



## Clinical trial results:

**A phase IIIb randomized, double-blind, controlled study to assess the safety, reactogenicity and immunogenicity of GlaxoSmithKline (GSK) Biologicals' 10-valent pneumococcal conjugate vaccine compared to Prevenar™, when co-administered with DTPw-HBV/Hib and OPV or IPV vaccines as a 3-dose primary immunization course during the first 6 months of age.**

### Summary

|                          |                 |
|--------------------------|-----------------|
| EudraCT number           | 2006-000557-21  |
| Trial protocol           | Outside EU/EEA  |
| Global end of trial date | 17 October 2007 |

### Results information

|                                |               |
|--------------------------------|---------------|
| Result version number          | v1            |
| This version publication date  | 15 March 2016 |
| First version publication date | 26 July 2015  |

### Trial information

#### Trial identification

|                       |        |
|-----------------------|--------|
| Sponsor protocol code | 107007 |
|-----------------------|--------|

#### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT00344318 |
| WHO universal trial number (UTN)   | -           |

Notes:

### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | GlaxoSmithKline Biologicals   |
| Sponsor organisation address | Rue de l'Institut 89, Rixensart, Belgium, B-1330  |
| Public contact               | Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com |
| Scientific contact           | Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com |

Notes:

### Paediatric regulatory details

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

Notes:

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**Results analysis stage**

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|  |                  |
|--|------------------|
| Analysis stage                                       | Final            |
| Date of interim/final analysis                       | 22 November 2007 |
| Is this the analysis of the primary completion data? | Yes              |
| Primary completion date                              | 27 April 2007    |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 17 October 2007  |
| Was the trial ended prematurely?                     | No               |

Notes:

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**General information about the trial**

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Main objective of the trial:

To demonstrate that the GSK Biologicals' 10-valent pneumococcal conjugate (10Pn-PD-DiT) vaccine administered as a 3-dose primary vaccination course (either at 6-10-14 weeks or at 2-4-6 months of age), was non-inferior to Prevenar (7Pn) vaccine in terms of the incidence of post-immunization rectal fever >39.0°C, when co-administered with DTPw-HBV/Hib and OPV or IPV vaccines.

Protection of trial subjects:

All subjects were supervised closely for at least 30 minutes following vaccination with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel. Vaccines were administered only to eligible subjects that had no contraindications to any components of the vaccines. Subjects were followed-up from the time the subject consents to participate in the study until she/he is discharged.

Background therapy: -

Evidence for comparator: -

|   |                |
|---|----------------|
| Actual start date of recruitment                          | 07 August 2006 |
| Long term follow-up planned                               | Yes            |
| Long term follow-up rationale                             | Safety         |
| Long term follow-up duration                              | 6 Months       |
| Independent data monitoring committee (IDMC) involvement? | No             |

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

|                                      |                  |
|--------------------------------------|------------------|
| Country: Number of subjects enrolled | Philippines: 400 |
| Country: Number of subjects enrolled | Poland: 406      |
| Worldwide total number of subjects   | 806              |
| EEA total number of subjects         | 406              |

Notes:

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**Subjects enrolled per age group**

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|   |     |
|---|-----|
| In utero                                  | 0   |
| Preterm newborn - gestational age < 37 wk | 0   |
| Newborns (0-27 days)                      | 0   |
| Infants and toddlers (28 days-23 months)  | 806 |
| Children (2-11 years)                     | 0   |

|                           |   |
|---------------------------|---|
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years)      | 0 |
| From 65 to 84 years       | 0 |
| 85 years and over         | 0 |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

During the screening the following steps occurred: check for inclusion/exclusion criteria, contraindications/precautions, medical history of the subjects and signing informed consent forms.

### Period 1

|                              |   |
|------------------------------|---|
| Period 1 title               | Overall (overall period)                        |
| Is this the baseline period? | Yes   |
| Allocation method            | Randomised - controlled                         |
| Blinding used                | Double blind                                    |
| Roles blinded                | Subject, Investigator, Monitor, Carer, Assessor |

Blinding implementation details:

The study was conducted in a double-blind fashion. Due to the different appearance of the 10Pn-PD-DiT and Prevenar vaccines, an observer blind procedure ( i.e. a different person than the one who performed safety assessments administered the vaccines) was followed in order to keep the study double-blind.

### Arms

|                              |               |
|------------------------------|---------------|
| Are arms mutually exclusive? | Yes           |
| <b>Arm title</b>             | 10PnEPI Group |

Arm description:

Subjects in the Philippines receiving 10Pn-PD-DiT vaccine, co-administered with DTPw-HBV, Hib and OPV vaccines at 6, 10, 14 weeks of age

|  |  |
|--|--|
| Arm type                               | Experimental                               |
| Investigational medicinal product name | Pneumococcal conjugate vaccine GSK1024850A |
| Investigational medicinal product code |  |
| Other name                             | 10Pn-PD-DiT vaccine                        |
| Pharmaceutical forms                   | Injection                                  |
| Routes of administration               | Intramuscular use                          |

Dosage and administration details:

3 doses administered in the right thigh at 6, 10, 14 weeks of age

|  |                   |
|--|-------------------|
| Investigational medicinal product name | Tritanrix™-HepB   |
| Investigational medicinal product code |                   |
| Other name                             | DTPw-HBV          |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

3 doses administered in the left thigh at 6, 10, 14 weeks of age, recombined with Hiberix

|  |                   |
|--|-------------------|
| Investigational medicinal product name | Hiberix™          |
| Investigational medicinal product code |                   |
| Other name                             | Hib vaccine       |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

Reconstituted with Tritanrix-HepB before injection , 3 doses administered in the left thigh at 6, 10, 14 weeks of age

|  |              |
|--|--------------|
| Investigational medicinal product name | Polio Sabin™ |
| Investigational medicinal product code |              |
| Other name                             | OPV vaccine  |

|  |  |
|--|--|
| Pharmaceutical forms   | Oral suspension                            |
| Routes of administration   | Oral use                                   |
| Dosage and administration details:   |  |
| 3 oral doses at 6, 10, 14 weeks of age   |  |
| <b>Arm title</b>   | 10Pn246 Group                              |
| Arm description:   |  |
| Subjects in Poland receiving 10Pn-PD-DiT vaccine co-administered with DTPw-HBV/Hib and IPV vaccines at 2, 4, 6 months of age |  |
| Arm type   | Experimental                               |
| Investigational medicinal product name   | Pneumococcal conjugate vaccine GSK1024850A |
| Investigational medicinal product code   |  |
| Other name   | 10Pn-PD-DiT vaccine                        |
| Pharmaceutical forms   | Injection                                  |
| Routes of administration   | Intramuscular use                          |
| Dosage and administration details:   |  |
| 3 doses administered in the right thigh at 2, 4, 6 months of age   |  |
| Investigational medicinal product name   | Tritanrix™-HepB                            |
| Investigational medicinal product code   |  |
| Other name   | DTPw-HBV                                   |
| Pharmaceutical forms   | Injection                                  |
| Routes of administration   | Intramuscular use                          |
| Dosage and administration details:   |  |
| 3 doses administered in the left thigh at 2, 4, 6 months of age, recombined with Hiberix                                     |  |
| Investigational medicinal product name   | Hiberix™                                   |
| Investigational medicinal product code   |  |
| Other name   | Hib vaccine                                |
| Pharmaceutical forms   | Injection                                  |
| Routes of administration   | Intramuscular use                          |
| Dosage and administration details:   |  |
| Reconstituted with Tritanrix-HepB before injection , 3 doses administered in the left thigh at 2, 4, 6 months of age         |  |
| Investigational medicinal product name   | Poliorix™                                  |
| Investigational medicinal product code   |  |
| Other name   | IPV vaccine                                |
| Pharmaceutical forms   | Injection                                  |
| Routes of administration   | Intramuscular use                          |
| Dosage and administration details:   |  |
| 3 doses administered in the lower left thigh at 2, 4, 6 months of age  |  |
| <b>Arm title</b>   | 7PnEPI Group                               |
| Arm description:   |  |
| Subjects in the Philippines receiving the 7Pn vaccine, co-administered with DTPw-HBV/Hib and OPV at 6, 10, 14 weeks of age.  |  |
| Arm type   | Experimental                               |
| Investigational medicinal product name   | Prevenar™                                  |
| Investigational medicinal product code   |  |
| Other name   | 7Pn vaccine                                |
| Pharmaceutical forms   | Injection                                  |
| Routes of administration   | Intramuscular use                          |
| Dosage and administration details:   |  |
| 3 doses administered in the right thigh at 6, 10, 14 weeks of age  |  |

|   |                   |
|---|-------------------|
| Investigational medicinal product name  | Tritanrix™-HepB   |
| Investigational medicinal product code  |                   |
| Other name  | DTPw-HBV vaccine  |
| Pharmaceutical forms  | Injection         |
| Routes of administration  | Intramuscular use |
| Dosage and administration details:  |                   |
| 3 doses administered in the left thigh at 6, 10, 14 weeks of age, recombined with Hiberix.                            |                   |
| Investigational medicinal product name  | Hiberix™          |
| Investigational medicinal product code  |                   |
| Other name  | Hib vaccine       |
| Pharmaceutical forms  | Injection         |
| Routes of administration  | Intramuscular use |
| Dosage and administration details:  |                   |
| Reconstituted with Tritanrix-HepB before injection , 3 doses administered in the left thigh at 6, 10, 14 weeks of age |                   |
| Investigational medicinal product name  | Polio Sabin™      |
| Investigational medicinal product code  |                   |
| Other name  | OPV vaccine       |
| Pharmaceutical forms  | Oral suspension   |
| Routes of administration  | Oral use          |
| Dosage and administration details:  |                   |
| 3 doses at 6, 10, 14 weeks of age   |                   |
| <b>Arm title</b>  | 7Pn246 Group      |
| Arm description:  |                   |
| Subjects in Poland receiving the 7Pn vaccine, co-administered with DTPw-HBV/Hib and IPV at 2, 4, 6 months of age.     |                   |
| Arm type  | Experimental      |
| Investigational medicinal product name  | Prevenar™         |
| Investigational medicinal product code  |                   |
| Other name  | 7Pn vaccine       |
| Pharmaceutical forms  | Injection         |
| Routes of administration  | Intramuscular use |
| Dosage and administration details:  |                   |
| 3 doses administered in the right thigh at 2, 4, 6 months of age  |                   |
| Investigational medicinal product name  | Tritanrix™-HepB   |
| Investigational medicinal product code  |                   |
| Other name  | DTPw-HBV vaccine  |
| Pharmaceutical forms  | Injection         |
| Routes of administration  | Intramuscular use |
| Dosage and administration details:  |                   |
| 3 doses administered in the left thigh at 2, 4, 6 months of age, recombined with Hiberix                              |                   |
| Investigational medicinal product name  | Hiberix™          |
| Investigational medicinal product code  |                   |
| Other name  | Hib vaccine       |
| Pharmaceutical forms  | Injection         |
| Routes of administration  | Intramuscular use |
| Dosage and administration details:  |                   |
| Reconstituted with Tritanrix-HepB before injection , 3 doses administered in the left thigh at 2, 4, 6 months of age  |                   |
| Investigational medicinal product name  | Poliorix™         |
| Investigational medicinal product code  |                   |
| Other name  | IPV vaccines      |

|                          |                   |
|--------------------------|-------------------|
| Pharmaceutical forms     | Injection         |
| Routes of administration | Intramuscular use |

Dosage and administration details:

3 doses administered in the lower left thigh at 2, 4, 6 months of age

| <b>Number of subjects in period 1</b> | 10PnEPI Group | 10Pn246 Group | 7PnEPI Group |
|---------------------------------------|---------------|---------------|--------------|
| Started                               | 300           | 303           | 100          |
| Completed                             | 296           | 298           | 99           |
| Not completed                         | 4             | 5             | 1            |
| Consent withdrawn by subject          | 2             | 2             | -            |
| Adverse event, non-fatal              | -             | 3             | -            |
| Lost to follow-up                     | 2             | -             | 1            |

| <b>Number of subjects in period 1</b> | 7Pn246 Group |
|---------------------------------------|--------------|
| Started                               | 103          |
| Completed                             | 100          |
| Not completed                         | 3            |
| Consent withdrawn by subject          | 2            |
| Adverse event, non-fatal              | 1            |
| Lost to follow-up                     | -            |

## Baseline characteristics

### Reporting groups

|  |               |
|--|---------------|
| Reporting group title  | 10PnEPI Group |
| Reporting group description:<br>Subjects in the Philippines receiving 10Pn-PD-DiT vaccine, co-administered with DTPw-HBV, Hib and OPV vaccines at 6, 10, 14 weeks of age |               |
| Reporting group title  | 10Pn246 Group |
| Reporting group description:<br>Subjects in Poland receiving 10Pn-PD-DiT vaccine co-administered with DTPw-HBV/Hib and IPV vaccines at 2, 4, 6 months of age             |               |
| Reporting group title  | 7PnEPI Group  |
| Reporting group description:<br>Subjects in the Philippines receiving the 7Pn vaccine, co-administered with DTPw-HBV/Hib and OPV at 6, 10, 14 weeks of age.              |               |
| Reporting group title  | 7Pn246 Group  |
| Reporting group description:<br>Subjects in Poland receiving the 7Pn vaccine, co-administered with DTPw-HBV/Hib and IPV at 2, 4, 6 months of age.                        |               |

| Reporting group values                             | 10PnEPI Group | 10Pn246 Group | 7PnEPI Group |
|--|---------------|---------------|--------------|
| Number of subjects                                 | 300           | 303           | 100          |
| Age categorical<br>Units: Subjects                 |               |               |              |
| In utero   |               |               |              |
| Preterm newborn infants (gestational age < 37 wks) |               |               |              |
| Newborns (0-27 days)                               |               |               |              |
| Infants and toddlers (28 days-23 months)           |               |               |              |
| Children (2-11 years)                              |               |               |              |
| Adolescents (12-17 years)                          |               |               |              |
| Adults (18-64 years)                               |               |               |              |
| From 65-84 years                                   |               |               |              |
| 85 years and over                                  |               |               |              |
| Age continuous<br>Units: weeks                     |               |               |              |
| arithmetic mean                                    | 7.5           | 7.4           | 7.4          |
| standard deviation                                 | ± 1.64        | ± 1.5         | ± 1.53       |
| Gender categorical<br>Units: Subjects              |               |               |              |
| Female   | 146           | 141           | 48           |
| Male   | 154           | 162           | 52           |

| Reporting group values                             | 7Pn246 Group | Total |  |
|--|--------------|-------|--|
| Number of subjects                                 | 103          | 806   |  |
| Age categorical<br>Units: Subjects                 |              |       |  |
| In utero   |              | 0     |  |
| Preterm newborn infants (gestational age < 37 wks) |              | 0     |  |



|  |        |     |  |
|--|--------|-----|--|
| Newborns (0-27 days)                     |        | 0   |  |
| Infants and toddlers (28 days-23 months) |        | 0   |  |
| Children (2-11 years)                    |        | 0   |  |
| Adolescents (12-17 years)                |        | 0   |  |
| Adults (18-64 years)                     |        | 0   |  |
| From 65-84 years                         |        | 0   |  |
| 85 years and over                        |        | 0   |  |
| Age continuous                           |        |     |  |
| Units: weeks                             |        |     |  |
| arithmetic mean                          | 7.5    |     |  |
| standard deviation                       | ± 1.55 | -   |  |
| Gender categorical                       |        |     |  |
| Units: Subjects                          |        |     |  |
| Female                                   | 46     | 381 |  |
| Male                                     | 57     | 425 |  |

## End points

### End points reporting groups

|  |                    |
|--|--------------------|
| Reporting group title  | 10PnEPI Group      |
| Reporting group description:<br>Subjects in the Philippines receiving 10Pn-PD-DiT vaccine, co-administered with DTPw-HBV, Hib and OPV vaccines at 6, 10, 14 weeks of age |                    |
| Reporting group title  | 10Pn246 Group      |
| Reporting group description:<br>Subjects in Poland receiving 10Pn-PD-DiT vaccine co-administered with DTPw-HBV/Hib and IPV vaccines at 2, 4, 6 months of age             |                    |
| Reporting group title  | 7PnEPI Group       |
| Reporting group description:<br>Subjects in the Philippines receiving the 7Pn vaccine, co-administered with DTPw-HBV/Hib and OPV at 6, 10, 14 weeks of age.              |                    |
| Reporting group title  | 7Pn246 Group       |
| Reporting group description:<br>Subjects in Poland receiving the 7Pn vaccine, co-administered with DTPw-HBV/Hib and IPV at 2, 4, 6 months of age.                        |                    |
| Subject analysis set title   | 10Pn Group         |
| Subject analysis set type  | Sub-group analysis |
| Subject analysis set description:<br>10PnEPI and 10Pn246 arms pooled together  |                    |
| Subject analysis set title   | 7Pn Group          |
| Subject analysis set type  | Sub-group analysis |
| Subject analysis set description:<br>7PnEPI and 7Pn246 arms pooled together  |                    |

### Primary: Number of subjects reporting rectal temperature above (>) 39.0 degrees Celsius (°C)

|  |   |
|--|---|
| End point title  | Number of subjects reporting rectal temperature above (>) 39.0 degrees Celsius (°C) |
| End point description:<br>Fever was measured as rectal temperature. Assessment of occurrences of fever > 39.0 °C was performed post doses 1, 2 and 3 and across doses of 10Pn-PD-DiT or 7Pn vaccine. |   |
| End point type   | Primary   |
| End point timeframe:<br>Within 4 day (Days 0-3) after each dose and across doses   |   |

| End point values                            | 10Pn Group           | 7Pn Group            |  |  |
|---|----------------------|----------------------|--|--|
| Subject group type                          | Subject analysis set | Subject analysis set |  |  |
| Number of subjects analysed                 | 599                  | 199                  |  |  |
| Units: Subjects                             |                      |                      |  |  |
| Fever > 39.0°C, post Dose 1<br>[N=598;199]  | 31                   | 6                    |  |  |
| Fever > 39.0°C, post Dose 2<br>[N=594;199]  | 30                   | 13                   |  |  |
| Fever > 39.0°C, post Dose 3<br>[N=594;199]  | 42                   | 8                    |  |  |
| Fever > 39.0°C, across doses<br>[N=599;199] | 88                   | 23                   |  |  |

## Statistical analyses

|   |   |
|---|---|
| <b>Statistical analysis title</b>   | Rectal fever-10Pn vs 7Pn - after Dose 1 |
| Statistical analysis description:   |   |
| Analysis aimed to demonstrate that 10Pn-PD-DiT vaccine administered as a 3-dose primary vaccination course (either at 6-10-14 weeks or at 2-4-6 months of age), is non-inferior to 7Pn in terms of the incidence of post-immunization rectal fever >39.0°C, when co-administered with DTPw-HBV/Hib and OPV or IPV vaccines..Towards this, standardized asymptotic 95% confidence interval (CI) for the difference [10Pn minus 7Pn] in terms of percentages of subjects reporting rectal fever >39.0°C was computed. |   |
| Comparison groups   | 10Pn Group v 7Pn Group                  |
| Number of subjects included in analysis   | 798                                     |
| Analysis specification  | Pre-specified                           |
| Analysis type   | non-inferiority <sup>[1]</sup>          |
| Parameter estimate  | Difference in percentage                |
| Point estimate  | 2.17                                    |
| Confidence interval   |   |
| level   | 95 %                                    |
| sides   | 2-sided                                 |
| lower limit   | -1.51                                   |
| upper limit   | 4.88                                    |

Notes:

[1] - Non-inferiority was demonstrated if the upper limit of the 95% CI of the difference (10Pn arm minus 7Pn arm) in terms of percentage of subjects with rectal fever > 39.0°C is lower than 10%.

|   |   |
|---|---|
| <b>Statistical analysis title</b>   | Rectal fever-10Pn vs 7Pn - after Dose 2 |
| Statistical analysis description:   |   |
| Analysis aimed to demonstrate that 10Pn-PD-DiT vaccine administered as a 3-dose primary vaccination course (either at 6-10-14 weeks or at 2-4-6 months of age), is non-inferior to 7Pn in terms of the incidence of post-immunization rectal fever >39.0°C, when co-administered with DTPw-HBV/Hib and OPV or IPV vaccines..Towards this, standardized asymptotic 95% confidence interval (CI) for the difference [10Pn minus 7Pn] in terms of percentages of subjects reporting rectal fever >39.0°C was computed. |   |
| Comparison groups   | 10Pn Group v 7Pn Group                  |
| Number of subjects included in analysis   | 798                                     |
| Analysis specification  | Pre-specified                           |
| Analysis type   | non-inferiority <sup>[2]</sup>          |
| Parameter estimate  | Difference in percentage                |
| Point estimate  | -1.48                                   |
| Confidence interval   |   |
| level   | 95 %                                    |
| sides   | 2-sided                                 |
| lower limit   | -6.05                                   |
| upper limit   | 1.92                                    |

Notes:

[2] - Non-inferiority was demonstrated if the upper limit of the 95% CI of the difference (10Pn arm minus 7Pn arm) in terms of percentage of subjects with rectal fever > 39.0°C is lower than 10%.

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Rectal fever-10Pn vs 7Pn - after Dose 3 |
|-----------------------------------|---|

**Statistical analysis description:**

Analysis aimed to demonstrate that 10Pn-PD-DiT vaccine administered as a 3-dose primary vaccination course (either at 6-10-14 weeks or at 2-4-6 months of age), is non-inferior to 7Pn in terms of the incidence of post-immunization rectal fever  $>39.0^{\circ}\text{C}$ , when co-administered with DTPw-HBV/Hib and OPV or IPV vaccines. Towards this, standardized asymptotic 95% confidence interval (CI) for the difference [10Pn minus 7Pn] in terms of percentages of subjects reporting rectal fever  $>39.0^{\circ}\text{C}$  was computed.

|   |                                |
|---|--------------------------------|
| Comparison groups                       | 10Pn Group v 7Pn Group         |
| Number of subjects included in analysis | 798                            |
| Analysis specification                  | Pre-specified                  |
| Analysis type                           | non-inferiority <sup>[3]</sup> |
| Parameter estimate                      | Difference in percentage       |
| Point estimate                          | 3.05                           |
| Confidence interval                     |                                |
| level                                   | 95 %                           |
| sides                                   | 2-sided                        |
| lower limit                             | -1.02                          |
| upper limit                             | 6.19                           |

**Notes:**

[3] - Non-inferiority was demonstrated if the upper limit of the 95% CI of the difference (10Pn arm minus 7Pn arm) in terms of percentage of subjects with rectal fever  $> 39.0^{\circ}\text{C}$  is lower than 10%.

|                                   |   |
|-----------------------------------|---|
| <b>Statistical analysis title</b> | Rectal fever-10Pn vs 7Pn - across doses |
|-----------------------------------|---|

**Statistical analysis description:**

Analysis aimed to demonstrate that 10Pn-PD-DiT vaccine administered as a 3-dose primary vaccination course (either at 6-10-14 weeks or at 2-4-6 months of age), is non-inferior to 7Pn in terms of the incidence of post-immunization rectal fever  $>39.0^{\circ}\text{C}$ , when co-administered with DTPw-HBV/Hib and OPV or IPV vaccines. Towards this, standardized asymptotic 95% confidence interval (CI) for the difference [10Pn minus 7Pn] in terms of percentages of subjects reporting rectal fever  $>39.0^{\circ}\text{C}$  was computed.

|   |                                |
|---|--------------------------------|
| Comparison groups                       | 10Pn Group v 7Pn Group         |
| Number of subjects included in analysis | 798                            |
| Analysis specification                  | Pre-specified                  |
| Analysis type                           | non-inferiority <sup>[4]</sup> |
| Parameter estimate                      | Difference in percentage       |
| Point estimate                          | 3.13                           |
| Confidence interval                     |                                |
| level                                   | 95 %                           |
| sides                                   | 2-sided                        |
| lower limit                             | -2.65                          |
| upper limit                             | 8.01                           |

**Notes:**

[4] - Non-inferiority was demonstrated if the upper limit of the 95% CI of the difference (10Pn arm minus 7Pn arm) in terms of percentage of subjects with rectal fever  $> 39.0^{\circ}\text{C}$  is lower than 10%.

**Secondary: Number of subjects with any and any Grade 3 solicited local symptoms**

|                 |  |
|-----------------|--|
| End point title | Number of subjects with any and any Grade 3 solicited local symptoms |
|-----------------|--|

**End point description:**

Solicited local symptoms assessed include pain, redness and swelling. Grade 3 pain was defined as crying when limb was moved/spontaneously painful. Grade 3 swelling/redness was defined as swelling/redness larger than ( $>$ ) 30 millimeters (mm). "Any" is defined as incidence of the specified symptom regardless of intensity.

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

**End point timeframe:**

Within 4 day (Days 0-3) after each dose and across doses

| End point values                                     | 10PnEPI Group   | 10Pn246 Group   | 7PnEPI Group    | 7Pn246 Group    |
|--|-----------------|-----------------|-----------------|-----------------|
| Subject group type                                   | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed                          | 299             | 300             | 99              | 100             |
| Units: Subjects                                      |                 |                 |                 |                 |
| Any Pain, Post Dose 1<br>[N=299;299;99;100]          | 240             | 206             | 76              | 65              |
| Grade 3 Pain, Post Dose 1<br>[N=299;299;99;100]      | 52              | 59              | 19              | 17              |
| Any Redness, Post Dose 1<br>[N=299;299;99;100]       | 126             | 199             | 35              | 65              |
| Grade 3 Redness, Post Dose 1<br>[N=299;299;99;100]   | 10              | 30              | 6               | 8               |
| Any Swelling, Post Dose 1<br>[N=299;299;99;100]      | 142             | 153             | 39              | 56              |
| Grade 3 Swelling, Post Dose 1<br>[N=299;299;99;100]  | 41              | 43              | 15              | 9               |
| Any Pain, Post Dose 2<br>[N=296;299;99;100]          | 191             | 186             | 55              | 61              |
| Grade 3 Pain, Post Dose 2<br>[N=296;299;99;100]      | 18              | 31              | 8               | 12              |
| Any Redness, Post Dose 2<br>[N=296;299;99;100]       | 135             | 204             | 44              | 59              |
| Grade 3 Redness, Post Dose 2<br>[N=296;299;99;100]   | 8               | 9               | 1               | 2               |
| Any Swelling, Post Dose 2<br>[N=296;299;99;100]      | 98              | 163             | 29              | 51              |
| Grade 3 Swelling, Post Dose 2<br>[N=296;299;99;100]  | 27              | 19              | 5               | 5               |
| Any Pain, Post Dose 3<br>[N=296;298;99;100]          | 168             | 173             | 44              | 56              |
| Grade 3 Pain, Post Dose 3<br>[N=296;298;99;100]      | 14              | 23              | 1               | 8               |
| Any Redness, Post Dose 3<br>[N=296;298;99;100]       | 158             | 209             | 45              | 70              |
| Grade 3 Redness, Post Dose 3<br>[N=296;298;99;100]   | 3               | 8               | 0               | 4               |
| Any Swelling, Post Dose 3<br>[N=296;298;99;100]      | 84              | 151             | 25              | 53              |
| Grade 3 Swelling, Post Dose 3<br>[N=296;298;99;100]  | 15              | 19              | 4               | 10              |
| Any Pain, Across Doses<br>[N=299;300;99;100]         | 258             | 255             | 82              | 89              |
| Grade 3 Pain, Across Doses<br>[N=299;300;99;100]     | 64              | 83              | 22              | 25              |
| Any Redness, Across Doses<br>[N=299;300;99;100]      | 221             | 265             | 67              | 90              |
| Grade 3 Redness, Across Doses<br>[N=299;300;99;100]  | 18              | 42              | 6               | 12              |
| Any Swelling, Across Doses<br>[N=299;300;99;100]     | 174             | 226             | 42              | 75              |
| Grade 3 Swelling, Across Doses<br>[N=299;300;99;100] | 57              | 65              | 16              | 16              |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with any, Grade 3 and related solicited general symptoms

|   |   |
|---|---|
| End point title   | Number of subjects with any, Grade 3 and related solicited general symptoms |
| End point description:  |   |
| Solicited general symptoms assessed include drowsiness, fever (defined as rectal temperature $\geq 38.0^{\circ}\text{C}$ ), irritability, and loss of appetite. Grade 3 (G3) drowsiness was defined as drowsiness which prevented normal everyday activities. Grade 3 (G3) fever was defined as fever (rectal temperature) above ( $>$ ) $40.0^{\circ}\text{C}$ . Grade 3 (G3) irritability was defined as crying that could not be comforted/preventing normal activity. Grade 3 (G3) loss of appetite was defined as the subject not eating at all. "Any" is defined as incidence of the specified symptom regardless of intensity or relationship to study vaccination. Related (REL) = Symptom assessed by the investigator as causally related to vaccination. |   |
| End point type  | Secondary   |
| End point timeframe:  |   |
| Within 4-day (Days 0-3) after each dose and across doses  |   |

| End point values                                   | 10PnEPI Group   | 10Pn246 Group   | 7PnEPI Group    | 7Pn246 Group    |
|--|-----------------|-----------------|-----------------|-----------------|
| Subject group type                                 | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed                        | 299             | 300             | 99              | 100             |
| Units: Subjects                                    |                 |                 |                 |                 |
| Any Drowsiness, Dose 1<br>[N=299;299;99;100]       | 154             | 223             | 45              | 75              |
| G3 Drowsiness, Dose 1<br>[N=299;299;99;100]        | 6               | 10              | 3               | 1               |
| REL Drowsiness Dose 1<br>[N=299;299;99;100]        | 154             | 222             | 45              | 75              |
| Any Fever, Dose 1 [N=299;299;99;100]               | 214             | 190             | 74              | 54              |
| G3 Fever, Dose 1 [N=299;299;99;100]                | 0               | 0               | 0               | 0               |
| REL Fever, Dose 1 [N=299;299;99;100]               | 214             | 190             | 74              | 54              |
| Any Irritability, Dose 1<br>[N=299;299;99;100]     | 236             | 269             | 78              | 83              |
| G3 Irritability, Dose 1<br>[N=299;299;99;100]      | 11              | 60              | 3               | 17              |
| REL Irritability, Dose 1<br>[N=299;299;99;100]     | 236             | 266             | 78              | 83              |
| Any Loss of appetite, Dose 1<br>[N=299;299;99;100] | 104             | 166             | 26              | 52              |
| G3 Loss of appetite, Dose 1<br>[N=299;299;99;100]  | 1               | 1               | 1               | 1               |
| REL Loss of appetite, Dose 1<br>[N=299;299;99;100] | 104             | 165             | 26              | 51              |
| Any Drowsiness, Dose 2<br>[N=296;298;99;100]       | 102             | 172             | 25              | 57              |
| G3 Drowsiness, Dose 2<br>[N=296;298;99;100]        | 1               | 9               | 1               | 2               |
| REL Drowsiness, Dose 2<br>[N=296;298;99;100]       | 102             | 172             | 24              | 56              |
| Any Fever, Dose 2 [N=296;298;99;100]               | 182             | 184             | 63              | 51              |
| G3 Fever, Dose 2 [N=296;298;99;100]                | 0               | 0               | 0               | 0               |
| REL Fever, Dose 2 [N=296;298;99;100]               | 182             | 184             | 63              | 50              |

|  |     |     |    |    |
|--|-----|-----|----|----|
| Any Irritability, Dose 2<br>[N=296;298;99;100]       | 185 | 238 | 49 | 73 |
| G3 Irritability, Dose 2<br>[N=296;298;99;100]        | 8   | 37  | 3  | 9  |
| REL Irritability, Dose 2<br>[N=296;298;99;100]       | 185 | 237 | 48 | 72 |
| Any Loss of appetite, Dose 2<br>[N=296;298;99;100]   | 66  | 117 | 20 | 28 |
| G3 Loss of appetite, Dose 2<br>[N=296;298;99;100]    | 0   | 0   | 0  | 0  |
| REL Loss of appetite, Dose 2<br>[N=296;298;99;100]   | 66  | 116 | 19 | 27 |
| Any Drowsiness, Dose 3<br>[N=296;298;99;100]         | 90  | 152 | 25 | 41 |
| G3 Drowsiness, Dose 3<br>[N=296;298;99;100]          | 2   | 5   | 0  | 0  |
| REL Drowsiness, Dose 3<br>[N=296;298;99;100]         | 90  | 151 | 25 | 40 |
| Any Fever, Dose 3 [N=296;298;99;100]                 | 147 | 163 | 50 | 49 |
| G3 Fever, Dose 3 [N=296;298;99;100]                  | 0   | 0   | 0  | 1  |
| REL Fever, Dose 3 [N=296;298;99;100]                 | 147 | 162 | 50 | 49 |
| Any Irritability, Dose 3<br>[N=296;298;99;100]       | 169 | 225 | 43 | 64 |
| G3 Irritability, Dose 3<br>[N=296;298;99;100]        | 7   | 22  | 1  | 2  |
| REL Irritability, Dose 3<br>[N=296;298;99;100]       | 169 | 223 | 43 | 64 |
| Any Loss of appetite, Dose 3<br>[N=296;298;99;100]   | 61  | 113 | 19 | 19 |
| G3 Loss of appetite, Dose 3<br>[N=296;298;99;100]    | 1   | 1   | 0  | 0  |
| REL Loss of appetite, Dose 3<br>[N=296;298;99;100]   | 61  | 113 | 19 | 19 |
| Any Drowsiness, Across Doses<br>[N=299;300;99;100]   | 184 | 256 | 56 | 85 |
| G3 Drowsiness, Across Doses<br>[N=299;300;99;100]    | 9   | 17  | 3  | 3  |
| REL Drowsiness, Across Doses<br>[N=299;300;99;100]   | 184 | 256 | 56 | 85 |
| Any Fever, Across Doses<br>[N=299;300;99;100]        | 255 | 261 | 88 | 77 |
| G3 Fever, Across Doses<br>[N=299;300;99;100]         | 0   | 0   | 0  | 1  |
| REL Fever, Across Doses<br>[N=299;300;99;100]        | 255 | 261 | 88 | 77 |
| Any Irritability, Across Doses<br>[N=299;300;99;100] | 258 | 289 | 82 | 93 |
| G3 Irritability, Across Doses<br>[N=299;300;99;100]  | 22  | 89  | 6  | 24 |
| REL Irritability, Across Doses<br>[N=299;300;99;100] | 258 | 289 | 82 | 93 |
| Any Loss of appetite, Across<br>[N=299;300;99;100]   | 140 | 221 | 39 | 64 |
| G3 Loss of appetite, Across<br>[N=299;300;99;100]    | 1   | 2   | 1  | 1  |
| REL Loss of appetite, Across<br>[N=299;300;99;100]   | 140 | 220 | 39 | 63 |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with unsolicited adverse events (AEs)

|  |  |
|--|--|
| End point title  | Number of subjects with unsolicited adverse events (AEs) |
| End point description:<br>An AE is any untoward medical occurrence in a clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. "Any" is defined as an incidence of an unsolicited AE regardless of intensity or relationship to study vaccination. |  |
| End point type   | Secondary  |
| End point timeframe:<br>Within 31 days (Days 0-30) after each vaccination  |  |

| End point values            | 10PnEPI Group   | 10Pn246 Group   | 7PnEPI Group    | 7Pn246 Group    |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type          | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 300             | 303             | 100             | 103             |
| Units: Subjects             |                 |                 |                 |                 |
| Any unsolicited AE(s)       | 168             | 166             | 46              | 61              |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with serious adverse events (SAEs)

|  |   |
|--|---|
| End point title  | Number of subjects with serious adverse events (SAEs) |
| End point description:   |   |
| End point type   | Secondary   |
| End point timeframe:<br>Throughout the active phase of the study |   |

| End point values            | 10PnEPI Group   | 10Pn246 Group   | 7PnEPI Group    | 7Pn246 Group    |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type          | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 300             | 303             | 100             | 103             |
| Units: Subjects             |                 |                 |                 |                 |
| Any SAEs                    | 6               | 34              | 1               | 9               |

## Statistical analyses



No statistical analyses for this end point

### Secondary: Number of subjects with serious adverse (SAEs)

|  |  |
|--|--|
| End point title  | Number of subjects with serious adverse (SAEs) |
| End point description:                                       |  |
| End point type   | Secondary                                      |
| End point timeframe:   |  |
| From study Day 0 until the 6-month extended safety follow-up |  |

| End point values            | 10PnEPI Group   | 10Pn246 Group   | 7PnEPI Group    | 7Pn246 Group    |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type          | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 300             | 303             | 100             | 103             |
| Units: Subjects             |                 |                 |                 |                 |
| Any SAEs                    | 16              | 52              | 4               | 19              |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Concentrations of antibodies against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F

|  |   |
|--|---|
| End point title  | Concentrations of antibodies against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F |
| End point description:   |   |
| Seropositivity status, defined as Anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations $\geq 0.05$ microgram per milliliter ( $\mu\text{g/mL}$ ). |   |
| End point type   | Secondary   |
| End point timeframe:   |   |
| One month after the administration of the 3rd vaccine dose of Pneumococcal conjugate vaccine GSK1024850A vaccine or Prevenar   |   |

| End point values                         | 10PnEPI Group       | 10Pn246 Group       | 7PnEPI Group        | 7Pn246 Group        |
|--|---------------------|---------------------|---------------------|---------------------|
| Subject group type                       | Reporting group     | Reporting group     | Reporting group     | Reporting group     |
| Number of subjects analysed              | 285                 | 285                 | 95                  | 96                  |
| Units: $\mu\text{g/mL}$                  |                     |                     |                     |                     |
| geometric mean (confidence interval 95%) |                     |                     |                     |                     |
| Anti-1 POST [N=285;285;94;96]            | 3.23 (2.94 to 3.54) | 1.04 (0.94 to 1.15) | 0.03 (0.03 to 0.04) | 0.03 (0.03 to 0.03) |
| Anti-4 POST [N=285;285;95;96]            | 4.96 (4.46 to 5.51) | 1.64 (1.49 to 1.8)  | 5.68 (4.94 to 6.53) | 2.14 (1.88 to 2.44) |
| Anti-5 POST [N=285;285;95;96]            | 4.87 (4.5 to 5.26)  | 1.62 (1.48 to 1.78) | 0.03 (0.03 to 0.04) | 0.03 (0.03 to 0.03) |

|                                 |                        |                     |                     |                     |
|---------------------------------|------------------------|---------------------|---------------------|---------------------|
| Anti-6B POST [N=285;285;95;96]  | 1.19 (1.02 to 1.38)    | 0.73 (0.64 to 0.84) | 1.06 (0.8 to 1.4)   | 1.23 (0.96 to 1.58) |
| Anti-7F POST [N=285;285;95;96]  | 4.84 (4.45 to 5.27)    | 2.25 (2.07 to 2.45) | 0.05 (0.04 to 0.06) | 0.04 (0.03 to 0.04) |
| Anti-9V POST [N=285;285;95;96]  | 4.04 (3.66 to 4.46)    | 1.51 (1.37 to 1.66) | 5.07 (4.32 to 5.96) | 2.7 (2.32 to 3.14)  |
| Anti-14 POST [N=285;285;95;96]  | 6.45 (5.65 to 7.38)    | 3.31 (2.98 to 3.68) | 5.88 (4.71 to 7.34) | 5.23 (4.39 to 6.24) |
| Anti-18C POST [N=285;285;95;96] | 11.56 (10.22 to 13.08) | 3.74 (3.28 to 4.28) | 3.71 (3.14 to 4.38) | 2.64 (2.25 to 3.11) |
| Anti-19F POST [N=285;285;95;96] | 10.46 (9.32 to 11.74)  | 5.3 (4.77 to 5.89)  | 4.68 (4.02 to 5.45) | 2.38 (2.04 to 2.78) |
| Anti-23F POST [N=285;285;95;96] | 2.23 (1.98 to 2.5)     | 1.11 (0.98 to 1.26) | 2.28 (1.7 to 3.06)  | 2.2 (1.83 to 2.65)  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects with anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations equal to or above ( $\geq$ ) 0.2 microgram per milliliter ( $\mu\text{g/mL}$ )

|                 |  |
|-----------------|--|
| End point title | Number of subjects with anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations equal to or above ( $\geq$ ) 0.2 microgram per milliliter ( $\mu\text{g/mL}$ ) |
|-----------------|--|

End point description:

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

End point timeframe:

One month after the administration of the 3rd vaccine dose of Pneumococcal conjugate vaccine GSK1024850A vaccine or Prevenar

| End point values                | 10PnEPI Group   | 10Pn246 Group   | 7PnEPI Group    | 7Pn246 Group    |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type              | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed     | 285             | 285             | 95              | 96              |
| Units: Subjects                 |                 |                 |                 |                 |
| Anti-1 POST [N=285;285;94;96]   | 285             | 280             | 3               | 3               |
| Anti-4 POST [N=285;285;95;96]   | 283             | 282             | 95              | 96              |
| Anti-5 POST [N=285;285;95;96]   | 285             | 282             | 3               | 2               |
| Anti-6B POST [N=285;285;95;96]  | 260             | 244             | 82              | 91              |
| Anti-7F POST [N=285;285;95;96]  | 284             | 285             | 9               | 5               |
| Anti-9V POST [N=285;285;95;96]  | 284             | 285             | 95              | 96              |
| Anti-14 POST [N=285;285;95;96]  | 285             | 285             | 95              | 96              |
| Anti-18C POST [N=285;285;95;96] | 284             | 281             | 95              | 95              |
| Anti-19F POST [N=285;285;95;96] | 285             | 282             | 94              | 95              |
| Anti-23F POST [N=285;285;95;96] | 277             | 269             | 90              | 95              |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations equal to or above ( $\geq$ ) 0.05 microgram per liter ( $\mu\text{g/mL}$ )

|                 |  |
|-----------------|--|
| End point title | Number of subjects with anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations equal to or above ( $\geq$ ) 0.05 microgram per liter ( $\mu\text{g/mL}$ ) |
|-----------------|--|

End point description:

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

End point timeframe:

One month after the administration of the 3rd vaccine dose of Pneumococcal conjugate vaccine GSK1024850A vaccine or Prevenar

| End point values                | 10PnEPI Group   | 10Pn246 Group   | 7PnEPI Group    | 7Pn246 Group    |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type              | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed     | 285             | 285             | 95              | 96              |
| Units: Subjects                 |                 |                 |                 |                 |
| Anti-1 POST [N=285;285;94;96]   | 285             | 285             | 20              | 13              |
| Anti-4 POST [N=285;285;95;96]   | 285             | 285             | 95              | 96              |
| Anti-5 POST [N=285;285;95;96]   | 285             | 285             | 19              | 13              |
| Anti-6B POST [N=285;285;95;96]  | 279             | 274             | 92              | 91              |
| Anti-7F POST [N=285;285;95;96]  | 285             | 285             | 37              | 22              |
| Anti-9V POST [N=285;285;95;96]  | 285             | 285             | 95              | 96              |
| Anti-14 POST [N=285;285;95;96]  | 285             | 285             | 95              | 96              |
| Anti-18C POST [N=285;285;95;96] | 284             | 285             | 95              | 95              |
| Anti-19F POST [N=285;285;95;96] | 285             | 285             | 95              | 95              |
| Anti-23F POST [N=285;285;95;96] | 285             | 279             | 91              | 96              |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Opsonophagocytic activity (OPA) against vaccine pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F

|                 |  |
|-----------------|--|
| End point title | Opsonophagocytic activity (OPA) against vaccine pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F |
|-----------------|--|

End point description:

Seropositivity status, defined as Opsonophagocytic activity against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F  $\geq 8$

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

End point timeframe:

One month after the administration of the 3rd vaccine dose of Pneumococcal conjugate vaccine GSK1024850A or Prevenar

| End point values                         | 10PnEPI Group             | 10Pn246 Group             | 7PnEPI Group              | 7Pn246 Group              |
|--|---------------------------|---------------------------|---------------------------|---------------------------|
| Subject group type                       | Reporting group           | Reporting group           | Reporting group           | Reporting group           |
| Number of subjects analysed              | 142                       | 145                       | 46                        | 49                        |
| Units: Titers                            |                           |                           |                           |                           |
| geometric mean (confidence interval 95%) |                           |                           |                           |                           |
| OPA Anti-1 [N=142;144;46;49]             | 93.7 (68.2 to 128.7)      | 14.8 (11.2 to 19.6)       | 4.2 (3.8 to 4.5)          | 4 (4 to 4)                |
| OPA Anti-4 [N=138;145;43;49]             | 1008.7 (849.1 to 1198.4)  | 602.9 (494.8 to 734.6)    | 1229.9 (975.5 to 1550.7)  | 513 (388.2 to 677.9)      |
| OPA Anti-5 [N=140;144;46;49]             | 209.3 (176.6 to 248)      | 67.2 (52.2 to 86.6)       | 4 (4 to 4)                | 4 (4 to 4)                |
| OPA Anti-6B [N=142;145;43;49]            | 963.5 (714.7 to 1299)     | 361.9 (255 to 513.7)      | 1762.2 (975.3 to 3184)    | 805 (436.9 to 1483.4)     |
| OPA Anti-7F [N=137;144;44;49]            | 5196.4 (4349.2 to 6208.6) | 2002.2 (1543.1 to 2597.9) | 14.2 (6.9 to 29.4)        | 6.9 (4.3 to 11.1)         |
| OPA Anti-9V [N=130;144;43;49]            | 1631.9 (1343.8 to 1981.9) | 1171.7 (966.1 to 1421.1)  | 1713.3 (1294.6 to 2267.5) | 1166 (782.6 to 1737.2)    |
| OPA Anti-14 [N=142;145;46;49]            | 1669.1 (1267.7 to 2197.6) | 640 (520.2 to 787.5)      | 2117.4 (1210.9 to 3702.6) | 947.6 (658.6 to 1363.4)   |
| OPA Anti-18C [N=139;144;45;49]           | 673.3 (569.7 to 795.8)    | 174.9 (137.1 to 223.1)    | 283.7 (209.6 to 384.1)    | 127 (86.4 to 186.5)       |
| OPA Anti-19F [N=139;143;46;49]           | 1121.7 (931.5 to 1350.6)  | 337.8 (262.9 to 434.1)    | 81.6 (53 to 125.5)        | 35.9 (25.7 to 50.1)       |
| OPA Anti-23F [N=141;143;43;49]           | 2186.6 (1845.4 to 2590.9) | 920.6 (678 to 1249.9)     | 4126.6 (2609 to 6526.8)   | 3895.4 (2842.8 to 5337.8) |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects with opsonophagocytic activity (OPA) against vaccine pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F equal to or above ( $\geq$ ) 8

|                 |   |
|-----------------|---|
| End point title | Number of subjects with opsonophagocytic activity (OPA) against vaccine pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F equal to or above ( $\geq$ ) 8 |
|-----------------|---|

End point description:

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

End point timeframe:

One month after the administration of the 3rd vaccine dose of Pneumococcal conjugate vaccine GSK1024850A or Prevenar

| End point values               | 10PnEPI Group   | 10Pn246 Group   | 7PnEPI Group    | 7Pn246 Group    |
|--------------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type             | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed    | 142             | 145             | 46              | 49              |
| Units: Subjects                |                 |                 |                 |                 |
| OPA Anti-1 [N=142;144;46;49]   | 117             | 62              | 1               | 0               |
| OPA Anti-4 [N=138;145;43;49]   | 137             | 143             | 43              | 49              |
| OPA Anti-5 [N=140;144;46;49]   | 139             | 127             | 0               | 0               |
| OPA Anti-6B [N=142;145;43;49]  | 132             | 122             | 40              | 44              |
| OPA Anti-7F [N=137;144;44;49]  | 137             | 141             | 10              | 5               |
| OPA Anti-9V [N=130;144;43;49]  | 130             | 144             | 43              | 49              |
| OPA Anti-14 [N=142;145;46;49]  | 138             | 142             | 43              | 48              |
| OPA Anti-18C [N=139;144;45;49] | 138             | 137             | 45              | 48              |
| OPA Anti-19F [N=139;143;46;49] | 137             | 142             | 42              | 45              |
| OPA Anti-23F [N=141;143;43;49] | 141             | 132             | 42              | 49              |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Concentrations of antibodies against cross-reactive pneumococcal serotypes 6A and 19A

|  |   |
|--|---|
| End point title  | Concentrations of antibodies against cross-reactive pneumococcal serotypes 6A and 19A |
| End point description:   |   |
| Seropositivity status, defined as Anti-pneumococcal cross-reactive serotypes 6A and 19A antibody concentrations $\geq 0.05$ microgram per milliliter ( $\mu\text{g/mL}$ ). |   |
| End point type   | Secondary   |
| End point timeframe:   |   |
| One month after the administration of the 3rd vaccine dose of Pneumococcal vaccine conjugate GSK1024850A or Prevenar   |   |

| End point values                         | 10PnEPI Group       | 10Pn246 Group       | 7PnEPI Group        | 7Pn246 Group       |
|--|---------------------|---------------------|---------------------|--------------------|
| Subject group type                       | Reporting group     | Reporting group     | Reporting group     | Reporting group    |
| Number of subjects analysed              | 285                 | 285                 | 95                  | 96                 |
| Units: $\mu\text{g/mL}$                  |                     |                     |                     |                    |
| geometric mean (confidence interval 95%) |                     |                     |                     |                    |
| Anti-6A [N=285;285;95;96]                | 0.3 (0.26 to 0.35)  | 0.17 (0.15 to 0.2)  | 0.23 (0.18 to 0.3)  | 0.26 (0.2 to 0.33) |
| Anti-19A [N=285;284;95;96]               | 0.36 (0.31 to 0.41) | 0.29 (0.25 to 0.34) | 0.18 (0.15 to 0.22) | 0.12 (0.1 to 0.15) |

### Statistical analyses

No statistical analyses for this end point

**Secondary: Number of subjects with concentrations of antibodies against cross-reactive pneumococcal serotypes 6A and 19A equal to or above ( $\geq$ ) 0.05 microgram per milliliter ( $\mu\text{g/mL}$ )**

|                 |   |
|-----------------|---|
| End point title | Number of subjects with concentrations of antibodies against cross-reactive pneumococcal serotypes 6A and 19A equal to or above ( $\geq$ ) 0.05 microgram per milliliter ( $\mu\text{g/mL}$ ) |
|-----------------|---|

End point description:

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

End point timeframe:

One month after the administration of the 3rd vaccine dose of Pneumococcal vaccine conjugate GSK1024850A or Prevenar

| End point values            | 10PnEPI Group   | 10Pn246 Group   | 7PnEPI Group    | 7Pn246 Group    |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type          | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 285             | 285             | 95              | 96              |
| Units: Subjects             |                 |                 |                 |                 |
| Anti-6A [N=285;285;95;96]   | 261             | 230             | 84              | 84              |
| Anti-19A [N=285;284;95;96]  | 269             | 264             | 90              | 83              |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Opsonophagocytic activity (OPA) against cross-reactive pneumococcal serotypes 6A and 19A**

|                 |  |
|-----------------|--|
| End point title | Opsonophagocytic activity (OPA) against cross-reactive pneumococcal serotypes 6A and 19A |
|-----------------|--|

End point description:

Seropositivity status, defined as Opsonophagocytic activity against pneumococcal cross-reactive serotypes 6A and 19A  $\geq 8$

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

End point timeframe:

One month after the administration of the 3rd vaccine dose of Pneumococcal conjugate vaccine GSK1024850A or Prevenar

| End point values                         | 10PnEPI Group        | 10Pn246 Group       | 7PnEPI Group          | 7Pn246 Group          |
|--|----------------------|---------------------|-----------------------|-----------------------|
| Subject group type                       | Reporting group      | Reporting group     | Reporting group       | Reporting group       |
| Number of subjects analysed              | 137                  | 143                 | 44                    | 49                    |
| Units: Titers                            |                      |                     |                       |                       |
| geometric mean (confidence interval 95%) |                      |                     |                       |                       |
| OPA Anti-6A [N=127;137;43;48]            | 93.1 (64.1 to 135.2) | 60.5 (40.7 to 89.9) | 137.3 (69.7 to 270.3) | 175.1 (87.2 to 351.6) |
| OPA Anti-19A [N=137;143;44;49]           | 10.6 (7.9 to 14.2)   | 10.1 (7.8 to 13.1)  | 4.2 (3.8 to 4.7)      | 4 (4 to 4)            |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with opsonophagocytic activity (OPA) against cross-reactive pneumococcal serotypes 6A and 19A equal to or above ( $\geq$ ) 8

|                 |   |
|-----------------|---|
| End point title | Number of subjects with opsonophagocytic activity (OPA) against cross-reactive pneumococcal serotypes 6A and 19A equal to or above ( $\geq$ ) 8 |
|-----------------|---|

End point description:

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

End point timeframe:

One month after the administration of the 3rd vaccine dose of Pneumococcal conjugate vaccine GSK1024850A or Prevenar

| End point values               | 10PnEPI Group   | 10Pn246 Group   | 7PnEPI Group    | 7Pn246 Group    |
|--------------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type             | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed    | 137             | 143             | 44              | 49              |
| Units: Subjects                |                 |                 |                 |                 |
| OPA Anti-6A [N=127;137;43;48]  | 91              | 83              | 34              | 36              |
| OPA Anti-19A [N=137;143;44;49] | 35              | 41              | 1               | 0               |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Concentrations of antibodies against protein D (Anti-PD)

|                 |  |
|-----------------|--|
| End point title | Concentrations of antibodies against protein D (Anti-PD) |
|-----------------|--|

End point description:

Seropositivity status, defined as Anti-PD antibody concentrations  $\geq$  100 ELISA units per milliliter (EL.U/mL)

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

End point timeframe:

One month after the administration of the 3rd vaccine dose of Pneumococcal conjugate vaccine GSK1024850A or Prevenar

| End point values                         | 10PnEPI Group         | 10Pn246 Group         | 7PnEPI Group          | 7Pn246 Group        |
|--|-----------------------|-----------------------|-----------------------|---------------------|
| Subject group type                       | Reporting group       | Reporting group       | Reporting group       | Reporting group     |
| Number of subjects analysed              | 284                   | 285                   | 95                    | 96                  |
| Units: EL.U/mL                           |                       |                       |                       |                     |
| geometric mean (confidence interval 95%) |                       |                       |                       |                     |
| Anti-PD                                  | 3800 (3481.2 to 4148) | 2002 (1780 to 2251.6) | 105.2 (85.3 to 129.6) | 66.6 (58.5 to 75.8) |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with concentrations of antibodies against protein D (Anti-PD) equal to or above ( $\geq$ ) 100 ELISA units per milliliter (EL.U/mL)

|                 |  |
|-----------------|--|
| End point title | Number of subjects with concentrations of antibodies against protein D (Anti-PD) equal to or above ( $\geq$ ) 100 ELISA units per milliliter (EL.U/mL) |
|-----------------|--|

End point description:

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

End point timeframe:

One month after the administration of the 3rd vaccine dose of Pneumococcal conjugate vaccine GSK1024850A or Prevenar

| End point values            | 10PnEPI Group   | 10Pn246 Group   | 7PnEPI Group    | 7Pn246 Group    |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type          | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 284             | 285             | 95              | 96              |
| Units: Subjects             |                 |                 |                 |                 |
| Anti-PD                     | 284             | 285             | 39              | 18              |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with anti-polyribosyl-ribitol phosphate (anti-PRP) antibody concentration equal to or above 0.15 microgram per milliliter ( $\mu$ g/ mL)

|                 |   |
|-----------------|---|
| End point title | Number of subjects with anti-polyribosyl-ribitol phosphate (anti-PRP) antibody concentration equal to or above 0.15 microgram per milliliter ( $\mu$ g/ mL) |
|-----------------|---|

End point description:

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

End point timeframe:

One month after the administration of the 3rd vaccine dose of DTPw-HBV/Hib + OPV or IPV



| End point values            | 10PnEPI Group   | 10Pn246 Group   | 7PnEPI Group    | 7Pn246 Group    |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type          | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 140             | 140             | 49              | 47              |
| Units: Subjects             |                 |                 |                 |                 |
| Anti-PRP                    | 140             | 140             | 49              | 47              |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with anti-polyribosyl-ribitol phosphate (anti-PRP) antibody concentration equal to or above 1.0 microgram per milliliter (µg/mL)

|                        |   |
|------------------------|---|
| End point title        | Number of subjects with anti-polyribosyl-ribitol phosphate (anti-PRP) antibody concentration equal to or above 1.0 microgram per milliliter (µg/mL) |
| End point description: |   |
| End point type         | Secondary   |
| End point timeframe:   | One month after the administration of the 3rd vaccine dose of DTPw-HBV/Hib + OPV or IPV   |

| End point values            | 10PnEPI Group   | 10Pn246 Group   | 7PnEPI Group    | 7Pn246 Group    |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type          | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 140             | 140             | 49              | 47              |
| Units: Subjects             |                 |                 |                 |                 |
| Anti-PRP                    | 139             | 137             | 48              | 45              |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Anti-polyribosyl-ribitol-phosphate (Anti-PRP) antibody concentrations

|                        |   |
|------------------------|---|
| End point title        | Anti-polyribosyl-ribitol-phosphate (Anti-PRP) antibody concentrations                                     |
| End point description: | Seroprotection status, defined as Anti-PRP antibody concentrations $\geq 0.15$ µg/mL and $\geq 1.0$ µg/mL |
| End point type         | Secondary   |
| End point timeframe:   | One month after the administration of the 3rd vaccine dose of DTPw-HBV/Hib + OPV or IPV                   |

| <b>End point values</b>                  | 10PnEPI Group             | 10Pn246 Group           | 7PnEPI Group              | 7Pn246 Group          |
|--|---------------------------|-------------------------|---------------------------|-----------------------|
| Subject group type                       | Reporting group           | Reporting group         | Reporting group           | Reporting group       |
| Number of subjects analysed              | 140                       | 140                     | 49                        | 47                    |
| Units: µg/mL                             |                           |                         |                           |                       |
| geometric mean (confidence interval 95%) |                           |                         |                           |                       |
| Anti-PRP                                 | 26.001 (21.196 to 31.894) | 9.376 (7.941 to 11.071) | 25.758 (17.669 to 37.548) | 8.86 (6.87 to 11.427) |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with anti-diphtheria (Anti D) and anti-tetanus toxoids (Anti TT) antibody concentrations equal to or above 0.1 International Units per milliliter (IU/mL)

|                 |  |
|-----------------|--|
| End point title | Number of subjects with anti-diphtheria (Anti D) and anti-tetanus toxoids (Anti TT) antibody concentrations equal to or above 0.1 International Units per milliliter (IU/mL) |
|-----------------|--|

End point description:

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

End point timeframe:

One month after the administration of the 3rd vaccine dose of DTPw-HBV/Hib + OPV or IPV

| <b>End point values</b>           | 10PnEPI Group   | 10Pn246 Group   | 7PnEPI Group    | 7Pn246 Group    |
|-----------------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type                | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed       | 140             | 140             | 49              | 47              |
| Units: Subjects                   |                 |                 |                 |                 |
| Anti-diphtheria [N=140;140;49;47] | 137             | 140             | 49              | 46              |
| Anti-tetanus [N=139;140;48;47]    | 139             | 140             | 48              | 47              |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Anti-diphtheria (Anti-D) and anti-tetanus toxoids (Anti-TT) antibody concentrations

|                 |   |
|-----------------|---|
| End point title | Anti-diphtheria (Anti-D) and anti-tetanus toxoids (Anti-TT) antibody concentrations |
|-----------------|---|

End point description:

Seroprotection status, defined as Anti-diphtheria toxoid or anti-tetanus toxoid antibody concentrations  $\geq$  0.1 IU/mL

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

End point timeframe:

One month after the administration of the 3rd vaccine dose of DTPw-HBV/Hib + OPV or IPV

| End point values                         | 10PnEPI Group          | 10Pn246 Group          | 7PnEPI Group           | 7Pn246 Group           |
|--|------------------------|------------------------|------------------------|------------------------|
| Subject group type                       | Reporting group        | Reporting group        | Reporting group        | Reporting group        |
| Number of subjects analysed              | 140                    | 140                    | 49                     | 47                     |
| Units: IU/mL                             |                        |                        |                        |                        |
| geometric mean (confidence interval 95%) |                        |                        |                        |                        |
| Anti-diphtheria [N=140;140;49;47]        | 1.735 (1.468 to 2.052) | 1.549 (1.356 to 1.771) | 1.252 (0.97 to 1.616)  | 1.039 (0.786 to 1.375) |
| Anti-tetanus [N=139;140;48;47]           | 5.195 (4.508 to 5.985) | 3.505 (3.148 to 3.904) | 3.476 (2.637 to 4.583) | 2.659 (2.091 to 3.381) |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects with anti-Hepatitis B surface antigen (HBs) antibody concentrations equal to or above 10 milli-International Units per milliliter (mIU/mL)

|                 |   |
|-----------------|---|
| End point title | Number of subjects with anti-Hepatitis B surface antigen (HBs) antibody concentrations equal to or above 10 milli-International Units per milliliter (mIU/mL) |
|-----------------|---|

End point description:

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

End point timeframe:

One month after the administration of the 3rd vaccine dose of DTPw-HBV/Hib + OPV or IPV

| End point values            | 10PnEPI Group   | 10Pn246 Group   | 7PnEPI Group    | 7Pn246 Group    |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type          | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 140             | 133             | 49              | 44              |
| Units: Subjects             |                 |                 |                 |                 |
| Anti-HBs                    | 127             | 132             | 44              | 44              |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Anti-hepatitis B surface antigen (HBs) antibody concentrations

|   |  |
|---|--|
| End point title   | Anti-hepatitis B surface antigen (HBs) antibody concentrations |
| End point description:<br>Seroprotection status, defined as Anti-HBs antibody concentrations $\geq 10$ mIU/mL   |  |
| End point type  | Secondary  |
| End point timeframe:<br>One month after the administration of the 3rd vaccine dose of DTPw-HBV/Hib + OPV or IPV |  |

| End point values                         | 10PnEPI Group         | 10Pn246 Group          | 7PnEPI Group          | 7Pn246 Group            |
|--|-----------------------|------------------------|-----------------------|-------------------------|
| Subject group type                       | Reporting group       | Reporting group        | Reporting group       | Reporting group         |
| Number of subjects analysed              | 140                   | 133                    | 49                    | 44                      |
| Units: mIU/mL                            |                       |                        |                       |                         |
| geometric mean (confidence interval 95%) |                       |                        |                       |                         |
| Anti-HBs                                 | 101.6 (79.7 to 129.5) | 756.7 (640.4 to 894.3) | 129.8 (83.3 to 202.1) | 792.2 (585.2 to 1072.2) |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with anti-polio type 1, 2 and 3 antibody titers equal to or above ( $\geq$ ) 8

|   |   |
|---|---|
| End point title   | Number of subjects with anti-polio type 1, 2 and 3 antibody titers equal to or above ( $\geq$ ) 8 |
| End point description:  |   |
| End point type  | Secondary   |
| End point timeframe:<br>One month after the administration of the 3rd vaccine dose of DTPw-HBV/Hib + OPV or IPV |   |

| End point values               | 10PnEPI Group   | 10Pn246 Group   | 7PnEPI Group    | 7Pn246 Group    |
|--------------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type             | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed    | 124             | 120             | 44              | 41              |
| Units: Subjects                |                 |                 |                 |                 |
| Anti-polio 1 [N=123;120;44;40] | 120             | 120             | 40              | 40              |
| Anti-polio 2 [N=124;116;43;41] | 124             | 115             | 43              | 41              |
| Anti-polio 3 [N=120;108;38;39] | 116             | 107             | 32              | 39              |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Anti-polio type 1, 2 and 3 (Anti-Polio 1, 2 and 3) antibody titers

|                 |  |
|-----------------|--|
| End point title | Anti-polio type 1, 2 and 3 (Anti-Polio 1, 2 and 3) antibody titers |
|-----------------|--|

End point description:

Seroprotection status, defined as Anti-polio type 1, Anti-polio type 2 and Anti-polio type 3 antibody titers  $\geq 8$

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

End point timeframe:

One month after the administration of the 3rd vaccine dose of DTPw-HBV/Hib + OPV or IPV

| End point values                         | 10PnEPI Group          | 10Pn246 Group          | 7PnEPI Group           | 7Pn246 Group           |
|--|------------------------|------------------------|------------------------|------------------------|
| Subject group type                       | Reporting group        | Reporting group        | Reporting group        | Reporting group        |
| Number of subjects analysed              | 124                    | 120                    | 44                     | 41                     |
| Units: Titers                            |                        |                        |                        |                        |
| geometric mean (confidence interval 95%) |                        |                        |                        |                        |
| Anti-polio 1 [N=123;120;44;40]           | 641.5 (485.7 to 847.3) | 331.1 (269.5 to 406.8) | 373.7 (207.4 to 673.4) | 267.6 (187.5 to 381.8) |
| Anti-polio 2 [N=124;116;43;41]           | 523.6 (436.9 to 627.5) | 276.8 (223 to 343.5)   | 546.2 (370.5 to 805.2) | 303.5 (207.1 to 444.8) |
| Anti-polio 3 [N=120;108;38;39]           | 204.5 (164.3 to 254.5) | 540.8 (433.7 to 674.3) | 101.9 (59.5 to 174.5)  | 611.5 (449.4 to 832.2) |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with anti-Bordetella pertussis (anti-BPT) antibody concentrations equal to or above 15 ELISA unit per milli-liter (EL.U/mL) (seropositivity)

|                 |   |
|-----------------|---|
| End point title | Number of subjects with anti-Bordetella pertussis (anti-BPT) antibody concentrations equal to or above 15 ELISA unit per milli-liter (EL.U/mL) (seropositivity) |
|-----------------|---|

End point description:

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

End point timeframe:

One month after the administration of the 3rd vaccine dose of DTPw-HBV/Hib + OPV or IPV

| End point values            | 10PnEPI Group   | 10Pn246 Group   | 7PnEPI Group    | 7Pn246 Group    |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type          | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 138             | 133             | 48              | 45              |
| Units: Subjects             |                 |                 |                 |                 |
| Anti-BPT                    | 137             | 126             | 47              | 42              |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Anti-Bordetella pertussis (anti-BPT) antibody concentrations

|                        |   |
|------------------------|---|
| End point title        | Anti-Bordetella pertussis (anti-BPT) antibody concentrations                            |
| End point description: | Seropositivity status, defined as Anti-BPT antibody concentrations $\geq 15$ EL.U/mL.   |
| End point type         | Secondary   |
| End point timeframe:   | One month after the administration of the 3rd vaccine dose of DTPw-HBV/Hib + OPV or IPV |

| End point values                         | 10PnEPI Group            | 10Pn246 Group             | 7PnEPI Group              | 7Pn246 Group              |
|--|--------------------------|---------------------------|---------------------------|---------------------------|
| Subject group type                       | Reporting group          | Reporting group           | Reporting group           | Reporting group           |
| Number of subjects analysed              | 138                      | 133                       | 48                        | 45                        |
| Units: EL.U/mL                           |                          |                           |                           |                           |
| geometric mean (confidence interval 95%) |                          |                           |                           |                           |
| Anti-BPT                                 | 72.465 (65.787 to 79.82) | 53.481 (47.215 to 60.579) | 77.175 (64.433 to 92.435) | 60.003 (46.394 to 77.604) |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with vaccine response to Bordetella pertussis)

|                        |  |
|------------------------|--|
| End point title        | Number of subjects with vaccine response to Bordetella pertussis)  |
| End point description: | Vaccine response to B. pertussis; defined as appearance of antibodies in subjects initially seronegative (S-) (i.e., concentrations $< 15$ EL.U/mL) or at least maintenance of pre-vaccination antibody concentrations in subjects who were initially seropositive (S+) (i.e., with concentrations $\geq 15$ EL.U/mL). |
| End point type         | Secondary  |
| End point timeframe:   | One month after the administration of the 3rd vaccine dose of DTPw-HBV/Hib + OPV or IPV  |

| <b>End point values</b>     | 10PnEPI Group   | 10Pn246 Group   | 7PnEPI Group    | 7Pn246 Group    |
|-----------------------------|-----------------|-----------------|-----------------|-----------------|
| Subject group type          | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 128             | 119             | 46              | 41              |
| Units: Subjects             |                 |                 |                 |                 |
| S- (N=128;119;46;41)        | 127             | 112             | 46              | 38              |
| S+ (N=9;14;2;4)             | 9               | 12              | 1               | 2               |

### Statistical analyses

---

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Solicited local and general symptoms: During the 4 days post vaccination Unsolicited AEs: During the 31 days post vaccination; SAEs: during the first 30 days after vaccination and during the extended safety follow-up period

Adverse event reporting additional description:

The occurrence of reported AEs (all/related) was not available and is encoded as equal to the number of subjects affected.

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 10.1 |
|--------------------|------|

### Reporting groups

|                       |               |
|-----------------------|---------------|
| Reporting group title | 10PnEPI Group |
|-----------------------|---------------|

Reporting group description:

Subjects in the Philippines receiving 10Pn-PD-DiT vaccine, co-administered with DTPw-HBV, Hib and OPV vaccines at 6, 10, 14 weeks of age

|                       |               |
|-----------------------|---------------|
| Reporting group title | 10Pn246 Group |
|-----------------------|---------------|

Reporting group description:

Subjects in Poland receiving 10Pn-PD-DiT vaccine co-administered with DTPw-HBV/Hib and IPV vaccines at 2, 4, 6 months of age

|                       |              |
|-----------------------|--------------|
| Reporting group title | 7PnEPI Group |
|-----------------------|--------------|

Reporting group description:

Subjects in the Philippines receiving the 7Pn vaccine, co-administered with DTPw-HBV/Hib and OPV at 6, 10, 14 weeks of age.

|                       |              |
|-----------------------|--------------|
| Reporting group title | 7Pn246 Group |
|-----------------------|--------------|

Reporting group description:

Subjects in Poland receiving the 7Pn vaccine, co-administered with DTPw-HBV/Hib and IPV at 2, 4, 6 months of age.

| Serious adverse events                               | 10PnEPI Group    | 10Pn246 Group     | 7PnEPI Group    |
|--|------------------|-------------------|-----------------|
| Total subjects affected by serious adverse events    |                  |                   |                 |
| subjects affected / exposed                          | 16 / 300 (5.33%) | 52 / 303 (17.16%) | 4 / 100 (4.00%) |
| number of deaths (all causes)                        | 0                | 0                 | 0               |
| number of deaths resulting from adverse events       |                  |                   |                 |
| General disorders and administration site conditions |                  |                   |                 |
| Pyrexia  |                  |                   |                 |
| subjects affected / exposed                          | 1 / 300 (0.33%)  | 1 / 303 (0.33%)   | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all      | 0 / 1            | 0 / 1             | 0 / 0           |
| deaths causally related to treatment / all           | 0 / 0            | 0 / 0             | 0 / 0           |
| Ill-defined disorder                                 |                  |                   |                 |



|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 300 (0.00%) | 0 / 303 (0.00%) | 0 / 100 (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           |
| Immune system disorders                         |                 |                 |                 |
| Milk allergy                                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 303 (0.33%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Respiratory, thoracic and mediastinal disorders |                 |                 |                 |
| Bronchial hyperreactivity                       |                 |                 |                 |
| subjects affected / exposed                     | 2 / 300 (0.67%) | 0 / 303 (0.00%) | 0 / 100 (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           |
| Pneumonitis                                     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 2 / 303 (0.66%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 2           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Investigations                                  |                 |                 |                 |
| Hepatic enzyme increased                        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 0 / 303 (0.00%) | 0 / 100 (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           |
| Injury, poisoning and procedural complications  |                 |                 |                 |
| Contusion                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 303 (0.33%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Head injury                                     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 303 (0.33%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Congenital, familial and genetic disorders      |                 |                 |                 |
| Atrial septal defect                            |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 303 (0.33%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Double ureter                                   |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 303 (0.33%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Nervous system disorders                        |                 |                 |                 |
| Febrile convulsion                              |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 2 / 303 (0.66%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 1 / 2           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Blood and lymphatic system disorders            |                 |                 |                 |
| Microcytic anaemia                              |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 303 (0.33%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Thrombocytopenic purpura                        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 0 / 303 (0.00%) | 0 / 100 (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 / 300 (0.00%) | 2 / 303 (0.66%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 2           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Enterocolitis                                   |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 4 / 303 (1.32%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 4           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Gastrooesophageal reflux disease                |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 3 / 303 (0.99%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 3           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| Aphthous stomatitis                             |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 303 (0.33%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Dyspepsia                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 303 (0.33%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Enteritis                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 303 (0.33%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Gastritis                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 303 (0.33%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Skin and subcutaneous tissue disorders          |                 |                 |                 |
| Dermatitis atopic                               |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 0 / 303 (0.00%) | 0 / 100 (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           |
| Rash  |                 |                 |                 |
| subjects affected / exposed                     | 1 / 300 (0.33%) | 0 / 303 (0.00%) | 0 / 100 (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           |
| Renal and urinary disorders                     |                 |                 |                 |
| Nephrotic syndrome                              |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 303 (0.33%) | 0 / 100 (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                     | 0 / 300 (0.00%) | 17 / 303 (5.61%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 17           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0            | 0 / 0           |
| Pneumonia                                       |                 |                  |                 |
| subjects affected / exposed                     | 7 / 300 (2.33%) | 8 / 303 (2.64%)  | 1 / 100 (1.00%) |
| occurrences causally related to treatment / all | 0 / 7           | 0 / 8            | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0            | 0 / 0           |
| Gastroenteritis                                 |                 |                  |                 |
| subjects affected / exposed                     | 5 / 300 (1.67%) | 9 / 303 (2.97%)  | 2 / 100 (2.00%) |
| occurrences causally related to treatment / all | 0 / 5           | 0 / 9            | 0 / 2           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0            | 0 / 0           |
| Gastroenteritis rotavirus                       |                 |                  |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 3 / 303 (0.99%)  | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 3            | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0            | 0 / 0           |
| Urinary tract infection                         |                 |                  |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 4 / 303 (1.32%)  | 1 / 100 (1.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 4            | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0            | 0 / 0           |
| Otitis media                                    |                 |                  |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 3 / 303 (0.99%)  | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 3            | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0            | 0 / 0           |
| Bronchopneumonia                                |                 |                  |                 |
| subjects affected / exposed                     | 2 / 300 (0.67%) | 0 / 303 (0.00%)  | 0 / 100 (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           |
| Nasopharyngitis                                 |                 |                  |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 3 / 303 (0.99%)  | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 3            | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0            | 0 / 0           |
| Bacterial infection                             |                 |                  |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 303 (0.33%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pharyngitis                                     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 303 (0.33%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pyelonephritis acute                            |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 2 / 303 (0.66%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 2           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Respiratory tract infection                     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 2 / 303 (0.66%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 2           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Rhinitis  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 2 / 303 (0.66%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 2           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Dengue fever                                    |                 |                 |                 |
| subjects affected / exposed                     | 1 / 300 (0.33%) | 0 / 303 (0.00%) | 0 / 100 (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 infection                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 303 (0.33%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Laryngitis                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 303 (0.33%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Paronychia                                      |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 303 (0.33%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pneumonia mycoplasmal                           |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 303 (0.33%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Upper respiratory tract infection               |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 303 (0.33%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Urosepsis                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 0 / 303 (0.00%) | 0 / 100 (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                     | 2 / 300 (0.67%) | 0 / 303 (0.00%) | 2 / 100 (2.00%) |
| occurrences causally related to treatment / all | 0 / 2           | 0 / 0           | 0 / 2           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Iron deficiency                                 |                 |                 |                 |
| subjects affected / exposed                     | 0 / 300 (0.00%) | 1 / 303 (0.33%) | 0 / 100 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

|  |                   |  |  |
|--|-------------------|--|--|
| <b>Serious adverse events</b>                        | 7Pn246 Group      |  |  |
| Total subjects affected by serious adverse events    |                   |  |  |
| subjects affected / exposed                          | 19 / 103 (18.45%) |  |  |
| number of deaths (all causes)                        | 0                 |  |  |
| number of deaths resulting from adverse events       |                   |  |  |
| General disorders and administration site conditions |                   |  |  |
| Pyrexia  |                   |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| subjects affected / exposed                     | 1 / 103 (0.97%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Ill-defined disorder                            |                 |  |  |
| subjects affected / exposed                     | 1 / 103 (0.97%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Immune system disorders                         |                 |  |  |
| Milk allergy                                    |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Respiratory, thoracic and mediastinal disorders |                 |  |  |
| Bronchial hyperreactivity                       |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Pneumonitis                                     |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Investigations                                  |                 |  |  |
| Hepatic enzyme increased                        |                 |  |  |
| subjects affected / exposed                     | 1 / 103 (0.97%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Injury, poisoning and procedural complications  |                 |  |  |
| Contusion                                       |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Head injury                                     |                 |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Congenital, familial and genetic disorders      |                 |  |  |
| Atrial septal defect                            |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Double ureter                                   |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Nervous system disorders                        |                 |  |  |
| Febrile convulsion                              |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Blood and lymphatic system disorders            |                 |  |  |
| Microcytic anaemia                              |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Thrombocytopenic purpura                        |                 |  |  |
| subjects affected / exposed                     | 1 / 103 (0.97%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Gastrointestinal disorders                      |                 |  |  |
| Diarrhoea                                       |                 |  |  |
| subjects affected / exposed                     | 3 / 103 (2.91%) |  |  |
| occurrences causally related to treatment / all | 0 / 3           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Enterocolitis                                   |                 |  |  |



|   |                 |  |  |
|---|-----------------|--|--|
| subjects affected / exposed                     | 1 / 103 (0.97%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Gastrooesophageal reflux disease                |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Aphthous stomatitis                             |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Dyspepsia                                       |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Enteritis                                       |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Gastritis                                       |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Skin and subcutaneous tissue disorders          |                 |  |  |
| Dermatitis atopic                               |                 |  |  |
| subjects affected / exposed                     | 1 / 103 (0.97%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Rash  |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Renal and urinary disorders                     |                 |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| Nephrotic syndrome                              |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Infections and infestations                     |                 |  |  |
| Bronchitis                                      |                 |  |  |
| subjects affected / exposed                     | 3 / 103 (2.91%) |  |  |
| occurrences causally related to treatment / all | 0 / 3           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Pneumonia                                       |                 |  |  |
| subjects affected / exposed                     | 3 / 103 (2.91%) |  |  |
| occurrences causally related to treatment / all | 0 / 3           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Gastroenteritis                                 |                 |  |  |
| subjects affected / exposed                     | 2 / 103 (1.94%) |  |  |
| occurrences causally related to treatment / all | 0 / 2           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Gastroenteritis rotavirus                       |                 |  |  |
| subjects affected / exposed                     | 3 / 103 (2.91%) |  |  |
| occurrences causally related to treatment / all | 0 / 3           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Urinary tract infection                         |                 |  |  |
| subjects affected / exposed                     | 1 / 103 (0.97%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Otitis media                                    |                 |  |  |
| subjects affected / exposed                     | 2 / 103 (1.94%) |  |  |
| occurrences causally related to treatment / all | 0 / 2           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Bronchopneumonia                                |                 |  |  |
| subjects affected / exposed                     | 2 / 103 (1.94%) |  |  |
| occurrences causally related to treatment / all | 0 / 2           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Nasopharyngitis                                 |                 |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Bacterial infection                             |                 |  |  |
| subjects affected / exposed                     | 1 / 103 (0.97%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Pharyngitis                                     |                 |  |  |
| subjects affected / exposed                     | 1 / 103 (0.97%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Pyelonephritis acute                            |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Respiratory tract infection                     |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Rhinitis  |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Dengue fever                                    |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Gastrointestinal infection                      |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Laryngitis                                      |                 |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Paronychia                                      |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Pneumonia mycoplasmal                           |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Upper respiratory tract infection               |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Urosepsis                                       |                 |  |  |
| subjects affected / exposed                     | 1 / 103 (0.97%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Metabolism and nutrition disorders              |                 |  |  |
| Dehydration                                     |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Iron deficiency                                 |                 |  |  |
| subjects affected / exposed                     | 0 / 103 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |

Frequency threshold for reporting non-serious adverse events: 5 %

| <b>Non-serious adverse events</b>                     | 10PnEPI Group      | 10Pn246 Group      | 7PnEPI Group      |
|---|--------------------|--------------------|-------------------|
| Total subjects affected by non-serious adverse events |                    |                    |                   |
| subjects affected / exposed                           | 258 / 300 (86.00%) | 289 / 303 (95.38%) | 88 / 100 (88.00%) |
| General disorders and administration site conditions  |                    |                    |                   |
| Pain  |                    |                    |                   |
| alternative assessment type: Systematic               |                    |                    |                   |
| subjects affected / exposed <sup>[1]</sup>            | 258 / 299 (86.29%) | 255 / 300 (85.00%) | 82 / 99 (82.83%)  |
| occurrences (all)                                     | 258                | 255                | 82                |
| Redness   |                    |                    |                   |
| alternative assessment type: Systematic               |                    |                    |                   |
| subjects affected / exposed <sup>[2]</sup>            | 221 / 299 (73.91%) | 265 / 300 (88.33%) | 67 / 99 (67.68%)  |
| occurrences (all)                                     | 221                | 265                | 67                |
| Swelling  |                    |                    |                   |
| alternative assessment type: Systematic               |                    |                    |                   |
| subjects affected / exposed <sup>[3]</sup>            | 174 / 299 (58.19%) | 226 / 300 (75.33%) | 42 / 99 (42.42%)  |
| occurrences (all)                                     | 174                | 226                | 42                |
| Drowsiness  |                    |                    |                   |
| alternative assessment type: Systematic               |                    |                    |                   |
| subjects affected / exposed <sup>[4]</sup>            | 184 / 299 (61.54%) | 256 / 300 (85.33%) | 56 / 99 (56.57%)  |
| occurrences (all)                                     | 184                | 256                | 56                |
| Fever   |                    |                    |                   |
| alternative assessment type: Systematic               |                    |                    |                   |
| subjects affected / exposed <sup>[5]</sup>            | 255 / 299 (85.28%) | 261 / 300 (87.00%) | 88 / 99 (88.89%)  |
| occurrences (all)                                     | 255                | 261                | 88                |
| Irritability  |                    |                    |                   |
| alternative assessment type: Systematic               |                    |                    |                   |
| subjects affected / exposed <sup>[6]</sup>            | 258 / 299 (86.29%) | 289 / 300 (96.33%) | 82 / 99 (82.83%)  |
| occurrences (all)                                     | 258                | 289                | 82                |
| Loss of appetite                                      |                    |                    |                   |
| alternative assessment type: Systematic               |                    |                    |                   |
| subjects affected / exposed <sup>[7]</sup>            | 140 / 299 (46.82%) | 221 / 300 (73.67%) | 39 / 99 (39.39%)  |
| occurrences (all)                                     | 140                | 221                | 39                |
| Gastrointestinal disorders                            |                    |                    |                   |
| Diarrhoea   |                    |                    |                   |

|  |                      |                        |                      |
|--|----------------------|------------------------|----------------------|
| subjects affected / exposed<br>occurrences (all) | 0 / 300 (0.00%)<br>0 | 19 / 303 (6.27%)<br>19 | 0 / 100 (0.00%)<br>0 |
| Infections and infestations                      |                      |                        |                      |
| Upper respiratory tract infection                |                      |                        |                      |
| subjects affected / exposed                      | 84 / 300 (28.00%)    | 17 / 303 (5.61%)       | 25 / 100 (25.00%)    |
| occurrences (all)                                | 84                   | 17                     | 25                   |
| Rhinitis   |                      |                        |                      |
| subjects affected / exposed                      | 38 / 300 (12.67%)    | 41 / 303 (13.53%)      | 7 / 100 (7.00%)      |
| occurrences (all)                                | 38                   | 41                     | 7                    |
| Bronchitis                                       |                      |                        |                      |
| subjects affected / exposed                      | 9 / 300 (3.00%)      | 28 / 303 (9.24%)       | 0 / 100 (0.00%)      |
| occurrences (all)                                | 9                    | 28                     | 0                    |
| Gastroenteritis                                  |                      |                        |                      |
| subjects affected / exposed                      | 17 / 300 (5.67%)     | 5 / 303 (1.65%)        | 8 / 100 (8.00%)      |
| occurrences (all)                                | 17                   | 5                      | 8                    |
| Pharyngitis                                      |                      |                        |                      |
| subjects affected / exposed                      | 4 / 300 (1.33%)      | 18 / 303 (5.94%)       | 2 / 100 (2.00%)      |
| occurrences (all)                                | 4                    | 18                     | 2                    |

|   |                   |  |  |
|---|-------------------|--|--|
| <b>Non-serious adverse events</b>                     | 7Pn246 Group      |  |  |
| Total subjects affected by non-serious adverse events |                   |  |  |
| subjects affected / exposed                           | 93 / 103 (90.29%) |  |  |
| General disorders and administration site conditions  |                   |  |  |
| Pain  |                   |  |  |
| alternative assessment type: Systematic               |                   |  |  |
| subjects affected / exposed <sup>[1]</sup>            | 89 / 100 (89.00%) |  |  |
| occurrences (all)                                     | 89                |  |  |
| Redness   |                   |  |  |
| alternative assessment type: Systematic               |                   |  |  |
| subjects affected / exposed <sup>[2]</sup>            | 90 / 100 (90.00%) |  |  |
| occurrences (all)                                     | 90                |  |  |
| Swelling  |                   |  |  |
| alternative assessment type: Systematic               |                   |  |  |
| subjects affected / exposed <sup>[3]</sup>            | 75 / 100 (75.00%) |  |  |
| occurrences (all)                                     | 75                |  |  |
| Drowsiness  |                   |  |  |

|   |  |  |  |
|---|--|--|--|
| <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[4]</sup></p> <p>occurrences (all)</p>  | <p>85 / 100 (85.00%)</p> <p>85</p>   |  |  |
| <p>Fever</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[5]</sup></p> <p>occurrences (all)</p>   | <p>77 / 100 (77.00%)</p> <p>77</p>   |  |  |
| <p>Irritability</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[6]</sup></p> <p>occurrences (all)</p>  | <p>93 / 100 (93.00%)</p> <p>93</p>   |  |  |
| <p>Loss of appetite</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[7]</sup></p> <p>occurrences (all)</p>  | <p>64 / 100 (64.00%)</p> <p>64</p>   |  |  |
| <p>Gastrointestinal disorders</p> <p>Diarrhoea</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>  | <p>9 / 103 (8.74%)</p> <p>9</p>  |  |  |
| <p>Infections and infestations</p> <p>Upper respiratory tract infection</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Rhinitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Bronchitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Gastroenteritis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Pharyngitis</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>12 / 103 (11.65%)</p> <p>12</p> <p>9 / 103 (8.74%)</p> <p>9</p> <p>7 / 103 (6.80%)</p> <p>7</p> <p>0 / 103 (0.00%)</p> <p>0</p> <p>3 / 103 (2.91%)</p> <p>3</p> |  |  |

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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: The analysis of the solicited symptom included only subjects with documented data.

[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: The analysis of the solicited symptom included only subjects with documented data.

[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: The analysis of the solicited symptom included only subjects with documented data.

[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: The analysis of the solicited symptom included only subjects with documented data.

[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: The analysis of the solicited symptom included only subjects with documented data.

[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: The analysis of the solicited symptom included only subjects with documented data.

[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: The analysis of the solicited symptom included only subjects with documented data.



## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date         | Amendment   |
|--------------|---|
| 06 July 2006 | <p>Amendment 1</p> <p>This study is designed to evaluate safety, reactogenicity and immunogenicity of GlaxoSmithKline (GSK) Biologicals' 10-valent pneumococcal conjugate vaccine compared to the licensed vaccine Prevenar when co-administered with DTPw-HBV/Hib and OPV or IPV vaccines. Both the immunization schedule for infants recommended by the WHO Expanded Programme on Immunization (EPI: 6, 10, 14 weeks of age) and a 2-4-6 months of age schedule will be evaluated.</p> <p>Incidence of fever is increased in infants following co-administration of the pneumococcal vaccine with standard infant vaccines when compared to infants that received either pneumococcal vaccine or standard vaccines separately. Therefore, this study will evaluate and compare the incidence of rectal fever &gt;39.0°C for both pneumococcal conjugate vaccines.</p> <p>Immune response of the vaccines, when co-administered with DTPw-HBV/Hib and OPV or IPV vaccines, will also be assessed according to the 2 different schedules.</p> |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported