 124, 246) | 1.7 (1.36 to 2.06) | 1.4 (1.17 to 1.59) | 1.5 (1.33 to 1.72) | |
| Serotype 6A (n = 125, 124, 249) | 1.4 (1.22 to 1.6) | 1.3 (1.15 to 1.55) | 1.4 (1.23 to 1.51) | |
| Serotype 6B (n = 121, 128, 249) | 1.3 (1.18 to 1.46) | 1.4 (1.2 to 1.56) | 1.3 (1.23 to 1.46) | |
| Serotype 7F (n = 125, 127, 252) | 1.3 (1.15 to 1.53) | 1.2 (1.03 to 1.4) | 1.3 (1.14 to 1.4) | |
| Serotype 9V (n = 118, 127, 245) | 1.4 (1.16 to 1.72) | 1.4 (1.18 to 1.65) | 1.4 (1.24 to 1.6) | |
| Serotype 14 (n = 117, 127, 244) | 1.1 (0.95 to 1.2) | 1.1 (0.98 to 1.24) | 1.1 (1 to 1.18) | |
| Serotype 18C (n = 117, 121, 238) | 1.2 (1.1 to 1.32) | 1.3 (1.08 to 1.63) | 1.3 (1.13 to 1.42) | |
| Serotype 19A (n = 125, 127, 252) | 1.5 (1.27 to 1.68) | 1.3 (1.18 to 1.52) | 1.4 (1.27 to 1.54) | |
| Serotype 19F (n = 122, 118, 240) | 1.6 (1.31 to 1.97) | 1.9 (1.45 to 2.48) | 1.7 (1.48 to 2.06) | |
| Serotype 23F (n = 120, 126, 246) | 1.6 (1.31 to 1.9) | 1.6 (1.34 to 2.02) | 1.6 (1.4 to 1.85) | |

Notes:

[9] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[10] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[11] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

### Statistical analyses

No statistical analyses for this end point

## Secondary: Geometric Mean Fold Rise (GMFR) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody From 1 Month After 13vPnC Dose 2 to 1 Month After 13vPnC Dose 3 in Pediatric and Adult Subjects

| End point title | Geometric Mean Fold Rise (GMFR) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody From 1 Month After 13vPnC Dose 2 to 1 Month After 13vPnC Dose 3 in Pediatric and Adult Subjects |
|---|---|

End point description:

GMFR for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) from 1 month after 13vPnC Dose 2 to 1 month after 13vPnC Dose 3 were computed using the logarithmically transformed assay results. CI for GMFR were back transformations of a CI based on the Student t distribution for the mean logarithm of the mean fold rise. GMFRs were calculated using all subjects with available data from both 1 month after 13vPnC Dose 2 and after 13vPnC Dose 3 blood draws. Evaluable immunogenicity population. Here "n" signifies subjects with valid and determinate assay results for specified serotype at both 1 month after 13vPnC Dose 2 and after 13vPnC Dose 3 blood draws for each treatment arm, respectively.

| End point type | Secondary |
|---|---|

End point timeframe:

1 month after 13vPnC Dose 2, 1 month after 13vPnC Dose 3

| End point values | 13vPnC, 23vPS (Pediatric Subjects) | 13vPnC, 23vPS (Adult Subjects) | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 128[12] | 131[13] | | |
| Units: fold rise | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 1 (n = 120, 128) | 1.07 (1.01 to 1.13) | 0.99 (0.93 to 1.06) | | |
| Serotype 3 (n = 118, 120) | 1.01 (0.95 to 1.08) | 1.09 (1.02 to 1.16) | | |
| Serotype 4 (n = 127, 130) | 1.1 (1.02 to 1.18) | 1.07 (1 to 1.16) | | |
| Serotype 5 (n = 126, 131) | 1.07 (1.01 to 1.14) | 0.96 (0.91 to 1.01) | | |
| Serotype 6A (n = 119, 130) | 1.04 (0.96 to 1.12) | 1 (0.95 to 1.06) | | |
| Serotype 6B (n = 127, 130) | 1.04 (0.99 to 1.1) | 1.04 (0.99 to 1.11) | | |
| Serotype 7F (n = 128, 131) | 1.19 (1.12 to 1.27) | 1.02 (0.95 to 1.1) | | |
| Serotype 9V (n = 128, 131) | 1.03 (0.98 to 1.09) | 1.07 (1.02 to 1.12) | | |
| Serotype 14 (n = 128, 131) | 1.09 (1.02 to 1.16) | 1 (0.95 to 1.05) | | |
| Serotype 18C (n = 128, 131) | 1.01 (0.96 to 1.07) | 0.97 (0.93 to 1.01) | | |
| Serotype 19A (n = 128, 131) | 0.99 (0.93 to 1.04) | 1 (0.96 to 1.04) | | |
| Serotype 19F (n = 124, 128) | 1.05 (0.98 to 1.13) | 1.06 (0.99 to 1.14) | | |
| Serotype 23F (n = 127, 131) | 1.03 (0.96 to 1.11) | 1.16 (1.07 to 1.26) | | |

Notes:

[12] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[13] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

### Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Geometric Mean Concentration (GMC) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody Before and 1 Month After 13vPnC Dose 1 in Pediatric, Adult and All Subjects

| End point title | Geometric Mean Concentration (GMC) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody Before and 1 Month After 13vPnC Dose 1 in Pediatric, Adult and All Subjects |
|---|---|

End point description:

Antibody GMC for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) for pediatric, adult and all subjects are presented. GMC (13vPnC) and corresponding 2-sided 95% CIs were evaluated. Geometric means were calculated using all subjects with available data for both the before and after 13vPnC Dose 1 blood draws. CI for GMC were back transformations of a CI based on

the Student t distribution for the mean logarithm of the concentrations. Evaluable immunogenicity population. Here "n" signifies subjects with valid and determinate assay results for specified serotype at both the before and 1 month after 13vPnC Dose 1 blood draws for each treatment arm, respectively.

| End point type | Other pre-specified |
|---|---|

End point timeframe:

Before 13vPnC Dose 1, 1 month after 13vPnC Dose 1

| **End point values** | 13vPnC, 23vPS (Pediatric Subjects) | 13vPnC, 23vPS (Adult Subjects) | 13vPnC, 23vPS (All Subjects) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 133[14] | 137[15] | 270[16] | |
| Units: mcg/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 1: Before 13vPnC Dose 1 (n=78,122,200) | 1.03 (0.72 to 1.48) | 0.82 (0.63 to 1.06) | 0.9 (0.73 to 1.1) | |
| Serotype 1: After 13vPnC Dose 1 (n=78,122,200) | 3.78 (2.97 to 4.8) | 4 (3.19 to 5.01) | 3.91 (3.32 to 4.61) | |
| Serotype 3: Before 13vPnC Dose 1 (n=99,127,226) | 0.83 (0.62 to 1.11) | 0.47 (0.37 to 0.58) | 0.6 (0.5 to 0.72) | |
| Serotype 3: After 13vPnC Dose 1 (n=99,127,226) | 1.25 (0.99 to 1.58) | 0.75 (0.62 to 0.92) | 0.94 (0.81 to 1.09) | |
| Serotype 4: Before 13vPnC Dose 1 (n=95,127,222) | 0.19 (0.14 to 0.25) | 0.35 (0.28 to 0.45) | 0.27 (0.22 to 0.33) | |
| Serotype 4: After 13vPnC Dose 1 (n=95,127,222) | 2.62 (1.97 to 3.5) | 2.91 (2.26 to 3.75) | 2.79 (2.31 to 3.36) | |
| Serotype 5: Before 13vPnC Dose 1 (n=122,137,259) | 4.18 (3.42 to 5.12) | 3.38 (2.84 to 4.02) | 3.74 (3.28 to 4.27) | |
| Serotype 5: After 13vPnC Dose 1 (n=122,137,259) | 4.81 (3.98 to 5.8) | 5.53 (4.63 to 6.61) | 5.18 (4.55 to 5.89) | |
| Serotype 6A: Before 13vPnC Dose 1 (n=99,136,235) | 6.22 (5.19 to 7.45) | 2.67 (2.24 to 3.18) | 3.81 (3.32 to 4.37) | |
| Serotype 6A: After 13vPnC Dose 1 (n=99,136,235) | 7.31 (6.07 to 8.79) | 6.77 (5.38 to 8.51) | 6.99 (6 to 8.15) | |
| Serotype 6B: Before 13vPnC Dose 1 (n=131,134,265) | 5.52 (4.59 to 6.64) | 3.23 (2.69 to 3.88) | 4.21 (3.69 to 4.81) | |
| Serotype 6B: After 13vPnC Dose 1 (n=131,134,265) | 10.26 (8.37 to 12.58) | 7.29 (5.81 to 9.15) | 8.63 (7.41 to 10.06) | |
| Serotype 7F: Before 13vPnC Dose 1 (n=111,134,245) | 0.85 (0.63 to 1.14) | 1.14 (0.94 to 1.37) | 1 (0.84 to 1.18) | |
| Serotype 7F: After 13vPnC Dose 1 (n=111,134,245) | 4.34 (3.68 to 5.11) | 5.57 (4.57 to 6.78) | 4.97 (4.36 to 5.67) | |
| Serotype 9V: Before 13vPnC Dose 1 (n=129,137,266) | 2.1 (1.74 to 2.54) | 1.56 (1.3 to 1.86) | 1.8 (1.58 to 2.05) | |
| Serotype 9V: After 13vPnC Dose 1 (n=129,137,266) | 4.77 (4.08 to 5.57) | 5.16 (4.24 to 6.27) | 4.97 (4.38 to 5.63) | |
| Serotype 14: Before 13vPnC Dose 1 (n=113,136,249) | 0.76 (0.57 to 1.03) | 2.45 (1.94 to 3.09) | 1.44 (1.18 to 1.76) | |
| Serotype 14: After 13vPnC Dose 1 (n=113,136,249) | 12.04 (8.48 to 17.1) | 16.46 (12.38 to 21.9) | 14.28 (11.44 to 17.84) | |
| Serotype 18C: Before 13vPnC Dose 1 (n=127,134,261) | 0.66 (0.52 to 0.85) | 0.85 (0.69 to 1.04) | 0.75 (0.64 to 0.88) | |
| Serotype 18C: After 13vPnC Dose 1 (n=127,134,261) | 3.92 (3.14 to 4.91) | 5.55 (4.51 to 6.84) | 4.69 (4.02 to 5.46) | |
| Serotype 19A: Before 13vPnC Dose 1 (n=133,137,270) | 7.51 (6.34 to 8.9) | 4.78 (4.04 to 5.66) | 5.97 (5.29 to 6.74) | |

| | | | | |
|---|---|---|---|---|
| Serotype 19A: After 13vPnC Dose 1 (n=133,137,270) | 13.28 (11.11 to 15.87) | 13.03 (10.75 to 15.8) | 13.15 (11.54 to 14.99) | |
| Serotype 19F: Before 13vPnC Dose 1 (n=93,126,219) | 1.36 (1.06 to 1.75) | 1.36 (1.07 to 1.73) | 1.36 (1.14 to 1.62) | |
| Serotype 19F: After 13vPnC Dose 1 (n=93,126,219) | 4.62 (3.55 to 6.02) | 4.98 (3.74 to 6.62) | 4.82 (3.96 to 5.88) | |
| Serotype 23F: Before 13vPnC Dose 1 (n=126,137,263) | 2.29 (1.83 to 2.86) | 1.61 (1.31 to 1.96) | 1.9 (1.64 to 2.21) | |
| Serotype 23F: After 13vPnC Dose 1 (n=126,137,263) | 5.65 (4.66 to 6.86) | 5.3 (4.16 to 6.75) | 5.47 (4.68 to 6.39) | |

Notes:

[14] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[15] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[16] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

### Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Geometric Mean Fold Rise (GMFR) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody From Before 13vPnC Dose 1 to 1 Month After 13vPnC Dose 1 in Pediatric, Adult and All Subjects

| | |
|---|---|
| End point title | Geometric Mean Fold Rise (GMFR) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody From Before 13vPnC Dose 1 to 1 Month After 13vPnC Dose 1 in Pediatric, Adult and All Subjects |

End point description:

GMFR for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) from before 13vPnC Dose 1 to 1 month after 13vPnC Dose 1 were computed using the logarithmically transformed assay results. CI for GMFR were back transformations of a CI based on the Student t distribution for the mean logarithm of the mean fold rise. GMFRs were calculated using all subjects with available data from both before 13vPnC Dose and after 13vPnC Dose 1 blood draws. Evaluable immunogenicity population. Here "n" signifies subjects with valid and determinate assay results for specified serotype at both the before and 1 month after 13vPnC Dose 1 blood draws for each treatment arm, respectively.

| | |
|---|---|
| End point type | Other pre-specified |

End point timeframe:

Before 13vPnC Dose 1, 1 month after 13vPnC Dose 1

| End point values | 13vPnC, 23vPS (Pediatric Subjects) | 13vPnC, 23vPS (Adult Subjects) | 13vPnC, 23vPS (All Subjects) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 133[17] | 137[18] | 270[19] | |
| Units: fold rise | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 1 (n = 78, 122, 200) | 3.67 (2.7 to 4.99) | 4.88 (3.87 to 6.15) | 4.37 (3.63 to 5.25) | |
| Serotype 3 (n = 99, 127, 226) | 1.51 (1.27 to 1.79) | 1.62 (1.43 to 1.83) | 1.57 (1.42 to 1.74) | |
| Serotype 4 (n = 95, 127, 222) | 14.02 (10.55 to 18.62) | 8.29 (6.55 to 10.49) | 10.38 (8.64 to 12.47) | |
| Serotype 5 (n = 122, 137, 259) | 1.15 (1.06 to 1.25) | 1.64 (1.44 to 1.85) | 1.38 (1.28 to 1.5) | |

| | | | | |
|---|---|---|---|---|
| Serotype 6A (n = 99, 136, 235) | 1.18 (1.02 to 1.35) | 2.54 (2.09 to 3.07) | 1.83 (1.6 to 2.1) | |
| Serotype 6B (n = 131, 134, 265) | 1.86 (1.55 to 2.22) | 2.26 (1.87 to 2.72) | 2.05 (1.8 to 2.33) | |
| Serotype 7F (n = 111, 134, 245) | 5.11 (3.92 to 6.65) | 4.9 (3.99 to 6.03) | 4.99 (4.24 to 5.88) | |
| Serotype 9V (n = 129, 137, 266) | 2.27 (1.97 to 2.61) | 3.32 (2.76 to 3.99) | 2.76 (2.45 to 3.1) | |
| Serotype 14 (n = 113, 136, 249) | 15.79 (11.84 to 21.05) | 6.73 (5.17 to 8.76) | 9.91 (8.11 to 12.11) | |
| Serotype 18C (n = 127, 134, 261) | 5.92 (4.64 to 7.55) | 6.55 (5.23 to 8.2) | 6.23 (5.29 to 7.35) | |
| Serotype 19A (n = 133, 137, 270) | 1.77 (1.55 to 2.02) | 2.73 (2.31 to 3.21) | 2.2 (1.98 to 2.45) | |
| Serotype 19F (n = 93, 126, 219) | 3.39 (2.71 to 4.25) | 3.66 (2.96 to 4.52) | 3.54 (3.04 to 4.13) | |
| Serotype 23F (n = 126, 137, 263) | 2.47 (2.02 to 3.02) | 3.3 (2.71 to 4.03) | 2.87 (2.49 to 3.31) | |

Notes:

[17] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[18] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[19] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

### Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMT) Before and 1 Month After 13vPnC Dose 1 in Pediatric, Adult and All Subjects

| | |
|---|---|
| End point title | Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMT) Before and 1 Month After 13vPnC Dose 1 in Pediatric, Adult and All Subjects |

End point description:

Serotype-specific OPA GMTs for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) were determined in the blood samples of pediatric, adult and all subjects using a microcolony OPA (mcOPA) assay. GMT (13vPnC) and corresponding 2-sided 95% CIs were evaluated. Geometric means were calculated using all subjects with available data for both the before and after 13vPnC Dose 1 blood draws. CI for GMT were back transformations of a CI based on the Student t distribution for the mean logarithm of the titers. Evaluable immunogenicity population. Here "n" signifies subjects with valid and determinate assay results for specified serotype at both the before and 1 month after 13vPnC Dose 1 blood draws for each treatment arm, respectively.

| | |
|---|---|
| End point type | Other pre-specified |

End point timeframe:

Before 13vPnC Dose 1, 1 month after 13vPnC Dose 1

| **End point values** | 13vPnC, 23vPS (Pediatric Subjects) | 13vPnC, 23vPS (Adult Subjects) | 13vPnC, 23vPS (All Subjects) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 129[20] | 128[21] | 257[22] | |
| Units: titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 1: Before 13vPnC Dose 1 (n=129,127,256) | 5 (4.3 to 5.8) | 5 (4.3 to 5.2) | 5 (4.4 to 5.3) | |

| | | | | |
|---|---|---|---|---|
| Serotype 1: After 13vPnC Dose 1 (n=129,127,256) | 49 (35.3 to 68.1) | 57 (41.6 to 79.3) | 53 (42.2 to 66.7) | |
| Serotype 3: Before 13vPnC Dose 1 (n=126,128,254) | 8 (6.6 to 10.8) | 5 (4.5 to 5.8) | 7 (5.7 to 7.5) | |
| Serotype 3: After 13vPnC Dose 1 (n=126,128,254) | 41 (31.7 to 52.6) | 21 (16.3 to 27.1) | 29 (24.3 to 35.1) | |
| Serotype 4: Before 13vPnC Dose 1 (n=108,119,227) | 25 (15.2 to 41.7) | 27 (17 to 42.1) | 26 (18.6 to 36.3) | |
| Serotype 4: After 13vPnC Dose 1 (n=108,119,227) | 2247 (1611.9 to 3131.4) | 1372 (958.8 to 1963.7) | 1735 (1356.9 to 2218.3) | |
| Serotype 5: Before 13vPnC Dose 1 (n=125,122,247) | 5 (4.5 to 6.7) | 6 (4.8 to 6.8) | 6 (4.9 to 6.4) | |
| Serotype 5: After 13vPnC Dose 1 (n=125,122,247) | 79 (52.5 to 118) | 123 (81.8 to 186.3) | 98 (73.7 to 131.1) | |
| Serotype 6A: Before 13vPnC Dose 1 (n=99,98,197) | 157 (84.4 to 292.5) | 61 (35.1 to 106.8) | 98 (64.6 to 149.4) | |
| Serotype 6A: After 13vPnC Dose 1 (n=99,98,197) | 3480 (2460.1 to 4921.8) | 1543 (984.4 to 2418.5) | 2322 (1743.1 to 3092.9) | |
| Serotype 6B: Before 13vPnC Dose 1 (n=101,120,221) | 279 (155.5 to 501.1) | 231 (143.4 to 372.5) | 252 (174.1 to 364.6) | |
| Serotype 6B: After 13vPnC Dose 1 (n=101,120,221) | 3852 (2888.3 to 5137.8) | 2099 (1455.6 to 3028.2) | 2771 (2179.2 to 3522.5) | |
| Serotype 7F: Before 13vPnC Dose 1 (n=110,113,223) | 416 (253.5 to 682.9) | 38 (22.9 to 64.6) | 124 (84.3 to 183.8) | |
| Serotype 7F: After 13vPnC Dose 1 (n=110,113,223) | 3775 (3019.4 to 4720.1) | 2005 (1443.9 to 2783.1) | 2739 (2237.5 to 3353.5) | |
| Serotype 9V: Before 13vPnC Dose 1 (n=109,117,226) | 152 (87.2 to 266.2) | 69 (40.7 to 117.2) | 101 (68.8 to 148.6) | |
| Serotype 9V: After 13vPnC Dose 1 (n=109,117,226) | 2533 (1822.7 to 3520.3) | 1231 (836.1 to 1812.2) | 1743 (1347 to 2256.4) | |
| Serotype 14: Before 13vPnC Dose 1 (n=107,126,233) | 328 (201.4 to 535.5) | 123 (79.6 to 191.4) | 193 (139 to 269.2) | |
| Serotype 14: After 13vPnC Dose 1 (n=107,126,233) | 3571 (2772.2 to 4600.1) | 1277 (944.9 to 1725.8) | 2048 (1660.8 to 2524.9) | |
| Serotype 18C: Before 13vPnC Dose 1 (n=95,120,215) | 42 (21.9 to 79) | 25 (15.5 to 39.6) | 31 (21.2 to 45.8) | |
| Serotype 18C: After 13vPnC Dose 1 (n=95,120,215) | 2821 (1891.1 to 4208.9) | 1031 (671.3 to 1584.6) | 1609 (1188.2 to 2178.5) | |
| Serotype 19A: Before 13vPnC Dose 1 (n=129,128,257) | 28 (19.1 to 40.8) | 23 (16.7 to 32.7) | 26 (19.9 to 32.9) | |
| Serotype 19A: After 13vPnC Dose 1 (n=129,128,257) | 506 (381.9 to 671.7) | 390 (275.2 to 552.8) | 445 (355.7 to 555.9) | |
| Serotype 19F: Before 13vPnC Dose 1 (n=123,123,246) | 11 (7.6 to 15.5) | 14 (9.5 to 20.1) | 12 (9.5 to 15.8) | |
| Serotype 19F: After 13vPnC Dose 1 (n=123,123,246) | 425 (285.3 to 632.5) | 214 (130.4 to 352.3) | 302 (219.3 to 415.2) | |
| Serotype 23F: Before 13vPnC Dose 1 (n=118,125,243) | 14 (9.3 to 22) | 7 (5.3 to 9) | 10 (7.6 to 12.7) | |
| Serotype 23F: After 13vPnC Dose 1 (n=118,125,243) | 587 (379.3 to 907.7) | 140 (86.6 to 227.6) | 281 (200.8 to 393.7) | |

Notes:

[20] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[21] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[22] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

## Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Geometric Mean Fold Rise (GMFR) for Serotype-Specific

## Pneumococcal Opsonophagocytic Activity (OPA) From Before 13vPnC Dose 1 to 1 Month After 13vPnC Dose 1 in Pediatric, Adult and All Subjects

| End point title | Geometric Mean Fold Rise (GMFR) for Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) From Before 13vPnC Dose 1 to 1 Month After 13vPnC Dose 1 in Pediatric, Adult and All Subjects |
|---|---|

End point description:

GMFR for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) from before 13vPnC Dose 1 to 1 month after 13vPnC Dose 1 were computed using the logarithmically transformed assay results. CI for GMFR were back transformations of a CI based on the Student t distribution for the mean logarithm of the mean fold rise. GMFRs were calculated using all subjects with available data from both before 13vPnC Dose and after 13vPnC Dose 1 blood draws. Evaluable immunogenicity population. Here "n" signifies subjects with valid and determinate assay results for specified serotype at both the before and 1 month after 13vPnC Dose 1 blood draws for each treatment arm, respectively.

| End point type | Other pre-specified |
|---|---|

End point timeframe:

Before 13vPnC Dose 1, 1 month after 13vPnC Dose 1

| **End point values** | 13vPnC, 23vPS (Pediatric Subjects) | 13vPnC, 23vPS (Adult Subjects) | 13vPnC, 23vPS (All Subjects) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 129[23] | 128[24] | 257[25] | |
| Units: fold rise | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 1 (n = 129, 127, 256) | 9.8 (6.97 to 13.81) | 12.2 (8.84 to 16.84) | 10.9 (8.65 to 13.81) | |
| Serotype 3 (n = 126, 128, 254) | 4.8 (3.72 to 6.3) | 4.1 (3.22 to 5.3) | 4.5 (3.73 to 5.35) | |
| Serotype 4 (n = 108, 119, 227) | 89.4 (51.43 to 155.31) | 51.3 (31.16 to 84.59) | 66.8 (46.17 to 96.75) | |
| Serotype 5 (n = 125, 122, 247) | 14.4 (9.56 to 21.67) | 21.7 (14.55 to 32.32) | 17.6 (13.25 to 23.44) | |
| Serotype 6A (n = 99, 98, 197) | 22.2 (12.61 to 38.9) | 25.2 (14.51 to 43.83) | 23.6 (15.98 to 34.94) | |
| Serotype 6B (n = 101, 120, 221) | 13.8 (8.12 to 23.45) | 9.1 (5.91 to 13.95) | 11 (7.87 to 15.37) | |
| Serotype 7F (n = 110, 113, 223) | 9.1 (5.79 to 14.23) | 52.2 (31.42 to 86.57) | 22 (15.42 to 31.42) | |
| Serotype 9V (n = 109, 117, 226) | 16.6 (9.71 to 28.47) | 17.8 (10.53 to 30.18) | 17.2 (11.87 to 25.04) | |
| Serotype 14 (n = 107, 126, 233) | 10.9 (6.79 to 17.41) | 10.3 (6.82 to 15.7) | 10.6 (7.76 to 14.44) | |
| Serotype 18C (n = 95, 120, 215) | 67.9 (35.25 to 130.73) | 41.6 (24.59 to 70.26) | 51.6 (34.27 to 77.78) | |
| Serotype 19A (n = 129, 128, 257) | 18.1 (12.52 to 26.25) | 16.7 (11.78 to 23.61) | 17.4 (13.51 to 22.38) | |
| Serotype 19F (n = 123, 123, 246) | 39 (24.56 to 62.05) | 15.5 (9.77 to 24.65) | 24.6 (17.69 to 34.25) | |
| Serotype 23F (n = 118, 125, 243) | 41.1 (24.94 to 67.81) | 20.2 (12.78 to 32.05) | 28.6 (20.34 to 40.1) | |

Notes:

[23] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[24] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[25] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

## Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Geometric Mean Concentration (GMC) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After 13vPnC Dose 3 and 1 Month After 23vPS Dose in Pediatric, Adult and All Subjects

| End point title | Geometric Mean Concentration (GMC) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After 13vPnC Dose 3 and 1 Month After 23vPS Dose in Pediatric, Adult and All Subjects |
|---|---|

End point description:

Antibody GMC for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) for pediatric, adult and all subjects are presented. GMC (13vPnC) and corresponding 2-sided 95% CIs were evaluated. Geometric means were calculated using all subjects with available data for both after 13vPnC Dose 3 and after 23vPS Dose blood draws. CI for GMC were back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Evaluable immunogenicity population. Here "n" signifies subjects with valid and determinate assay results for specified serotype at both 1 month after 13vPnC Dose 3 and after 23vPS Dose blood draws for each treatment arm, respectively.

| End point type | Other pre-specified |
|---|---|

End point timeframe:

1 month after 13vPnC Dose 3, 1 month after 23vPS Dose

| **End point values** | 13vPnC, 23vPS (Pediatric Subjects) | 13vPnC, 23vPS (Adult Subjects) | 13vPnC, 23vPS (All Subjects) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 133[26] | 130[27] | 263[28] | |
| Units: mcg/mL | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 1: After 13vPnC Dose 3 (n=128,127,255) | 4.08 (3.53 to 4.73) | 3.94 (3.22 to 4.82) | 4.01 (3.54 to 4.54) | |
| Serotype 1: After 23vPS Dose (n=128,127,255) | 4.42 (3.8 to 5.14) | 4.02 (3.32 to 4.85) | 4.21 (3.74 to 4.75) | |
| Serotype 3: After 13vPnC Dose 3 (n=124,118,242) | 1.49 (1.27 to 1.75) | 1.04 (0.87 to 1.26) | 1.25 (1.11 to 1.42) | |
| Serotype 3: After 23vPS Dose (n=124,118,242) | 1.65 (1.42 to 1.92) | 0.98 (0.82 to 1.17) | 1.28 (1.14 to 1.44) | |
| Serotype 4: After 13vPnC Dose 3 (n=133,128,261) | 3.29 (2.79 to 3.87) | 3.19 (2.59 to 3.93) | 3.24 (2.84 to 3.7) | |
| Serotype 4: After 23vPS Dose (n=133,128,261) | 3.28 (2.77 to 3.88) | 3.01 (2.44 to 3.72) | 3.15 (2.75 to 3.59) | |
| Serotype 5: After 13vPnC Dose 3 (n=132,130,262) | 4.73 (4.02 to 5.57) | 5.54 (4.64 to 6.63) | 5.12 (4.54 to 5.78) | |
| Serotype 5: After 23vPS Dose (n=132,130,262) | 5.08 (4.33 to 5.95) | 6.2 (5.23 to 7.35) | 5.61 (4.99 to 6.3) | |

| | | | | |
|---|---|---|---|---|
| Serotype 6A: After 13vPnC Dose 3 (n=122,129,251) | 8.2 (6.99 to 9.61) | 7.07 (5.75 to 8.69) | 7.6 (6.67 to 8.66) | |
| Serotype 6A: After 23vPS Dose (n=122,129,251) | 7.98 (6.85 to 9.31) | 6.71 (5.51 to 8.17) | 7.3 (6.44 to 8.27) | |
| Serotype 6B: After 13vPnC Dose 3 (n=133,129,262) | 12.25 (10.31 to 14.55) | 8.29 (6.78 to 10.13) | 10.1 (8.84 to 11.55) | |
| Serotype 6B: After 23vPS Dose (n=133,129,262) | 11.1 (9.39 to 13.13) | 8.25 (6.8 to 10.01) | 9.59 (8.44 to 10.9) | |
| Serotype 7F: After 13vPnC Dose 3 (n=133,130,263) | 5.05 (4.39 to 5.81) | 5.88 (4.93 to 7.02) | 5.44 (4.87 to 6.09) | |
| Serotype 7F: After 23vPS Dose (n=133,130,263) | 5.15 (4.5 to 5.9) | 5.93 (5.02 to 7) | 5.52 (4.96 to 6.14) | |
| Serotype 9V: After 13vPnC Dose 3 (n=133,130,263) | 5.02 (4.4 to 5.72) | 5.49 (4.59 to 6.57) | 5.25 (4.7 to 5.86) | |
| Serotype 9V: After 23vPS Dose (n=133,130,263) | 5.27 (4.62 to 6) | 5.83 (4.88 to 6.96) | 5.54 (4.96 to 6.18) | |
| Serotype 14: After 13vPnC Dose 3 (n=133,130,263) | 13.18 (10.19 to 17.05) | 15.35 (11.97 to 19.69) | 14.21 (11.89 to 16.98) | |
| Serotype 14: After 23vPS Dose (n=133,130,263) | 12.98 (10.1 to 16.67) | 16.24 (12.82 to 20.57) | 14.5 (12.21 to 17.21) | |
| Serotype 18C: After 13vPnC Dose 3 (n=132,130,262) | 3.84 (3.21 to 4.59) | 5.17 (4.25 to 6.28) | 4.45 (3.9 to 5.08) | |
| Serotype 18C: After 23vPS Dose (n=132,130,262) | 3.54 (2.98 to 4.2) | 4.8 (3.98 to 5.79) | 4.12 (3.62 to 4.68) | |
| Serotype 19A: After 13vPnC Dose 3 (n=133,130,263) | 14.16 (12.21 to 16.41) | 13.21 (11.13 to 15.68) | 13.68 (12.22 to 15.31) | |
| Serotype 19A: After 23vPS Dose (n=133,130,263) | 13.16 (11.31 to 15.33) | 13.28 (11.24 to 15.69) | 13.22 (11.82 to 14.79) | |
| Serotype 19F: After 13vPnC Dose 3 (n=130,127,257) | 6.15 (5.09 to 7.45) | 5.67 (4.47 to 7.19) | 5.91 (5.08 to 6.87) | |
| Serotype 19F: After 23vPS Dose (n=130,127,257) | 6.78 (5.65 to 8.14) | 5.84 (4.62 to 7.39) | 6.3 (5.44 to 7.3) | |
| Serotype 23F: After 13vPnC Dose 3 (n=132,129,261) | 6.69 (5.6 to 7.98) | 7.3 (5.87 to 9.09) | 6.98 (6.07 to 8.03) | |
| Serotype 23F: After 23vPS Dose (n=132,129,261) | 5.99 (5.05 to 7.11) | 7.03 (5.69 to 8.7) | 6.49 (5.66 to 7.43) | |

Notes:

[26] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[27] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[28] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

### Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Geometric Mean Fold Rise (GMFR) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody From 1 Month After 13vPnC Dose 3 to 1 Month After 23vPS Dose in Pediatric, Adult and All Subjects

| | |
|---|---|
| End point title | Geometric Mean Fold Rise (GMFR) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody From 1 Month After 13vPnC Dose 3 to 1 Month After 23vPS Dose in Pediatric, Adult and All Subjects |

End point description:

GMFR for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) from 1 month after 13vPnC Dose 3 to 1 month after 23vPS Dose were computed using the logarithmically transformed assay results. CI for GMFR were back transformations of a CI based on the Student t distribution for the mean logarithm of the mean fold rise. GMFRs were calculated using all subjects with available data from both 1 month after 13vPnC Dose 3 and 1 month after 23vPS Dose blood draws. Evaluable immunogenicity population. Here "n" signifies subjects with valid and determinate assay results for specified serotype at both 1 month after 13vPnC Dose 3 and after 23vPS Dose blood draws for each treatment arm, respectively.

| End point type | Other pre-specified |
|---|---|

End point timeframe:

1 month after 13vPnC Dose 3, 1 month after 23vPS Dose

| **End point values** | 13vPnC, 23vPS (Pediatric Subjects) | 13vPnC, 23vPS (Adult Subjects) | 13vPnC, 23vPS (All Subjects) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 133[29] | 130[30] | 263[31] | |
| Units: fold rise | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 1 (n = 128, 127, 255) | 1.08 (1.01 to 1.16) | 1.02 (0.96 to 1.08) | 1.05 (1 to 1.1) | |
| Serotype 3 (n = 124, 118, 242) | 1.11 (1.03 to 1.2) | 0.94 (0.88 to 1) | 1.02 (0.97 to 1.08) | |
| Serotype 4 (n = 133, 128, 261) | 1 (0.94 to 1.05) | 0.94 (0.9 to 0.99) | 0.97 (0.94 to 1.01) | |
| Serotype 5 (n = 132, 130, 262) | 1.07 (1.02 to 1.13) | 1.12 (1.05 to 1.19) | 1.09 (1.05 to 1.14) | |
| Serotype 6A (n = 122, 129, 251) | 0.97 (0.92 to 1.04) | 0.95 (0.91 to 0.99) | 0.96 (0.93 to 1) | |
| Serotype 6B (n = 133, 129, 262) | 0.91 (0.87 to 0.95) | 1 (0.96 to 1.04) | 0.95 (0.92 to 0.98) | |
| Serotype 7F (n = 133, 130, 263) | 1.02 (0.97 to 1.07) | 1.01 (0.95 to 1.06) | 1.01 (0.98 to 1.05) | |
| Serotype 9V (n = 133, 130, 263) | 1.05 (1 to 1.1) | 1.06 (1.01 to 1.11) | 1.06 (1.02 to 1.09) | |
| Serotype 14 (n = 133, 130, 263) | 0.98 (0.91 to 1.06) | 1.06 (0.99 to 1.13) | 1.02 (0.97 to 1.07) | |
| Serotype 18C (n = 132, 130, 262) | 0.92 (0.88 to 0.96) | 0.93 (0.89 to 0.97) | 0.92 (0.9 to 0.95) | |
| Serotype 19A (n = 133, 130, 263) | 0.93 (0.89 to 0.97) | 1.01 (0.96 to 1.05) | 0.97 (0.94 to 1) | |
| Serotype 19F (n = 130, 127, 257) | 1.1 (1.04 to 1.17) | 1.03 (0.97 to 1.09) | 1.07 (1.02 to 1.11) | |
| Serotype 23F (n = 132, 129, 261) | 0.9 (0.86 to 0.94) | 0.96 (0.91 to 1.02) | 0.93 (0.89 to 0.96) | |

Notes:

[29] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[30] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[31] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

### Statistical analyses

No statistical analyses for this end point

### Other pre-specified: Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMT) 1 Month After 13vPnC Dose 3 and 1 Month After 23vPS Dose in Pediatric, Adult and All Subjects

| End point title | Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMT) 1 Month After 13vPnC Dose 3 and 1 Month After 23vPS Dose in Pediatric, Adult and All Subjects |
|---|---|

End point description:

Serotype-specific OPA GMTs for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C,

19A, 19F, and 23F) were determined in the blood samples of pediatric, adult and all subjects using a mcOPA assay. GMT (13vPnC) and corresponding 2-sided 95% CIs were evaluated. Geometric means were calculated using all subjects with available data for both after 13vPnC Dose 3 and after 23vPS Dose blood draws. CI for GMT were back transformations of a CI based on the Student t distribution for the mean logarithm of the titers. Evaluable immunogenicity population. Here "n" signifies subjects with valid and determinate assay results for specified serotype at both 1 month after 13vPnC Dose 3 and after 23vPS Dose blood draws for each treatment arm, respectively.

| End point type | Other pre-specified |
|---|---|

End point timeframe:

1 month after 13vPnC Dose 3, 1 month after 23vPS Dose

| **End point values** | 13vPnC, 23vPS (Pediatric Subjects) | 13vPnC, 23vPS (Adult Subjects) | 13vPnC, 23vPS (All Subjects) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 132[32] | 128[33] | 260[34] | |
| Units: titers | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 1: After 13vPnC Dose 3 (n=131,125,256) | 70 (53.4 to 93) | 67 (50.2 to 90.6) | 69 (56.4 to 84.3) | |
| Serotype 1: After 23vPS Dose (n=131,125,256) | 100 (76.6 to 130.3) | 66 (49 to 90.2) | 82 (66.9 to 100.2) | |
| Serotype 3: After 13vPnC Dose 3 (n=132,128,260) | 114 (94.6 to 136.7) | 78 (61.3 to 98.7) | 94 (81.1 to 109.7) | |
| Serotype 3: After 23vPS Dose (n=132,128,260) | 148 (123.9 to 177.3) | 103 (81.6 to 130.9) | 124 (107 to 144) | |
| Serotype 4: After 13vPnC Dose 3 (n=127,126,253) | 3213 (2698.5 to 3826.6) | 1888 (1427.3 to 2498.1) | 2466 (2087 to 2913.5) | |
| Serotype 4: After 23vPS Dose (n=127,126,253) | 3553 (2984.9 to 4229.7) | 1831 (1366 to 2453.7) | 2554 (2146.3 to 3038.7) | |
| Serotype 5: After 13vPnC Dose 3 (n=129,124,253) | 270 (197 to 370.1) | 143 (97.5 to 209.6) | 198 (154.2 to 253.5) | |
| Serotype 5: After 23vPS Dose (n=129,124,253) | 378 (276.5 to 516.9) | 186 (130.9 to 264.4) | 267 (210.6 to 338.6) | |
| Serotype 6A: After 13vPnC Dose 3 (n=132,127,259) | 8011 (6580 to 9752.1) | 2956 (2240.1 to 3900.3) | 4913 (4109.7 to 5873.6) | |
| Serotype 6A: After 23vPS Dose (n=132,127,259) | 7236 (5936.2 to 8819.4) | 2707 (2060.8 to 3556.3) | 4468 (3743.3 to 5333.1) | |
| Serotype 6B: After 13vPnC Dose 3 (n=130,126,256) | 7102 (5853.9 to 8615.8) | 3666 (2720.7 to 4940.5) | 5129 (4283.9 to 6141) | |
| Serotype 6B: After 23vPS Dose (n=130,126,256) | 6652 (5460.8 to 8102.8) | 3324 (2496.6 to 4426.2) | 4728 (3961.1 to 5643.2) | |
| Serotype 7F: After 13vPnC Dose 3 (n=131,125,256) | 4640 (3915.9 to 5497.9) | 2821 (2283.2 to 3484.4) | 3639 (3171.6 to 4174.8) | |
| Serotype 7F: After 23vPS Dose (n=131,125,256) | 5260 (4470.4 to 6189.9) | 3027 (2455.7 to 3731.3) | 4016 (3508.3 to 4597.9) | |
| Serotype 9V: After 13vPnC Dose 3 (n=127,125,252) | 4501 (3606.4 to 5618) | 1980 (1394.6 to 2811.7) | 2995 (2424.2 to 3700.8) | |
| Serotype 9V: After 23vPS Dose (n=127,125,252) | 5114 (4090.6 to 6393) | 2037 (1452.6 to 2857.6) | 3240 (2629.5 to 3991.2) | |
| Serotype 14: After 13vPnC Dose 3 (n=127,126,253) | 4023 (3317.5 to 4879.5) | 1431 (1115.7 to 1836.1) | 2405 (2030.8 to 2847.1) | |
| Serotype 14: After 23vPS Dose (n=127,126,253) | 4718 (3861.6 to 5764.9) | 1620 (1284.5 to 2043) | 2771 (2346.9 to 3270.7) | |
| Serotype 18C: After 13vPnC Dose 3 (n=129,121,250) | 5455 (4401.5 to 6761.4) | 1667 (1172.5 to 2370.8) | 3074 (2479.2 to 3810.5) | |

| | | | | |
|---|---|---|---|---|
| Serotype 18C: After 23vPS Dose (n=129,121,250) | 6468 (5341.1 to 7832.2) | 1835 (1328.1 to 2535.5) | 3515 (2878.5 to 4292.8) | |
| Serotype 19A: After 13vPnC Dose 3 (n=131,125,256) | 1021 (837.5 to 1245.6) | 603 (456.7 to 796.3) | 790 (665.2 to 937.4) | |
| Serotype 19A: After 23vPS Dose (n=131,125,256) | 1244 (1012.1 to 1529.5) | 691 (531 to 898.6) | 933 (788.2 to 1105.5) | |
| Serotype 19F: After 13vPnC Dose 3 (n=126,117,243) | 1166 (884.3 to 1537.7) | 564 (375 to 848.1) | 822 (642.8 to 1051) | |
| Serotype 19F: After 23vPS Dose (n=126,117,243) | 1696 (1296.5 to 2217.5) | 790 (547.5 to 1139.7) | 1174 (934.2 to 1474.8) | |
| Serotype 23F: After 13vPnC Dose 3 (n=128,126,254) | 2346 (1883.3 to 2922.6) | 650 (435.3 to 969.9) | 1241 (976.6 to 1576.7) | |
| Serotype 23F: After 23vPS Dose (n=128,126,254) | 2595 (2143.3 to 3141.5) | 580 (386.1 to 871.8) | 1234 (970.1 to 1570.3) | |

Notes:

[32] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[33] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[34] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

### Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Fold Rise (GMFR) From 1 Month After 13vPnC Dose 3 to 1 Month After 23vPS Dose in Pediatric, Adult and All Subjects

| | |
|---|---|
| End point title | Serotype-Specific Pneumococcal Opsonophagocytic Activity (OPA) Geometric Mean Fold Rise (GMFR) From 1 Month After 13vPnC Dose 3 to 1 Month After 23vPS Dose in Pediatric, Adult and All Subjects |

End point description:

GMFR for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) from 1 month after 13vPnC Dose 3 to 1 month after 23vPS Dose were computed using the logarithmically transformed assay results. CI for GMFR were back transformations of a CI based on the Student t distribution for the mean logarithm of the mean fold rise. GMFRs were calculated using all subjects with available data from both 1 month after 13vPnC Dose 3 and 1 month after 23vPS Dose blood draws. Evaluable immunogenicity population. Here "n" signifies subjects with valid and determinate assay results for specified serotype at both 1 month after 13vPnC Dose 3 and after 23vPS Dose blood draws for each treatment arm, respectively.

| | |
|---|---|
| End point type | Other pre-specified |

End point timeframe:

1 month after 13vPnC Dose 3, 1 month after 23vPS Dose

| End point values | 13vPnC, 23vPS (Pediatric Subjects) | 13vPnC, 23vPS (Adult Subjects) | 13vPnC, 23vPS (All Subjects) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 132[35] | 128[36] | 260[37] | |
| Units: fold rise | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 1 (n = 131, 125, 256) | 1.4 (1.23 to 1.63) | 1 (0.86 to 1.13) | 1.2 (1.08 to 1.31) | |
| Serotype 3 (n = 132, 128, 260) | 1.3 (1.15 to 1.48) | 1.3 (1.17 to 1.51) | 1.3 (1.2 to 1.44) | |

| | | | | |
|---|---|---|---|---|
| Serotype 4 (n = 127, 126, 253) | 1.1 (1.04 to 1.18) | 1 (0.87 to 1.09) | 1 (0.97 to 1.1) | |
| Serotype 5 (n = 129, 124, 253) | 1.4 (1.15 to 1.71) | 1.3 (1.13 to 1.5) | 1.4 (1.2 to 1.53) | |
| Serotype 6A (n = 132, 127, 259) | 0.9 (0.85 to 0.96) | 0.9 (0.86 to 0.97) | 0.9 (0.87 to 0.95) | |
| Serotype 6B (n = 130, 126, 256) | 0.9 (0.87 to 1.01) | 0.9 (0.79 to 1.04) | 0.9 (0.86 to 0.99) | |
| Serotype 7F (n = 131, 125, 256) | 1.1 (1.06 to 1.21) | 1.1 (0.93 to 1.23) | 1.1 (1.02 to 1.19) | |
| Serotype 9V (n = 127, 125, 252) | 1.1 (1.05 to 1.23) | 1 (0.84 to 1.27) | 1.1 (0.97 to 1.21) | |
| Serotype 14 (n = 127, 126, 253) | 1.2 (1.07 to 1.28) | 1.1 (1.03 to 1.24) | 1.2 (1.08 to 1.23) | |
| Serotype 18C (n = 129, 121, 250) | 1.2 (1.04 to 1.35) | 1.1 (0.92 to 1.31) | 1.1 (1.03 to 1.27) | |
| Serotype 19A (n = 131, 125, 256) | 1.2 (1.11 to 1.34) | 1.1 (1.03 to 1.27) | 1.2 (1.1 to 1.27) | |
| Serotype 19F (n = 126, 117, 243) | 1.5 (1.25 to 1.69) | 1.4 (1.14 to 1.72) | 1.4 (1.26 to 1.62) | |
| Serotype 23F (n = 128, 126, 254) | 1.1 (0.96 to 1.28) | 0.9 (0.81 to 0.98) | 1 (0.91 to 1.09) | |

Notes:

[35] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[36] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

[37] - "Number of subjects analyzed" signifies those subjects who were evaluable for this measure.

### Statistical analyses

No statistical analyses for this end point

### Other pre-specified: Percentage of Pediatric, Adult and All Subjects Reporting Pre-Specified Local Reactions: 13vPnC Dose 1

| End point title | Percentage of Pediatric, Adult and All Subjects Reporting Pre-Specified Local Reactions: 13vPnC Dose 1 |
|---|---|

End point description:

Specific local reactions were prompted for each day, and reported using an electronic diary (e-diary). Redness and Swelling were scaled as Any (redness present or swelling present); Mild (0.5 to 2.0 centimeters (cm) for subjects aged 6 to <12 years and 2.5 to 5.0 cm for subjects aged greater than (>) 12 years); Moderate (2.5 to 7.0 cm for subjects aged 6 to <12 years and 5.1 to 10.0 cm for subjects aged >12 years); Severe (>7 cm for subjects aged 6 to <12 years and >10 cm for subjects aged >12 years). Pain at injection site was scaled as Any (pain present); Mild (did not interfere with activity); Moderate (interfered with activity); Severe (prevented daily activity). Report of severe swelling was confirmed as data entry error. Safety population included all enrolled subjects who received at least 1 dose of investigational product. Here "n" signifies subjects with known values for specified local reaction. Subjects may be represented in more than 1 category.

| End point type | Other pre-specified |
|---|---|

End point timeframe:

Within 14 days after 13vPnC Dose 1

| End point values | 13vPnC, 23vPS (Pediatric Subjects) | 13vPnC, 23vPS (Adult Subjects) | 13vPnC, 23vPS (All Subjects) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 120[38] | 123[39] | 243[40] | |
| Units: percentage of subjects | | | | |
| number (not applicable) | | | | |
| Redness: Any (n = 92, 88, 180) | 20.7 | 2.3 | 11.7 | |
| Redness: Mild (n = 91, 88, 179) | 19.8 | 2.3 | 11.2 | |
| Redness: Moderate (n = 85, 88, 173) | 2.4 | 0 | 1.2 | |
| Redness: Severe (n = 84, 88, 172) | 0 | 0 | 0 | |
| Swelling: Any (n = 97, 94, 191) | 29.9 | 9.6 | 19.9 | |
| Swelling: Mild (n = 91, 93, 184) | 17.6 | 8.6 | 13 | |
| Swelling: Moderate (n = 92, 89, 181) | 16.3 | 1.1 | 8.8 | |
| Swelling: Severe (n = 84, 88, 172) | 1.2 | 0 | 0.6 | |
| Pain at Injection Site: Any (n = 117, 121, 238) | 68.4 | 62.8 | 65.5 | |
| Pain at Injection Site: Mild (n = 112, 116, 228) | 55.4 | 56 | 55.7 | |
| Pain at Injection Site: Moderate (n = 94, 94, 188) | 28.7 | 18.1 | 23.4 | |
| Pain at Injection Site: Severe (n = 86, 89, 175) | 8.1 | 2.2 | 5.1 | |

Notes:

[38] - "Number of subjects analyzed" signifies subjects with known values for any local reaction.

[39] - "Number of subjects analyzed" signifies subjects with known values for any local reaction.

[40] - "Number of subjects analyzed" signifies subjects with known values for any local reaction.

### Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Percentage of Pediatric, Adult and All Subjects Reporting Pre-Specified Local Reactions: 13vPnC Dose 2

| End point title | Percentage of Pediatric, Adult and All Subjects Reporting Pre-Specified Local Reactions: 13vPnC Dose 2 |
|---|---|

End point description:

Specific local reactions were prompted for each day, and reported using an e-diary. Redness and Swelling were scaled as Any (redness present or swelling present); Mild (0.5 to 2.0 cm for subjects aged 6 to <12 years and 2.5 to 5.0 cm for subjects aged >12 years); Moderate (2.5 to 7.0 cm for subjects aged 6 to <12 years and 5.1 to 10.0 cm for subjects aged >12 years); Severe (>7 cm for subjects aged 6 to <12 years and >10 cm for subjects aged >12 years). Pain at injection site was scaled as Any (pain present); Mild (did not interfere with activity); Moderate (interfered with activity); Severe (prevented daily activity). Safety population. Here "n" signifies subjects with known values for specified local reaction. Subjects may be represented in more than 1 category.

| End point type | Other pre-specified |
|---|---|

End point timeframe:

Within 14 days after 13vPnC Dose 2

| End point values | 13vPnC, 23vPS (Pediatric Subjects) | 13vPnC, 23vPS (Adult Subjects) | 13vPnC, 23vPS (All Subjects) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 120[41] | 119[42] | 239[43] | |
| Units: percentage of subjects | | | | |
| number (not applicable) | | | | |
| Redness: Any (n = 101, 86, 187) | 13.9 | 2.3 | 8.6 | |
| Redness: Mild (n = 100, 86, 186) | 10 | 2.3 | 6.5 | |
| Redness: Moderate (n = 95, 85, 180) | 4.2 | 0 | 2.2 | |
| Redness: Severe (n = 93, 85, 178) | 1.1 | 0 | 0.6 | |
| Swelling: Any (n = 103, 88, 191) | 25.2 | 8 | 17.3 | |
| Swelling: Mild (n = 102, 88, 190) | 18.6 | 8 | 13.7 | |
| Swelling: Moderate (n = 99, 85, 184) | 12.1 | 0 | 6.5 | |
| Swelling: Severe (n = 93, 85, 178) | 0 | 0 | 0 | |
| Pain at Injection Site: Any (n = 117, 119, 236) | 60.7 | 79.8 | 70.3 | |
| Pain at Injection Site: Mild (n = 110, 117, 227) | 49.1 | 72.6 | 61.2 | |
| Pain at Injection Site: Moderate (n= 103, 96, 199) | 24.3 | 27.1 | 25.6 | |
| Pain at Injection Site: Severe (n = 93, 86, 179) | 5.4 | 3.5 | 4.5 | |

Notes:

[41] - "Number of subjects analyzed" signifies subjects with known values for any local reaction.

[42] - "Number of subjects analyzed" signifies subjects with known values for any local reaction.

[43] - "Number of subjects analyzed" signifies subjects with known values for any local reaction.

### Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Percentage of Pediatric, Adult and All Subjects Reporting Pre-Specified Local Reactions: 13vPnC Dose 3

| End point title | Percentage of Pediatric, Adult and All Subjects Reporting Pre-Specified Local Reactions: 13vPnC Dose 3 |
|---|---|

End point description:

Specific local reactions were prompted for each day, and reported using an e-diary. Redness and Swelling were scaled as Any (redness present or swelling present); Mild (0.5 to 2.0 cm for subjects aged 6 to <12 years and 2.5 to 5.0 cm for subjects aged >12 years); Moderate (2.5 to 7.0 cm for subjects aged 6 to <12 years and 5.1 to 10.0 cm for subjects aged >12 years); Severe (>7 cm for subjects aged 6 to <12 years and >10 cm for subjects aged >12 years). Pain at injection site was scaled as Any (pain present); Mild (did not interfere with activity); Moderate (interfered with activity); Severe (prevented daily activity). Safety population. Here "n" signifies subjects with known values for specified local reaction. Subjects may be represented in more than 1 category.

| End point type | Other pre-specified |
|---|---|

End point timeframe:

Within 14 days after 13vPnC Dose 3

| End point values | 13vPnC, 23vPS (Pediatric Subjects) | 13vPnC, 23vPS (Adult Subjects) | 13vPnC, 23vPS (All Subjects) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 104[44] | 109[45] | 213[46] | |
| Units: percentage of subjects | | | | |
| number (not applicable) | | | | |
| Redness: Any (n = 84, 70, 154) | 8.3 | 0 | 4.5 | |
| Redness: Mild (n = 83, 70, 153) | 7.2 | 0 | 3.9 | |
| Redness: Moderate (n = 82, 70, 152) | 2.4 | 0 | 1.3 | |
| Redness: Severe (n = 80, 70, 150) | 0 | 0 | 0 | |
| Swelling: Any (n = 89, 71, 160) | 18 | 4.2 | 11.9 | |
| Swelling: Mild (n = 86, 71, 157) | 10.5 | 4.2 | 7.6 | |
| Swelling: Moderate (n = 84, 70, 154) | 9.5 | 0 | 5.2 | |
| Swelling: Severe (n = 80, 70, 150) | 0 | 0 | 0 | |
| Pain at Injection Site: Any (n = 104, 109, 213) | 52.9 | 69.7 | 61.5 | |
| Pain at Injection Site: Mild (n = 96, 105, 201) | 41.7 | 63.8 | 53.2 | |
| Pain at Injection Site: Moderate (n = 89, 78, 167) | 19.1 | 24.4 | 21.6 | |
| Pain at Injection Site: Severe (n = 83, 73, 156) | 4.8 | 5.5 | 5.1 | |

Notes:

[44] - "Number of subjects analyzed" signifies subjects with known values for any local reaction.

[45] - "Number of subjects analyzed" signifies subjects with known values for any local reaction.

[46] - "Number of subjects analyzed" signifies subjects with known values for any local reaction.

### Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Percentage of Pediatric, Adult and All Subjects Reporting Pre-Specified Systemic Events: 13vPnC Dose 1

| End point title | Percentage of Pediatric, Adult and All Subjects Reporting Pre-Specified Systemic Events: 13vPnC Dose 1 |
|---|---|

End point description:

Specific systemic events(fever >=38 degrees Celsius[C],fatigue,headache,vomiting,diarrhea,muscle pain,joint pain,use of medication to treat pain/fever) were prompted for each day, and reported using an e-diary. Fatigue,headache,muscle pain,joint pain were scaled as: Any(symptom present); Mild(did not interfere with activity); Moderate(some interference with activity); Severe(prevented routine daily activity). Vomiting was scaled as: Any(vomiting present); Mild(1-2 times in 24 hours); Moderate(>2 times in 24 hours); Severe(required intravenous hydration). Diarrhea was scaled as: Any(diarrhea present); Mild(2-3 loose stools in 24 hours); Moderate(4-5 loose stools 24 hours); Severe(>=6 loose stools in 24 hours). All reporting of fever >40 degrees C and all reporting of severe vomiting, after 13vPnC Dose 1, were confirmed as data entry errors. Safety population.n=subjects with known values for specified systemic event. Subjects may be represented in more than 1 category.

| End point type | Other pre-specified |
|---|---|

End point timeframe:

Within 14 days after 13vPnC Dose 1

| End point values | 13vPnC, 23vPS (Pediatric Subjects) | 13vPnC, 23vPS (Adult Subjects) | 13vPnC, 23vPS (All Subjects) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 128[47] | 138[48] | 266[49] | |
| Units: percentage of subjects | | | | |
| number (not applicable) | | | | |
| Fever: >=38 degrees C (n= 94, 95, 189) | 19.1 | 17.9 | 18.5 | |
| Fever: >=38, <38.5 degrees C (n = 87, 92, 179) | 8 | 8.7 | 8.4 | |
| Fever: >=38.5, <39 degrees C (n = 85, 89, 174) | 2.4 | 3.4 | 2.9 | |
| Fever: >=39, =<40 degrees C (n = 86, 88, 174) | 4.7 | 2.3 | 3.4 | |
| Fever: >40 degrees C (n = 88, 93, 181) | 6.8 | 8.6 | 7.7 | |
| Fatigue: Any (n = 111, 119, 230) | 47.7 | 58.8 | 53.5 | |
| Fatigue: Mild (n = 105, 113, 218) | 33.3 | 51.3 | 42.7 | |
| Fatigue: Moderate (n = 96, 99, 195) | 26 | 28.3 | 27.2 | |
| Fatigue: Severe (n = 86, 92, 178) | 9.3 | 8.7 | 9 | |
| Headache: Any (n = 107, 113, 220) | 39.3 | 61.1 | 50.5 | |
| Headache: Mild (n = 100, 109, 209) | 33 | 57.8 | 45.9 | |
| Headache: Moderate (n = 94, 97, 191) | 18.1 | 22.7 | 20.4 | |
| Headache: Severe (n = 87, 89, 176) | 6.9 | 9 | 8 | |
| Vomiting: Any (n = 89, 91, 180) | 18 | 7.7 | 12.8 | |
| Vomiting: Mild (n = 89, 91, 180) | 14.6 | 7.7 | 11.1 | |
| Vomiting: Moderate (n = 84, 88, 172) | 2.4 | 0 | 1.2 | |
| Vomiting: Severe (n = 85, 88, 173) | 2.4 | 0 | 1.2 | |
| Diarrhea: Any (n = 94, 105, 199) | 25.5 | 34.3 | 30.2 | |
| Diarrhea: Mild (n = 92, 104, 196) | 19.6 | 29.8 | 25 | |
| Diarrhea: Moderate (n = 86, 91, 177) | 8.1 | 7.7 | 7.9 | |
| Diarrhea: Severe (n = 85, 88, 173) | 1.2 | 1.1 | 1.2 | |
| Muscle Pain: Any (n = 108, 118, 226) | 48.1 | 62.7 | 55.8 | |
| Muscle Pain: Mild (n = 103, 110, 213) | 36.9 | 56.4 | 46.9 | |
| Muscle Pain: Moderate (n = 89, 98, 187) | 19.1 | 19.4 | 19.3 | |
| Muscle Pain: Severe (n = 86, 91, 177) | 5.8 | 5.5 | 5.6 | |
| Joint Pain: Any (n = 100, 105, 205) | 34 | 42.9 | 38.5 | |
| Joint Pain: Mild (n = 98, 101, 199) | 26.5 | 36.6 | 31.7 | |
| Joint Pain: Moderate (n = 89, 95, 184) | 12.4 | 17.9 | 15.2 | |
| Joint Pain: Severe (n = 84, 91, 175) | 4.8 | 4.4 | 4.6 | |
| Use of Medication to Treat Pain (n = 101, 96, 197) | 33.7 | 24 | 28.9 | |
| Use of Medication to Treat Fever (n=112, 107, 219) | 44.6 | 39.3 | 42 | |

Notes:

[47] - "Number of subjects analyzed" signifies subjects with known values for any systemic event.

[48] - "Number of subjects analyzed" signifies subjects with known values for any systemic event.

[49] - "Number of subjects analyzed" signifies subjects with known values for any systemic event.

## Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Percentage of Pediatric, Adult and All Subjects Reporting Pre-

## Specified Systemic Events: 13vPnC Dose 2

| End point title | Percentage of Pediatric, Adult and All Subjects Reporting Pre-Specified Systemic Events: 13vPnC Dose 2 |
|---|---|

End point description:

Specific systemic events(fever >=38 degrees Celsius[C],fatigue,headache,vomiting,diarrhea,muscle pain,joint pain,use of medication to treat pain/fever) were prompted for each day, and reported using an e-diary. Fatigue,headache,muscle pain,joint pain were scaled as: Any(symptom present); Mild(did not interfere with activity); Moderate(some interference with activity); Severe(prevented routine daily activity). Vomiting was scaled as: Any(vomiting present); Mild(1-2 times in 24 hours); Moderate(>2 times in 24 hours); Severe(required intravenous hydration). Diarrhea was scaled as: Any(diarrhea present); Mild(2-3 loose stools in 24 hours); Moderate(4-5 loose stools 24 hours); Severe(>=6 loose stools in 24 hours). All reporting of fever >40 degrees C and all reporting of severe vomiting, after 13vPnC Dose 2, were confirmed as data entry errors. Safety population.n=subjects with known values for specified systemic event. Subjects may be represented in more than 1 category.

| End point type | Other pre-specified |
|---|---|

End point timeframe:

Within 14 days after 13vPnC Dose 2

| **End point values** | 13vPnC, 23vPS (Pediatric Subjects) | 13vPnC, 23vPS (Adult Subjects) | 13vPnC, 23vPS (All Subjects) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 123[50] | 120[51] | 243[52] | |
| Units: percentage of subjects | | | | |
| number (not applicable) | | | | |
| Fever: >=38 degrees C (n= 102, 88, 190) | 16.7 | 11.4 | 14.2 | |
| Fever: >=38, <38.5 degrees C (n = 96, 87, 183) | 7.3 | 9.2 | 8.2 | |
| Fever: >=38.5, <39 degrees C (n = 98, 85, 183) | 6.1 | 1.2 | 3.8 | |
| Fever: >=39, =<40 degrees C (n = 97, 87, 184) | 7.2 | 3.4 | 5.4 | |
| Fever: >40 degrees C (n = 95, 85, 180) | 1.1 | 1.2 | 1.1 | |
| Fatigue: Any (n = 106, 105, 211) | 33 | 48.6 | 40.8 | |
| Fatigue: Mild (n = 104, 103, 207) | 24 | 42.7 | 33.3 | |
| Fatigue: Moderate (n = 96, 88, 184) | 10.4 | 21.6 | 15.8 | |
| Fatigue: Severe (n = 95, 88, 183) | 7.4 | 5.7 | 6.6 | |
| Headache: Any (n = 101, 106, 207) | 28.7 | 49.1 | 39.1 | |
| Headache: Mild (n = 97, 102, 199) | 18.6 | 40.2 | 29.6 | |
| Headache: Moderate (n = 97, 93, 190) | 13.4 | 28 | 20.5 | |
| Headache: Severe (n = 94, 88, 182) | 2.1 | 3.4 | 2.7 | |
| Vomiting: Any (n = 96, 89, 185) | 10.4 | 10.1 | 10.3 | |
| Vomiting: Mild (n = 94, 89, 183) | 6.4 | 9 | 7.7 | |
| Vomiting: Moderate (n = 94, 85, 179) | 3.2 | 1.2 | 2.2 | |
| Vomiting: Severe (n = 94, 85, 179) | 3.2 | 0 | 1.7 | |
| Diarrhea: Any (n = 95, 95, 190) | 10.5 | 26.3 | 18.4 | |
| Diarrhea: Mild (n = 94, 93, 187) | 7.4 | 24.7 | 16 | |
| Diarrhea: Moderate (n = 93, 87, 180) | 3.2 | 8 | 5.6 | |
| Diarrhea: Severe (n = 94, 85, 179) | 4.3 | 1.2 | 2.8 | |
| Muscle Pain: Any (n = 112, 104, 216) | 37.5 | 52.9 | 44.9 | |
| Muscle Pain: Mild (n = 105, 103, 208) | 25.7 | 46.6 | 36.1 | |

| | | | | |
|---|---|---|---|---|
| Muscle Pain: Moderate (n = 100, 91, 191) | 15 | 20.9 | 17.8 | |
| Muscle Pain: Severe (n = 95, 85, 180) | 5.3 | 2.4 | 3.9 | |
| Joint Pain: Any (n = 106, 95, 201) | 26.4 | 34.7 | 30.3 | |
| Joint Pain: Mild (n = 100, 93, 193) | 16 | 29 | 22.3 | |
| Joint Pain: Moderate (n = 99, 89, 188) | 11.1 | 12.4 | 11.7 | |
| Joint Pain: Severe (n = 94, 85, 179) | 4.3 | 2.4 | 3.4 | |
| Use of Medication to Treat Pain (n = 100, 91, 191) | 20 | 17.6 | 18.8 | |
| Use of Medication to Treat Fever (n=102, 96, 198) | 28.4 | 26 | 27.3 | |

Notes:

[50] - "Number of subjects analyzed" signifies subjects with known values for any systemic event.

[51] - "Number of subjects analyzed" signifies subjects with known values for any systemic event.

[52] - "Number of subjects analyzed" signifies subjects with known values for any systemic event.

### Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Percentage of Pediatric, Adult and All Subjects Reporting Pre-Specified Systemic Events: 13vPnC Dose 3

| End point title | Percentage of Pediatric, Adult and All Subjects Reporting Pre-Specified Systemic Events: 13vPnC Dose 3 |
|---|---|

End point description:

Specific systemic events(fever >=38 degrees Celsius[C],fatigue,headache,vomiting,diarrhea,muscle pain,joint pain,use of medication to treat pain/fever) were prompted for each day, and reported using an e-diary. Fatigue,headache,muscle pain,joint pain were scaled as: Any(symptom present); Mild(did not interfere with activity); Moderate(some interference with activity); Severe(prevented routine daily activity). Vomiting was scaled as: Any(vomiting present); Mild(1-2 times in 24 hours); Moderate(>2 times in 24 hours); Severe(required intravenous hydration). Diarrhea was scaled as: Any(diarrhea present); Mild(2-3 loose stools in 24 hours); Moderate(4-5 loose stools 24 hours); Severe(>=6 loose stools in 24 hours). All reporting of fever >40 degrees C except 1 subject and all reporting of severe vomiting, after 13vPnC Dose 3, were confirmed as data entry errors. Safety population.n=subjects with known values for specified systemic event. Subjects may be represented in more than 1 category.

| End point type | Other pre-specified |
|---|---|

End point timeframe:

Within 14 days after 13vPnC Dose 3

| End point values | 13vPnC, 23vPS (Pediatric Subjects) | 13vPnC, 23vPS (Adult Subjects) | 13vPnC, 23vPS (All Subjects) | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 106[53] | 113[54] | 219[55] | |
| Units: percentage of subjects | | | | |
| number (not applicable) | | | | |
| Fever: >=38 degrees C (n= 85, 73, 158) | 10.6 | 11 | 10.8 | |
| Fever: >=38, <38.5 degrees C (n = 82, 73, 155) | 6.1 | 5.5 | 5.8 | |
| Fever: >=38.5, <39 degrees C (n = 81, 72, 153) | 2.5 | 5.6 | 3.9 | |
| Fever: >=39, =<40 degrees C (n = 82, 70, 152) | 2.4 | 2.9 | 2.6 | |
| Fever: >40 degrees C (n = 83, 70, 153) | 3.6 | 1.4 | 2.6 | |

| | | | | |
|---|---|---|---|---|
| Fatigue: Any (n = 92, 91, 183) | 25 | 47.3 | 36.1 | |
| Fatigue: Mild (n = 89, 88, 177) | 20.2 | 39.8 | 29.9 | |
| Fatigue: Moderate (n = 83, 80, 163) | 6 | 25 | 15.3 | |
| Fatigue: Severe (n = 83, 73, 156) | 4.8 | 8.2 | 6.4 | |
| Headache: Any (n = 88, 89, 177) | 18.2 | 46.1 | 32.2 | |
| Headache: Mild (n = 84, 87, 171) | 10.7 | 41.4 | 26.3 | |
| Headache: Moderate (n = 83, 77, 160) | 8.4 | 19.5 | 13.8 | |
| Headache: Severe (n = 82, 72, 154) | 3.7 | 6.9 | 5.2 | |
| Vomiting: Any (n = 85, 74, 159) | 8.2 | 9.5 | 8.8 | |
| Vomiting: Mild (n = 84, 72, 156) | 7.1 | 5.6 | 6.4 | |
| Vomiting: Moderate (n = 82, 73, 155) | 2.4 | 5.5 | 3.9 | |
| Vomiting: Severe (n = 81, 72, 153) | 1.2 | 2.8 | 2 | |
| Diarrhea: Any (n = 81, 81, 162) | 4.9 | 28.4 | 16.7 | |
| Diarrhea: Mild (n = 81, 79, 160) | 4.9 | 25.3 | 15 | |
| Diarrhea: Moderate (n = 80, 73, 153) | 1.3 | 6.8 | 3.9 | |
| Diarrhea: Severe (n = 81, 73, 154) | 1.2 | 4.1 | 2.6 | |
| Muscle Pain: Any (n = 99, 92, 191) | 37.4 | 47.8 | 42.4 | |
| Muscle Pain: Mild (n = 93, 89, 182) | 25.8 | 37.1 | 31.3 | |
| Muscle Pain: Moderate (n = 85, 78, 163) | 12.9 | 24.4 | 18.4 | |
| Muscle Pain: Severe (n = 84, 72, 156) | 8.3 | 5.6 | 7.1 | |
| Joint Pain: Any (n = 91, 83, 174) | 24.2 | 32.5 | 28.2 | |
| Joint Pain: Mild (n = 88, 82, 170) | 15.9 | 28 | 21.8 | |
| Joint Pain: Moderate (n = 82, 77, 159) | 7.3 | 15.6 | 11.3 | |
| Joint Pain: Severe (n = 81, 71, 152) | 2.5 | 2.8 | 2.6 | |
| Use of Medication to Treat Pain (n = 90, 79, 169) | 17.8 | 21.5 | 19.5 | |
| Use of Medication to Treat Fever (n = 89, 75, 164) | 20.2 | 20 | 20.1 | |

Notes:

[53] - "Number of subjects analyzed" signifies subjects with known values for any systemic event.

[54] - "Number of subjects analyzed" signifies subjects with known values for any systemic event.

[55] - "Number of subjects analyzed" signifies subjects with known values for any systemic event.

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Informed consent through 6-month follow-up after 13vPnC Dose 3. Local reactions(LRs),systemic events(SEs) assessed within 14 days after: 13vPnC Dose 1(Day 1); 13vPnC Dose 2(28-42 days after 13vPnC Dose 1); and 13vPnC Dose 3(28-42 days after 13vPnC Dose 2)

Adverse event reporting additional description:

Adverse Event (AE) may be reported as both serious/non-serious, but are distinct events. AE may=serious for 1 subject, non-serious for another or subject may have experienced both serious, non-serious AE. AEs/SAEs=non-systematic assessment; LRs/SEs=systematic assessment. Here 0.0 is mentioned for dictionary version as version was not captured.

| | |
|---|---|
| Assessment type | Non-systematic |

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 16.0 |

### Reporting groups

| | |
|---|---|
| Reporting group title | Prior 13vPnC Dose 1 |

Reporting group description:

Subjects >=6 years of age (all subjects) who received at least 1 of 3 doses of 0.5 mL of 13vPnC intramuscularly 1 month apart, followed by 1 dose of 0.5 mL of 23vPS intramuscularly 1 month after 13vPnC Dose 3 (23vPS Dose), assessed between signing of informed consent form and before 13vPnC Dose 1.

| | |
|---|---|
| Reporting group title | 13vPnC Dose 1 |

Reporting group description:

Subjects >=6 years of age (all subjects) who received a single dose of 0.5 mL of 13vPnC intramuscularly on Day 1 (13vPnC Dose 1), assessed between 13vPnC Dose 1 and before 13vPnC Dose 2.

| | |
|---|---|
| Reporting group title | 13vPnC Dose 2 |

Reporting group description:

Subjects >=6 years of age (all subjects) who received a single dose of 0.5 mL of 13vPnC intramuscularly 1 month after 13vPnC Dose 1 (13vPnC Dose 2), assessed between 13vPnC Dose 2 and before 13vPnC Dose 3.

| | |
|---|---|
| Reporting group title | 13vPnC Dose 3 |

Reporting group description:

Subjects >=6 years of age (all subjects) who received a single dose of 0.5 mL of 13vPnC intramuscularly 1 month after 13vPnC Dose 2 (13vPnC Dose 3), assessed between 13vPnC Dose 3 and before 23vPS Dose.

| | |
|---|---|
| Reporting group title | 23vPS Dose |

Reporting group description:

Subjects >=6 years of age (all subjects) who received a single dose of 0.5 mL of 23vPS intramuscularly 1 month after 13vPnC Dose 3 (23vPS Dose), assessed between 23vPS Dose and before 23vPS Dose blood draw 1 month after 23vPS Dose.

| | |
|---|---|
| Reporting group title | Follow-up |

Reporting group description:

Subjects >=6 years of age (all subjects) who received 3 doses of 0.5 mL of 13vPnC intramuscularly 1 month apart, followed by 1 dose of 0.5 mL of 23vPS intramuscularly 1 month after 13vPnC Dose 3 (23vPS Dose), assessed from 23vPS blood draw to the 6-month follow-up telephone contact after 13vPnC Dose 3.

| **Serious adverse events** | Prior 13vPnC Dose 1 | 13vPnC Dose 1 | 13vPnC Dose 2 |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 1 / 301 (0.33%) | 4 / 290 (1.38%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Injury, poisoning and procedural complications | | | |
| Road traffic accident | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Convulsion | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 301 (0.33%) | 0 / 290 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 1 / 290 (0.34%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Lobar pneumonia | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 1 / 290 (0.34%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pharyngitis bacterial | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 1 / 290 (0.34%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 1 / 290 (0.34%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Croup infectious | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | 13vPnC Dose 3 | 23vPS Dose | Follow-up |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 286 (0.35%) | 0 / 282 (0.00%) | 1 / 282 (0.35%) |
| number of deaths (all causes) | 1 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | | |
| Injury, poisoning and procedural complications | | | |
| Road traffic accident | | | |
| subjects affected / exposed | 1 / 286 (0.35%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Nervous system disorders | | | |
| Convulsion | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Haemorrhoids | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Lobar pneumonia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pharyngitis bacterial | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 1 / 282 (0.35%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Croup infectious | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

Frequency threshold for reporting non-serious adverse events: 0 %

| **Non-serious adverse events** | Prior 13vPnC Dose 1 | 13vPnC Dose 1 | 13vPnC Dose 2 |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 16 / 301 (5.32%) | 216 / 301 (71.76%) | 171 / 290 (58.97%) |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 1 / 290 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 3 / 301 (1.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 2 / 301 (0.66%) | 2 / 290 (0.69%) |
| occurrences (all) | 0 | 3 | 2 |
| Influenza like illness | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 1 / 290 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Injection site pain | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site reaction | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site swelling | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaccination site swelling | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fever (≥38°C) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[1] | 0 / 301 (0.00%) | 35 / 189 (18.52%) | 27 / 190 (14.21%) |
| occurrences (all) | 0 | 35 | 27 |
| Fever (≥38°C but <38.5°C) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed for 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[2] | 0 / 301 (0.00%) | 15 / 179 (8.38%) | 15 / 183 (8.20%) |
| occurrences (all) | 0 | 15 | 15 |
| Fever (≥38.5°C but <39°C) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[3] | 0 / 301 (0.00%) | 5 / 174 (2.87%) | 7 / 183 (3.83%) |
| occurrences (all) | 0 | 5 | 7 |
| Fever (≥39°C but ≤40°C) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: | | | |

| | | | |
|---|---|---|---|
| Systematic | | | |
| subjects affected / exposed[4] | 0 / 301 (0.00%) | 6 / 174 (3.45%) | 10 / 184 (5.43%) |
| occurrences (all) | 0 | 6 | 10 |
| Fever (>40°C) | Additional description: Subjects affected, occurrences for LRs,SEs is same as data collected through e-diaries cannot distinguish 1 occurrence from another within a subject. All temperature >40°C were confirmed as data entry errors except 1 subject at Dose 3. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[5] | 0 / 301 (0.00%) | 14 / 181 (7.73%) | 2 / 180 (1.11%) |
| occurrences (all) | 0 | 14 | 2 |
| Fatigue (Any) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[6] | 0 / 301 (0.00%) | 123 / 230 (53.48%) | 86 / 211 (40.76%) |
| occurrences (all) | 0 | 123 | 86 |
| Fatigue (Mild) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[7] | 0 / 301 (0.00%) | 93 / 218 (42.66%) | 69 / 207 (33.33%) |
| occurrences (all) | 0 | 93 | 69 |
| Fatigue (Moderate) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[8] | 0 / 301 (0.00%) | 53 / 195 (27.18%) | 29 / 184 (15.76%) |
| occurrences (all) | 0 | 53 | 29 |
| Fatigue (Severe) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[9] | 0 / 301 (0.00%) | 16 / 178 (8.99%) | 12 / 183 (6.56%) |
| occurrences (all) | 0 | 16 | 12 |
| Headache (Any) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one | | |

| | | | |
|---|---|---|---|
| | occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[10]<br>occurrences (all) | 0 / 301 (0.00%)<br>0 | 111 / 220 (50.45%)<br>111 | 81 / 207 (39.13%)<br>81 |
| Headache (Mild) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[11]<br>occurrences (all) | 0 / 301 (0.00%)<br>0 | 96 / 209 (45.93%)<br>96 | 59 / 199 (29.65%)<br>59 |
| Headache (Moderate) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[12]<br>occurrences (all) | 0 / 301 (0.00%)<br>0 | 39 / 191 (20.42%)<br>39 | 39 / 190 (20.53%)<br>39 |
| Headache (Severe) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[13]<br>occurrences (all) | 0 / 301 (0.00%)<br>0 | 14 / 176 (7.95%)<br>14 | 5 / 182 (2.75%)<br>5 |
| Vomiting (Any) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[14]<br>occurrences (all) | 0 / 301 (0.00%)<br>0 | 23 / 180 (12.78%)<br>23 | 19 / 185 (10.27%)<br>19 |
| Vomiting (Mild) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed[15] | 0 / 301 (0.00%) | 20 / 180 (11.11%) | 14 / 183 (7.65%) |
| occurrences (all) | 0 | 20 | 14 |
| Vomiting (Moderate) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[16] | 0 / 301 (0.00%) | 2 / 172 (1.16%) | 4 / 179 (2.23%) |
| occurrences (all) | 0 | 2 | 4 |
| Vomiting (Severe) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.All reporting of severe vomiting were confirmed as data entry errors. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[17] | 0 / 301 (0.00%) | 2 / 173 (1.16%) | 3 / 179 (1.68%) |
| occurrences (all) | 0 | 2 | 3 |
| Diarrhea (Any) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[18] | 0 / 301 (0.00%) | 60 / 199 (30.15%) | 35 / 190 (18.42%) |
| occurrences (all) | 0 | 60 | 35 |
| Diarrhea (Mild) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[19] | 0 / 301 (0.00%) | 49 / 196 (25.00%) | 30 / 187 (16.04%) |
| occurrences (all) | 0 | 49 | 30 |
| Diarrhea (Moderate) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed for 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[20] | 0 / 301 (0.00%) | 14 / 177 (7.91%) | 10 / 180 (5.56%) |
| occurrences (all) | 0 | 14 | 10 |
| Diarrhea (Severe) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |

| | | | |
|---|---|---|---|
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[21]<br>occurrences (all) | 0 / 301 (0.00%)<br>0 | 2 / 173 (1.16%)<br>2 | 5 / 179 (2.79%)<br>5 |
| Muscle pain (Any) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[22]<br>occurrences (all) | 0 / 301 (0.00%)<br>0 | 126 / 226 (55.75%)<br>126 | 97 / 216 (44.91%)<br>97 |
| Muscle pain (Mild) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[23]<br>occurrences (all) | 0 / 301 (0.00%)<br>0 | 100 / 213 (46.95%)<br>100 | 75 / 208 (36.06%)<br>75 |
| Muscle pain (Moderate) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[24]<br>occurrences (all) | 0 / 301 (0.00%)<br>0 | 36 / 187 (19.25%)<br>36 | 34 / 191 (17.80%)<br>34 |
| Muscle pain (Severe) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[25]<br>occurrences (all) | 0 / 301 (0.00%)<br>0 | 10 / 177 (5.65%)<br>10 | 7 / 180 (3.89%)<br>7 |
| Joint pain (Any) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed[26] | 0 / 301 (0.00%) | 79 / 205 (38.54%) | 61 / 201 (30.35%) |
| occurrences (all) | 0 | 79 | 61 |
| Joint pain (Mild) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[27] | 0 / 301 (0.00%) | 63 / 199 (31.66%) | 43 / 193 (22.28%) |
| occurrences (all) | 0 | 63 | 43 |
| Joint pain (Moderate) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[28] | 0 / 301 (0.00%) | 28 / 184 (15.22%) | 22 / 188 (11.70%) |
| occurrences (all) | 0 | 28 | 22 |
| Joint pain (Severe) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[29] | 0 / 301 (0.00%) | 8 / 175 (4.57%) | 6 / 179 (3.35%) |
| occurrences (all) | 0 | 8 | 6 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 1 / 290 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Gynaecomastia | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 4 / 301 (1.33%) | 4 / 301 (1.33%) | 3 / 290 (1.03%) |
| occurrences (all) | 4 | 4 | 3 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 301 (0.33%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

| | | | |
|---|---|---|---|
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 301 (0.33%) | 1 / 290 (0.34%) |
| occurrences (all) | 0 | 1 | 1 |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 1 / 290 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Wheezing | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 1 / 290 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Nasal disorder | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Psychiatric disorders | | | |
| Abnormal dreams | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Agitation | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Depression | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Radius fracture | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 301 (0.33%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Lip injury | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 1 / 290 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 1 / 290 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 3 / 301 (1.00%) | 1 / 290 (0.34%) |
| occurrences (all) | 0 | 3 | 1 |

| | | | |
|---|---|---|---|
| Intercostal neuralgia | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Sciatica | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eye disorders | | | |
| Conjunctivitis | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 1 / 301 (0.33%) | 0 / 290 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Gastrointestinal disorders | | | |
| Nausea | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 301 (0.33%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Salivary gland enlargement | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 301 (0.33%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 301 (0.33%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastritis | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Stomatitis | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain upper | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroduodenitis | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Eczema | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 301 (0.33%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Exfoliative rash | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 301 (0.33%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rash | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Redness (Any) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[30] | 0 / 301 (0.00%) | 21 / 180 (11.67%) | 16 / 187 (8.56%) |
| occurrences (all) | 0 | 21 | 16 |
| Redness (Mild) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed[31] | 0 / 301 (0.00%) | 20 / 179 (11.17%) | 12 / 186 (6.45%) |
| occurrences (all) | 0 | 20 | 12 |
| Redness (Moderate) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[32] | 0 / 301 (0.00%) | 2 / 173 (1.16%) | 4 / 180 (2.22%) |
| occurrences (all) | 0 | 2 | 4 |
| Redness (Severe) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[33] | 0 / 301 (0.00%) | 0 / 172 (0.00%) | 1 / 178 (0.56%) |
| occurrences (all) | 0 | 0 | 1 |
| Swelling (Any) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[34] | 0 / 301 (0.00%) | 38 / 191 (19.90%) | 33 / 191 (17.28%) |
| occurrences (all) | 0 | 38 | 33 |
| Swelling (Mild) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[35] | 0 / 301 (0.00%) | 24 / 184 (13.04%) | 26 / 190 (13.68%) |
| occurrences (all) | 0 | 24 | 26 |
| Swelling (Moderate) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[36] | 0 / 301 (0.00%) | 16 / 181 (8.84%) | 12 / 184 (6.52%) |
| occurrences (all) | 0 | 16 | 12 |
| Swelling (Severe) | Additional description: Subjects affected, occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish 1 occurrence from another within subject. LRs, SEs were assessed at 13vPnC Dose 1,2 and 3 only. Swelling(severe)= data entry error. | | |

| | | | |
|---|---|---|---|
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[37] | 0 / 301 (0.00%) | 1 / 172 (0.58%) | 0 / 178 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pain at injection site (Any) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[38] | 0 / 301 (0.00%) | 156 / 238 (65.55%) | 166 / 236 (70.34%) |
| occurrences (all) | 0 | 156 | 166 |
| Pain at injection site (Mild) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[39] | 0 / 301 (0.00%) | 127 / 228 (55.70%) | 139 / 227 (61.23%) |
| occurrences (all) | 0 | 127 | 139 |
| Pain at injection site (Moderate) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[40] | 0 / 301 (0.00%) | 44 / 188 (23.40%) | 51 / 199 (25.63%) |
| occurrences (all) | 0 | 44 | 51 |
| Pain at injection site (Severe) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[41] | 0 / 301 (0.00%) | 9 / 175 (5.14%) | 8 / 179 (4.47%) |
| occurrences (all) | 0 | 9 | 8 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 301 (0.33%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pain in extremity | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 1 / 290 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Myalgia | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Back pain | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Spondylolisthesis | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Scoliosis | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Influenza | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 5 / 301 (1.66%) | 1 / 290 (0.34%) |
| occurrences (all) | 0 | 5 | 1 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 3 / 301 (1.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 3 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 6 / 301 (1.99%) | 3 / 301 (1.00%) | 4 / 290 (1.38%) |
| occurrences (all) | 6 | 3 | 4 |
| Sinusitis | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 2 / 301 (0.66%) | 1 / 290 (0.34%) |
| occurrences (all) | 0 | 2 | 1 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 301 (0.33%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Herpes virus infection | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 301 (0.33%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oral herpes | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 301 (0.33%) | 1 / 290 (0.34%) |
| occurrences (all) | 0 | 1 | 1 |

| | | | |
|---|---|---|---|
| Otitis media | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 301 (0.33%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 301 (0.33%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 1 / 301 (0.33%) | 2 / 290 (0.69%) |
| occurrences (all) | 1 | 1 | 2 |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 301 (0.33%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tinea capitis | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 301 (0.33%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 1 / 301 (0.33%) | 0 / 290 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Tooth infection | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 301 (0.33%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Viraemia | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 1 / 301 (0.33%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Body tinea | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 1 / 290 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 1 / 290 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 1 / 290 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |
| Pharyngitis bacterial | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 1 / 290 (0.34%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|---|---|---|
| Tooth abscess | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Varicella | | | |
| subjects affected / exposed | 3 / 301 (1.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Impetigo | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Parotitis | | | |
| subjects affected / exposed | 1 / 301 (0.33%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Hypercholesterolaemia | | | |
| subjects affected / exposed | 0 / 301 (0.00%) | 0 / 301 (0.00%) | 0 / 290 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | 13vPnC Dose 3 | 23vPS Dose | Follow-up |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 137 / 286 (47.90%) | 31 / 282 (10.99%) | 2 / 282 (0.71%) |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Pyrexia | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 1 / 282 (0.35%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Influenza like illness | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site pain | | | |
| subjects affected / exposed | 1 / 286 (0.35%) | 6 / 282 (2.13%) | 0 / 282 (0.00%) |
| occurrences (all) | 1 | 6 | 0 |
| Injection site reaction | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 2 / 282 (0.71%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Injection site swelling | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 2 / 282 (0.71%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Vaccination site swelling | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 2 / 282 (0.71%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Fever (≥38°C) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[1] | 17 / 158 (10.76%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 17 | 0 | 0 |
| Fever (≥38°C but <38.5°C) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed for 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[2] | 9 / 155 (5.81%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 9 | 0 | 0 |
| Fever (≥38.5°C but <39°C) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[3] | 6 / 153 (3.92%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 6 | 0 | 0 |

| | | | |
|---|---|---|---|
| Fever (≥39°C but ≤40°C) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[4] | 4 / 152 (2.63%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Fever (>40°C) | Additional description: Subjects affected, occurrences for LRs,SEs is same as data collected through e-diaries cannot distinguish 1 occurrence from another within a subject. All temperature >40°C were confirmed as data entry errors except 1 subject at Dose 3. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[5] | 4 / 153 (2.61%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Fatigue (Any) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[6] | 66 / 183 (36.07%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 66 | 0 | 0 |
| Fatigue (Mild) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[7] | 53 / 177 (29.94%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 53 | 0 | 0 |
| Fatigue (Moderate) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[8] | 25 / 163 (15.34%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 25 | 0 | 0 |
| Fatigue (Severe) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed[9] | 10 / 156 (6.41%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 10 | 0 | 0 |
| Headache (Any) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[10] | 57 / 177 (32.20%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 57 | 0 | 0 |
| Headache (Mild) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[11] | 45 / 171 (26.32%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 45 | 0 | 0 |
| Headache (Moderate) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[12] | 22 / 160 (13.75%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 22 | 0 | 0 |
| Headache (Severe) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[13] | 8 / 154 (5.19%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 8 | 0 | 0 |
| Vomiting (Any) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[14] | 14 / 159 (8.81%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 14 | 0 | 0 |
| Vomiting (Mild) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |

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| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[15]<br>occurrences (all) | 10 / 156 (6.41%)<br>10 | 0 / 282 (0.00%)<br>0 | 0 / 282 (0.00%)<br>0 |
| Vomiting (Moderate) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[16]<br>occurrences (all) | 6 / 155 (3.87%)<br>6 | 0 / 282 (0.00%)<br>0 | 0 / 282 (0.00%)<br>0 |
| Vomiting (Severe) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination.All reporting of severe vomiting were confirmed as data entry errors. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[17]<br>occurrences (all) | 3 / 153 (1.96%)<br>3 | 0 / 282 (0.00%)<br>0 | 0 / 282 (0.00%)<br>0 |
| Diarrhea (Any) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[18]<br>occurrences (all) | 27 / 162 (16.67%)<br>27 | 0 / 282 (0.00%)<br>0 | 0 / 282 (0.00%)<br>0 |
| Diarrhea (Mild) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[19]<br>occurrences (all) | 24 / 160 (15.00%)<br>24 | 0 / 282 (0.00%)<br>0 | 0 / 282 (0.00%)<br>0 |
| Diarrhea (Moderate) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed for 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed[20] | 6 / 153 (3.92%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 6 | 0 | 0 |
| Diarrhea (Severe) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[21] | 4 / 154 (2.60%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Muscle pain (Any) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[22] | 81 / 191 (42.41%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 81 | 0 | 0 |
| Muscle pain (Mild) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[23] | 57 / 182 (31.32%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 57 | 0 | 0 |
| Muscle pain (Moderate) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[24] | 30 / 163 (18.40%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 30 | 0 | 0 |
| Muscle pain (Severe) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Systemic Events 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[25] | 11 / 156 (7.05%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 11 | 0 | 0 |
| Joint pain (Any) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |

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|---|---|---|---|
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[26] | 49 / 174 (28.16%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 49 | 0 | 0 |
| Joint pain (Mild) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[27] | 37 / 170 (21.76%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 37 | 0 | 0 |
| Joint pain (Moderate) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[28] | 18 / 159 (11.32%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 18 | 0 | 0 |
| Joint pain (Severe) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[29] | 4 / 152 (2.63%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Reproductive system and breast disorders | | | |
| Dysmenorrhoea<br>subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gynaecomastia<br>subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough<br>subjects affected / exposed | 1 / 286 (0.35%) | 4 / 282 (1.42%) | 0 / 282 (0.00%) |
| occurrences (all) | 1 | 4 | 0 |
| Oropharyngeal pain | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 286 (0.70%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Rhinorrhoea | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper-airway cough syndrome | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Wheezing | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nasal disorder | | | |
| subjects affected / exposed | 1 / 286 (0.35%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Psychiatric disorders | | | |
| Abnormal dreams | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Agitation | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Depression | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injury, poisoning and procedural complications | | | |
| Radius fracture | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lip injury | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Procedural pain | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Nervous system disorders | | | |

| | | | |
|---|---|---|---|
| Headache | | | |
| subjects affected / exposed | 1 / 286 (0.35%) | 2 / 282 (0.71%) | 0 / 282 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Intercostal neuralgia | | | |
| subjects affected / exposed | 1 / 286 (0.35%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sciatica | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 1 / 282 (0.35%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dizziness | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Lymphadenopathy | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 1 / 282 (0.35%) |
| occurrences (all) | 0 | 0 | 1 |
| Eye disorders | | | |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 1 / 282 (0.35%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gastrointestinal disorders | | | |
| Nausea | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Salivary gland enlargement | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 286 (0.35%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastritis | | | |
| subjects affected / exposed | 1 / 286 (0.35%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Stomatitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 286 (0.35%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Abdominal pain upper | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 1 / 282 (0.35%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 1 / 282 (0.35%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gastroduodenitis | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 1 / 282 (0.35%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| Eczema | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Exfoliative rash | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash | | | |
| subjects affected / exposed | 2 / 286 (0.70%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Pruritus | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 1 / 282 (0.35%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Urticaria | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 1 / 282 (0.35%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Redness (Any) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[30] | 7 / 154 (4.55%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 7 | 0 | 0 |
| Redness (Mild) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local | | | |

| | | | |
|---|---|---|---|
| Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[31] | 6 / 153 (3.92%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 6 | 0 | 0 |
| Redness (Moderate) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[32] | 2 / 152 (1.32%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Redness (Severe) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[33] | 0 / 150 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Swelling (Any) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[34] | 19 / 160 (11.88%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 19 | 0 | 0 |
| Swelling (Mild) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[35] | 12 / 157 (7.64%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 12 | 0 | 0 |
| Swelling (Moderate) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed[36] | 8 / 154 (5.19%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 8 | 0 | 0 |
| Swelling (Severe) | Additional description: Subjects affected, occurrences for LRs, SEs is same as data collected through e-diaries cannot be used to distinguish 1 occurrence from another within subject. LRs, SEs were assessed at 13vPnC Dose 1,2 and 3 only. Swelling(severe)= data entry error. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[37] | 0 / 150 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pain at injection site (Any) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[38] | 131 / 213 (61.50%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 131 | 0 | 0 |
| Pain at injection site (Mild) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[39] | 107 / 201 (53.23%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 107 | 0 | 0 |
| Pain at injection site (Moderate) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[40] | 36 / 167 (21.56%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 36 | 0 | 0 |
| Pain at injection site (Severe) | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. LRs and SEs were to be assessed at 13vPnC Dose 1, 2 and 3 only. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[41] | 8 / 156 (5.13%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 8 | 0 | 0 |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|---|---|---|---|
| Arthralgia | | | |
| subjects affected / exposed | 2 / 286 (0.70%) | 1 / 282 (0.35%) | 0 / 282 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Pain in extremity | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Myalgia | | | |
| subjects affected / exposed | 1 / 286 (0.35%) | 1 / 282 (0.35%) | 0 / 282 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Back pain | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 1 / 282 (0.35%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Spondylolisthesis | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 1 / 282 (0.35%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Scoliosis | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 1 / 282 (0.35%) |
| occurrences (all) | 0 | 0 | 1 |
| Infections and infestations | | | |
| Influenza | | | |
| subjects affected / exposed | 8 / 286 (2.80%) | 3 / 282 (1.06%) | 1 / 282 (0.35%) |
| occurrences (all) | 8 | 3 | 1 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 286 (0.35%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Sinusitis | | | |
| subjects affected / exposed | 1 / 286 (0.35%) | 1 / 282 (0.35%) | 1 / 282 (0.35%) |
| occurrences (all) | 1 | 1 | 1 |
| Cystitis | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Herpes virus infection | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral herpes | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 1 / 286 (0.35%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 1 / 286 (0.35%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Rhinitis | | | |
| subjects affected / exposed | 4 / 286 (1.40%) | 2 / 282 (0.71%) | 0 / 282 (0.00%) |
| occurrences (all) | 4 | 2 | 0 |
| Subcutaneous abscess | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tinea capitis | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 2 / 286 (0.70%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Tooth infection | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viraemia | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Body tinea | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pharyngitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 286 (0.35%) | 1 / 282 (0.35%) | 1 / 282 (0.35%) |
| occurrences (all) | 1 | 1 | 1 |
| Pharyngitis bacterial | | | |
| subjects affected / exposed | 1 / 286 (0.35%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tooth abscess | | | |
| subjects affected / exposed | 1 / 286 (0.35%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Varicella | | | |
| subjects affected / exposed | 1 / 286 (0.35%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Impetigo | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 1 / 282 (0.35%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 1 / 282 (0.35%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 1 / 282 (0.35%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 1 / 282 (0.35%) |
| occurrences (all) | 0 | 0 | 1 |
| Parotitis | | | |
| subjects affected / exposed | 0 / 286 (0.00%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Metabolism and nutrition disorders | | | |
| Hypercholesterolaemia | | | |
| subjects affected / exposed | 1 / 286 (0.35%) | 0 / 282 (0.00%) | 0 / 282 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Here number of subjects exposed signifies subjects with known values.

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## More information

## Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 01 September 2010 | 1. Reference to the 7443-V form was removed from the Safety Evaluation section, Adverse Event (AE) and Serious Adverse Event (SAE) Recording and Reporting section, and Serious Adverse Event Reporting Requirements section.<br>2. Updated informed consent procedures in Visit 1 (Baseline Visit) to add "If Visit 0 was not applicable, obtain informed consent…" and new text pertaining to determination of AEs or SAEs for subjects who had a Screening Visit was added to Visit 1.<br>3. Reporting time lines for SAEs were updated to "24 hours" and wordings "instructing sites to follow-up on reported SAEs by phone" and "A business day was defined as any day except weekends, December 25, and January 1" was removed from the Serious Adverse Event Reporting Requirements section.<br>4. Updated commencement of concomitant medications reporting to "Visit 1" and the text "In addition for subjects undergoing Visit 0 (Screening Visit), concomitant medications received following an AE or SAE was recorded at Visit 0" was added to Concomitant Treatment sections.<br>5. Subject Discontinuation or Withdrawal section was updated to reflect follow-up for safety reporting applied "If the subject had received at least one dose of investigational product" and that "Subjects who were discontinued prior to Visit 1 were not be followed for safety". |
| 28 February 2012 | 1. Section of Adverse Events, revised to reflect EU CT-3 (European Union Clinical Trials - 3) requirements and standard Pfizer safety terminology.<br>2. Section of Reporting of Safety Issues and Serious Breaches of the Protocol or ICH (International Conference on Harmonisation) GCP (Good Clinical Practice), was added to clarify the need for immediate notification should there be a clinical hold or similar issue taken for purposes of safety so that Pfizer can fulfill its reporting obligations as sponsor in accordance with local legislation. |
| 28 March 2013 | 1. In a Protocol Administrative Changes and Clarifications letter, dated 28 March 2013, the participating sites' requirements to report SAEs after active reporting period in Amendment 3, wording was clarified from "Should an investigator be made aware of any SAE occurring any time after the active reporting period, it must be promptly reported." This was updated as follows: "Serious adverse events occurring to a subject after the active reporting period has ended should be reported to the Sponsor if the investigator becomes aware of them; at a minimum, all serious adverse events that the investigator believes have at least a reasonable possibility of being related to study drug are to be reported to the Sponsor." |

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

None reported