# Clinical trial results:
# A PHASE 3, RANDOMIZED, OPEN-LABEL TRIAL TO EVALUATE THE SAFETY, TOLERABILITY, AND IMMUNOGENICITY OF 13-VALENT PNEUMOCOCCAL CONJUGATE VACCINE FORMULATED IN MULTIDOSE VIALS GIVEN WITH ROUTINE PEDIATRIC VACCINATIONS IN HEALTHY INFANTS

## Summary

| | |
|---|---|
| EudraCT number | 2012-000482-21 |
| Trial protocol | Outside EU/EEA |
| Global end of trial date | 01 September 2014 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 29 June 2016 |
| First version publication date | 18 March 2015 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | B4671001 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT01964716 |
| WHO universal trial number (UTN) | - |

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 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com |
| Scientific contact | Pfizer ClinicalTrials.gov Call Center, Pfizer, Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com |

Notes:

**Paediatric regulatory details**

| | |
|---|---|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| 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 | 13 February 2015 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 01 September 2014 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

To demonstrate that the immune response induced by 13-valent pneumococcal conjugate vaccine (13vPnC) with 2-phenoxyethanol in multi-dose vials (MDVs) is noninferior to the immune response induced by 13vPnC without 2-phenoxyethanol in single-dose syringes (SDSs) as measured by serotype-specific immunoglobulin G (IgG) concentrations 1 month after the infant series.

Protection of trial subjects:

This study was conducted in compliance with the ethical principles originating in or derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice (GCP) Guidelines. In addition, all local regulatory requirements were followed; in particular, those affording greater protection to the safety of study subjects.

| |
|---|
| Background therapy: - |
| Evidence for comparator: - |

| | |
|---|---|
| Actual start date of recruitment | 09 January 2014 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Gambia: 500 |
| Worldwide total number of subjects | 500 |
| EEA total number of subjects | 0 |

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) | 500 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 0 |
| From 65 to 84 years | 0 |

| | |
|---|---|
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

Total number of subjects screened were 526, out of which 500 were enrolled in the study. The study was conducted in Gambia which started on 09 January 2014 and completed on 01 September 2014.

### Period 1

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

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | 13vPnC Multi-dose Vial (MDV) |

Arm description:

Subjects received three doses of 0.5 milliliter (mL) of 13-valent pneumococcal conjugate vaccine (13vPnC) with 2-phenoxyethanol (2-PE) in MDV intramuscularly at 8, 12 and 16 weeks of age.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | 13-valent pneumococcal conjugate vaccine in a multidose vial |
| Investigational medicinal product code | PF-06414256 |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Subjects received three doses of 0.5 mL of 13vPnC with 2-PE in MDV intramuscularly at 8, 12 and 16 weeks of age.

| | |
|---|---|
| **Arm title** | 13vPnC Single-Dose Syringe (SDS) |

Arm description:

Subjects received three doses of 0.5 milliliter (mL) of 13-valent pneumococcal conjugate vaccine (13vPnC) without 2-phenoxyethanol (2-PE) in single dose syringe (SDS) intramuscularly at 8, 12 and 16 weeks of age.

| | |
|---|---|
| Arm type | Active comparator |
| Investigational medicinal product name | 13-valent pneumococcal conjugate vaccine in Single-Dose Syringe |
| Investigational medicinal product code | PF-05208760 |
| Other name | |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Subjects received three doses of 0.5 mL of 13vPnC without 2-PE in single dose syringe (SDS) intramuscularly at 8, 12 and 16 weeks of age.

| **Number of subjects in period 1** | 13vPnC Multi-dose Vial (MDV) | 13vPnC Single-Dose Syringe (SDS) |
|---|---|---|
| Started | 250 | 250 |
| Vaccinated Dose 1 | 250 | 250 |
| Vaccinated Dose 2 | 249 | 248 |
| Vaccinated Dose 3 | 247 | 244 |
| Completed | 245 | 244 |
| Not completed | 5 | 6 |
| Consent withdrawn by subject | 2 | 3 |
| Death | 1 | - |
| No longer met eligibility criteria | 1 | 1 |
| Lost to follow-up | 1 | 2 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | 13vPnC Multi-dose Vial (MDV) |
| Reporting group description: | |
| Subjects received three doses of 0.5 milliliter (mL) of 13-valent pneumococcal conjugate vaccine (13vPnC) with 2-phenoxyethanol (2-PE) in MDV intramuscularly at 8, 12 and 16 weeks of age. | |
| Reporting group title | 13vPnC Single-Dose Syringe (SDS) |
| Reporting group description: | |
| Subjects received three doses of 0.5 milliliter (mL) of 13-valent pneumococcal conjugate vaccine (13vPnC) without 2-phenoxyethanol (2-PE) in single dose syringe (SDS) intramuscularly at 8, 12 and 16 weeks of age. | |

| Reporting group values | 13vPnC Multi-dose Vial (MDV) | 13vPnC Single-Dose Syringe (SDS) | Total |
|---|---|---|---|
| Number of subjects | 250 | 250 | 500 |
| Age categorical | | | |
| Units: Subjects | | | |
| Age continuous | | | |
| Units: days | | | |
| arithmetic mean | 57.3 | 56.9 | |
| standard deviation | ± 8.6 | ± 8.8 | - |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 129 | 130 | 259 |
| Male | 121 | 120 | 241 |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | 13vPnC Multi-dose Vial (MDV) |
| Reporting group description: | |
| Subjects received three doses of 0.5 milliliter (mL) of 13-valent pneumococcal conjugate vaccine (13vPnC) with 2-phenoxyethanol (2-PE) in MDV intramuscularly at 8, 12 and 16 weeks of age. | |
| Reporting group title | 13vPnC Single-Dose Syringe (SDS) |
| Reporting group description: | |
| Subjects received three doses of 0.5 milliliter (mL) of 13-valent pneumococcal conjugate vaccine (13vPnC) without 2-phenoxyethanol (2-PE) in single dose syringe (SDS) intramuscularly at 8, 12 and 16 weeks of age. | |
| Subject analysis set title | Screened Only |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: | |
| Subjects who were screened for this study but were not randomized, assessed between signing of informed consent form and before randomization. | |

### Primary: Percentage of Subjects Achieving a Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody concentration Greater Than or Equal To (>=) 0.35 Microgram per Milliliter (mcg/mL) 1 Month After the Infant Series for Each Vaccine Group

| | |
|---|---|
| End point title | Percentage of Subjects Achieving a Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody concentration Greater Than or Equal To (>=) 0.35 Microgram per Milliliter (mcg/mL) 1 Month After the Infant Series for Each Vaccine Group |
| End point description: | |
| Percentage of subjects achieving predefined antibody threshold >=0.35 mcg/mL along with the corresponding 95% confidence interval (CI) for the 13 pneumococcal serotypes (serotypes 1, 3, 4, 5, 6A, 6B, 7F 9V, 14, 18C, 19A, 19F and 23F) are presented. Exact 2-sided confidence interval (Clopper and Pearson) based on the observed proportion of subjects. Evaluable immunogenicity population: eligible subjects who received vaccine (as randomized) at all 3 doses, had blood drawn within protocol-specified time frames, had at least 1 valid and determinate assay result for proposed analysis, had no major protocol violations. Here "n"= subjects with valid and determinate IgG concentration to the given serotype. | |
| End point type | Primary |
| End point timeframe: | |
| 1 month after the infant series | |

| End point values | 13vPnC Multi-dose Vial (MDV) | 13vPnC Single-Dose Syringe (SDS) | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 245 | 244 | | |
| Units: percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Serotype 1 (n=245,244) | 99.2 (97.1 to 99.9) | 100 (98.5 to 100) | | |
| Serotype 3 (n=245,243) | 98.8 (96.5 to 99.7) | 99.6 (97.7 to 100) | | |
| Serotype 4 (n=245,244) | 99.6 (97.7 to 100) | 99.6 (97.7 to 100) | | |

| | | | | |
|---|---|---|---|---|
| Serotype 5 (n=245,244) | 95.9 (92.6 to 98) | 97.1 (94.2 to 98.8) | | |
| Serotype 6A (n=243,244) | 96.3 (93.1 to 98.3) | 97.5 (94.7 to 99.1) | | |
| Serotype 6B (n=245,244) | 95.1 (91.6 to 97.4) | 95.1 (91.6 to 97.4) | | |
| Serotype 7F (n=245,244) | 99.6 (97.7 to 100) | 100 (98.5 to 100) | | |
| Serotype 9V (n=245,244) | 98 (95.3 to 99.3) | 98.4 (95.9 to 99.6) | | |
| Serotype 14 (n=245,244) | 97.6 (94.7 to 99.1) | 98.4 (95.9 to 99.6) | | |
| Serotype 18C (n=245,244) | 99.2 (97.1 to 99.9) | 98 (95.3 to 99.3) | | |
| Serotype 19A (n=245,244) | 99.6 (97.7 to 100) | 98.8 (96.4 to 99.7) | | |
| Serotype 19F (n=245,244) | 96.7 (93.7 to 98.6) | 97.1 (94.2 to 98.8) | | |
| Serotype 23F (n=245,244) | 95.9 (92.6 to 98) | 95.9 (92.6 to 98) | | |

**Statistical analyses**

| **Statistical analysis title** | Serotype 1 |
|---|---|

Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[1] |
| Parameter estimate | percent difference |
| Point estimate | -0.8 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | -3.4 |
| upper limit | 1.2 |

Notes:

[1] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

| **Statistical analysis title** | Serotype 3 |
|---|---|

Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |

| | |
|---|---|
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[2] |
| Parameter estimate | percent difference |
| Point estimate | -0.8 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | -3.7 |
| upper limit | 1.6 |

Notes:

