



Clinical trial results:

A Phase 3, Randomized, Active-Controlled, Double-Blind Trial Evaluating the Safety, Tolerability, and Immunogenicity of Manufacturing Scale 13-valent Pneumococcal Conjugate Vaccine Summary

| | |
|--------------------------|-------------------|
| EudraCT number | 2006-006204-11 |
| Trial protocol | PL |
| Global end of trial date | 18 September 2008 |

Results information

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

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | 6096A1-3000 |
|-----------------------|-------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT00464945 |
| 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, Inc., Pfizer ClinicalTrials.gov Call Center, 1 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com |
| Scientific contact | Pfizer, Inc., Pfizer ClinicalTrials.gov Call Center, 1 800-718-1021, ClinicalTrials.gov_Inquiries@pfizer.com |

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

| | |
|--|-------------------|
| Analysis stage | Final |
| Date of interim/final analysis | 12 January 2009 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 08 September 2008 |
| Global end of trial reached? | Yes |
| Global end of trial date | 18 September 2008 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

Primary Objective:

To assess the pneumococcal immune responses induced by manufacturing scale 13-valent pneumococcal conjugate vaccine (13vPnC) relative to the immune responses induced by pilot scale 13vPnC when measured 1month after the infant series.

To evaluate the acceptability of the safety profile of 13vPnC as measured by the incidence rates of local reactions, systemic events, and adverse events (AEs).

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

| | |
|---|--------------|
| Actual start date of recruitment | 29 June 2007 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|-------------|
| Country: Number of subjects enrolled | Poland: 269 |
| Worldwide total number of subjects | 269 |
| EEA total number of subjects | 269 |

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) | 269 |
| 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:

Subjects were recruited in Poland from June 2007 to August 2007.

Pre-assignment

Screening details:

Subjects were enrolled into the study according to inclusion/exclusion criteria without a screening period.

Period 1

| | |
|------------------------------|--|
| Period 1 title | Infant Series |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Carer, Assessor |

Arms

| | |
|------------------------------|------------------------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | 13vPnC Manufacturing Infant Series |

Arm description:

Subjects received manufacturing scale dose of 13vPnC coadministered with combined diphtheria, tetanus, and acellular pertussis inactivated poliovirus, and hemophilus influenza type b vaccine (DTaP-IPV-Hib) and hepatitis B virus vaccine (HBV) at 2 months (infant series, dose 1). Subjects received manufacturing scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3).

| | |
|--|----------------------------|
| Arm type | Experimental |
| Investigational medicinal product name | 13vPnC Manufacturing Scale |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Single 0.5mL manufacturing scale dose of 13vPnC administered at 2, 3, 4 months (infant series).

| | |
|--|-------------------|
| Investigational medicinal product name | DTaP-IPV-Hib |
| Investigational medicinal product code | |
| Other name | Pentaxim |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

DTaP-IPV-Hib administered at 2, 3, 4 months (infant series).

| | |
|--|-------------------|
| Investigational medicinal product name | HBV |
| Investigational medicinal product code | |
| Other name | Engerix-B |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

HBV administered at month 2 (infant series).

| | |
|------------------|----------------------------|
| Arm title | 13vPnC Pilot Infant Series |
|------------------|----------------------------|

Arm description:

Subjects received pilot scale dose of 13vPnC coadministered with combined diphtheria, tetanus, and acellular pertussis inactivated poliovirus, and hemophilus influenza type b vaccine (DTaP-IPV-Hib) and

hepatitis B virus vaccine (HBV) at 2 months (infant series, dose 1). Subjects received pilot scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3).

| | |
|--|--------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | 13vPnC Pilot Scale |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Single 0.5mL pilot scale dose of 13vPnC administered at 2, 3, 4 months (infant series).

| | |
|--|-------------------|
| Investigational medicinal product name | DTaP-IPV-Hib |
| Investigational medicinal product code | |
| Other name | Pentaxim |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

DTaP-IPV-Hib administered at 2, 3, 4 months (infant series).

| | |
|--|-------------------|
| Investigational medicinal product name | HBV |
| Investigational medicinal product code | |
| Other name | Engerix-B |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

HBV administered at month 2 (infant series).

| Number of subjects in period 1 | 13vPnC Manufacturing Infant Series | 13vPnC Pilot Infant Series |
|---------------------------------------|------------------------------------|----------------------------|
| Started | 135 | 134 |
| Vaccinated Dose 1 | 134 | 134 |
| Vaccinated Dose 3 | 132 | 133 |
| Vaccinated Dose 2 | 132 | 133 |
| Completed | 131 | 133 |
| Not completed | 4 | 1 |
| Protocol Violation | 1 | - |
| Lost to follow-up | 1 | - |
| Withdrawal by parent/guardian request | 2 | 1 |

Period 2

| | |
|------------------------------|--|
| Period 2 title | After Infant Series |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Carer, Assessor |

Arms

| | |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

| | |
|------------------|--|
| Arm title | 13vPnC Manufacturing After Infant Series |
|------------------|--|

Arm description:

Included subjects who received manufacturing scale dose of 13vPnC coadministered with combined DTaP-IPV-Hib and HBV at 2 months (infant series, dose 1) and manufacturing scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3).

| | |
|----------|-----------------|
| Arm type | No intervention |
|----------|-----------------|

No investigational medicinal product assigned in this arm

| | |
|------------------|----------------------------------|
| Arm title | 13vPnC Pilot After Infant Series |
|------------------|----------------------------------|

Arm description:

Included subjects who received pilot scale dose of 13vPnC coadministered with combined DTaP-IPV-Hib and HBV at 2 months (infant series, dose 1) and pilot scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3).

| | |
|----------|-----------------|
| Arm type | No intervention |
|----------|-----------------|

No investigational medicinal product assigned in this arm

| Number of subjects in period 2 | 13vPnC Manufacturing After Infant Series | 13vPnC Pilot After Infant Series |
|---------------------------------------|--|----------------------------------|
| Started | 131 | 133 |
| Completed | 131 | 131 |
| Not completed | 0 | 2 |
| Consent withdrawn by subject | - | 2 |

Period 3

| | |
|------------------------------|--|
| Period 3 title | Toddler Dose |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Carer, Assessor |

Arms

| | |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

| | |
|--|-----------------------------------|
| Arm title | 13vPnC Manufacturing Toddler Dose |
| Arm description: Subjects received manufacturing scale dose of 13vPnC coadministered with measles, mumps, and rubella vaccine (MMR) at 12 months of age (toddler dose). | |
| Arm type | Experimental |
| Investigational medicinal product name | 13vPnC Manufacturing Scale |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: Single 0.5mL manufacturing scale dose administered at 12 months of age (toddler dose). | |
| Investigational medicinal product name | MMR |
| Investigational medicinal product code | |
| Other name | Priorix |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: MMR administered at 12 months of age (toddler dose). | |
| Arm title | 13vPnC Pilot Toddler Dose |

| | |
|--|--------------------|
| Arm description: Subjects received pilot scale dose of 13vPnC coadministered with MMR at 12 months of age (toddler dose). | |
| Arm type | Active comparator |
| Investigational medicinal product name | MMR |
| Investigational medicinal product code | |
| Other name | Priorix |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: MMR administered at 12 months of age (toddler dose). | |
| Investigational medicinal product name | 13vPnC Pilot Scale |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Intramuscular use |
| Dosage and administration details: Single 0.5mL pilot scale dose of 13vPnC administered at 12 months of age (toddler dose). | |

| Number of subjects in period 3 | 13vPnC Manufacturing Toddler Dose | 13vPnC Pilot Toddler Dose |
|--------------------------------|-----------------------------------|---------------------------|
| | | |
| Started | 131 | 131 |
| Completed | 131 | 130 |
| Not completed | 0 | 1 |
| Lost to follow-up | - | 1 |

Baseline characteristics

Reporting groups

| | |
|---|------------------------------------|
| Reporting group title | 13vPnC Manufacturing Infant Series |
| Reporting group description: | |
| Subjects received manufacturing scale dose of 13vPnC coadministered with combined diphtheria, tetanus, and acellular pertussis inactivated poliovirus, and hemophilus influenza type b vaccine (DTaP-IPV-Hib) and hepatitis B virus vaccine (HBV) at 2 months (infant series, dose 1). Subjects received manufacturing scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3). | |
| Reporting group title | 13vPnC Pilot Infant Series |
| Reporting group description: | |
| Subjects received pilot scale dose of 13vPnC coadministered with combined diphtheria, tetanus, and acellular pertussis inactivated poliovirus, and hemophilus influenza type b vaccine (DTaP-IPV-Hib) and hepatitis B virus vaccine (HBV) at 2 months (infant series, dose 1). Subjects received pilot scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3). | |

| Reporting group values | 13vPnC Manufacturing Infant Series | 13vPnC Pilot Infant Series | Total |
|--|------------------------------------|----------------------------|-------|
| Number of subjects | 135 | 134 | 269 |
| Age categorical Units: Subjects | | | |
| Age continuous Units: months arithmetic mean standard deviation | 2.1 ± 0.6 | 2.1 ± 0.5 | - |
| Gender categorical Units: Subjects | | | |
| Female | 65 | 67 | 132 |
| Male | 70 | 67 | 137 |

End points

End points reporting groups

| | |
|---|--|
| Reporting group title | 13vPnC Manufacturing Infant Series |
| Reporting group description: Subjects received manufacturing scale dose of 13vPnC coadministered with combined diphtheria, tetanus, and acellular pertussis inactivated poliovirus, and hemophilus influenza type b vaccine (DTaP-IPV-Hib) and hepatitis B virus vaccine (HBV) at 2 months (infant series, dose 1). Subjects received manufacturing scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3). | |
| Reporting group title | 13vPnC Pilot Infant Series |
| Reporting group description: Subjects received pilot scale dose of 13vPnC coadministered with combined diphtheria, tetanus, and acellular pertussis inactivated poliovirus, and hemophilus influenza type b vaccine (DTaP-IPV-Hib) and hepatitis B virus vaccine (HBV) at 2 months (infant series, dose 1). Subjects received pilot scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3). | |
| Reporting group title | 13vPnC Manufacturing After Infant Series |
| Reporting group description: Included subjects who received manufacturing scale dose of 13vPnC coadministered with combined DTaP-IPV-Hib and HBV at 2 months (infant series, dose 1) and manufacturing scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3). | |
| Reporting group title | 13vPnC Pilot After Infant Series |
| Reporting group description: Included subjects who received pilot scale dose of 13vPnC coadministered with combined DTaP-IPV-Hib and HBV at 2 months (infant series, dose 1) and pilot scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3). | |
| Reporting group title | 13vPnC Manufacturing Toddler Dose |
| Reporting group description: Subjects received manufacturing scale dose of 13vPnC coadministered with measles, mumps, and rubella vaccine (MMR) at 12 months of age (toddler dose). | |
| Reporting group title | 13vPnC Pilot Toddler Dose |
| Reporting group description: Subjects received pilot scale dose of 13vPnC coadministered with MMR at 12 months of age (toddler dose). | |
| Subject analysis set title | 13vPnC Manufacturing Dose 1 |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: Subjects received one single 0.5mL manufacturing scale dose of 13vPnC coadministered with DTaP-IPV-Hib and HBV at 2 months (infant series, dose 1). | |
| Subject analysis set title | 13vPnC Pilot Dose 1 |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: Subjects received one single 0.5mL pilot scale dose of 13vPnC coadministered with DTaP-IPV-Hib and HBV at 2 months (infant series, dose 1). | |
| Subject analysis set title | 13vPnC Manufacturing Dose 2 |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: Subjects received one single 0.5mL manufacturing scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3). | |
| Subject analysis set title | 13vPnC Pilot Dose 2 |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: Subjects received one single 0.5mL pilot scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3). | |
| Subject analysis set title | 13vPnC Pilot Dose 3 |
| Subject analysis set type | Safety analysis |

Subject analysis set description:

Subjects received one single 0.5mL pilot scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3).

| | |
|----------------------------|-----------------------------|
| Subject analysis set title | 13vPnC Manufacturing Dose 3 |
| Subject analysis set type | Safety analysis |

Subject analysis set description:

Subjects received one single 0.5mL manufacturing scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3).

| | |
|----------------------------|-----------------------------------|
| Subject analysis set title | 13vPnC Manufacturing Toddler Dose |
| Subject analysis set type | Safety analysis |

Subject analysis set description:

Subjects received one single 0.5mL manufacturing scale dose of 13vPnC coadministered with MMR at 12 months of age (toddler dose).

| | |
|----------------------------|---------------------------|
| Subject analysis set title | 13vPnC Pilot Toddler Dose |
| Subject analysis set type | Safety analysis |

Subject analysis set description:

Subjects received one single 0.5mL pilot scale dose of 13vPnC coadministered with MMR at 12 months of age (toddler dose).

Primary: Percentage of Subjects Achieving Antibody Level Greater than or Equal to (\geq) 0.35 μ g/mL in 13vPnC Manufacturing Scale Group Relative to 13vPnC Pilot Scale Group After the 3-Dose Infant Series

| | |
|-----------------|---|
| End point title | Percentage of Subjects Achieving Antibody Level Greater than or Equal to (\geq) 0.35 μ g/mL in 13vPnC Manufacturing Scale Group Relative to 13vPnC Pilot Scale Group After the 3-Dose Infant Series |
|-----------------|---|

End point description:

Percentages of subjects achieving WHO predefined antibody threshold \geq 0.35 μ g/mL along with the corresponding 95% confidence interval (CI) for the 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. Evaluable immunogenicity (per protocol) population consisting of eligible subjects who adhered to protocol requirements, had valid and determinate assay results, and had no other major protocol violations.

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

End point timeframe:

One month after 3-dose infant series (5 months of age)

| End point values | 13vPnC Manufacturing Infant Series | 13vPnC Pilot Infant Series | | |
|----------------------------------|------------------------------------|----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 128 | 131 | | |
| Units: Percentage of subjects | | | | |
| number (confidence interval 95%) | | | | |
| Common Serotypes-Serotype 4 | 97.7 (93.3 to 99.5) | 96.9 (92.4 to 99.2) | | |
| Common Serotypes-Serotype 6B | 77.3 (69.1 to 84.3) | 74 (65.7 to 81.3) | | |
| Common Serotypes-Serotype 9V | 98.4 (94.5 to 99.8) | 96.2 (91.3 to 98.7) | | |
| Common Serotypes-Serotype 14 | 92.9 (87 to 96.7) | 94.5 (89.1 to 97.8) | | |
| Common Serotypes-Serotype 18C | 96.1 (91.1 to 98.7) | 93.1 (87.4 to 96.8) | | |

| | | | | |
|-----------------------------------|---------------------|---------------------|--|--|
| Common Serotypes-Serotype 19F | 98.4 (94.4 to 99.8) | 97.7 (93.5 to 99.5) | | |
| Common Serotypes-Serotype 23F | 82.8 (75.1 to 88.9) | 81.7 (74 to 87.9) | | |
| Additional Serotypes-Serotype 1 | 93 (87.1 to 96.7) | 90.8 (84.5 to 95.2) | | |
| Additional Serotypes-Serotype 3 | 93.7 (88 to 97.2) | 95.4 (90.3 to 98.3) | | |
| Additional Serotypes-Serotype 5 | 90.6 (84.2 to 95.1) | 88.5 (81.8 to 93.4) | | |
| Additional Serotypes-Serotype 6A | 85.2 (77.8 to 90.8) | 86.3 (79.2 to 91.6) | | |
| Additional Serotypes-Serotype 7F | 100 (97.2 to 100) | 100 (97.2 to 100) | | |
| Additional Serotypes-Serotype 19A | 99.2 (95.7 to 100) | 99.2 (95.8 to 100) | | |

Statistical analyses

| | |
|--|---|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 4 |
| Statistical analysis description: For serotype 4 the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated. | |
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Difference |
| Point estimate | 0.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -3.9 |
| upper limit | 5.6 |

| | |
|---|---|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 6B |
| Statistical analysis description: For serotype 6B the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated. | |
| Comparison groups | 13vPnC Pilot Infant Series v 13vPnC Manufacturing Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Difference |
| Point estimate | 3.3 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -7.3 |
| upper limit | 13.8 |

| | |
|-----------------------------------|--|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 9V |
|-----------------------------------|--|

Statistical analysis description:

For serotype 9V the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated.

| | |
|---|---|
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Difference |
| Point estimate | 2.3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.1 |
| upper limit | 7.3 |

| | |
|-----------------------------------|--|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 14 |
|-----------------------------------|--|

Statistical analysis description:

For serotype 14 the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated.

| | |
|---|---|
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Difference |
| Point estimate | -1.6 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.2 |
| upper limit | 4.7 |

| | |
|-----------------------------------|---|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 18C |
|-----------------------------------|---|

Statistical analysis description:

For serotype 18C the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated.

| | |
|-------------------|---|
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
|-------------------|---|

| | |
|---|---------------|
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Difference |
| Point estimate | 3 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.8 |
| upper limit | 9.2 |

| | |
|-----------------------------------|---|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 19F |
|-----------------------------------|---|

Statistical analysis description:

For serotype 19F the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated.

| | |
|---|---|
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Difference |
| Point estimate | 0.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -3.5 |
| upper limit | 5.1 |

| | |
|-----------------------------------|---|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 23F |
|-----------------------------------|---|

Statistical analysis description:

For serotype 23F the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated.

| | |
|---|---|
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Difference |
| Point estimate | 1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -8.4 |
| upper limit | 10.6 |

| | |
|--|---|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 1 |
| Statistical analysis description: For serotype 1 the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated. | |
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Difference |
| Point estimate | 2.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -4.8 |
| upper limit | 9.2 |

| | |
|--|---|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 3 |
| Statistical analysis description: For serotype 3 the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated. | |
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Difference |
| Point estimate | -1.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -7.9 |
| upper limit | 4.2 |

| | |
|--|---|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 5 |
| Statistical analysis description: For serotype 5 the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated. | |
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Difference |
| Point estimate | 2.1 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.6 |
| upper limit | 9.9 |

| | |
|-----------------------------------|--|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 6A |
|-----------------------------------|--|

Statistical analysis description:

For serotype 6A the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated.

| | |
|---|---|
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Difference |
| Point estimate | -1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -9.9 |
| upper limit | 7.6 |

| | |
|-----------------------------------|--|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 7F |
|-----------------------------------|--|

Statistical analysis description:

For serotype 7F the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated.

| | |
|---|---|
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Difference |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -3 |
| upper limit | 2.8 |

| | |
|-----------------------------------|---|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 19A |
|-----------------------------------|---|

Statistical analysis description:

For serotype 19A the difference in percentages between the two groups (13vPnC Manufacturing - 13vPnC Pilot) was calculated.

| | |
|-------------------|---|
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
|-------------------|---|

| | |
|---|---------------|
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Difference |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -3.6 |
| upper limit | 3.5 |

Primary: Percentage of Subjects Reporting Pre-Specified Local Reactions

| | |
|-----------------|--|
| End point title | Percentage of Subjects Reporting Pre-Specified Local |
|-----------------|--|

End point description:

Local reactions (LRs) were reported using an electronic diary. Tenderness was scaled as Any (tenderness present); Significant(Sig) (present and interfered with limb movement). Induration and erythema were scaled as Any (induration or erythema present); Mild (0.5 centimeters [cm] to 2.0 cm); Moderate (Mod) (2.5 to 7.0 cm); Severe (>7.0 cm). Subjects may be represented in more than 1 category. The safety population included all subjects who received at least 1 dose of vaccine; (n) = number of subjects reporting yes for at least 1 day or no for all days.

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

End point timeframe:

During the 4-day period after each dose

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned to be reported for this outcome measure.

| End point values | 13vPnC Manufacturing Dose 1 | 13vPnC Pilot Dose 1 | 13vPnC Manufacturing Dose 2 | 13vPnC Pilot Dose 2 |
|---|-----------------------------|----------------------|-----------------------------|----------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 134 | 134 | 132 | 133 |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Tenderness-Any (n=133,130,128,128,124,119,115,117) | 18.8 | 20 | 20.3 | 17.2 |
| Tenderness-Sig (n=131,129,128,128,124,119,112,114) | 0.8 | 3.9 | 1.6 | 3.1 |
| Swelling-Any (n=132,130,129,129,126,122,113,115) | 25 | 20 | 30.2 | 27.1 |
| Swelling-Mild (n=132,130,129,129,126,121,113,115) | 22.7 | 17.7 | 29.5 | 25.6 |
| Swelling-Mod (n=132,129,128,128,124,120,113,114) | 6.1 | 7 | 8.6 | 8.6 |
| Swelling-Severe (n=131,129,128,128,124,119,111) | 0 | 0 | 0 | 0 |
| Redness-Any (n=132,131,129,131,125,123,115,116) | 28.8 | 24.4 | 37.2 | 33.6 |
| Redness-Mild (n=132,131,129,131,125,123,115,115) | 28.8 | 22.9 | 36.4 | 33.6 |
| Redness-Mod (n=131,129,128,128,124,119,113,114) | 0 | 1.6 | 3.1 | 1.6 |

| | | | | |
|---|---|---|---|---|
| Redness- Severe(n=131,129,128,128,124,119,11 | 0 | 0 | 0 | 0 |
|---|---|---|---|---|

| End point values | 13vPnC Manufacturing Dose 3 | 13vPnC Pilot Dose 3 | 13vPnC Manufacturing Toddler Dose | 13vPnC Pilot Toddler Dose |
|---|-----------------------------------|------------------------|---|------------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 132 | 133 | 131 | 131 |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Tenderness-Any (n=133,130,128,128,124,119,115,117) | 15.3 | 12.6 | 24.3 | 29.1 |
| Tenderness-Sig (n=131,129,128,128,124,119,112,114) | 1.6 | 0 | 1.8 | 3.5 |
| Swelling-Any (n=132,130,129,129,126,122,113,115) | 29.4 | 30.3 | 22.1 | 26.1 |
| Swelling-Mild (n=132,130,129,129,126,121,113,115) | 27 | 25.6 | 22.1 | 25.2 |
| Swelling-Mod (n=132,129,128,128,124,120,113,114) | 8.9 | 13.3 | 8.8 | 8.8 |
| Swelling- Severe(n=131,129,128,128,124,119,11 | 0 | 0 | 0 | 0 |
| Redness-Any (n=132,131,129,131,125,123,115,116) | 40 | 34.1 | 37.4 | 42.2 |
| Redness-Mild (n=132,131,129,131,125,123,115,115) | 38.4 | 33.3 | 33.9 | 36.5 |
| Redness-Mod (n=131,129,128,128,124,119,113,114) | 5.6 | 3.4 | 10.6 | 12.3 |
| Redness- Severe(n=131,129,128,128,124,119,11 | 0 | 0 | 0 | 0.9 |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Pre-Specified Systemic Events (Infant Series)

| | |
|-----------------|---|
| End point title | Percentage of Subjects Reporting Pre-Specified Systemic Events (Infant Series) ^[2] |
|-----------------|---|

End point description:

Systemic events (SEs) (fever greater than or equal to [\geq] 38 degrees Celsius [C] but less than or equal to [\leq] 39 C, fever more than [$>$]39 C but [\leq] 40 C, fever $>$ 40 C), decreased appetite, irritability, increased sleep, decreased sleep, use of medication (Meds) to prevent symptoms (sx), and use of medication to treat symptoms) were collected using an electronic diary. Subjects may be represented in more than 1 category. The safety population included all subjects (268) who received at least 1 dose of vaccine; (n) = number of subjects reporting yes for at least 1 day or no for all days.

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

End point timeframe:

During the 4-day period after each dose

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned to be reported for this outcome measure.

| End point values | 13vPnC Manufacturing Dose 1 | 13vPnC Pilot Dose 1 | 13vPnC Manufacturing Dose 2 | 13vPnC Pilot Dose 2 |
|--|-----------------------------------|------------------------|-----------------------------------|------------------------|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | Subject analysis set |
| Number of subjects analysed | 134 | 134 | 132 | 133 |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Fever ≥ 38 C but ≤ 39 C (n=132,130,129,130,124,121) | 18.2 | 19.2 | 16.3 | 20 |
| Fever > 39 C but ≤ 40 C (n=131,129,128,128,124,119) | 0.8 | 0.8 | 0.8 | 1.6 |
| Fever > 40 C (n=131,129,128,128,124,119) | 0 | 0 | 0 | 0 |
| Decreased appetite (n=133,129,129,128,125,121) | 20.3 | 24 | 14.7 | 15.6 |
| Irritability (n=134,131,130,131,127,123) | 50 | 51.9 | 53.8 | 49.6 |
| Increased sleep (n=132,129,128,129,124,121) | 41.7 | 39.5 | 25 | 29.5 |
| Decreased sleep (n=132,130,129,129,124,123) | 27.3 | 32.3 | 24 | 20.9 |
| Meds to treat sx (n=132,130,128,128,124,123) | 12.9 | 17.7 | 13.3 | 14.1 |
| Meds to prevent sx (n=132,130,128,129,124,121) | 12.9 | 9.2 | 11.7 | 10.1 |

| End point values | 13vPnC Manufacturing Dose 3 | 13vPnC Pilot Dose 3 | | |
|--|-----------------------------------|------------------------|--|--|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 132 | 133 | | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Fever ≥ 38 C but ≤ 39 C (n=132,130,129,130,124,121) | 11.3 | 17.4 | | |
| Fever > 39 C but ≤ 40 C (n=131,129,128,128,124,119) | 0 | 3.4 | | |
| Fever > 40 C (n=131,129,128,128,124,119) | 0 | 0 | | |
| Decreased appetite (n=133,129,129,128,125,121) | 16.8 | 19 | | |
| Irritability (n=134,131,130,131,127,123) | 41.7 | 37.4 | | |
| Increased sleep (n=132,129,128,129,124,121) | 20.2 | 30.6 | | |
| Decreased sleep (n=132,130,129,129,124,123) | 18.5 | 19.5 | | |
| Meds to treat sx (n=132,130,128,128,124,123) | 8.9 | 14.6 | | |
| Meds to prevent sx (n=132,130,128,129,124,121) | 10.5 | 8.3 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Reporting Pre-Specified Systemic Events (Toddler Series)

| | |
|-----------------|--|
| End point title | Percentage of Subjects Reporting Pre-Specified Systemic Events (Toddler Series) ^[3] |
|-----------------|--|

End point description:

Systemic events (fever ≥ 38 C but ≤ 39 C, fever >39 C but ≤ 40 C, fever > 40 C), decreased appetite, irritability, increased sleep, decreased sleep, use of medication to prevent symptoms, and use of medication to treat symptoms) were collected using an electronic diary. Subjects may be represented in more than 1 category. The safety population included all subjects who received at least 1 dose of vaccine; (n) = number of subjects reporting yes for at least 1 day or no for all days.

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

End point timeframe:

During the 4-day period after toddler dose

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive data was planned to be reported for this outcome measure.

| End point values | 13vPnC Manufacturing Infant Series | 13vPnC Pilot Infant Series | | |
|---|------------------------------------|----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 131 | 131 | | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | | | | |
| Fever ≥ 38 degrees C but ≤ 39 degrees C (n=114,114) | 14 | 13.2 | | |
| Fever >39 degrees C but ≤ 40 degrees C (n=112,113) | 0.9 | 0.9 | | |
| Fever >40 degrees C (n=112,113) | 0 | 0 | | |
| Decreased appetite (n=115,117) | 20.9 | 23.1 | | |
| Irritability (n=119,123) | 40.3 | 44.7 | | |
| Increased sleep (n=114,119) | 18.4 | 16.8 | | |
| Decreased sleep (n=116,117) | 13.8 | 13.7 | | |
| Medication to treat symptoms (n=113,115) | 17.7 | 17.4 | | |
| Medication to prevent symptoms (n=114,114) | 12.3 | 12.3 | | |

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Antibody Concentration in 13vPnC Manufacturing Scale Group Relative to 13vPnC Pilot Scale Group After the 3-Dose Infant Series

| | |
|-----------------|---|
| End point title | Geometric Mean Antibody Concentration in 13vPnC Manufacturing Scale Group Relative to 13vPnC Pilot Scale Group After the 3-Dose Infant Series |
|-----------------|---|

End point description:

Antibody concentration/geometric mean concentration (GMC) as measured by enzyme-linked immunosorbent assay (ELISA) for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F,

and 19A) are presented. Evaluable immunogenicity (per protocol) population were subjects who adhered to the protocol requirements, had valid and determinate assay results, and had no other major protocol violations.

| | |
|--|---------|
| End point type | Primary |
| End point timeframe: | |
| One month after 3-dose infant series (5 months of age) | |

| End point values | 13vPnC Manufacturing Infant Series | 13vPnC Pilot Infant Series | | |
|--|------------------------------------|----------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 128 | 131 | | |
| Units: microgram per milliliter | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Common Serotypes-Serotype 4 | 2.09 (1.81 to 2.4) | 1.55 (1.34 to 1.79) | | |
| Common Serotypes - Serotype 6B | 0.8 (0.65 to 0.98) | 0.83 (0.66 to 1.06) | | |
| Common Serotypes - Serotype 9V | 1.28 (1.13 to 1.43) | 1.21 (1.08 to 1.37) | | |
| Common Serotypes - Serotype 14 | 2.15 (1.77 to 2.61) | 2.3 (1.91 to 2.77) | | |
| Common Serotypes - Serotype 18C | 1.6 (1.38 to 1.87) | 1.51 (1.31 to 1.75) | | |
| Common Serotypes - Serotype 19F | 1.6 (1.4 to 1.83) | 1.64 (1.44 to 1.86) | | |
| Common Serotypes - Serotype 23F | 0.82 (0.69 to 0.98) | 0.92 (0.77 to 1.1) | | |
| Additional Serotypes - Serotype 1 | 1.42 (1.21 to 1.66) | 1.29 (1.1 to 1.51) | | |
| Additional Serotypes - Serotype 3 | 1.2 (1.05 to 1.38) | 1.21 (1.06 to 1.37) | | |
| Additional Serotypes - Serotype 5 | 0.96 (0.84 to 1.09) | 1 (0.87 to 1.16) | | |
| Additional Serotypes - Serotype 6A | 0.87 (0.74 to 1.03) | 1.05 (0.89 to 1.25) | | |
| Additional Serotypes - Serotype 7F | 2 (1.77 to 2.25) | 2.14 (1.89 to 2.42) | | |
| Additional Serotypes - Serotype 19A | 2.19 (1.91 to 2.5) | 2.31 (2.05 to 2.61) | | |

Statistical analyses

| | |
|--|---|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 4 |
| Statistical analysis description: | |
| For serotype 4 the GMC ratio was calculated. | |
| Comparison groups | 13vPnC Pilot Infant Series v 13vPnC Manufacturing Infant Series |

| | |
|---|---------------|
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Ratio |
| Point estimate | 1.35 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.1 |
| upper limit | 1.65 |

| | |
|--|---|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 6B |
| Statistical analysis description: For serotype 6B the GMC ratio was calculated. | |
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Ratio |
| Point estimate | 0.96 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.7 |
| upper limit | 1.31 |

| | |
|--|---|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 9V |
| Statistical analysis description: For serotype 9V the GMC ratio was calculated. | |
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Ratio |
| Point estimate | 1.05 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.89 |
| upper limit | 1.24 |

| | |
|-----------------------------------|--|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 14 |
|-----------------------------------|--|

Statistical analysis description:

For serotype 14 the GMC ratio was calculated.

| | |
|---|---|
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Ratio |
| Point estimate | 0.93 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.71 |
| upper limit | 1.22 |

Statistical analysis title

13vPnC Manufacturing vs 13vPnC Pilot-Serotype 18C

Statistical analysis description:

For serotype 18C the GMC ratio was calculated.

| | |
|---|---|
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Ratio |
| Point estimate | 1.06 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.86 |
| upper limit | 1.3 |

Statistical analysis title

13vPnC Manufacturing vs 13vPnC Pilot-Serotype 19F

Statistical analysis description:

For serotype 19F the GMC ratio was calculated.

| | |
|---|---|
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Ratio |
| Point estimate | 0.98 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.81 |
| upper limit | 1.17 |

| | |
|---|---|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 23F |
| Statistical analysis description: For serotype 23F the GMC ratio was calculated. | |
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Ratio |
| Point estimate | 0.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.7 |
| upper limit | 1.15 |

| | |
|---|---|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 1 |
| Statistical analysis description: For serotype 1 the GMC ratio was calculated. | |
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Ratio |
| Point estimate | 1.1 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.88 |
| upper limit | 1.37 |

| | |
|---|---|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 3 |
| Statistical analysis description: For serotype 3 the GMC ratio was calculated. | |
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Ratio |
| Point estimate | 1 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.83 |
| upper limit | 1.2 |

| | |
|-----------------------------------|---|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 5 |
|-----------------------------------|---|

Statistical analysis description:

For serotype 5 the GMC ratio was calculated.

| | |
|---|---|
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Ratio |
| Point estimate | 0.95 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.79 |
| upper limit | 1.16 |

| | |
|-----------------------------------|--|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 6A |
|-----------------------------------|--|

Statistical analysis description:

For serotype 6A the GMC ratio was calculated.

| | |
|---|---|
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Ratio |
| Point estimate | 0.83 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.66 |
| upper limit | 1.05 |

| | |
|-----------------------------------|--|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 7F |
|-----------------------------------|--|

Statistical analysis description:

For serotype 7F the GMC ratio was calculated.

| | |
|-------------------|---|
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
|-------------------|---|

| | |
|---|---------------|
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Ratio |
| Point estimate | 0.93 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.79 |
| upper limit | 1.11 |

| | |
|--|---|
| Statistical analysis title | 13vPnC Manufacturing vs 13vPnC Pilot-Serotype 19A |
| Statistical analysis description: | |
| For serotype 19A the GMC ratio was calculated. | |
| Comparison groups | 13vPnC Manufacturing Infant Series v 13vPnC Pilot Infant Series |
| Number of subjects included in analysis | 259 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| Parameter estimate | Ratio |
| Point estimate | 0.95 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.79 |
| upper limit | 1.13 |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs were reported from signing of informed consent from (ICF) to 1 month after third dose in infant series & from toddler dose to 1 month after last study vaccination. SAEs were reported from the signing of the ICF to 1 month after last study vaccination

Adverse event reporting additional description:

SAEs and AEs were grouped by system organ class and summarized. AEs included AEs collected in electronic diary (local, systemic reactions for 13vPnC; systematic assessment) and AEs collected on case report form at each visit (non systematic assessment). Subjects who received specified dose and had safety data available were evaluable for safety.

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

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|-----|
| Dictionary version | 0.0 |
|--------------------|-----|

Reporting groups

| | |
|-----------------------|------------------------------------|
| Reporting group title | 13vPnC Manufacturing Infant Series |
|-----------------------|------------------------------------|

Reporting group description:

Subjects received one single 0.5mL manufacturing scale dose of 13vPnC coadministered with DTaP-IPV-Hib and HBV at 2 months (infant series, dose 1). Subjects received one single 0.5mL manufacturing scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3).

| | |
|-----------------------|----------------------------|
| Reporting group title | 13vPnC Pilot Infant Series |
|-----------------------|----------------------------|

Reporting group description:

Subjects received one single 0.5mL pilot scale dose of 13vPnC coadministered with DTaP-IPV-Hib and HBV at 2 months (infant series, dose 1). Subjects received one single 0.5mL pilot scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3).

| | |
|-----------------------|---|
| Reporting group title | 13vPnC Manufacturing Post-Infant Series |
|-----------------------|---|

Reporting group description:

Subjects received one single 0.5mL manufacturing scale dose of 13vPnC coadministered with DTaP-IPV-Hib and HBV at 2 months (infant series, dose 1). Subjects received one single 0.5mL manufacturing scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3). Assessment done at 5 months of age, 1 month after infant series.

| | |
|-----------------------|---------------------------------|
| Reporting group title | 13vPnC Pilot Post-Infant Series |
|-----------------------|---------------------------------|

Reporting group description:

Subjects received one single 0.5mL pilot scale dose of 13vPnC coadministered with DTaP-IPV-Hib and HBV at 2 months (infant series, dose 1). Subjects received one single 0.5mL pilot scale dose of 13vPnC coadministered with DTaP-IPV-Hib at 3 and 4 months (infant series, dose 2 and 3). Assessment done at 5 months of age, 1 month after infant series.

| | |
|-----------------------|-------------------------------------|
| Reporting group title | 13vPnC Manufacturing Toddler Series |
|-----------------------|-------------------------------------|

Reporting group description:

Subjects received one single 0.5mL manufacturing scale dose of 13vPnC coadministered with MMR at 12 months of age (toddler dose).

| | |
|-----------------------|------------------------------|
| Reporting group title | 113vPnC Pilot Toddler Series |
|-----------------------|------------------------------|

Reporting group description:

Subjects received one single 0.5mL pilot scale dose of 13vPnC coadministered with MMR at 12 months of age (toddler dose).

| Serious adverse events | 13vPnC Manufacturing Infant Series | 13vPnC Pilot Infant Series | 13vPnC Manufacturing Post- Infant Series |
|--|--|-------------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 4 / 134 (2.99%) | 2 / 134 (1.49%) | 10 / 134 (7.46%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 1 / 134 (0.75%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Eye disorders | | | |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 0 / 134 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 1 / 134 (0.75%) | 2 / 134 (1.49%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 0 / 134 (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 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Bronchospasm | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 134 (0.00%) | 0 / 134 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Asthma | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 2 / 134 (1.49%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Psychiatric disorders | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| Crying | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 1 / 134 (0.75%) | 0 / 134 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 134 (0.00%) | 1 / 134 (0.75%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Laryngitis | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 134 (0.00%) | 2 / 134 (1.49%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 134 (0.00%) | 2 / 134 (1.49%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 134 (0.00%) | 0 / 134 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 134 (0.00%) | 0 / 134 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 1 / 134 (0.75%) | 1 / 134 (0.75%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchopneumonia | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 1 / 134 (0.75%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Enterocolitis infectious | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 0 / 134 (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 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 3 / 134 (2.24%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 3 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infectious mononucleosis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 1 / 134 (0.75%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 0 / 134 (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 |
| Otitis media | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 0 / 134 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 0 / 134 (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 |
| Pneumonia primary atypical | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 0 / 134 (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 |
| Rotavirus infection | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 1 / 134 (0.75%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 0 / 134 (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 Pilot Post-Infant Series | 13vPnC Manufacturing Toddler Series | 113vPnC Pilot Toddler Series |
|--|---------------------------------|-------------------------------------|------------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 11 / 134 (8.21%) | 0 / 131 (0.00%) | 1 / 131 (0.76%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (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 |
| Eye disorders | | | |
| Conjunctivitis | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroesophageal reflux disease | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Bronchospasm | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (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 |
| Asthma | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (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 |
| Psychiatric disorders | | | |
| Crying | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 2 / 134 (1.49%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Laryngitis | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 3 / 134 (2.24%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (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 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (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 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 2 / 134 (1.49%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchopneumonia | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (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 |
| Enterocolitis infectious | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 4 / 134 (2.99%) | 0 / 131 (0.00%) | 1 / 131 (0.76%) |
| occurrences causally related to treatment / all | 0 / 4 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infectious mononucleosis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (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 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis media | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia primary atypical | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rotavirus infection | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (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 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

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

| Non-serious adverse events | 13vPnC Manufacturing Infant Series | 13vPnC Pilot Infant Series | 13vPnC Manufacturing Post-Infant Series |
|--|---|----------------------------|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 70 / 134 (52.24%) | 68 / 134 (50.75%) | 3 / 134 (2.24%) |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 2 / 134 (1.49%) | 0 / 134 (0.00%) | 0 / 134 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 1 / 134 (0.75%) | 0 / 134 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 1 / 134 (0.75%) | 0 / 134 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Fever ≥38°C but ≤39°C: Infant series Dose 1 and Toddler Dose | 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 / 132 (18.18%) | 25 / 130 (19.23%) | 0 / 134 (0.00%) |
| occurrences (all) | 24 | 25 | 0 |
| Fever >39°C but ≤40°C: Infant Series Dose 1 and Toddler Dose | 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] occurrences (all) | 1 / 131 (0.76%) 1 | 1 / 129 (0.78%) 1 | 0 / 134 (0.00%) 0 |
| Decreased appetite: Infant Series Dose 1 and Toddler Dose | 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] occurrences (all) | 27 / 133 (20.30%) 27 | 31 / 129 (24.03%) 31 | 0 / 134 (0.00%) 0 |
| Irritability: Infant Series Dose 1 and Toddler Dose | 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] occurrences (all) | 67 / 134 (50.00%) 67 | 68 / 131 (51.91%) 68 | 0 / 134 (0.00%) 0 |
| Increased sleep: Infant Series Dose 1 and Toddler Dose | 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] occurrences (all) | 55 / 132 (41.67%) 55 | 51 / 129 (39.53%) 51 | 0 / 134 (0.00%) 0 |
| Decreased sleep: Infant Series Dose 1 and Toddler Dose | 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] occurrences (all) | 36 / 132 (27.27%) 36 | 42 / 130 (32.31%) 42 | 0 / 134 (0.00%) 0 |
| Fever ≥38°C but ≤39°C: Infant Series Dose 2 | 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 ^[7] occurrences (all) | 21 / 129 (16.28%) 21 | 26 / 130 (20.00%) 26 | 0 / 134 (0.00%) 0 |
| Fever >39°C but ≤40°C: Infant Series Dose 2 | 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. | | |

| | | | |
|---|--|------------------------------------|---------------------------------|
| <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[8]</p> <p>occurrences (all)</p> | <p>1 / 128 (0.78%)</p> <p>1</p> | <p>2 / 128 (1.56%)</p> <p>2</p> | <p>0 / 134 (0.00%)</p> <p>0</p> |
| <p>Decreased appetite: Infant Series Dose 2</p> | <p>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.</p> | | |
| <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[9]</p> <p>occurrences (all)</p> | <p>19 / 129 (14.73%)</p> <p>19</p> | <p>20 / 128 (15.63%)</p> <p>20</p> | <p>0 / 134 (0.00%)</p> <p>0</p> |
| <p>Irritability: Infant Series Dose 2</p> | <p>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.</p> | | |
| <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[10]</p> <p>occurrences (all)</p> | <p>70 / 130 (53.85%)</p> <p>70</p> | <p>65 / 131 (49.62%)</p> <p>65</p> | <p>0 / 134 (0.00%)</p> <p>0</p> |
| <p>Increased sleep: Infant Series Dose 2</p> | <p>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.</p> | | |
| <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[11]</p> <p>occurrences (all)</p> | <p>32 / 128 (25.00%)</p> <p>32</p> | <p>38 / 129 (29.46%)</p> <p>38</p> | <p>0 / 134 (0.00%)</p> <p>0</p> |
| <p>Decreased sleep: Infant Series Dose 2</p> | <p>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.</p> | | |
| <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[12]</p> <p>occurrences (all)</p> | <p>31 / 129 (24.03%)</p> <p>31</p> | <p>27 / 129 (20.93%)</p> <p>27</p> | <p>0 / 134 (0.00%)</p> <p>0</p> |
| <p>Fever ≥38°C but ≤39°C: Infant Series Dose 3</p> | <p>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.</p> | | |
| <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> | | | |

| | | | |
|---|---|-------------------|-----------------|
| subjects affected / exposed ^[13] | 14 / 124 (11.29%) | 21 / 121 (17.36%) | 0 / 134 (0.00%) |
| occurrences (all) | 14 | 21 | 0 |
| Fever >39°C but ≤40°C: Infant Series Dose 3 | 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 ^[14] | 0 / 124 (0.00%) | 4 / 119 (3.36%) | 0 / 134 (0.00%) |
| occurrences (all) | 0 | 4 | 0 |
| Decreased appetite: Infant Series Dose 3 | 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 ^[15] | 21 / 125 (16.80%) | 23 / 121 (19.01%) | 0 / 134 (0.00%) |
| occurrences (all) | 21 | 23 | 0 |
| Irritability: Infant Series Dose 3 | 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 ^[16] | 53 / 127 (41.73%) | 46 / 123 (37.40%) | 0 / 134 (0.00%) |
| occurrences (all) | 53 | 46 | 0 |
| Increased sleep: Infant Series Dose 3 | 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 ^[17] | 25 / 124 (20.16%) | 37 / 121 (30.58%) | 0 / 134 (0.00%) |
| occurrences (all) | 25 | 37 | 0 |
| Decreased sleep: Infant Series Dose 3 | 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 ^[18] | 23 / 124 (18.55%) | 24 / 123 (19.51%) | 0 / 134 (0.00%) |
| occurrences (all) | 23 | 24 | 0 |
| Immune system disorders | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| Food allergy subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 134 (0.00%) 0 | 0 / 134 (0.00%) 0 |
| Milk allergy subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 134 (0.00%) 0 | 1 / 134 (0.75%) 1 |
| Reproductive system and breast disorders Posthitis subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Rhinorrhoea subjects affected / exposed occurrences (all) | 2 / 134 (1.49%) 2 | 0 / 134 (0.00%) 0 | 0 / 134 (0.00%) 0 |
| Asthma subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 |
| Cough subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 |
| Dysphonia subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 |
| Psychiatric disorders Crying subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 |
| Psychomotor retardation subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 |
| Injury, poisoning and procedural complications Corneal abrasion subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 | 0 / 134 (0.00%) 0 |
| Congenital, familial and genetic disorders | | | |

| | | | |
|---|----------------------|----------------------|----------------------|
| Hip dysplasia subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 |
| Atrial septal defect subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 |
| Dacryostenosis congenital subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 | 0 / 134 (0.00%) 0 |
| Hydrocele subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 | 0 / 134 (0.00%) 0 |
| Plagiocephaly subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 | 0 / 134 (0.00%) 0 |
| Nervous system disorders | | | |
| Hypertonia subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 |
| Hypotonia subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 134 (0.00%) 0 | 0 / 134 (0.00%) 0 |
| Poor quality sleep subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 134 (0.00%) 0 | 0 / 134 (0.00%) 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia subjects affected / exposed occurrences (all) | 2 / 134 (1.49%) 2 | 2 / 134 (1.49%) 2 | 0 / 134 (0.00%) 0 |
| Iron deficiency anaemia subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 |
| Lymphadenitis subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 |
| Eye disorders | | | |

| | | | |
|--|----------------------|----------------------|----------------------|
| Conjunctivitis subjects affected / exposed occurrences (all) | 5 / 134 (3.73%) 5 | 4 / 134 (2.99%) 5 | 0 / 134 (0.00%) 0 |
| Dacryostenosis acquired subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 |
| Eyelid oedema subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea subjects affected / exposed occurrences (all) | 4 / 134 (2.99%) 5 | 3 / 134 (2.24%) 3 | 0 / 134 (0.00%) 0 |
| Dyspepsia subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 4 / 134 (2.99%) 4 | 0 / 134 (0.00%) 0 |
| Constipation subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 2 / 134 (1.49%) 2 | 0 / 134 (0.00%) 0 |
| Abdominal pain subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 | 0 / 134 (0.00%) 0 |
| Enlarged uvula subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 | 0 / 134 (0.00%) 0 |
| Frequent bowel movements subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 | 0 / 134 (0.00%) 0 |
| Infantile colic subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 | 0 / 134 (0.00%) 0 |
| Infrequent bowel movements subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 |
| Teething | | | |

| | | | |
|---|--|-------------------|-----------------|
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 134 (0.00%) | 0 / 134 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 1 / 134 (0.75%) |
| occurrences (all) | 0 | 0 | 1 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 0 / 134 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Skin and subcutaneous tissue disorders | | | |
| Rash | | | |
| subjects affected / exposed | 2 / 134 (1.49%) | 2 / 134 (1.49%) | 0 / 134 (0.00%) |
| occurrences (all) | 3 | 2 | 0 |
| Dermatitis atopic | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 2 / 134 (1.49%) | 1 / 134 (0.75%) |
| occurrences (all) | 1 | 2 | 1 |
| Dermatitis | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 134 (0.00%) | 0 / 134 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Eczema | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 1 / 134 (0.75%) | 0 / 134 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dermatitis allergic | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 0 / 134 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tenderness (any): Infant series Dose 1 and Toddler Dose | Additional description: Subjects affected and occurrences for LR 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] | 25 / 133 (18.80%) | 26 / 130 (20.00%) | 0 / 134 (0.00%) |
| occurrences (all) | 25 | 26 | 0 |
| Tenderness (significant): Infant series Dose 1 and Toddler Dose | Additional description: Subjects affected and occurrences for LR 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] | 1 / 131 (0.76%) | 5 / 129 (3.88%) | 0 / 134 (0.00%) |
| occurrences (all) | 1 | 5 | 0 |
| Induration (any): Infant Series Dose 1 and Toddler Dose | 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] | 33 / 132 (25.00%) | 26 / 130 (20.00%) | 0 / 134 (0.00%) |
| occurrences (all) | 33 | 26 | 0 |
| Induration (mild): Infant Series Dose 1 and Toddler Dose | 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] | 30 / 132 (22.73%) | 23 / 130 (17.69%) | 0 / 134 (0.00%) |
| occurrences (all) | 30 | 23 | 0 |
| Induration (moderate): Infant Series Dose 1 and Toddler Dose | 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 | | | |
| subjects affected / exposed ^[23] | 8 / 132 (6.06%) | 9 / 129 (6.98%) | 0 / 134 (0.00%) |
| occurrences (all) | 8 | 9 | 0 |
| Erythema (any): Infant Series Dose 1 and Toddler Dose | 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 ^[24] | 38 / 132 (28.79%) | 32 / 131 (24.43%) | 0 / 134 (0.00%) |
| occurrences (all) | 38 | 32 | 0 |
| Erythema (mild): Infant Series Dose 1 and Toddler Dose | 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 ^[25] | 38 / 132 (28.79%) | 30 / 131 (22.90%) | 0 / 134 (0.00%) |
| occurrences (all) | 38 | 30 | 0 |
| Erythema (moderate): Infant Series Dose 1 and Toddler Dose | 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. | | |

| | | | |
|--|---|-------------------|-----------------|
| subjects affected / exposed ^[26] | 0 / 131 (0.00%) | 2 / 129 (1.55%) | 0 / 134 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Erythema (severe): Infant Series Dose 1 and Toddler Dose | 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 ^[27] | 0 / 131 (0.00%) | 0 / 129 (0.00%) | 0 / 134 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tenderness (any): Infant Series Dose 2 | 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 ^[28] | 26 / 128 (20.31%) | 22 / 128 (17.19%) | 0 / 134 (0.00%) |
| occurrences (all) | 26 | 22 | 0 |
| Tenderness (significant): Infant series Dose 2 | 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 ^[29] | 2 / 128 (1.56%) | 4 / 128 (3.13%) | 0 / 134 (0.00%) |
| occurrences (all) | 2 | 4 | 0 |
| Induration (any): Infant Series Dose 2 | 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 ^[30] | 39 / 129 (30.23%) | 35 / 129 (27.13%) | 0 / 134 (0.00%) |
| occurrences (all) | 39 | 35 | 0 |
| Induration (mild): Infant Series Dose 2 | 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 ^[31] | 38 / 129 (29.46%) | 33 / 129 (25.58%) | 0 / 134 (0.00%) |
| occurrences (all) | 38 | 33 | 0 |
| Induration (moderate): Infant Series Dose 2 | 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. | | |

| | | | |
|---|--|------------------------------------|---------------------------------|
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[32]</p> <p>occurrences (all)</p> | <p>11 / 128 (8.59%)</p> <p>11</p> | <p>11 / 128 (8.59%)</p> <p>11</p> | <p>0 / 134 (0.00%)</p> <p>0</p> |
| <p>Erythema (any): Infant Series Dose 2</p> | <p>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.</p> | | |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[33]</p> <p>occurrences (all)</p> | <p>48 / 129 (37.21%)</p> <p>48</p> | <p>44 / 131 (33.59%)</p> <p>44</p> | <p>0 / 134 (0.00%)</p> <p>0</p> |
| <p>Erythema (mild): Infant Series Dose 2</p> | <p>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.</p> | | |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[34]</p> <p>occurrences (all)</p> | <p>47 / 129 (36.43%)</p> <p>47</p> | <p>44 / 131 (33.59%)</p> <p>44</p> | <p>0 / 134 (0.00%)</p> <p>0</p> |
| <p>Erythema (moderate): Infant Series Dose 2</p> | <p>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.</p> | | |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[35]</p> <p>occurrences (all)</p> | <p>4 / 128 (3.13%)</p> <p>4</p> | <p>2 / 128 (1.56%)</p> <p>2</p> | <p>0 / 134 (0.00%)</p> <p>0</p> |
| <p>Tenderness (any): Infant Series Dose 3</p> | <p>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.</p> | | |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[36]</p> <p>occurrences (all)</p> | <p>19 / 124 (15.32%)</p> <p>19</p> | <p>15 / 119 (12.61%)</p> <p>15</p> | <p>0 / 134 (0.00%)</p> <p>0</p> |
| <p>Tenderness(significant): Infant Series Dose 3</p> | <p>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.</p> | | |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> | | | |

| | | | |
|--|---|-------------------|-----------------|
| subjects affected / exposed ^[37] | 2 / 124 (1.61%) | 0 / 119 (0.00%) | 0 / 134 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Induration (any): Infant Series Dose 3 | 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 ^[38] | 37 / 126 (29.37%) | 37 / 122 (30.33%) | 0 / 134 (0.00%) |
| occurrences (all) | 37 | 37 | 0 |
| Induration (mild): Infant Series Dose 3 | 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 ^[39] | 34 / 126 (26.98%) | 31 / 121 (25.62%) | 0 / 134 (0.00%) |
| occurrences (all) | 34 | 31 | 0 |
| Induration (moderate): Infant Series Dose 3 | 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 ^[40] | 11 / 124 (8.87%) | 16 / 120 (13.33%) | 0 / 134 (0.00%) |
| occurrences (all) | 11 | 16 | 0 |
| Erythema (any): Infant Series Dose 3 | 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 ^[41] | 50 / 125 (40.00%) | 42 / 123 (34.15%) | 0 / 134 (0.00%) |
| occurrences (all) | 50 | 42 | 0 |
| Erythema (mild): Infant Series Dose 3 | 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 ^[42] | 48 / 125 (38.40%) | 41 / 123 (33.33%) | 0 / 134 (0.00%) |
| occurrences (all) | 48 | 42 | 0 |
| Erythema (moderate): Infant Series Dose 3 | 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 ^[43] occurrences (all) | 7 / 124 (5.65%) 7 | 4 / 119 (3.36%) 4 | 0 / 134 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders Rickets subjects affected / exposed occurrences (all) Posture abnormal subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 1 / 134 (0.75%) 1 | 1 / 134 (0.75%) 2 0 / 134 (0.00%) 0 | 0 / 134 (0.00%) 0 0 / 134 (0.00%) 0 |
| Infections and infestations Rhinitis subjects affected / exposed occurrences (all) Pharyngitis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all) Bronchitis subjects affected / exposed occurrences (all) Candidiasis subjects affected / exposed occurrences (all) Ear infection subjects affected / exposed occurrences (all) Exanthema subitum | 12 / 134 (8.96%) 12 9 / 134 (6.72%) 10 8 / 134 (5.97%) 8 8 / 134 (5.97%) 8 5 / 134 (3.73%) 5 2 / 134 (1.49%) 2 2 / 134 (1.49%) 2 | 10 / 134 (7.46%) 11 10 / 134 (7.46%) 10 11 / 134 (8.21%) 12 9 / 134 (6.72%) 10 7 / 134 (5.22%) 8 1 / 134 (0.75%) 1 1 / 134 (0.75%) 1 | 0 / 134 (0.00%) 0 0 / 134 (0.00%) 0 0 / 134 (0.00%) 0 0 / 134 (0.00%) 0 0 / 134 (0.00%) 0 0 / 134 (0.00%) 0 |

| | | | |
|-----------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 2 / 134 (1.49%) | 1 / 134 (0.75%) | 0 / 134 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Viral infection | | | |
| subjects affected / exposed | 2 / 134 (1.49%) | 1 / 134 (0.75%) | 0 / 134 (0.00%) |
| occurrences (all) | 2 | 1 | 0 |
| Bronchopneumonia | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 1 / 134 (0.75%) | 0 / 134 (0.00%) |
| occurrences (all) | 1 | 1 | 0 |
| Gastrointestinal infection | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 134 (0.00%) | 0 / 134 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 134 (0.00%) | 0 / 134 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 1 / 134 (0.75%) | 0 / 134 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 134 (0.00%) | 0 / 134 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 0 / 134 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 0 / 134 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 0 / 134 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 0 / 134 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 134 (0.00%) | 0 / 134 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |

| Non-serious adverse events | 13vPnC Pilot Post-Infant Series | 13vPnC Manufacturing Toddler Series | 113vPnC Pilot Toddler Series |
|---|---|-------------------------------------|------------------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 7 / 134 (5.22%) | 48 / 131 (36.64%) | 55 / 131 (41.98%) |
| General disorders and administration site conditions | | | |
| Pyrexia | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 2 / 131 (1.53%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Irritability | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Malaise | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Fever $\geq 38^{\circ}\text{C}$ but $\leq 39^{\circ}\text{C}$: Infant series Dose 1 and Toddler Dose | 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 / 134 (0.00%) | 16 / 114 (14.04%) | 15 / 114 (13.16%) |
| occurrences (all) | 0 | 16 | 15 |
| Fever $> 39^{\circ}\text{C}$ but $\leq 40^{\circ}\text{C}$: Infant Series Dose 1 and Toddler Dose | 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 / 134 (0.00%) | 1 / 112 (0.89%) | 1 / 113 (0.88%) |
| occurrences (all) | 0 | 1 | 1 |
| Decreased appetite: Infant Series Dose 1 and Toddler Dose | 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 / 134 (0.00%) | 24 / 115 (20.87%) | 27 / 117 (23.08%) |
| occurrences (all) | 0 | 24 | 27 |
| Irritability: Infant Series Dose 1 and Toddler Dose | 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 | | | |

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| <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[4]</p> <p>occurrences (all)</p> | <p>0 / 134 (0.00%)</p> <p>0</p> | <p>48 / 119 (40.34%)</p> <p>48</p> | <p>55 / 123 (44.72%)</p> <p>55</p> |
| <p>Increased sleep: Infant Series Dose 1 and Toddler Dose</p> <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[5]</p> <p>occurrences (all)</p> | <p>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.</p> | | |
| <p>0 / 134 (0.00%)</p> <p>0</p> | <p>21 / 114 (18.42%)</p> <p>21</p> | <p>20 / 119 (16.81%)</p> <p>20</p> | |
| <p>Decreased sleep: Infant Series Dose 1 and Toddler Dose</p> <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[6]</p> <p>occurrences (all)</p> | <p>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.</p> | | |
| <p>0 / 134 (0.00%)</p> <p>0</p> | <p>16 / 116 (13.79%)</p> <p>16</p> | <p>16 / 117 (13.68%)</p> <p>16</p> | |
| <p>Fever ≥38°C but ≤39°C: Infant Series Dose 2</p> <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[7]</p> <p>occurrences (all)</p> | <p>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</p> | | |
| <p>0 / 134 (0.00%)</p> <p>0</p> | <p>0 / 131 (0.00%)</p> <p>0</p> | <p>0 / 131 (0.00%)</p> <p>0</p> | |
| <p>Fever >39°C but ≤40°C: Infant Series Dose 2</p> <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[8]</p> <p>occurrences (all)</p> | <p>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.</p> | | |
| <p>0 / 134 (0.00%)</p> <p>0</p> | <p>0 / 131 (0.00%)</p> <p>0</p> | <p>0 / 131 (0.00%)</p> <p>0</p> | |
| <p>Decreased appetite: Infant Series Dose 2</p> <p>alternative dictionary used: Systemic Events 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[9]</p> <p>occurrences (all)</p> | <p>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.</p> | | |
| <p>0 / 134 (0.00%)</p> <p>0</p> | <p>0 / 131 (0.00%)</p> <p>0</p> | <p>0 / 131 (0.00%)</p> <p>0</p> | |
| <p>Irritability: Infant Series Dose 2</p> | <p>Additional description: Subjects affected and occurrences for LRs and SEs is</p> | | |

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| 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 ^[10] occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Increased sleep: Infant Series Dose 2 | 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 ^[11] occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Decreased sleep: Infant Series Dose 2 | 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 ^[12] occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Fever $\geq 38^{\circ}\text{C}$ but $\leq 39^{\circ}\text{C}$: Infant Series Dose 3 | 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 ^[13] occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Fever $> 39^{\circ}\text{C}$ but $\leq 40^{\circ}\text{C}$: Infant Series Dose 3 | 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 ^[14] occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Decreased appetite: Infant Series Dose 3 | 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 | | | |

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| subjects affected / exposed ^[15] occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Irritability: Infant Series Dose 3 | 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 ^[16] occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Increased sleep: Infant Series Dose 3 | 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 ^[17] occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Decreased sleep: Infant Series Dose 3 | 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 ^[18] occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Immune system disorders Food allergy subjects affected / exposed occurrences (all) | 1 / 134 (0.75%) 1 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Milk allergy subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Reproductive system and breast disorders Posthitis subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Rhinoorrhoea | | | |

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| subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Asthma subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Cough subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 1 / 131 (0.76%) 1 |
| Dysphonia subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Psychiatric disorders Crying subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Psychomotor retardation subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Injury, poisoning and procedural complications Corneal abrasion subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Congenital, familial and genetic disorders Hip dysplasia subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Atrial septal defect subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Dacryostenosis congenital subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Hydrocele subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Plagiocephaly | | | |

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| subjects affected / exposed occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Nervous system disorders | | | |
| Hypertonia | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Hypotonia | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Poor quality sleep | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 1 / 131 (0.76%) |
| occurrences (all) | 0 | 0 | 1 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 2 / 134 (1.49%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 4 | 0 | 0 |
| Iron deficiency anaemia | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lymphadenitis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 1 / 131 (0.76%) |
| occurrences (all) | 0 | 0 | 1 |
| Eye disorders | | | |
| Conjunctivitis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 1 / 131 (0.76%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |
| Dacryostenosis acquired | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Eyelid oedema | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 3 / 131 (2.29%) | 1 / 131 (0.76%) |
| occurrences (all) | 0 | 3 | 1 |
| Dyspepsia | | | |

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| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Constipation | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Abdominal pain | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Enlarged uvula | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Frequent bowel movements | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infantile colic | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Infrequent bowel movements | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Teething | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrooesophageal reflux disease | | | |
| subjects affected / exposed | 1 / 134 (0.75%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 1 | 0 | 0 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 1 / 131 (0.76%) |
| occurrences (all) | 0 | 0 | 1 |
| Skin and subcutaneous tissue disorders | | | |
| Rash | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Dermatitis atopic | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 1 / 131 (0.76%) | 1 / 131 (0.76%) |
| occurrences (all) | 0 | 1 | 1 |

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| Dermatitis | subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 1 / 131 (0.76%) |
| | occurrences (all) | 0 | 0 | 1 |
| Eczema | subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| | occurrences (all) | 0 | 0 | 0 |
| Dermatitis allergic | subjects affected / exposed | 2 / 134 (1.49%) | 1 / 131 (0.76%) | 0 / 131 (0.00%) |
| | occurrences (all) | 2 | 1 | 0 |
| Tenderness (any): Infant series Dose 1 and Toddler Dose | | 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 / 134 (0.00%) | 28 / 115 (24.35%) | 34 / 117 (29.06%) |
| occurrences (all) | | 0 | 28 | 34 |
| Tenderness (significant): Infant series Dose 1 and Toddler Dose | | 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 / 134 (0.00%) | 2 / 112 (1.79%) | 4 / 114 (3.51%) |
| occurrences (all) | | 0 | 2 | 4 |
| Induration (any): Infant Series Dose 1 and Toddler Dose | | 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 / 134 (0.00%) | 25 / 113 (22.12%) | 30 / 115 (26.09%) |
| occurrences (all) | | 0 | 25 | 30 |
| Induration (mild): Infant Series Dose 1 and Toddler Dose | | 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 / 134 (0.00%) | 25 / 113 (22.12%) | 29 / 115 (25.22%) |
| occurrences (all) | | 0 | 25 | 29 |
| Induration (moderate): Infant Series Dose 1 and Toddler Dose | | Additional description: Subjects affected and occurrences for LRs and SEs is same as data collected through e diaries cannot be used to distinguish one | | |

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| 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 subjects affected / exposed ^[23] occurrences (all) | 0 / 134 (0.00%) 0 | 10 / 113 (8.85%) 10 | 10 / 114 (8.77%) 10 |
| Erythema (any): Infant Series Dose 1 and Toddler Dose | Additional description: Subjects affected and occurrences for LR 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 ^[24] occurrences (all) | 0 / 134 (0.00%) 0 | 43 / 115 (37.39%) 43 | 49 / 116 (42.24%) 49 |
| Erythema (mild): Infant Series Dose 1 and Toddler Dose | Additional description: Subjects affected and occurrences for LR 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 ^[25] occurrences (all) | 0 / 134 (0.00%) 0 | 39 / 115 (33.91%) 39 | 42 / 115 (36.52%) 42 |
| Erythema (moderate): Infant Series Dose 1 and Toddler Dose | Additional description: Subjects affected and occurrences for LR 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. | | |
| subjects affected / exposed ^[26] occurrences (all) | 0 / 134 (0.00%) 0 | 12 / 113 (10.62%) 12 | 14 / 114 (12.28%) 14 |
| Erythema (severe): Infant Series Dose 1 and Toddler Dose | Additional description: Subjects affected and occurrences for LR 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 ^[27] occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 112 (0.00%) 0 | 1 / 113 (0.88%) 1 |
| Tenderness (any): Infant Series Dose 2 | Additional description: Subjects affected and occurrences for LR 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 ^[28] occurrences (all) | 0 / 134 (0.00%) 0 | 0 / 131 (0.00%) 0 | 0 / 131 (0.00%) 0 |
| Tenderness (significant): Infant series Dose 2 | Additional description: Subjects affected and occurrences for LR 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. | | |

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| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[29]</p> <p>occurrences (all)</p> | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| <p>0</p> | 0 | 0 | 0 |
| <p>Induration (any): Infant Series Dose 2</p> | <p>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.</p> | | |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[30]</p> <p>occurrences (all)</p> | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| <p>0</p> | 0 | 0 | 0 |
| <p>Induration (mild): Infant Series Dose 2</p> | <p>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.</p> | | |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[31]</p> <p>occurrences (all)</p> | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| <p>0</p> | 0 | 0 | 0 |
| <p>Induration (moderate): Infant Series Dose 2</p> | <p>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.</p> | | |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[32]</p> <p>occurrences (all)</p> | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| <p>0</p> | 0 | 0 | 0 |
| <p>Erythema (any): Infant Series Dose 2</p> | <p>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.</p> | | |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[33]</p> <p>occurrences (all)</p> | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| <p>0</p> | 0 | 0 | 0 |
| <p>Erythema (mild): Infant Series Dose 2</p> | <p>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.</p> | | |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> | | | |

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| subjects affected / exposed ^[34] | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Erythema (moderate): Infant Series Dose 2 | 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 ^[35] | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tenderness (any): Infant Series Dose 3 | 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 ^[36] | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tenderness(significant): Infant Series Dose 3 | 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 ^[37] | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Induration (any): Infant Series Dose 3 | 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 ^[38] | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Induration (mild): Infant Series Dose 3 | 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 ^[39] | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Induration (moderate): Infant Series Dose 3 | 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. | | |

| | | | |
|---|--|---------------------------------|---------------------------------|
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[40]</p> <p>occurrences (all)</p> | <p>0 / 134 (0.00%)</p> <p>0</p> | <p>0 / 131 (0.00%)</p> <p>0</p> | <p>0 / 131 (0.00%)</p> <p>0</p> |
| <p>Erythema (any): Infant Series Dose 3</p> | <p>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.</p> | | |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[41]</p> <p>occurrences (all)</p> | <p>0 / 134 (0.00%)</p> <p>0</p> | <p>0 / 131 (0.00%)</p> <p>0</p> | <p>0 / 131 (0.00%)</p> <p>0</p> |
| <p>Erythema (mild): Infant Series Dose 3</p> | <p>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.</p> | | |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[42]</p> <p>occurrences (all)</p> | <p>0 / 134 (0.00%)</p> <p>0</p> | <p>0 / 131 (0.00%)</p> <p>0</p> | <p>0 / 131 (0.00%)</p> <p>0</p> |
| <p>Erythema (moderate): Infant Series Dose 3</p> | <p>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.</p> | | |
| <p>alternative dictionary used: Local Reactions 0.0</p> <p>alternative assessment type: Systematic</p> <p>subjects affected / exposed^[43]</p> <p>occurrences (all)</p> | <p>0 / 134 (0.00%)</p> <p>0</p> | <p>0 / 131 (0.00%)</p> <p>0</p> | <p>0 / 131 (0.00%)</p> <p>0</p> |
| <p>Musculoskeletal and connective tissue disorders</p> <p>Rickets</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 134 (0.00%)</p> <p>0</p> | <p>0 / 131 (0.00%)</p> <p>0</p> | <p>0 / 131 (0.00%)</p> <p>0</p> |
| <p>Posture abnormal</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 134 (0.00%)</p> <p>0</p> | <p>0 / 131 (0.00%)</p> <p>0</p> | <p>0 / 131 (0.00%)</p> <p>0</p> |
| <p>Infections and infestations</p> <p>Rhinitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>0 / 134 (0.00%)</p> <p>0</p> | <p>1 / 131 (0.76%)</p> <p>1</p> | <p>2 / 131 (1.53%)</p> <p>2</p> |
| <p>Pharyngitis</p> | | | |

| | | | |
|-----------------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 134 (0.00%) | 5 / 131 (3.82%) | 5 / 131 (3.82%) |
| occurrences (all) | 0 | 5 | 5 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 2 / 131 (1.53%) | 1 / 131 (0.76%) |
| occurrences (all) | 0 | 2 | 2 |
| Nasopharyngitis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 1 / 131 (0.76%) | 2 / 131 (1.53%) |
| occurrences (all) | 0 | 1 | 2 |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 1 / 131 (0.76%) | 2 / 131 (1.53%) |
| occurrences (all) | 0 | 1 | 2 |
| Candidiasis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Ear infection | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Exanthema subitum | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 1 / 131 (0.76%) |
| occurrences (all) | 0 | 0 | 1 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 1 / 131 (0.76%) | 3 / 131 (2.29%) |
| occurrences (all) | 0 | 1 | 3 |
| Bronchopneumonia | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastrointestinal infection | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Lower respiratory tract infection | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Oral candidiasis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Tonsillitis | | | |

| | | | |
|-----------------------------|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 0 | 0 |
| Gastroenteritis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 2 / 131 (1.53%) | 2 / 131 (1.53%) |
| occurrences (all) | 0 | 2 | 2 |
| Laryngitis | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 2 / 131 (1.53%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 2 | 0 |
| Urinary tract infection | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 1 / 131 (0.76%) | 1 / 131 (0.76%) |
| occurrences (all) | 0 | 1 | 1 |
| Otitis media acute | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 0 / 131 (0.00%) | 1 / 131 (0.76%) |
| occurrences (all) | 0 | 0 | 1 |
| Respiratory tract infection | | | |
| subjects affected / exposed | 0 / 134 (0.00%) | 1 / 131 (0.76%) | 0 / 131 (0.00%) |
| occurrences (all) | 0 | 1 | 0 |

Notes:

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

Justification:

Here number of subjects exposed signifies subjects 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.

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.

[43] - 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