



## Clinical trial results:

### A Phase 3, Open-label Study to Evaluate Persistence of the Antibody Response Elicited by Pneumococcal Conjugate Vaccine in Healthy Children Who Have Been Previously Immunized With a 4-Dose Series of a Pneumococcal Conjugate Vaccine During Infancy in Study 6096A1-008-EU and the Safety and Immunogenicity of 13-valent Pneumococcal Conjugate Vaccine Administered at Least 24 Months After the Last Toddler Dose of Pneumococcal Conjugate Vaccine

#### Summary

|                          |                  |
|--------------------------|------------------|
| EudraCT number           | 2009-015321-37   |
| Trial protocol           | FR               |
| Global end of trial date | 17 November 2010 |

#### Results information

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

#### Trial information

##### Trial identification

|                       |               |
|-----------------------|---------------|
| Sponsor protocol code | 6096A1-3021FR |
|-----------------------|---------------|

##### Additional study identifiers

|                                    |                 |
|------------------------------------|-----------------|
| ISRCTN number                      | -               |
| ClinicalTrials.gov id (NCT number) | NCT01026038     |
| WHO universal trial number (UTN)   | -               |
| Other trial identifiers            | Alias: B1851016 |

Notes:

#### Sponsors

|                              |                                                                                                                   |
|------------------------------|-------------------------------------------------------------------------------------------------------------------|
| Sponsor organisation name    | Pfizer Inc.                                                                                                       |
| Sponsor organisation address | 235 E 42nd Street, New York, United States, NY 10017                                                              |
| Public contact               | Pfizer ClinicalTrials.gov Call Center<br>, Pfizer Inc, 001 8007181021,<br>ClinicalTrials.gov_Inquiries@pfizer.com |
| Scientific contact           | Pfizer ClinicalTrials.gov Call Center<br>, Pfizer Inc, 001 8007181021,<br>ClinicalTrials.gov_Inquiries@pfizer.com |

Notes:

#### Paediatric regulatory details

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

Notes:

## Results analysis stage

|                                                      |                  |
|------------------------------------------------------|------------------|
| Analysis stage                                       | Final            |
| Date of interim/final analysis                       | 25 May 2011      |
| Is this the analysis of the primary completion data? | No               |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 17 November 2010 |
| Was the trial ended prematurely?                     | No               |

Notes:

## General information about the trial

Main objective of the trial:

To evaluate the antibody levels to the 13 pneumococcal vaccine serotypes not earlier than 24 months and the immune response to 13-valent pneumococcal conjugate vaccine(13vPnC) serotypes 1 month after a dose of 13vPnC administered not earlier than 24 months after the toddler dose in study 6096A1-008-EU, as measured by serotype specific immunoglobulin G (IgG) concentrations.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

|                                                           |               |
|-----------------------------------------------------------|---------------|
| Actual start date of recruitment                          | 12 April 2010 |
| Long term follow-up planned                               | No            |
| Independent data monitoring committee (IDMC) involvement? | No            |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |             |
|--------------------------------------|-------------|
| Country: Number of subjects enrolled | France: 262 |
| Worldwide total number of subjects   | 262         |
| EEA total number of subjects         | 262         |

Notes:

### Subjects enrolled per age group

|                                           |     |
|-------------------------------------------|-----|
| In utero                                  | 0   |
| Preterm newborn - gestational age < 37 wk | 0   |
| Newborns (0-27 days)                      | 0   |
| Infants and toddlers (28 days-23 months)  | 0   |
| Children (2-11 years)                     | 262 |
| 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:

A total of 263 subjects who had received a 4-dose vaccination series of pneumococcal conjugate vaccine as part of study 6096A1-008 (NCT00366678) were enrolled for this study. Out of those 1 subject was a screen failure and was not included in results.

### Period 1

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

### Arms

|                              |                      |
|------------------------------|----------------------|
| Are arms mutually exclusive? | Yes                  |
| <b>Arm title</b>             | 13vPnC/13vPnC/13vPnC |

Arm description:

Single dose of 13vPnC, 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 13vPnC/13vPnC vaccine.

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

Dosage and administration details:

Single dose (0.5 milliliter [mL]) of 13vPnC vaccine intramuscularly (IM), 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 13vPnC/13vPnC vaccine.

|                  |                    |
|------------------|--------------------|
| <b>Arm title</b> | 7vPnC/7vPnC/13vPnC |
|------------------|--------------------|

Arm description:

Single dose of 13vPnC vaccine, 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 7-valent pneumococcal conjugate (7vPnC)/7vPnC vaccine.

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

Dosage and administration details:

Single dose (0.5 mL) of 13vPnC vaccine IM, 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 7vPnC/7vPnC vaccine.

|                  |                     |
|------------------|---------------------|
| <b>Arm title</b> | 7vPnC/13vPnC/13vPnC |
|------------------|---------------------|

Arm description:

Single dose of 13vPnC vaccine, 2 years after receiving a full schedule of (3 infant doses/1 toddler dose) 7vPnC/13vPnC vaccine.

|          |              |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

|                                        |                   |
|----------------------------------------|-------------------|
| Investigational medicinal product name | 13vPnC            |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

Single dose (0.5 mL) of 13vPnC vaccine IM, 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 7vPnC/13vPnC vaccine.

| <b>Number of subjects in period 1</b> | 13vPnC/13vPnC/13vPnC | 7vPnC/7vPnC/13vPnC | 7vPnC/13vPnC/13vPnC |
|---------------------------------------|----------------------|--------------------|---------------------|
| Started                               | 130                  | 65                 | 67                  |
| Completed                             | 129                  | 64                 | 67                  |
| Not completed                         | 1                    | 1                  | 0                   |
| Lost to follow-up                     | 1                    | 1                  | -                   |

## Baseline characteristics

### Reporting groups

|                       |                      |
|-----------------------|----------------------|
| Reporting group title | 13vPnC/13vPnC/13vPnC |
|-----------------------|----------------------|

Reporting group description:

Single dose of 13vPnC, 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 13vPnC/13vPnC vaccine.

|                       |                    |
|-----------------------|--------------------|
| Reporting group title | 7vPnC/7vPnC/13vPnC |
|-----------------------|--------------------|

Reporting group description:

Single dose of 13vPnC vaccine, 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 7-valent pneumococcal conjugate (7vPnC)/7vPnC vaccine.

|                       |                     |
|-----------------------|---------------------|
| Reporting group title | 7vPnC/13vPnC/13vPnC |
|-----------------------|---------------------|

Reporting group description:

Single dose of 13vPnC vaccine, 2 years after receiving a full schedule of (3 infant doses/1 toddler dose) 7vPnC/13vPnC vaccine.

| Reporting group values             | 13vPnC/13vPnC/13vPnC | 7vPnC/7vPnC/13vPnC | 7vPnC/13vPnC/13vPnC |
|------------------------------------|----------------------|--------------------|---------------------|
| Number of subjects                 | 130                  | 65                 | 67                  |
| Age categorical<br>Units: Subjects |                      |                    |                     |

|                                                                         |               |               |               |
|-------------------------------------------------------------------------|---------------|---------------|---------------|
| Age continuous<br>Units: years<br>arithmetic mean<br>standard deviation | 3.4<br>± 0.25 | 3.4<br>± 0.24 | 3.5<br>± 0.25 |
| Gender categorical<br>Units: Subjects                                   |               |               |               |
| Female                                                                  | 70            | 29            | 40            |
| Male                                                                    | 60            | 36            | 27            |

| Reporting group values             | Total |  |  |
|------------------------------------|-------|--|--|
| Number of subjects                 | 262   |  |  |
| Age categorical<br>Units: Subjects |       |  |  |

|                                                                         |     |  |  |
|-------------------------------------------------------------------------|-----|--|--|
| Age continuous<br>Units: years<br>arithmetic mean<br>standard deviation | -   |  |  |
| Gender categorical<br>Units: Subjects                                   |     |  |  |
| Female                                                                  | 139 |  |  |
| Male                                                                    | 123 |  |  |

## End points

### End points reporting groups

|                                                                                                                                                                                                  |                      |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| Reporting group title                                                                                                                                                                            | 13vPnC/13vPnC/13vPnC |
| Reporting group description:<br>Single dose of 13vPnC, 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 13vPnC/13vPnC vaccine.                                         |                      |
| Reporting group title                                                                                                                                                                            | 7vPnC/7vPnC/13vPnC   |
| Reporting group description:<br>Single dose of 13vPnC vaccine, 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 7-valent pneumococcal conjugate (7vPnC)/7vPnC vaccine. |                      |
| Reporting group title                                                                                                                                                                            | 7vPnC/13vPnC/13vPnC  |
| Reporting group description:<br>Single dose of 13vPnC vaccine, 2 years after receiving a full schedule of (3 infant doses/1 toddler dose) 7vPnC/13vPnC vaccine.                                  |                      |

### Primary: Serotype-specific Pneumococcal Immunoglobulin G (IgG) Geometric Mean Concentration (GMC) 1 Month After Single Dose of 13 Valent Pneumococcal Conjugate (13vPnC) Vaccine

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Serotype-specific Pneumococcal Immunoglobulin G (IgG)<br>Geometric Mean Concentration (GMC) 1 Month After Single<br>Dose of 13 Valent Pneumococcal Conjugate (13vPnC) Vaccine |
| End point description:<br>Antibody GMC as measured by microgram per millilitre (mcg/mL) for 7 common pneumococcal serotypes (serotypes 4, 6B, 9V, 14, 18C, 19F, and 23F) and 6 additional pneumococcal serotypes specific to 13vPnC (Serotypes 1, 3, 5, 6A, 7F, and 19A) are presented. GMC (13vPnC) and corresponding 2-sided 95% confidence interval (CI) were evaluated. Geometric means (GMs) were calculated using all subjects with available data for the specified blood draw. Evaluable immunogenicity population: eligible subjects, randomised, blood drawn within required timeframes, at least 1 valid and determinate assay result for proposed analysis, received no prohibited vaccines, no major protocol violations. |                                                                                                                                                                               |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Primary                                                                                                                                                                       |
| End point timeframe:<br>One month after vaccination                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                               |

| End point values                         | 13vPnC/13vPnC/13vPnC   | 7vPnC/7vPnC/13vPnC     | 7vPnC/13vPnC/13vPnC    |  |
|------------------------------------------|------------------------|------------------------|------------------------|--|
| Subject group type                       | Reporting group        | Reporting group        | Reporting group        |  |
| Number of subjects analysed              | 120 <sup>[1]</sup>     | 57 <sup>[2]</sup>      | 58 <sup>[3]</sup>      |  |
| Units: mcg/mL                            |                        |                        |                        |  |
| geometric mean (confidence interval 95%) |                        |                        |                        |  |
| Serotype 4                               | 10.34 (8.94 to 11.97)  | 12.79 (10 to 16.35)    | 8.98 (6.98 to 11.56)   |  |
| Serotype 6B                              | 31.62 (27.02 to 37.01) | 51.07 (38.65 to 67.49) | 35.38 (27.25 to 45.93) |  |
| Serotype 9V                              | 6.76 (5.9 to 7.73)     | 6.5 (5.31 to 7.95)     | 6.19 (5.04 to 7.61)    |  |
| Serotype 14                              | 21.55 (18.41 to 25.24) | 21.15 (16.89 to 26.48) | 20.73 (16.45 to 26.12) |  |

|              |                        |                        |                        |  |
|--------------|------------------------|------------------------|------------------------|--|
| Serotype 18C | 4.56 (3.93 to 5.29)    | 6.12 (4.89 to 7.65)    | 5.35 (4.27 to 6.71)    |  |
| Serotype 19F | 16.59 (13.57 to 20.28) | 12.07 (9.35 to 15.59)  | 15.09 (11.17 to 20.39) |  |
| Serotype 23F | 8.68 (7.5 to 10.03)    | 10.87 (8.3 to 14.22)   | 9.1 (7.34 to 11.28)    |  |
| Serotype 1   | 10.72 (9.17 to 12.52)  | 2.96 (2.45 to 3.59)    | 20.69 (16.14 to 26.53) |  |
| Serotype 3   | 1.81 (1.46 to 2.23)    | 1.6 (1.19 to 2.17)     | 2.07 (1.66 to 2.59)    |  |
| Serotype 5   | 10 (8.63 to 11.58)     | 2.86 (2.37 to 3.46)    | 19.2 (14.93 to 24.7)   |  |
| Serotype 6A  | 23.09 (19.5 to 27.33)  | 14.38 (10.53 to 19.64) | 18.6 (13.87 to 24.93)  |  |
| Serotype 7F  | 8.23 (7.11 to 9.52)    | 5.04 (4.16 to 6.11)    | 8.02 (6.66 to 9.67)    |  |
| Serotype 19A | 17.1 (14.54 to 20.11)  | 8.58 (6.7 to 10.99)    | 16.46 (13.42 to 20.19) |  |

Notes:

[1] - N= number of subjects with determinate IgG antibody concentration to serotype.

[2] - N= number of subjects with determinate IgG antibody concentration to serotype.

[3] - N= number of subjects with determinate IgG antibody concentration to serotype

## Statistical analyses

|                                                                                                                                                                                                                              |                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                            | 4: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                            |                                               |
| Serotype 4: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                            | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC     |
| Number of subjects included in analysis                                                                                                                                                                                      | 177                                           |
| Analysis specification                                                                                                                                                                                                       | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                                | superiority                                   |
| Parameter estimate                                                                                                                                                                                                           | GMC ratio                                     |
| Point estimate                                                                                                                                                                                                               | 0.81                                          |
| Confidence interval                                                                                                                                                                                                          |                                               |
| level                                                                                                                                                                                                                        | 95 %                                          |
| sides                                                                                                                                                                                                                        | 2-sided                                       |
| lower limit                                                                                                                                                                                                                  | 0.61                                          |
| upper limit                                                                                                                                                                                                                  | 1.07                                          |

|                                                                                                                                                                                                                               |                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 4: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                 |
| Serotype 4: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                             | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |



|                                         |               |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 178           |
| Analysis specification                  | Pre-specified |
| Analysis type                           | superiority   |
| Parameter estimate                      | GMC ratio     |
| Point estimate                          | 1.15          |
| Confidence interval                     |               |
| level                                   | 95 %          |
| sides                                   | 2-sided       |
| lower limit                             | 0.87          |
| upper limit                             | 1.52          |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 4: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 4: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMC ratio                                |
| Point estimate                          | 1.42                                     |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 1.03                                     |
| upper limit                             | 1.96                                     |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 6B: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 6B: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 0.62                                      |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.46                                      |
| upper limit                             | 0.84                                      |

|                                                                                                                                                                                                                                |                                                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                              | 6B: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                              |                                                  |
| Serotype 6B: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                  |
| Comparison groups                                                                                                                                                                                                              | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                        | 178                                              |
| Analysis specification                                                                                                                                                                                                         | Pre-specified                                    |
| Analysis type                                                                                                                                                                                                                  | superiority                                      |
| Parameter estimate                                                                                                                                                                                                             | GMC ratio                                        |
| Point estimate                                                                                                                                                                                                                 | 0.89                                             |
| Confidence interval                                                                                                                                                                                                            |                                                  |
| level                                                                                                                                                                                                                          | 95 %                                             |
| sides                                                                                                                                                                                                                          | 2-sided                                          |
| lower limit                                                                                                                                                                                                                    | 0.66                                             |
| upper limit                                                                                                                                                                                                                    | 1.2                                              |

|                                                                                                                                                                                                                              |                                                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                            | 6B: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                            |                                                |
| Serotype 6B: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                |
| Comparison groups                                                                                                                                                                                                            | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                      | 115                                            |
| Analysis specification                                                                                                                                                                                                       | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                | superiority                                    |
| Parameter estimate                                                                                                                                                                                                           | GMC ratio                                      |
| Point estimate                                                                                                                                                                                                               | 1.44                                           |
| Confidence interval                                                                                                                                                                                                          |                                                |
| level                                                                                                                                                                                                                        | 95 %                                           |
| sides                                                                                                                                                                                                                        | 2-sided                                        |
| lower limit                                                                                                                                                                                                                  | 1.02                                           |
| upper limit                                                                                                                                                                                                                  | 2.04                                           |

|                                                                                                                                                                                                                               |                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 9V: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                |
| Serotype 9V: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                                |
| Comparison groups                                                                                                                                                                                                             | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                       | 177                                            |
| Analysis specification                                                                                                                                                                                                        | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                 | superiority                                    |
| Parameter estimate                                                                                                                                                                                                            | GMC ratio                                      |
| Point estimate                                                                                                                                                                                                                | 1.04                                           |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.82    |
| upper limit         | 1.32    |

|                                   |                                                  |
|-----------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b> | 9V: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|--------------------------------------------------|

Statistical analysis description:

Serotype 9V: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMC ratio                                  |
| Point estimate                          | 1.09                                       |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.86                                       |
| upper limit                             | 1.39                                       |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 9V: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 9V: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMC ratio                                |
| Point estimate                          | 1.05                                     |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.79                                     |
| upper limit                             | 1.39                                     |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 14: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 14: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 1.02                                      |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.77                                      |
| upper limit                             | 1.34                                      |

|                                   |                                                  |
|-----------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b> | 14: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|--------------------------------------------------|

Statistical analysis description:

Serotype 14: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMC ratio                                  |
| Point estimate                          | 1.04                                       |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.79                                       |
| upper limit                             | 1.37                                       |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 14: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 14: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMC ratio                                |
| Point estimate                          | 1.02                                     |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.74                                     |
| upper limit                             | 1.4                                      |

|                                                                                                                                                                                                                                                                     |                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                   | 18C: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 18C: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                                                                   | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                                                             | 177                                             |
| Analysis specification                                                                                                                                                                                                                                              | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                                                       | superiority                                     |
| Parameter estimate                                                                                                                                                                                                                                                  | GMC ratio                                       |
| Point estimate                                                                                                                                                                                                                                                      | 0.75                                            |
| Confidence interval                                                                                                                                                                                                                                                 |                                                 |
| level                                                                                                                                                                                                                                                               | 95 %                                            |
| sides                                                                                                                                                                                                                                                               | 2-sided                                         |
| lower limit                                                                                                                                                                                                                                                         | 0.57                                            |
| upper limit                                                                                                                                                                                                                                                         | 0.97                                            |

|                                                                                                                                                                                                                                                                      |                                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                    | 18C: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 18C: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                   |
| Comparison groups                                                                                                                                                                                                                                                    | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                                                                              | 178                                               |
| Analysis specification                                                                                                                                                                                                                                               | Pre-specified                                     |
| Analysis type                                                                                                                                                                                                                                                        | superiority                                       |
| Parameter estimate                                                                                                                                                                                                                                                   | GMC ratio                                         |
| Point estimate                                                                                                                                                                                                                                                       | 0.85                                              |
| Confidence interval                                                                                                                                                                                                                                                  |                                                   |
| level                                                                                                                                                                                                                                                                | 95 %                                              |
| sides                                                                                                                                                                                                                                                                | 2-sided                                           |
| lower limit                                                                                                                                                                                                                                                          | 0.65                                              |
| upper limit                                                                                                                                                                                                                                                          | 1.11                                              |

|                                                                                                                                                                                                                                                                    |                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                  | 18C: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 18C: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                                                                  | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |

|                                         |               |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 115           |
| Analysis specification                  | Pre-specified |
| Analysis type                           | superiority   |
| Parameter estimate                      | GMCratio      |
| Point estimate                          | 1.14          |
| Confidence interval                     |               |
| level                                   | 95 %          |
| sides                                   | 2-sided       |
| lower limit                             | 0.84          |
| upper limit                             | 1.56          |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 19F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 19F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 1.37                                      |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.97                                      |
| upper limit                             | 1.94                                      |

|                                   |                                                   |
|-----------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b> | 19F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|---------------------------------------------------|

Statistical analysis description:

Serotype 19F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMC ratio                                  |
| Point estimate                          | 1.1                                        |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.78                                       |
| upper limit                             | 1.55                                       |

|                                                                                                                                                                                                                               |                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 19F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                 |
| Serotype 19F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                             | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                                       | 115                                             |
| Analysis specification                                                                                                                                                                                                        | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                 | superiority                                     |
| Parameter estimate                                                                                                                                                                                                            | GMC ratio                                       |
| Point estimate                                                                                                                                                                                                                | 0.8                                             |
| Confidence interval                                                                                                                                                                                                           |                                                 |
| level                                                                                                                                                                                                                         | 95 %                                            |
| sides                                                                                                                                                                                                                         | 2-sided                                         |
| lower limit                                                                                                                                                                                                                   | 0.54                                            |
| upper limit                                                                                                                                                                                                                   | 1.19                                            |

|                                                                                                                                                                                                                                |                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                              | 23F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                              |                                                 |
| Serotype 23F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                              | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                        | 177                                             |
| Analysis specification                                                                                                                                                                                                         | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                  | superiority                                     |
| Parameter estimate                                                                                                                                                                                                             | GMC ratio                                       |
| Point estimate                                                                                                                                                                                                                 | 0.8                                             |
| Confidence interval                                                                                                                                                                                                            |                                                 |
| level                                                                                                                                                                                                                          | 95 %                                            |
| sides                                                                                                                                                                                                                          | 2-sided                                         |
| lower limit                                                                                                                                                                                                                    | 0.61                                            |
| upper limit                                                                                                                                                                                                                    | 1.05                                            |

|                                                                                                                                                                                                                                 |                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                               | 23F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                               |                                                   |
| Serotype 23F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                   |
| Comparison groups                                                                                                                                                                                                               | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                                         | 178                                               |
| Analysis specification                                                                                                                                                                                                          | Pre-specified                                     |
| Analysis type                                                                                                                                                                                                                   | superiority                                       |
| Parameter estimate                                                                                                                                                                                                              | GMC ratio                                         |
| Point estimate                                                                                                                                                                                                                  | 0.95                                              |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.73    |
| upper limit         | 1.25    |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 23F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 23F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMC ratio                                |
| Point estimate                          | 1.19                                     |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.87                                     |
| upper limit                             | 1.64                                     |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 1: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 1: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 3.62                                      |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 2.76                                      |
| upper limit                             | 4.74                                      |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 1: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 1: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).



|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMC ratio                                  |
| Point estimate                          | 0.52                                       |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.4                                        |
| upper limit                             | 0.68                                       |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 1: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 1: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMC ratio                                |
| Point estimate                          | 0.14                                     |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.1                                      |
| upper limit                             | 0.2                                      |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 3: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 3: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 1.13                                      |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.8                                       |
| upper limit                             | 1.59                                      |

|                                                                                                                                                                                                                               |                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 3: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                 |
| Serotype 3: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                             | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                       | 178                                             |
| Analysis specification                                                                                                                                                                                                        | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                 | superiority                                     |
| Parameter estimate                                                                                                                                                                                                            | GMC ratio                                       |
| Point estimate                                                                                                                                                                                                                | 0.87                                            |
| Confidence interval                                                                                                                                                                                                           |                                                 |
| level                                                                                                                                                                                                                         | 95 %                                            |
| sides                                                                                                                                                                                                                         | 2-sided                                         |
| lower limit                                                                                                                                                                                                                   | 0.62                                            |
| upper limit                                                                                                                                                                                                                   | 1.23                                            |

|                                                                                                                                                                                                                             |                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                           | 3: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                           |                                               |
| Serotype 3: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                           | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                     | 115                                           |
| Analysis specification                                                                                                                                                                                                      | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                               | superiority                                   |
| Parameter estimate                                                                                                                                                                                                          | GMC ratio                                     |
| Point estimate                                                                                                                                                                                                              | 0.77                                          |
| Confidence interval                                                                                                                                                                                                         |                                               |
| level                                                                                                                                                                                                                       | 95 %                                          |
| sides                                                                                                                                                                                                                       | 2-sided                                       |
| lower limit                                                                                                                                                                                                                 | 0.52                                          |
| upper limit                                                                                                                                                                                                                 | 1.15                                          |

|                                                                                                                                                                                                                              |                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                            | 5: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                            |                                               |
| Serotype 5: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                            | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC     |

|                                         |               |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 177           |
| Analysis specification                  | Pre-specified |
| Analysis type                           | superiority   |
| Parameter estimate                      | GMC ratio     |
| Point estimate                          | 3.49          |
| Confidence interval                     |               |
| level                                   | 95 %          |
| sides                                   | 2-sided       |
| lower limit                             | 2.68          |
| upper limit                             | 4.54          |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 5: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 5: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMC ratio                                  |
| Point estimate                          | 0.52                                       |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.4                                        |
| upper limit                             | 0.68                                       |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 5: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 5: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMC ratio                                |
| Point estimate                          | 0.15                                     |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.11                                     |
| upper limit                             | 0.2                                      |

|                                                                                                                                                                                                                               |                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 6A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                |
| Serotype 6A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                                |
| Comparison groups                                                                                                                                                                                                             | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                       | 177                                            |
| Analysis specification                                                                                                                                                                                                        | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                 | superiority                                    |
| Parameter estimate                                                                                                                                                                                                            | GMC ratio                                      |
| Point estimate                                                                                                                                                                                                                | 1.61                                           |
| Confidence interval                                                                                                                                                                                                           |                                                |
| level                                                                                                                                                                                                                         | 95 %                                           |
| sides                                                                                                                                                                                                                         | 2-sided                                        |
| lower limit                                                                                                                                                                                                                   | 1.15                                           |
| upper limit                                                                                                                                                                                                                   | 2.23                                           |

|                                                                                                                                                                                                                                |                                                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                              | 6A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                              |                                                  |
| Serotype 6A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                  |
| Comparison groups                                                                                                                                                                                                              | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                        | 178                                              |
| Analysis specification                                                                                                                                                                                                         | Pre-specified                                    |
| Analysis type                                                                                                                                                                                                                  | superiority                                      |
| Parameter estimate                                                                                                                                                                                                             | GMC ratio                                        |
| Point estimate                                                                                                                                                                                                                 | 1.24                                             |
| Confidence interval                                                                                                                                                                                                            |                                                  |
| level                                                                                                                                                                                                                          | 95 %                                             |
| sides                                                                                                                                                                                                                          | 2-sided                                          |
| lower limit                                                                                                                                                                                                                    | 0.89                                             |
| upper limit                                                                                                                                                                                                                    | 1.72                                             |

|                                                                                                                                                                                                                              |                                                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                            | 6A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                            |                                                |
| Serotype 6A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                |
| Comparison groups                                                                                                                                                                                                            | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                      | 115                                            |
| Analysis specification                                                                                                                                                                                                       | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                | superiority                                    |
| Parameter estimate                                                                                                                                                                                                           | GMC ratio                                      |
| Point estimate                                                                                                                                                                                                               | 0.77                                           |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.53    |
| upper limit         | 1.13    |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 7F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 7F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 1.63                                      |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 1.28                                      |
| upper limit                             | 2.08                                      |

|                                   |                                                  |
|-----------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b> | 7F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|--------------------------------------------------|

Statistical analysis description:

Serotype 7F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMC ratio                                  |
| Point estimate                          | 1.03                                       |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.81                                       |
| upper limit                             | 1.3                                        |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 7F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 7F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMC ratio                                |
| Point estimate                          | 0.63                                     |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.47                                     |
| upper limit                             | 0.83                                     |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 19A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 19A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 1.99                                      |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 1.51                                      |
| upper limit                             | 2.63                                      |

|                                   |                                                   |
|-----------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b> | 19A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|---------------------------------------------------|

Statistical analysis description:

Serotype 19A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMC ratio                                  |
| Point estimate                          | 1.04                                       |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.79                                       |
| upper limit                             | 1.37                                       |

|                                                                                                                                                                                                                               |                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 19A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                 |
| Serotype 19A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                             | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                                       | 115                                             |
| Analysis specification                                                                                                                                                                                                        | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                 | superiority                                     |
| Parameter estimate                                                                                                                                                                                                            | GMC ratio                                       |
| Point estimate                                                                                                                                                                                                                | 0.52                                            |
| Confidence interval                                                                                                                                                                                                           |                                                 |
| level                                                                                                                                                                                                                         | 95 %                                            |
| sides                                                                                                                                                                                                                         | 2-sided                                         |
| lower limit                                                                                                                                                                                                                   | 0.38                                            |
| upper limit                                                                                                                                                                                                                   | 0.72                                            |

### Primary: Percentage of Subjects with Prespecified Local Reactions

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Percentage of Subjects with Prespecified Local Reactions |
| End point description:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                          |
| Local reactions (redness, swelling and pain) were reported using electronic diary. Redness and swelling were recorded in caliper units (range 1 to 14+), each caliper unit represented 0.5 centimeter (cm). Categorized as any, absent (no redness or swelling present; 0 caliper units), mild (0.5 to 2.0 cm; 1 to 4 caliper units); moderate (2.5 to 7.0 cm; 5 to 14 caliper units); or severe (greater than (>)7.0 cm; >14 caliper units). Pain was categorized as any, mild: does not interfere with activity; moderate: interferes with activity; severe: prevents daily activity. Subjects may be reported in more than 1 category. Safety population: all subjects who received the single dose of 13vPnC vaccination. n = number of subjects reporting yes for at least 1 day or no for all days, for each group, respectively. |                                                          |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Primary                                                  |
| End point timeframe:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                          |
| Seven days after vaccination                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                          |

| End point values                   | 13vPnC/13vPnC/13vPnC | 7vPnC/7vPnC/13vPnC | 7vPnC/13vPnC/13vPnC |  |
|------------------------------------|----------------------|--------------------|---------------------|--|
| Subject group type                 | Reporting group      | Reporting group    | Reporting group     |  |
| Number of subjects analysed        | 130                  | 64                 | 64                  |  |
| Units: percentage of subjects      |                      |                    |                     |  |
| number (not applicable)            |                      |                    |                     |  |
| Pain: Any (n= 112, 52, 53)         | 55.4                 | 55.8               | 64.2                |  |
| Pain: Mild (n= 109, 51, 51)        | 50.5                 | 49                 | 56.9                |  |
| Pain: Moderate (n= 95, 47, 48)     | 17.9                 | 25.5               | 20.8                |  |
| Pain: Severe (n= 90, 43, 45)       | 1.1                  | 2.3                | 2.2                 |  |
| Swelling: Any (101, 48, 47)        | 39.6                 | 41.7               | 27.7                |  |
| Swelling: Mild (n= 96, 48, 47)     | 28.1                 | 35.4               | 23.4                |  |
| Swelling: Moderate (n= 97, 44, 46) | 24.7                 | 20.5               | 10.9                |  |

|                                   |      |      |      |  |
|-----------------------------------|------|------|------|--|
| Swelling: Severe (n= 90, 43, 45)  | 0    | 2.3  | 0    |  |
| Redness: Any (n= 105, 50, 50)     | 48.6 | 54   | 46   |  |
| Redness: Mild (n= 101, 49, 48)    | 38.6 | 40.8 | 37.5 |  |
| Redness: Moderate (n= 95, 45, 47) | 22.1 | 31.1 | 17   |  |
| Redness: Severe (n= 90, 43, 45)   | 0    | 2.3  | 0    |  |

## Statistical analyses

| Statistical analysis title                                                                                                         | Pain (Any)                                |
|------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| Statistical analysis description:                                                                                                  |                                           |
| Pain (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC. |                                           |
| Comparison groups                                                                                                                  | 7vPnC/7vPnC/13vPnC v 13vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis                                                                                            | 194                                       |
| Analysis specification                                                                                                             | Pre-specified                             |
| Analysis type                                                                                                                      | superiority                               |
| P-value                                                                                                                            | > 0.99                                    |
| Method                                                                                                                             | Fisher exact                              |

| Statistical analysis title                                                                                                        | Pain (Any)                               |
|-----------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| Statistical analysis description:                                                                                                 |                                          |
| Pain (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC. |                                          |
| Comparison groups                                                                                                                 | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis                                                                                           | 128                                      |
| Analysis specification                                                                                                            | Pre-specified                            |
| Analysis type                                                                                                                     | superiority                              |
| P-value                                                                                                                           | = 0.429                                  |
| Method                                                                                                                            | Fisher exact                             |

| Statistical analysis title                                                                                                          | Pain (Any)                                 |
|-------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| Statistical analysis description:                                                                                                   |                                            |
| Pain (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC. |                                            |
| Comparison groups                                                                                                                   | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis                                                                                             | 194                                        |
| Analysis specification                                                                                                              | Pre-specified                              |
| Analysis type                                                                                                                       | superiority                                |
| P-value                                                                                                                             | = 0.314                                    |
| Method                                                                                                                              | Fisher exact                               |

| Statistical analysis title | Pain (Mild) |
|----------------------------|-------------|
|----------------------------|-------------|



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**Statistical analysis description:**

Pain (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 194                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| P-value                                 | > 0.99                                    |
| Method                                  | Fisher exact                              |

---

|                                   |             |
|-----------------------------------|-------------|
| <b>Statistical analysis title</b> | Pain (Mild) |
|-----------------------------------|-------------|

**Statistical analysis description:**

Pain (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 128                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| P-value                                 | = 0.552                                  |
| Method                                  | Fisher exact                             |

---

|                                   |             |
|-----------------------------------|-------------|
| <b>Statistical analysis title</b> | Pain (Mild) |
|-----------------------------------|-------------|

**Statistical analysis description:**

Pain (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 194                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| P-value                                 | = 0.499                                    |
| Method                                  | Fisher exact                               |

---

|                                   |                 |
|-----------------------------------|-----------------|
| <b>Statistical analysis title</b> | Pain (Moderate) |
|-----------------------------------|-----------------|

**Statistical analysis description:**

Pain (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 194                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| P-value                                 | = 0.376                                   |
| Method                                  | Fisher exact                              |

|                                                                                                                                        |                                          |
|----------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                      | Pain (Moderate)                          |
| Statistical analysis description:                                                                                                      |                                          |
| Pain (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC. |                                          |
| Comparison groups                                                                                                                      | 7vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis                                                                                                | 128                                      |
| Analysis specification                                                                                                                 | Pre-specified                            |
| Analysis type                                                                                                                          | superiority                              |
| P-value                                                                                                                                | = 0.633                                  |
| Method                                                                                                                                 | Fisher exact                             |

|                                                                                                                                          |                                            |
|------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                        | Pain (Moderate)                            |
| Statistical analysis description:                                                                                                        |                                            |
| Pain (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC. |                                            |
| Comparison groups                                                                                                                        | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis                                                                                                  | 194                                        |
| Analysis specification                                                                                                                   | Pre-specified                              |
| Analysis type                                                                                                                            | superiority                                |
| P-value                                                                                                                                  | = 0.658                                    |
| Method                                                                                                                                   | Fisher exact                               |

|                                                                                                                                       |                                           |
|---------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                     | Pain (Severe)                             |
| Statistical analysis description:                                                                                                     |                                           |
| Pain (Severe): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC. |                                           |
| Comparison groups                                                                                                                     | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis                                                                                               | 194                                       |
| Analysis specification                                                                                                                | Pre-specified                             |
| Analysis type                                                                                                                         | superiority                               |
| P-value                                                                                                                               | = 0.544                                   |
| Method                                                                                                                                | Fisher exact                              |

|                                                                                                                                      |                                          |
|--------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                    | Pain (Severe)                            |
| Statistical analysis description:                                                                                                    |                                          |
| Pain (Severe): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC. |                                          |
| Comparison groups                                                                                                                    | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis                                                                                              | 128                                      |
| Analysis specification                                                                                                               | Pre-specified                            |
| Analysis type                                                                                                                        | superiority                              |
| P-value                                                                                                                              | > 0.99                                   |
| Method                                                                                                                               | Fisher exact                             |

|                                                                                                                                                                             |                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                           | Pain (Severe)                              |
| Statistical analysis description:<br>Pain (Severe): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC. |                                            |
| Comparison groups                                                                                                                                                           | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis                                                                                                                                     | 194                                        |
| Analysis specification                                                                                                                                                      | Pre-specified                              |
| Analysis type                                                                                                                                                               | superiority                                |
| P-value                                                                                                                                                                     | > 0.99                                     |
| Method                                                                                                                                                                      | Fisher exact                               |

|                                                                                                                                                                             |                                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                           | Swelling (Any)                            |
| Statistical analysis description:<br>Swelling (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC. |                                           |
| Comparison groups                                                                                                                                                           | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis                                                                                                                                     | 194                                       |
| Analysis specification                                                                                                                                                      | Pre-specified                             |
| Analysis type                                                                                                                                                               | superiority                               |
| P-value                                                                                                                                                                     | = 0.859                                   |
| Method                                                                                                                                                                      | Fisher exact                              |

|                                                                                                                                                                            |                                          |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                          | Swelling (Any)                           |
| Statistical analysis description:<br>Swelling (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC. |                                          |
| Comparison groups                                                                                                                                                          | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis                                                                                                                                    | 128                                      |
| Analysis specification                                                                                                                                                     | Pre-specified                            |
| Analysis type                                                                                                                                                              | superiority                              |
| P-value                                                                                                                                                                    | = 0.197                                  |
| Method                                                                                                                                                                     | Fisher exact                             |

|                                                                                                                                                                              |                                            |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                            | Swelling (Any)                             |
| Statistical analysis description:<br>Swelling (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC. |                                            |
| Comparison groups                                                                                                                                                            | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |

|                                         |               |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 194           |
| Analysis specification                  | Pre-specified |
| Analysis type                           | superiority   |
| P-value                                 | = 0.198       |
| Method                                  | Fisher exact  |

|                                   |                 |
|-----------------------------------|-----------------|
| <b>Statistical analysis title</b> | Swelling (Mild) |
|-----------------------------------|-----------------|

Statistical analysis description:

Swelling (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 194                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| P-value                                 | = 0.443                                   |
| Method                                  | Fisher exact                              |

|                                   |                 |
|-----------------------------------|-----------------|
| <b>Statistical analysis title</b> | Swelling (Mild) |
|-----------------------------------|-----------------|

Statistical analysis description:

Swelling (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 128                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| P-value                                 | = 0.261                                  |
| Method                                  | Fisher exact                             |

|                                   |                 |
|-----------------------------------|-----------------|
| <b>