[2] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

| **Statistical analysis title** | Serotype 4 |
|---|---|

Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

| | |
|---|---|
| Comparison groups | 13vPnC Single-Dose Syringe (SDS) v 13vPnC Multi-dose Vial (MDV) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[3] |
| Parameter estimate | percent difference |
| Point estimate | 0 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | -2.3 |
| upper limit | 2.4 |

Notes:

[3] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

| **Statistical analysis title** | Serotype 5 |
|---|---|

Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[4] |
| Parameter estimate | percent difference |
| Point estimate | -1.2 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | -5.4 |
| upper limit | 2.8 |

Notes:

[4] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

| **Statistical analysis title** | Serotype 6A |
|---|---|

Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[5] |
| Parameter estimate | percent difference |
| Point estimate | -1.2 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | -5.3 |
| upper limit | 2.6 |

Notes:

[5] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

| **Statistical analysis title** | Serotype 6B |
|---|---|

Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[6] |
| Parameter estimate | percent difference |
| Point estimate | 0 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | -4.7 |
| upper limit | 4.7 |

Notes:

[6] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

| **Statistical analysis title** | Serotype 7F |
|---|---|

Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |

| | |
|---|---|
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[7] |
| Parameter estimate | percent difference |
| Point estimate | -0.4 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | -2.7 |
| upper limit | 1.6 |

Notes:

[7] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

| **Statistical analysis title** | Serotype 9V |
|---|---|

Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[8] |
| Parameter estimate | percent difference |
| Point estimate | -0.4 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | -3.8 |
| upper limit | 2.8 |

Notes:

[8] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

| **Statistical analysis title** | Serotype 14 |
|---|---|

Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[9] |
| Parameter estimate | percent difference |
| Point estimate | -0.8 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | -4.3 |
| upper limit | 2.5 |

Notes:

[9] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

| **Statistical analysis title** | Serotype 18C |
|---|---|

Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[10] |
| Parameter estimate | percent difference |
| Point estimate | 1.2 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | -1.6 |
| upper limit | 4.5 |

Notes:

[10] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

| **Statistical analysis title** | Serotype 19A |
|---|---|

Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[11] |
| Parameter estimate | percent difference |
| Point estimate | 0.8 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | -1.6 |
| upper limit | 3.6 |

Notes:

[11] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

| **Statistical analysis title** | Serotype 19F |
|---|---|

Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |

| | |
|---|---|
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[12] |
| Parameter estimate | percent difference |
| Point estimate | -0.4 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | -4.4 |
| upper limit | 3.5 |

Notes:

[12] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

| **Statistical analysis title** | Serotype 23F |
|---|---|

Statistical analysis description:

Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed.

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[13] |
| Parameter estimate | percent difference |
| Point estimate | 0 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | -4.3 |
| upper limit | 4.4 |

Notes:

[13] - Non-inferiority for a given antibody was demonstrated if the lower bound of the 2-sided, 97.5% confidence interval, computed using the Chan and Zhang procedure, for the difference in proportions (13vPnC MDV – 13vPnC SDS) was greater than -0.10.

## Primary: Geometric Mean Concentration (GMC) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After the Infant Series for Each Vaccine Group

| | |
|---|---|
| End point title | Geometric Mean Concentration (GMC) for Serotype-Specific Pneumococcal Immunoglobulin G (IgG) Antibody 1 Month After the Infant Series for Each Vaccine Group |

End point description:

Antibody GMC for the 13 pneumococcal serotypes (serotypes 1, 3, 4, 5, 6A, 6B, 7F 9V, 14, 18C, 19A, 19F and 23F) are presented. GMC (13vPnC) and corresponding 2-sided 95% CI were evaluated. Geometric means (GMs) were calculated using all subjects with available data for the specified blood draw. CIs were back transformations of a confidence interval based on the Student t distribution for the mean logarithm of the concentrations. Evaluable immunogenicity population: eligible subjects who received vaccine (as randomized) at all 3 doses, had blood drawn within protocol-specified time frames, had at least 1 valid and determinate assay result for proposed analysis, had no major protocol violations. Here "n"= subjects with valid and determinate IgG concentration to the given serotype.

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

End point timeframe:

1 month after the infant series

| End point values | 13vPnC Multi-dose Vial (MDV) | 13vPnC Single-Dose Syringe (SDS) | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 245 | 244 | | |
| Units: microgram per milliliter (mcg/mL) | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 1 (n=245,244) | 4.59 (4.11 to 5.12) | 4.45 (4.01 to 4.93) | | |
| Serotype 3 (n=245,243) | 1.38 (1.29 to 1.49) | 1.74 (1.62 to 1.87) | | |
| Serotype 4 (n=245,244) | 5.3 (4.84 to 5.81) | 5.28 (4.76 to 5.85) | | |
| Serotype 5 (n=245,244) | 2 (1.79 to 2.22) | 1.98 (1.79 to 2.2) | | |
| Serotype 6A (n=243,244) | 2.25 (2.02 to 2.5) | 2.19 (1.96 to 2.44) | | |
| Serotype 6B (n=245,244) | 3.42 (2.91 to 4.02) | 3.24 (2.77 to 3.78) | | |
| Serotype 7F (n=245,244) | 3.92 (3.59 to 4.27) | 4.18 (3.83 to 4.55) | | |
| Serotype 9V (n=245,244) | 2.83 (2.56 to 3.13) | 2.75 (2.49 to 3.04) | | |
| Serotype 14 (n=245,244) | 4.78 (4.06 to 5.63) | 4.96 (4.27 to 5.77) | | |
| Serotype 18C (n=245,244 | 3.47 (3.17 to 3.79) | 2.72 (2.46 to 3) | | |
| Serotype 19A (n=245,244) | 6.49 (5.7 to 7.38) | 6.44 (5.66 to 7.32) | | |
| Serotype 19F (n=245,244) | 5.19 (4.59 to 5.86) | 5 (4.43 to 5.63) | | |
| Serotype 23F (n=245,244) | 2.61 (2.3 to 2.97) | 2.17 (1.92 to 2.46) | | |

## Statistical analyses

| Statistical analysis title | Serotype 1 |
|---|---|

Statistical analysis description:

Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[14] |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.03 |

| | |
|---|---|
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.87 |
| upper limit | 1.22 |

Notes:

[14] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

| **Statistical analysis title** | Serotype 3 |
|---|---|

Statistical analysis description:

Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[15] |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.79 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.71 |
| upper limit | 0.9 |

Notes:

[15] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

| **Statistical analysis title** | Serotype 4 |
|---|---|

Statistical analysis description:

Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[16] |
| Parameter estimate | GMC Ratio |
| Point estimate | 1 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.86 |
| upper limit | 1.18 |

Notes:

[16] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

| **Statistical analysis title** | Serotype 5 |
|---|---|

Statistical analysis description:

Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

| | |
|---|---|
| Comparison groups | 13vPnC Single-Dose Syringe (SDS) v 13vPnC Multi-dose Vial (MDV) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[17] |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.01 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.85 |
| upper limit | 1.19 |

Notes:

[17] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

| **Statistical analysis title** | Serotype 6A |
|---|---|

Statistical analysis description:

Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[18] |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.03 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.86 |
| upper limit | 1.22 |

Notes:

[18] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

| **Statistical analysis title** | Serotype 6B |
|---|---|

Statistical analysis description:

Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |

| | |
|---|---|
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[19] |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.06 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.82 |
| upper limit | 1.36 |

Notes:

[19] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

| **Statistical analysis title** | Serotype 7F |
|---|---|

Statistical analysis description:

Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[20] |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.94 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.82 |
| upper limit | 1.08 |

Notes:

[20] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

| **Statistical analysis title** | Serotype 9V |
|---|---|

Statistical analysis description:

Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[21] |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.03 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.87 |
| upper limit | 1.21 |

Notes:

[21] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

| **Statistical analysis title** | Serotype 14 |
|---|---|

Statistical analysis description:

Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

| | |
|---|---|
| Comparison groups | 13vPnC Single-Dose Syringe (SDS) v 13vPnC Multi-dose Vial (MDV) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[22] |
| Parameter estimate | GMC Ratio |
| Point estimate | 0.96 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.75 |
| upper limit | 1.24 |

Notes:

[22] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

| **Statistical analysis title** | Serotype 18C |
|---|---|

Statistical analysis description:

Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[23] |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.28 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 1.09 |
| upper limit | 1.49 |

Notes:

[23] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

| **Statistical analysis title** | Serotype 19A |
|---|---|

Statistical analysis description:

Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[24] |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.01 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.82 |
| upper limit | 1.24 |

Notes:

[24] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

| **Statistical analysis title** | Serotype 19F |
|---|---|

Statistical analysis description:

Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[25] |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.04 |
| Confidence interval | |
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.85 |
| upper limit | 1.26 |

Notes:

[25] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

| **Statistical analysis title** | Serotype 23F |
|---|---|

Statistical analysis description:

Ratio of GMCs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale; CIs for the ratio are back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 489 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[26] |
| Parameter estimate | GMC Ratio |
| Point estimate | 1.2 |

| Confidence interval | |
|---|---|
| level | Other: 97.5 % |
| sides | 2-sided |
| lower limit | 0.98 |
| upper limit | 1.48 |

Notes:

[26] - Non-inferiority for a given antibody serotype was declared if lower bound of the 2-sided, 97.5% confidence interval for the geometric mean concentration ratio (GMC MDV /GMC SDS) was greater than 0.5 (2-fold criterion).

## Primary: Number of Subjects Reporting Local Reaction Within 5 Days After Dose 1 in MDV and SDS Group

| End point title | Number of Subjects Reporting Local Reaction Within 5 Days After Dose 1 in MDV and SDS Group[27] |
|---|---|

End point description:

Local reactions were reported within 5 days (Day 2 to Day 6) using an electronic diary. Tenderness was scaled as Any (tenderness present); Mild (hurt if gently touched; Moderate (hurt if gently touched with crying); Severe (caused limitation of limb movement). Redness and swelling were scaled as Any (redness or swelling present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (2.1 to 7.0 cm); Severe (greater than [>] 7.0 cm). Subject may be represented in more than 1 category. Safety population included subects who received at least 1 dose of study vaccine.

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

End point timeframe:

Within 5 days after Dose 1 (Day 2 to Day 6) of the infant series

Notes:

[27] - 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: Statistical analysis was not planned for numbers of subjects with local reactions or systemic events.

| **End point values** | 13vPnC Multi-dose Vial (MDV) | 13vPnC Single-Dose Syringe (SDS) | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 248[28] | 250 | | |
| Units: subjects | | | | |
| Redness: Any | 1 | 0 | | |
| Redness: Mild | 1 | 0 | | |
| Redness: Moderate | 0 | 0 | | |
| Redness: Severe | 0 | 0 | | |
| Swelling: Any | 1 | 0 | | |
| Swelling: Mild | 1 | 0 | | |
| Swelling: Moderate | 0 | 0 | | |
| Swelling: Severe | 0 | 0 | | |
| Tenderness: Any | 42 | 47 | | |
| Tenderness: Mild | 32 | 37 | | |
| Tenderness: Moderate | 13 | 14 | | |
| Tenderness: Severe | 0 | 0 | | |

Notes:

[28] - 'N' (number of subjects analyzed)= subjects whose response=Yes for any day or No for all days.

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Subjects Reporting Local Reaction Within 5 Days After Dose 2 in MDV and SDS Group

| End point title | Number of Subjects Reporting Local Reaction Within 5 Days After Dose 2 in MDV and SDS Group[29] |
|---|---|

End point description:

Local reactions were reported within 5 days (Day 2 to Day 6) using an electronic diary. Tenderness was scaled as Any (tenderness present); Mild (hurt if gently touched; Moderate (hurt if gently touched with crying); Severe (caused limitation of limb movement). Redness and swelling were scaled as Any (redness or swelling present); Mild (0.5 cm to 2.0 cm); Moderate (2.1 to 7.0 cm); Severe (>7.0 cm). Subjects may be represented in more than 1 category. Safety population included subjects who received at least 1 dose of study vaccine. Here 'n' = subjects whose response was “Yes” for any day or “No” for all days for specified local reaction.

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

End point timeframe:

Within 5 days after Dose 2 (Day 2 to Day 6) of the infant series

Notes:

[29] - 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: Statistical analysis was not planned for numbers of subjects with local reactions or systemic events.

| End point values | 13vPnC Multi-dose Vial (MDV) | 13vPnC Single-Dose Syringe (SDS) | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 248[30] | 247[31] | | |
| Units: subjects | | | | |
| Redness: Any (n=247, 247) | 2 | 0 | | |
| Redness: Mild (n=247, 247) | 2 | 0 | | |
| Redness: Moderate (n=247, 247) | 0 | 0 | | |
| Redness: Severe (n=247, 247) | 0 | 0 | | |
| Swelling: Any (n=247, 247) | 2 | 0 | | |
| Swelling: Mild (n=247, 247) | 2 | 0 | | |
| Swelling: Moderate (n=247, 247) | 1 | 0 | | |
| Swelling: Severe (n=247, 247) | 0 | 0 | | |
| Tenderness: Any (n=248, 247) | 34 | 32 | | |
| Tenderness: Mild (n=248, 247) | 27 | 28 | | |
| Tenderness: Moderate (n=247, 247) | 7 | 5 | | |
| Tenderness: Severe (n=247, 247) | 0 | 0 | | |

Notes:

[30] - ‘N’ (number of subjects analyzed)= subjects whose response=Yes for any day or No for all days

[31] - ‘N’ (number of subjects analyzed)= subjects whose response=Yes for any day or No for all days

### Statistical analyses

No statistical analyses for this end point

## Primary: Number of Subjects Reporting Local Reaction Within 5 Days After Dose 3 in MDV and SDS Group

| End point title | Number of Subjects Reporting Local Reaction Within 5 Days After Dose 3 in MDV and SDS Group[32] |
|---|---|

End point description:

Local reactions were reported within 5 days (Day 2 to Day 6) using an electronic diary. Tenderness was scaled as Any (tenderness present); Mild (hurt if gently touched; Moderate (hurt if gently touched with crying); Severe (caused limitation of limb movement). Redness and swelling were scaled as Any (redness or swelling present); Mild (0.5 cm to 2.0 cm); Moderate (2.1 to 7.0 cm); Severe (>7.0 cm). Subjects may be represented in more than 1 category. Safety population included subjects who received

at least 1 dose of study vaccine.

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

End point timeframe:

Within 5 days after Dose 3 (Day 2 to Day 6) of the infant series

Notes:

[32] - 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: Statistical analysis was not planned for numbers of subjects with local reactions or systemic events.

| **End point values** | 13vPnC Multi-dose Vial (MDV) | 13vPnC Single-Dose Syringe (SDS) | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 246[33] | 241[34] | | |
| Units: subjects | | | | |
| Redness: Any | 0 | 0 | | |
| Redness: Mild | 0 | 0 | | |
| Redness: Moderate | 0 | 0 | | |
| Redness: Severe | 0 | 0 | | |
| Swelling: Any | 0 | 0 | | |
| Swelling: Mild | 0 | 0 | | |
| Swelling: Moderate | 0 | 0 | | |
| Swelling: Severe | 0 | 0 | | |
| Tenderness: Any | 37 | 35 | | |
| Tenderness: Mild | 30 | 32 | | |
| Tenderness: Moderate | 9 | 4 | | |
| Tenderness: Severe | 0 | 0 | | |

Notes:

[33] - 'N' (number of subjects analyzed)= subjects whose response=Yes for any day or No for all days

[34] - 'N' (number of subjects analyzed)= subjects whose response=Yes for any day or No for all days

### Statistical analyses

No statistical analyses for this end point

## Primary: Number of Subjects Reporting Systemic Events Within 5 Days After Dose 1 in MDV and SDS Group

| End point title | Number of Subjects Reporting Systemic Events Within 5 Days After Dose 1 in MDV and SDS Group[35] |
|---|---|

End point description:

Systemic events (any fever greater than or equal to [>=] 38.0 degrees Celsius [C], decreased appetite was scaled as; Moderate (decreased oral intake); Severe (refusal to feed). Irritability scaled as; Mild (easily consolable); Moderate (requiring increased attention); Severe (Inconsolable, crying that cannot be comforted). Increased sleep was scale as; mild (increased or prolonged sleeping bouts); Moderate (slightly subdued interfering with daily activity); Severe (Disabling not interested in usual daily activity) and use of antipyretic medication were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population included subjects who received at least 1 dose of study vaccine. Here 'n' included subjects whose response was "Yes" for any day or "No" for all days for specified systemic event.

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

End point timeframe:

Within 5 days after Dose 1 (Day 2 to Day 6) of infant series

Notes:

[35] - 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: Statistical analysis was not planned for numbers of subjects with local reactions or systemic events.

| **End point values** | 13vPnC Multi-dose Vial (MDV) | 13vPnC Single-Dose Syringe (SDS) | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 249[36] | 250 | | |
| Units: subjects | | | | |
| Fever: >=38.0 degrees C (n=248, 250) | 9 | 7 | | |
| Fever: >=38.0 but <=39.0 degrees C (n=248, 250) | 9 | 7 | | |
| Fever: >39.0 but <=40.0 degrees C (n=248, 250) | 0 | 0 | | |
| Fever: >40.0 degrees C (n=248, 250) | 0 | 0 | | |
| Decreased appetite: Any (n=248, 250) | 17 | 26 | | |
| Decreased appetite: Moderate (n=248, 250) | 17 | 26 | | |
| Decreased appetite: Severe (n=248, 250) | 0 | 0 | | |
| Irritability: Any (n=249, 250) | 103 | 93 | | |
| Irritability: Mild (n=249, 250) | 86 | 77 | | |
| Irritability: Moderate (n=248, 250) | 19 | 17 | | |
| Irritability: Severe (n=248, 250) | 0 | 0 | | |
| Increased sleep: Any (n=248, 250) | 16 | 14 | | |
| Increased sleep: Mild (n=248, 250) | 11 | 10 | | |
| Increased sleep: Moderate (n=248, 250) | 6 | 4 | | |
| Increased sleep: Severe (n=248, 250) | 0 | 0 | | |
| Use of antipyretic medication (n=248, 250) | 55 | 58 | | |

Notes:

[36] - 'N' (number of subjects analyzed)= subjects whose response=Yes for any day or No for all days

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Subjects Reporting Systemic Events Within 5 Days After Dose 2 in MDV and SDS Group

| End point title | Number of Subjects Reporting Systemic Events Within 5 Days After Dose 2 in MDV and SDS Group[37] |
|---|---|

End point description:

Systemic events (>= 38.0 degrees C, decreased appetite was scaled as; Moderate (decreased oral intake); Severe (refusal to feed). Irritability scaled as; Mild (easily consolable); Moderate (requiring increased attention); Severe (Inconsolable, crying that cannot be comforted). Increased sleep was scale as; mild (increased or prolonged sleeping bouts); Moderate (slightly subdued interfering with daily activity); Severe (Disabling not interested in usual daily activity) and use of antipyretic medication were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population included subjects who received at least 1 dose of study vaccine. Here 'n' included subjects whose response was "Yes" for any day or "No" for all days for specified systemic event.

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

End point timeframe:

Within 5 days after Dose 2 (Day 2 to Day 6) of infant series

Notes:

[37] - 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: Statistical analysis was not planned for numbers of subjects with local reactions or systemic events.

| End point values | 13vPnC Multi-dose Vial (MDV) | 13vPnC Single-Dose Syringe (SDS) | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 248[38] | 247[39] | | |
| Units: subjects | | | | |
| Fever: >=38.0 degrees C (n=247, 247) | 7 | 7 | | |
| Fever: >=38.0 but <=39.0 degrees C (n=247, 247) | 7 | 7 | | |
| Fever: >39.0 but <=40.0 degrees C (n=247, 247) | 1 | 0 | | |
| Fever: >40.0 degrees C (n=247, 247) | 0 | 0 | | |
| Decreased appetite: Any(n=247, 247) | 28 | 18 | | |
| Decreased appetite: Moderate (n=247, 247) | 28 | 18 | | |
| Decreased appetite: Severe (n=247, 247) | 0 | 0 | | |
| Irritability: Any (n=248, 247) | 93 | 83 | | |
| Irritability: Mild (n=248, 247) | 75 | 67 | | |
| Irritability: Moderate (n=247, 247) | 23 | 17 | | |
| Irritability: Severe (n=247, 247) | 0 | 3 | | |
| Increased sleep: Any (n=247, 247) | 24 | 14 | | |
| Increased sleep: Mild (n=247, 247) | 20 | 12 | | |
| Increased sleep: Moderate (n=247, 247) | 4 | 1 | | |
| Increased sleep: Severe (n=247, 247) | 0 | 1 | | |
| Use of antipyretic medication (n=248, 247) | 46 | 43 | | |

Notes:

[38] - 'N' (number of subjects analyzed)= subjects whose response=Yes for any day or No for all days

[39] - 'N' (number of subjects analyzed)= subjects whose response=Yes for any day or No for all days

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Subjects Reporting Systemic Events Within 5 Days After Dose 3 in MDV and SDS Group

| End point title | Number of Subjects Reporting Systemic Events Within 5 Days After Dose 3 in MDV and SDS Group[40] |
|---|---|

End point description:

Systemic events (any fever >= 38.0 degrees C, decreased appetite was scaled as; Moderate (decreased oral intake); Severe (refusal to feed). Irritability scaled as; Mild (easily consolable); Moderate (requiring increased attention); Severe (Inconsolable, crying that cannot be comforted). Increased sleep was scale as; mild (increased or prolonged sleeping bouts); Moderate (slightly subdued interfering with daily activity); Severe (Disabling not interested in usual daily activity) and use of antipyretic medication were reported using an electronic diary. Subjects may be represented in more than 1 category. Safety population included subjects who received at least 1 dose of study vaccine. Here 'n' included subjects whose response was "Yes" for any day or "No" for all days for specified systemic event.

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

End point timeframe:

Within 5 days after Dose 3 (Day 2 to Day 6) of infant series

Notes:

[40] - 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: Statistical analysis was not planned for numbers of subjects with local reactions or systemic events.

| End point values | 13vPnC Multi-dose Vial (MDV) | 13vPnC Single-Dose Syringe (SDS) | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 246[41] | 243[42] | | |
| Units: subjects | | | | |
| Fever: >=38.0 degrees C (n=246, 241) | 3 | 8 | | |
| Fever: >=38.0 but <=39.0 degrees C (n=246, 241) | 3 | 7 | | |
| Fever: >39.0 but <=40.0 degrees C (n=246, 241) | 0 | 1 | | |
| Fever: >40.0 degrees C (n=246, 241) | 0 | 0 | | |
| Decreased appetite: Any (n=246, 242) | 24 | 20 | | |
| Decreased appetite: Moderate (n=246, 242) | 24 | 19 | | |
| Decreased appetite: Severe (n=246, 241) | 0 | 1 | | |
| Irritability: Any (n=246, 243) | 83 | 92 | | |
| Irritability: Mild (n=246, 242) | 71 | 74 | | |
| Irritability: Moderate (n=246, 242) | 15 | 18 | | |
| Irritability: Severe (n=246, 241) | 1 | 5 | | |
| Increased sleep: Any (n=246, 241) | 12 | 12 | | |
| Increased sleep: Mild (n=246, 241) | 10 | 11 | | |
| Increased sleep: Moderate (n=246, 241) | 2 | 1 | | |
| Increased sleep: Severe (n=246, 241) | 1 | 0 | | |
| Use of antipyretic medication (n=246, 241) | 34 | 36 | | |

Notes:

[41] - 'N' (number of subjects analyzed)= subjects whose response=Yes for any day or No for all days

[42] - 'N' (number of subjects analyzed)= subjects whose response=Yes for any day or No for all days

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Subjects With Adverse Events (AEs) and Serious Adverse Events (SAEs) in the Infant Series

| End point title | Number of Subjects With Adverse Events (AEs) and Serious Adverse Events (SAEs) in the Infant Series[43] |
|---|---|

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. An SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Treatment-emergent are events between first dose of study drug and up to 28 to 42 days after last dose that were absent before treatment or that worsened relative to pre-treatment state. Safety population included all subjects who received at least 1 dose of study vaccine.

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

End point timeframe:

Dose 1 up to 28 to 42 Days after Dose 3

Notes:

[43] - 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: Statistical analysis was not planned for numbers of subjects with local reactions or systemic events.

| **End point values** | 13vPnC Multi-dose Vial (MDV) | 13vPnC Single-Dose Syringe (SDS) | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 250 | 250 | | |
| Units: subjects | | | | |
| AEs | 123 | 127 | | |
| SAEs | 1 | 0 | | |

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of Subjects With Adverse Events (AEs) and Serious Adverse Events (SAEs) Prior to Dose 1

| End point title | Number of Subjects With Adverse Events (AEs) and Serious Adverse Events (SAEs) Prior to Dose 1[44] |
|---|---|

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. An SAE was an AE resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged inpatient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly. Adverse events were also reported in subjects who provided consent but were not randomized in this study. The data of these subjects has been reported under 'Screened Only' arm. Safety population included subjects who received at least 1 dose of study vaccine.

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

End point timeframe:

Informed consent up to Dose 1

Notes:

[44] - 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: Statistical analysis was not planned for numbers of subjects with local reactions or systemic events.

| **End point values** | 13vPnC Multi-dose Vial (MDV) | 13vPnC Single-Dose Syringe (SDS) | Screened Only | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Subject analysis set | |
| Number of subjects analysed | 250 | 250 | 26 | |
| Units: subjects | | | | |
| AEs | 2 | 0 | 9 | |
| SAEs | 0 | 0 | 0 | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Subjects Achieving a Serotype-Specific Opsonophagocytic Activity (OPA) Titer >= lower limit of quantitation (LLOQ) 1 Month After Infant Series

| End point title | Percentage of Subjects Achieving a Serotype-Specific Opsonophagocytic Activity (OPA) Titer >= lower limit of quantitation (LLOQ) 1 Month After Infant Series |
|---|---|

End point description:

Percentage of subjects achieving OPA Titer >= lower limit of quantitation (LLOQ) along with 95% CI for the 13 pneumococcal serotypes (serotypes 1, 3, 4, 5, 6A, 6B, 7F 9V, 14, 18C, 19A, 19F and 23F) are presented. The LLOQ in titers for each serotype was: Pn001, 18; Pn003, 12; Pn004, 21; Pn005, 29; Pn06A, 37; Pn06B, 43, Pn7F, 210; Pn09V, 345; Pn014, 35; Pn18C, 31; Pn19A, 18; Pn19F, 48; and Pn23F, 13. Exact 2-sided confidence interval (Clopper and Pearson) based on the observed proportion of subjects. Here "n"= Number of subjects with an antibody titer >= LLOQ for the given serotype. Evaluable immunogenicity population: subjects who received vaccine (randomized) at all 3 doses, had blood drawn within protocol-specified time frames, had at least 1 valid and determinate assay result for proposed analysis, had no major protocol violations. OPA analysis was performed in a subset of randomly selected subjects from each group.

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

End point timeframe:

1 month after the infant series

| **End point values** | 13vPnC Multi-dose Vial (MDV) | 13vPnC Single-Dose Syringe (SDS) | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 160 | 160 | | |
| Units: percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Serotype 1 (n=159,160) | 71.7 (64 to 78.5) | 79.4 (72.3 to 85.4) | | |
| Serotype 3 (n=160,160) | 98.8 (95.6 to 99.8) | 100 (97.7 to 100) | | |
| Serotype 4 (n=159,159) | 100 (97.7 to 100) | 100 (97.7 to 100) | | |
| Serotype 5 (n=160,159) | 83.1 (76.4 to 88.6) | 85.5 (79.1 to 90.6) | | |
| Serotype 6A (n=160,160) | 99.4 (96.6 to 100) | 99.4 (96.6 to 100) | | |
| Serotype 6B (n=156,155) | 96.8 (92.7 to 99) | 96.8 (92.6 to 98.9) | | |
| Serotype 7F (n=159,160) | 100 (97.7 to 100) | 100 (97.7 to 100) | | |
| Serotype 9V (n=158,160) | 79.7 (72.6 to 85.7) | 75 (67.6 to 81.5) | | |
| Serotype 14 (n=157,160) | 81.5 (74.6 to 87.3) | 89.4 (83.5 to 93.7) | | |
| Serotype 18C (n=159,160) | 99.4 (96.5 to 100) | 99.4 (96.6 to 100) | | |
| Serotype 19A (n=160,160) | 95.6 (91.2 to 98.2) | 97.5 (93.7 to 99.3) | | |
| Serotype 19F (n=158,159) | 93.7 (88.7 to 96.9) | 94.3 (89.5 to 97.4) | | |
| Serotype 23F (n=159,160) | 96.2 (92 to 98.6) | 97.5 (93.7 to 99.3) | | |

**Statistical analyses**

| **Statistical analysis title** | Serotype 1 |
|---|---|
| Statistical analysis description: | |
| Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed. | |
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | percent difference |
| Point estimate | -7.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -17.2 |
| upper limit | 1.9 |

| **Statistical analysis title** | Serotype 3 |
|---|---|
| Statistical analysis description: | |
| Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed. | |
| Comparison groups | 13vPnC Single-Dose Syringe (SDS) v 13vPnC Multi-dose Vial (MDV) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | percent difference |
| Point estimate | -1.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -4.4 |
| upper limit | 1.1 |

| **Statistical analysis title** | Serotype 4 |
|---|---|
| Statistical analysis description: | |
| Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed. | |
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |

| | |
|---|---|
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | percent difference |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.3 |
| upper limit | 2.3 |

| **Statistical analysis title** | Serotype 5 |
|---|---|
| Statistical analysis description: | |
| Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed. | |
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | percent difference |
| Point estimate | -2.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -10.6 |
| upper limit | 5.7 |

| **Statistical analysis title** | Serotype 6A |
|---|---|
| Statistical analysis description: | |
| Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed. | |
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | percent difference |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.9 |
| upper limit | 2.8 |

| **Statistical analysis title** | Serotype 6B |
|---|---|
| Statistical analysis description: | |
| Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed. | |
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | percent difference |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -4.5 |
| upper limit | 4.6 |

| **Statistical analysis title** | Serotype 7F |
|---|---|
| Statistical analysis description: | |
| Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed. | |
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | percent difference |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.3 |
| upper limit | 2.3 |

| **Statistical analysis title** | Serotype 9V |
|---|---|
| Statistical analysis description: | |
| Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed. | |
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | percent difference |
| Point estimate | 4.7 |

| | |
|---|---|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -4.5 |
| upper limit | 14.1 |

| **Statistical analysis title** | Serotype 14 |
|---|---|
| Statistical analysis description: | |
| Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed. | |
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | percent difference |
| Point estimate | -7.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -15.8 |
| upper limit | 0 |

| **Statistical analysis title** | Serotype 18C |
|---|---|
| Statistical analysis description: | |
| Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed. | |
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | percent difference |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.9 |
| upper limit | 2.9 |

| **Statistical analysis title** | Serotype 19A |
|---|---|
| Statistical analysis description: | |
| Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed. | |
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |

| | |
|---|---|
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | percent difference |
| Point estimate | -1.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -6.6 |
| upper limit | 2.4 |

| **Statistical analysis title** | Serotype 19F |
|---|---|
| Statistical analysis description: | |
| Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed. | |
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | percent difference |
| Point estimate | -0.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -6.3 |
| upper limit | 4.9 |

| **Statistical analysis title** | Serotype 23F |
|---|---|
| Statistical analysis description: | |
| Exact 2-sided confidence interval (based on Chan and Zhang) for the difference in proportions, 13vPnC MDV – 13vPnC SDS, expressed as a percentage was analyzed. | |
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | percent difference |
| Point estimate | -1.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.8 |
| upper limit | 3 |

## Secondary: Serotype-Specific Opsonophagocytic Activity (OPA) Geometric Mean Titer (GMT) 1 Month After the Infant Series

| End point title | Serotype-Specific Opsonophagocytic Activity (OPA) Geometric Mean Titer (GMT) 1 Month After the Infant Series |
|---|---|

End point description:

Antibody geometric mean titers as measured by OPA assay for the 13 pneumococcal serotypes (serotypes 1, 3, 4, 5, 6A, 6B, 7F 9V, 14, 18C, 19A, 19F and 23F) are presented. GMTs were calculated using all subjects with available data for the specified blood draw. CIs were back transformations of a confidence interval based on the Student t distribution for the mean logarithm of the titers. Evaluable immunogenicity population: subjects who received vaccine (randomized) at all 3 doses, had blood drawn within protocol-specified time frames, had at least 1 valid and determinate assay result for proposed analysis, had no major protocol violations. OPA analysis was performed in a subset of randomly selected subjects from each group. Here "n"= subjects evaluable =specified category.

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

End point timeframe:

1 month after the infant series

| **End point values** | 13vPnC Multi-dose Vial (MDV) | 13vPnC Single-Dose Syringe (SDS) | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 160 | 160 | | |
| Units: titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serotype 1 (n=159,160) | 48 (39 to 58) | 52 (43.2 to 62.6) | | |
| Serotype 3 (n=160,160) | 97 (87.3 to 108.8) | 122 (110.1 to 135.7) | | |
| Serotype 4 (n=159,159) | 1666 (1412.3 to 1966.3) | 1492 (1285.2 to 1732.3) | | |
| Serotype 5 (n=160,159) | 79 (67.7 to 92.4) | 80 (69.1 to 92.6) | | |
| Serotype 6A (n=160,160) | 1690 (1460.5 to 1955.9) | 1968 (1698.5 to 2279.3) | | |
| Serotype 6B (n=156,155) | 1990 (1611.7 to 2456.9) | 2014 (1639.1 to 2475.4) | | |
| Serotype 7F (n=159,160) | 2891 (2565.4 to 3258.5) | 3450 (3014.7 to 3947.9) | | |
| Serotype 9V (n=158,160) | 709 (600.5 to 836.2) | 706 (597 to 835.3) | | |
| Serotype 14 (n=157,160) | 567 (415.4 to 773.5) | 786 (607.8 to 1015.3) | | |
| Serotype 18C (n=159,160) | 2792 (2387.5 to 3264.8) | 1605 (1352 to 1904.4) | | |
| Serotype 19A (n=160,160) | 305 (256.2 to 362.9) | 329 (284.8 to 379.8) | | |
| Serotype 19F (n=158,159) | 430 (357.6 to 517.1) | 470 (391.4 to 565.3) | | |
| Serotype 23F (n=159,160) | 918 (729 to 1156.4) | 998 (810.6 to 1229.6) | | |

## Statistical analyses

| **Statistical analysis title** | Serotype 1 |
|---|---|

Statistical analysis description:

Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.7 |
| upper limit | 1.2 |

| **Statistical analysis title** | Serotype 3 |
|---|---|

Statistical analysis description:

Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.69 |
| upper limit | 0.93 |

| **Statistical analysis title** | Serotype 4 |
|---|---|

Statistical analysis description:

Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |

| | |
|---|---|
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.89 |
| upper limit | 1.39 |

| **Statistical analysis title** | Serotype 5 |
|---|---|

Statistical analysis description:

Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | GMT Ratio |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.8 |
| upper limit | 1.22 |

| **Statistical analysis title** | Serotype 6A |
|---|---|

Statistical analysis description:

Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.7 |
| upper limit | 1.06 |

| **Statistical analysis title** | Serotype 6B |
|---|---|
| Statistical analysis description: | |
| Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS). | |
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | GMT Ratio |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.74 |
| upper limit | 1.33 |

| **Statistical analysis title** | Serotype 7F |
|---|---|
| Statistical analysis description: | |
| Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS). | |
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.7 |
| upper limit | 1 |

| **Statistical analysis title** | Serotype 9V |
|---|---|
| Statistical analysis description: | |
| Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS). | |
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |

| | |
|---|---|
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | GMT Ratio |
| Point estimate | 1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.79 |
| upper limit | 1.27 |

| **Statistical analysis title** | Serotype 14 |
|---|---|

Statistical analysis description:

Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.48 |
| upper limit | 1.08 |

| **Statistical analysis title** | Serotype 18C |
|---|---|

Statistical analysis description:

Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS).

| | |
|---|---|
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | GMT Ratio |
| Point estimate | 1.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.38 |
| upper limit | 2.19 |

| **Statistical analysis title** | Serotype 19A |
|---|---|
| Statistical analysis description: | |
| Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS). | |
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.74 |
| upper limit | 1.16 |

| **Statistical analysis title** | Serotype 19F |
|---|---|
| Statistical analysis description: | |
| Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS). | |
| Comparison groups | 13vPnC Multi-dose Vial (MDV) v 13vPnC Single-Dose Syringe (SDS) |
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.71 |
| upper limit | 1.18 |

| **Statistical analysis title** | Serotype 23F |
|---|---|
| Statistical analysis description: | |
| Ratio of GMTs, MDV to SDS, was calculated by back transforming the mean difference between the vaccine groups on the logarithmic scale. CIs for the ratio were back transformations of a confidence interval based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC MDV – 13vPnC SDS). | |
| Comparison groups | 13vPnC Single-Dose Syringe (SDS) v 13vPnC Multi-dose Vial (MDV) |

| | |
|---|---|
| Number of subjects included in analysis | 320 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | GMT Ratio |
| Point estimate | 0.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.67 |
| upper limit | 1.25 |

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Adverse events (AEs)/serious AEs (SAEs): recorded from signing of informed consent form to 28 to 42 days after dose 3. Pre-specified AEs were recorded in an electronic diary: local reactions, systemic events (Day 2 to Day 6 after each vaccination).

Adverse event reporting additional description:

SAEs, AEs grouped by system organ class and summarized. AEs included AEs collected in electronic diary (local, systemic reactions; systematic assessment), events collected on case report form at each visit (non-systematic assessment). AEs also reported in subjects who provided consent but were not randomized (reported under 'Screened Only' arm).

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

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 17.1 |

### Reporting groups

| | |
|---|---|
| Reporting group title | 13vPnC MDV: Informed Consent to Dose 1 |

Reporting group description:

Subjects who were randomized to receive 13vPnC (PF-06414256) MDV at 8, 12, and 16 weeks of age, assessed between signing of informed consent and before Dose 1.

| | |
|---|---|
| Reporting group title | 13vPnC SDS: Informed Consent to Dose 1 |

Reporting group description:

Subjects who were randomized to receive 13vPnC (PF-05208760) SDS at 8, 12, and 16 weeks of age, assessed between signing of informed consent and before Dose 1.

| | |
|---|---|
| Reporting group title | 13vPnC MDV: After Dose 1 |

Reporting group description:

Subjects who received single 0.5 mL dose of 13vPnC (PF-06414256) using MDV intramuscularly into the anterolateral thigh muscle of the left leg at 8 weeks of age, assessed after Dose 1 and before Dose 2.

| | |
|---|---|
| Reporting group title | 13vPnC SDS: After Dose 1 |

Reporting group description:

Subjects who received single 0.5 mL dose of 13vPnC (PF-05208760) using SDS intramuscularly into the anterolateral thigh muscle of the left leg at 8 weeks of age, assessed after Dose 1 and before Dose 2.

| | |
|---|---|
| Reporting group title | 13vPnC MDV: After Dose 2 |

Reporting group description:

Subjects who received two 0.5 mL doses of 13vPnC (PF-06414256) using MDV intramuscularly into the anterolateral thigh muscle of the left leg 8, 12 weeks of age, assessed after Dose 2 and before Dose 3.

| | |
|---|---|
| Reporting group title | 13vPnC SDS: After Dose 2 |

Reporting group description:

Subjects who received two 0.5 mL doses of 13vPnC (PF-05208760) using SDS intramuscularly into the anterolateral thigh muscle of the left leg 8, 12 weeks of age, assessed after Dose 2 and before Dose 3.

| | |
|---|---|
| Reporting group title | 13vPnC MDV: After Dose 3 |

Reporting group description:

Subjects who received all three 0.5mL doses of 13vPnC (PF-06414256) using MDV intramuscularly into the anterolateral thigh muscle of the left leg at 8 weeks of age, assessed after Dose 3 and up to blood draw at 4 weeks.

| | |
|---|---|
| Reporting group title | 13vPnC SDS: After Dose 3 |

Reporting group description:

Subjects who received all three 0.5mL doses of 13vPnC (PF-05208760) using SDS intramuscularly into the anterolateral thigh muscle of the left leg at 8 weeks of age, assessed after Dose 3 and up to blood draw at 4 weeks.

| | |
|---|---|
| Reporting group title | Screened Only |

Reporting group description:

Subjects who were screened for this study but were not randomized, assessed between signing of informed consent form and before randomization.

| Serious adverse events | 13vPnC MDV: Informed Consent to Dose 1 | 13vPnC SDS: Informed Consent to Dose 1 | 13vPnC MDV: After Dose 1 |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Sudden infant death syndrome | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (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 |

| Serious adverse events | 13vPnC SDS: After Dose 1 | 13vPnC MDV: After Dose 2 | 13vPnC SDS: After Dose 2 |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Sudden infant death syndrome | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 0 / 248 (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 |

| Serious adverse events | 13vPnC MDV: After Dose 3 | 13vPnC SDS: After Dose 3 | Screened Only |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 247 (0.40%) | 0 / 244 (0.00%) | 0 / 26 (0.00%) |
| number of deaths (all causes) | 1 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Sudden infant death syndrome | | | |
| subjects affected / exposed | 1 / 247 (0.40%) | 0 / 244 (0.00%) | 0 / 26 (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 |

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

| **Non-serious adverse events** | 13vPnC MDV: Informed Consent to Dose 1 | 13vPnC SDS: Informed Consent to Dose 1 | 13vPnC MDV: After Dose 1 |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 2 / 250 (0.80%) | 0 / 250 (0.00%) | 113 / 250 (45.20%) |
| Injury, poisoning and procedural complications | | | |
| Burns first degrees | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Congenital, familial and genetic disorders | | | |
| Heart disease congenital | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Umbilical granuloma | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 2 / 250 (0.80%) |
| occurrences (all) | 0 | 0 | 2 |
| General disorders and administration site conditions | | | |
| Decreased appetite: 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. 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[1] | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 17 / 248 (6.85%) |
| occurrences (all) | 0 | 0 | 17 |
| Decreased appetite: 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. 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[2] | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 17 / 248 (6.85%) |
| occurrences (all) | 0 | 0 | 17 |
| Decreased appetite: 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 | | | |
| subjects affected / exposed[3] | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fever: >=38.0 but <=39.0 degrees 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[4] | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 9 / 248 (3.63%) |
| occurrences (all) | 0 | 0 | 9 |
| Fever: >=38.0 degrees 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[5] | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 9 / 248 (3.63%) |
| occurrences (all) | 0 | 0 | 9 |
| Fever: >39.0 but <=40.0 degrees 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[6] | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Increased sleep: 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[7] | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 16 / 248 (6.45%) |
| occurrences (all) | 0 | 0 | 16 |
| Increased sleep: 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. 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[8]<br>occurrences (all) | 0 / 250 (0.00%)<br>0 | 0 / 250 (0.00%)<br>0 | 11 / 248 (4.44%)<br>11 |
| Increased sleep: 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative assessment type: Systematic<br>subjects affected / exposed[9]<br>occurrences (all) | 0 / 250 (0.00%)<br>0 | 0 / 250 (0.00%)<br>0 | 6 / 248 (2.42%)<br>6 |
| Increased sleep: 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[10]<br>occurrences (all) | 0 / 250 (0.00%)<br>0 | 0 / 250 (0.00%)<br>0 | 0 / 248 (0.00%)<br>0 |
| Irritability: 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. 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[11]<br>occurrences (all) | 0 / 250 (0.00%)<br>0 | 0 / 250 (0.00%)<br>0 | 103 / 249 (41.37%)<br>103 |
| Irritability: 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. 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[12]<br>occurrences (all) | 0 / 250 (0.00%)<br>0 | 0 / 250 (0.00%)<br>0 | 86 / 249 (34.54%)<br>86 |
| Irritability: 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. 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[13]<br>occurrences (all) | 0 / 250 (0.00%)<br>0 | 0 / 250 (0.00%)<br>0 | 19 / 248 (7.66%)<br>19 |
| Irritability: 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[14] | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ulcer | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Vaccination site swelling | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 1 / 250 (0.40%) |
| occurrences (all) | 0 | 0 | 1 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 3 / 250 (1.20%) |
| occurrences (all) | 0 | 0 | 3 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cough | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 2 / 250 (0.80%) |
| occurrences (all) | 0 | 0 | 2 |
| Skin and subcutaneous tissue disorders | | | |
| Eczema | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 1 / 250 (0.40%) |
| occurrences (all) | 0 | 0 | 1 |
| Dermatitis | | | |
| subjects affected / exposed | 1 / 250 (0.40%) | 0 / 250 (0.00%) | 8 / 250 (3.20%) |
| occurrences (all) | 1 | 0 | 8 |

| | | | |
|---|---|---|---|
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis diaper | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 1 / 250 (0.40%) |
| occurrences (all) | 0 | 0 | 1 |
| Rash papular | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[15] | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 1 / 248 (0.40%) |
| occurrences (all) | 0 | 0 | 1 |
| 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[16] | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 1 / 248 (0.40%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin ulcer | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[17] | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 1 / 248 (0.40%) |
| occurrences (all) | 0 | 0 | 1 |
| 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed[18] | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 1 / 248 (0.40%) |
| occurrences (all) | 0 | 0 | 1 |
| 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[19] | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tenderness: 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[20] | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 42 / 248 (16.94%) |
| occurrences (all) | 0 | 0 | 42 |
| Tenderness: 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[21] | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 32 / 248 (12.90%) |
| occurrences (all) | 0 | 0 | 32 |
| Tenderness: 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[22] | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 13 / 248 (5.24%) |
| occurrences (all) | 0 | 0 | 13 |
| Musculoskeletal and connective tissue disorders | | | |
| Growth retardation | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |

| | | | |
|---|---|---|---|
| Atypical pneumonia | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Breast abscess | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 1 / 250 (0.40%) |
| occurrences (all) | 0 | 0 | 1 |
| Bronchopneumonia | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Chest wall abscess | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 3 / 250 (1.20%) |
| occurrences (all) | 0 | 0 | 3 |
| Dysentery | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Furuncle | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Impetigo | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site abscess | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 1 / 250 (0.40%) |
| occurrences (all) | 0 | 0 | 1 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 1 / 250 (0.40%) |
| occurrences (all) | 0 | 0 | 1 |

| | | | |
|---|---|---|---|
| Otitis media | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 1 / 250 (0.40%) |
| occurrences (all) | 0 | 0 | 1 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 1 / 250 (0.40%) |
| occurrences (all) | 0 | 0 | 1 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash pustular | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 1 / 250 (0.40%) |
| occurrences (all) | 0 | 0 | 1 |
| Tinea capitis | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 4 / 250 (1.60%) |
| occurrences (all) | 0 | 0 | 4 |
| Tinea faciei | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tinea infection | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tinea versicolour | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 1 / 250 (0.40%) | 0 / 250 (0.00%) | 27 / 250 (10.80%) |
| occurrences (all) | 1 | 0 | 28 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Varicella | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| | | | |
|---|---|---|---|
| Viral diarrhoea | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 6 / 250 (2.40%) |
| occurrences (all) | 0 | 0 | 6 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 3 / 250 (1.20%) |
| occurrences (all) | 0 | 0 | 3 |
| Metabolism and nutrition disorders | | | |
| Failure to thrive | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 250 (0.00%) | 0 / 250 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | 13vPnC SDS: After Dose 1 | 13vPnC MDV: After Dose 2 | 13vPnC SDS: After Dose 2 |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 107 / 250 (42.80%) | 114 / 249 (45.78%) | 99 / 248 (39.92%) |
| Injury, poisoning and procedural complications | | | |
| Burns first degrees | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Contusion | | | |
| subjects affected / exposed | 1 / 250 (0.40%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Fall | | | |
| subjects affected / exposed | 1 / 250 (0.40%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Congenital, familial and genetic disorders | | | |
| Heart disease congenital | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Umbilical granuloma | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Decreased appetite: 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. 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[1] | 26 / 250 (10.40%) | 28 / 247 (11.34%) | 18 / 247 (7.29%) |
| occurrences (all) | 26 | 28 | 18 |
| Decreased appetite: 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. 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[2] | 26 / 250 (10.40%) | 28 / 247 (11.34%) | 18 / 247 (7.29%) |
| occurrences (all) | 26 | 28 | 18 |
| Decreased appetite: 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[3] | 0 / 250 (0.00%) | 0 / 247 (0.00%) | 0 / 247 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fever: >=38.0 but <=39.0 degrees 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. 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[4] | 7 / 250 (2.80%) | 7 / 247 (2.83%) | 7 / 247 (2.83%) |
| occurrences (all) | 7 | 7 | 7 |
| Fever: >=38.0 degrees 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. 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[5] | 7 / 250 (2.80%) | 7 / 247 (2.83%) | 7 / 247 (2.83%) |
| occurrences (all) | 7 | 7 | 7 |
| Fever: >39.0 but <=40.0 degrees 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. 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[6] | 0 / 250 (0.00%) | 1 / 247 (0.40%) | 0 / 247 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Increased sleep: 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. 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[7]<br>occurrences (all) | 14 / 250 (5.60%)<br>14 | 24 / 247 (9.72%)<br>24 | 14 / 247 (5.67%)<br>14 |
| Increased sleep: 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. 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[8]<br>occurrences (all) | 10 / 250 (4.00%)<br>10 | 20 / 247 (8.10%)<br>20 | 12 / 247 (4.86%)<br>12 |
| Increased sleep: 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative assessment type: Systematic<br>subjects affected / exposed[9]<br>occurrences (all) | 4 / 250 (1.60%)<br>4 | 4 / 247 (1.62%)<br>4 | 1 / 247 (0.40%)<br>1 |
| Increased sleep: 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[10]<br>occurrences (all) | 0 / 250 (0.00%)<br>0 | 0 / 247 (0.00%)<br>0 | 1 / 247 (0.40%)<br>1 |
| Irritability: 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. 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[11]<br>occurrences (all) | 93 / 250 (37.20%)<br>93 | 93 / 248 (37.50%)<br>93 | 83 / 247 (33.60%)<br>83 |
| Irritability: 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed[12] | 77 / 250 (30.80%) | 75 / 248 (30.24%) | 67 / 247 (27.13%) |
| occurrences (all) | 77 | 75 | 67 |
| Irritability: 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[13] | 17 / 250 (6.80%) | 23 / 247 (9.31%) | 17 / 247 (6.88%) |
| occurrences (all) | 17 | 23 | 17 |
| Irritability: 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 | | | |
| subjects affected / exposed[14] | 0 / 250 (0.00%) | 0 / 247 (0.00%) | 3 / 247 (1.21%) |
| occurrences (all) | 0 | 0 | 3 |
| Pyrexia | | | |
| subjects affected / exposed | 2 / 250 (0.80%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Ulcer | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 1 / 248 (0.40%) |
| occurrences (all) | 0 | 0 | 1 |
| Vaccination site swelling | | | |
| subjects affected / exposed | 1 / 250 (0.40%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 1 / 249 (0.40%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 1 / 250 (0.40%) | 0 / 249 (0.00%) | 1 / 248 (0.40%) |
| occurrences (all) | 1 | 0 | 1 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 1 / 249 (0.40%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Cough | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 250 (0.80%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Eczema | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 1 / 249 (0.40%) | 1 / 248 (0.40%) |
| occurrences (all) | 0 | 1 | 1 |
| Dermatitis | | | |
| subjects affected / exposed | 12 / 250 (4.80%) | 5 / 249 (2.01%) | 7 / 248 (2.82%) |
| occurrences (all) | 12 | 5 | 7 |
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 1 / 248 (0.40%) |
| occurrences (all) | 0 | 0 | 1 |
| Dermatitis diaper | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash papular | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 1 / 248 (0.40%) |
| occurrences (all) | 0 | 0 | 1 |
| 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[15] | 0 / 250 (0.00%) | 2 / 247 (0.81%) | 0 / 247 (0.00%) |
| occurrences (all) | 0 | 2 | 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic | | | |
| subjects affected / exposed[16] | 0 / 250 (0.00%) | 2 / 247 (0.81%) | 0 / 247 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Skin ulcer | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 0 / 248 (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. Version not captured, here 0.0 is mentioned for dictionary version. | | |

| | | | |
|---|---|---|---|
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[17]<br>occurrences (all) | 0 / 250 (0.00%)<br>0 | 2 / 247 (0.81%)<br>2 | 0 / 247 (0.00%)<br>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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[18]<br>occurrences (all) | 0 / 250 (0.00%)<br>0 | 2 / 247 (0.81%)<br>2 | 0 / 247 (0.00%)<br>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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[19]<br>occurrences (all) | 0 / 250 (0.00%)<br>0 | 0 / 247 (0.00%)<br>0 | 1 / 247 (0.40%)<br>1 |
| Tenderness: 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[20]<br>occurrences (all) | 47 / 250 (18.80%)<br>47 | 34 / 248 (13.71%)<br>34 | 32 / 247 (12.96%)<br>32 |
| Tenderness: 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[21]<br>occurrences (all) | 37 / 250 (14.80%)<br>37 | 27 / 248 (10.89%)<br>27 | 28 / 247 (11.34%)<br>28 |
| Tenderness: 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed[22] | 14 / 250 (5.60%) | 7 / 247 (2.83%) | 5 / 247 (2.02%) |
| occurrences (all) | 14 | 7 | 5 |
| Musculoskeletal and connective tissue disorders | | | |
| Growth retardation | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Musculoskeletal pain | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infections and infestations | | | |
| Atypical pneumonia | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Breast abscess | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 1 / 249 (0.40%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Bronchopneumonia | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 1 / 248 (0.40%) |
| occurrences (all) | 0 | 0 | 1 |
| Chest wall abscess | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Conjunctivitis | | | |
| subjects affected / exposed | 3 / 250 (1.20%) | 3 / 249 (1.20%) | 1 / 248 (0.40%) |
| occurrences (all) | 3 | 3 | 1 |
| Dysentery | | | |
| subjects affected / exposed | 1 / 250 (0.40%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Furuncle | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 1 / 250 (0.40%) | 1 / 249 (0.40%) | 0 / 248 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Gastroenteritis viral | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Impetigo | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Injection site abscess | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 1 / 249 (0.40%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 2 / 250 (0.80%) | 2 / 249 (0.80%) | 1 / 248 (0.40%) |
| occurrences (all) | 2 | 2 | 1 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 1 / 249 (0.40%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Rash pustular | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 1 / 249 (0.40%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 1 / 249 (0.40%) | 3 / 248 (1.21%) |
| occurrences (all) | 0 | 1 | 3 |
| Tinea capitis | | | |
| subjects affected / exposed | 3 / 250 (1.20%) | 3 / 249 (1.20%) | 1 / 248 (0.40%) |
| occurrences (all) | 3 | 3 | 1 |
| Tinea faciei | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 1 / 249 (0.40%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tinea infection | | | |
| subjects affected / exposed | 1 / 250 (0.40%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tinea versicolour | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 250 (0.40%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 17 / 250 (6.80%) | 17 / 249 (6.83%) | 10 / 248 (4.03%) |
| occurrences (all) | 17 | 17 | 10 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Varicella | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Viral diarrhoea | | | |
| subjects affected / exposed | 10 / 250 (4.00%) | 8 / 249 (3.21%) | 10 / 248 (4.03%) |
| occurrences (all) | 10 | 8 | 10 |
| Viral infection | | | |
| subjects affected / exposed | 1 / 250 (0.40%) | 1 / 249 (0.40%) | 3 / 248 (1.21%) |
| occurrences (all) | 1 | 1 | 3 |
| Metabolism and nutrition disorders | | | |
| Failure to thrive | | | |
| subjects affected / exposed | 0 / 250 (0.00%) | 0 / 249 (0.00%) | 0 / 248 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| **Non-serious adverse events** | 13vPnC MDV: After Dose 3 | 13vPnC SDS: After Dose 3 | Screened Only |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 97 / 247 (39.27%) | 102 / 244 (41.80%) | 9 / 26 (34.62%) |
| Injury, poisoning and procedural complications | | | |
| Burns first degrees | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 1 / 244 (0.41%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Contusion | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 0 / 244 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fall | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 0 / 244 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Congenital, familial and genetic disorders | | | |

| | | | |
|---|---|---|---|
| Heart disease congenital | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 0 / 244 (0.00%) | 1 / 26 (3.85%) |
| occurrences (all) | 0 | 0 | 1 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Umbilical granuloma | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 0 / 244 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Decreased appetite: 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. 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[1] | 24 / 246 (9.76%) | 20 / 242 (8.26%) | 0 / 26 (0.00%) |
| occurrences (all) | 24 | 20 | 0 |
| Decreased appetite: 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. 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[2] | 24 / 246 (9.76%) | 19 / 242 (7.85%) | 0 / 26 (0.00%) |
| occurrences (all) | 24 | 19 | 0 |
| Decreased appetite: 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[3] | 0 / 246 (0.00%) | 1 / 241 (0.41%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Fever: >=38.0 but <=39.0 degrees 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. 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[4] | 3 / 246 (1.22%) | 7 / 241 (2.90%) | 0 / 26 (0.00%) |
| occurrences (all) | 3 | 7 | 0 |
| Fever: >=38.0 degrees 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. 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[5]<br>occurrences (all) | 3 / 246 (1.22%)<br>3 | 8 / 241 (3.32%)<br>8 | 0 / 26 (0.00%)<br>0 |
| Fever: >39.0 but <=40.0 degrees 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. 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[6]<br>occurrences (all) | 0 / 246 (0.00%)<br>0 | 1 / 241 (0.41%)<br>1 | 0 / 26 (0.00%)<br>0 |
| Increased sleep: 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. 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[7]<br>occurrences (all) | 12 / 246 (4.88%)<br>12 | 12 / 241 (4.98%)<br>12 | 0 / 26 (0.00%)<br>0 |
| Increased sleep: 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. 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[8]<br>occurrences (all) | 10 / 246 (4.07%)<br>10 | 11 / 241 (4.56%)<br>11 | 0 / 26 (0.00%)<br>0 |
| Increased sleep: 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative assessment type: Systematic<br>subjects affected / exposed[9]<br>occurrences (all) | 2 / 246 (0.81%)<br>2 | 1 / 241 (0.41%)<br>1 | 0 / 26 (0.00%)<br>0 |
| Increased sleep: 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[10]<br>occurrences (all) | 1 / 246 (0.41%)<br>1 | 0 / 241 (0.00%)<br>0 | 0 / 26 (0.00%)<br>0 |
| Irritability: 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systemic<br>subjects affected / exposed[11]<br>occurrences (all) | 83 / 246 (33.74%)<br>83 | 92 / 243 (37.86%)<br>92 | 0 / 26 (0.00%)<br>0 |
| Irritability: 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systemic<br>subjects affected / exposed[12]<br>occurrences (all) | 71 / 246 (28.86%)<br>71 | 74 / 242 (30.58%)<br>74 | 0 / 26 (0.00%)<br>0 |
| Irritability: 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Systemic Events 0.0<br>alternative assessment type: Systemic<br>subjects affected / exposed[13]<br>occurrences (all) | 15 / 246 (6.10%)<br>15 | 18 / 242 (7.44%)<br>18 | 0 / 26 (0.00%)<br>0 |
| Irritability: 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: Systemic<br>subjects affected / exposed[14]<br>occurrences (all) | 1 / 246 (0.41%)<br>1 | 5 / 241 (2.07%)<br>5 | 0 / 26 (0.00%)<br>0 |
| Pyrexia<br>subjects affected / exposed<br>occurrences (all) | 1 / 247 (0.40%)<br>1 | 1 / 244 (0.41%)<br>1 | 0 / 26 (0.00%)<br>0 |
| Ulcer<br>subjects affected / exposed<br>occurrences (all) | 0 / 247 (0.00%)<br>0 | 0 / 244 (0.00%)<br>0 | 0 / 26 (0.00%)<br>0 |
| Vaccination site swelling<br>subjects affected / exposed<br>occurrences (all) | 0 / 247 (0.00%)<br>0 | 0 / 244 (0.00%)<br>0 | 0 / 26 (0.00%)<br>0 |
| Gastrointestinal disorders | | | |

| | | | |
|---|---|---|---|
| Abdominal pain | | | |
| subjects affected / exposed | 1 / 247 (0.40%) | 0 / 244 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 1 / 247 (0.40%) | 0 / 244 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Bronchial hyperreactivity | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 0 / 244 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Cough | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 0 / 244 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Eczema | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 0 / 244 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis | | | |
| subjects affected / exposed | 2 / 247 (0.81%) | 6 / 244 (2.46%) | 0 / 26 (0.00%) |
| occurrences (all) | 2 | 6 | 0 |
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 0 / 244 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis diaper | | | |
| subjects affected / exposed | 1 / 247 (0.40%) | 2 / 244 (0.82%) | 0 / 26 (0.00%) |
| occurrences (all) | 1 | 2 | 0 |
| Rash papular | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 0 / 244 (0.00%) | 0 / 26 (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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0 | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed[15] | 0 / 246 (0.00%) | 0 / 241 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[16] | 0 / 246 (0.00%) | 0 / 241 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin ulcer | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 1 / 244 (0.41%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 1 | 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[17] | 0 / 246 (0.00%) | 0 / 241 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[18] | 0 / 246 (0.00%) | 0 / 241 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[19] | 0 / 246 (0.00%) | 0 / 241 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tenderness: 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[20] | 37 / 246 (15.04%) | 35 / 241 (14.52%) | 0 / 26 (0.00%) |
| occurrences (all) | 37 | 35 | 0 |
| Tenderness: 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. Version not captured, here | | |

| | | | |
|---|---|---|---|
| | 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[21]<br>occurrences (all) | 30 / 246 (12.20%)<br>30 | 32 / 241 (13.28%)<br>32 | 0 / 26 (0.00%)<br>0 |
| Tenderness: 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. Version not captured, here 0.0 is mentioned for dictionary version. | | |
| alternative dictionary used: Local Reactions 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed[22]<br>occurrences (all) | 9 / 246 (3.66%)<br>9 | 4 / 241 (1.66%)<br>4 | 0 / 26 (0.00%)<br>0 |
| Musculoskeletal and connective tissue disorders | | | |
| Growth retardation<br>subjects affected / exposed<br>occurrences (all) | 0 / 247 (0.00%)<br>0 | 0 / 244 (0.00%)<br>0 | 1 / 26 (3.85%)<br>1 |
| Musculoskeletal pain<br>subjects affected / exposed<br>occurrences (all) | 1 / 247 (0.40%)<br>1 | 0 / 244 (0.00%)<br>0 | 0 / 26 (0.00%)<br>0 |
| Infections and infestations | | | |
| Atypical pneumonia<br>subjects affected / exposed<br>occurrences (all) | 1 / 247 (0.40%)<br>0 | 0 / 244 (0.00%)<br>0 | 0 / 26 (0.00%)<br>0 |
| Breast abscess<br>subjects affected / exposed<br>occurrences (all) | 0 / 247 (0.00%)<br>0 | 0 / 244 (0.00%)<br>0 | 0 / 26 (0.00%)<br>0 |
| Bronchopneumonia<br>subjects affected / exposed<br>occurrences (all) | 1 / 247 (0.40%)<br>1 | 4 / 244 (1.64%)<br>5 | 2 / 26 (7.69%)<br>2 |
| Chest wall abscess<br>subjects affected / exposed<br>occurrences (all) | 1 / 247 (0.40%)<br>1 | 0 / 244 (0.00%)<br>0 | 0 / 26 (0.00%)<br>0 |
| Conjunctivitis<br>subjects affected / exposed<br>occurrences (all) | 4 / 247 (1.62%)<br>4 | 3 / 244 (1.23%)<br>3 | 1 / 26 (3.85%)<br>1 |
| Dysentery | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 247 (0.00%) | 0 / 244 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Furuncle | | | |
| subjects affected / exposed | 3 / 247 (1.21%) | 0 / 244 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 3 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 1 / 244 (0.41%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Gastroenteritis viral | | | |
| subjects affected / exposed | 1 / 247 (0.40%) | 1 / 244 (0.41%) | 0 / 26 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Impetigo | | | |
| subjects affected / exposed | 2 / 247 (0.81%) | 1 / 244 (0.41%) | 0 / 26 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Injection site abscess | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 0 / 244 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 1 / 247 (0.40%) | 0 / 244 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Otitis media | | | |
| subjects affected / exposed | 3 / 247 (1.21%) | 2 / 244 (0.82%) | 0 / 26 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 0 / 244 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Pneumonia | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 2 / 244 (0.82%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Rash pustular | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 0 / 244 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 6 / 247 (2.43%) | 3 / 244 (1.23%) | 0 / 26 (0.00%) |
| occurrences (all) | 6 | 3 | 0 |
| Tinea capitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 247 (0.81%) | 1 / 244 (0.41%) | 0 / 26 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Tinea faciei | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 0 / 244 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tinea infection | | | |
| subjects affected / exposed | 1 / 247 (0.40%) | 0 / 244 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Tinea versicolour | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 0 / 244 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 19 / 247 (7.69%) | 25 / 244 (10.25%) | 0 / 26 (0.00%) |
| occurrences (all) | 19 | 25 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 0 / 244 (0.00%) | 1 / 26 (3.85%) |
| occurrences (all) | 0 | 0 | 1 |
| Varicella | | | |
| subjects affected / exposed | 1 / 247 (0.40%) | 0 / 244 (0.00%) | 0 / 26 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Viral diarrhoea | | | |
| subjects affected / exposed | 5 / 247 (2.02%) | 10 / 244 (4.10%) | 0 / 26 (0.00%) |
| occurrences (all) | 5 | 10 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 4 / 244 (1.64%) | 0 / 26 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| Metabolism and nutrition disorders | | | |
| Failure to thrive | | | |
| subjects affected / exposed | 0 / 247 (0.00%) | 1 / 244 (0.41%) | 3 / 26 (11.54%) |
| occurrences (all) | 0 | 1 | 3 |

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 reporting yes for at least 1 day or no for all days.
[2] - 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 reporting yes for at least 1 day or no for all days.

[3] - 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 reporting yes for at least 1 day or no for all days.
[4] - 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 reporting yes for at least 1 day or no for all days.
[5] - 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 reporting yes for at least 1 day or no for all days.
[6] - 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 reporting yes for at least 1 day or no for all days.
[7] - 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 reporting yes for at least 1 day or no for all days.
[8] - 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 reporting yes for at least 1 day or no for all days.
[9] - 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 reporting yes for at least 1 day or no for all days.
[10] - 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 reporting yes for at least 1 day or no for all days.
[11] - 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 reporting yes for at least 1 day or no for all days.
[12] - 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 reporting yes for at least 1 day or no for all days.
[13] - 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 reporting yes for at least 1 day or no for all days.
[14] - 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 reporting yes for at least 1 day or no for all days.
[15] - 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 reporting yes for at least 1 day or no for all days.
[16] - 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 reporting yes for at least 1 day or no for all days.
[17] - 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 reporting yes for at least 1 day or no for all days.
[18] - 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 reporting yes for at least 1 day or no for all days.
[19] - 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 reporting yes for at least 1 day or no

for all days.

[20] - 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 reporting yes for at least 1 day or no for all days.

[21] - 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 reporting yes for at least 1 day or no for all days.

[22] - 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 reporting yes for at least 1 day or no for all days.

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported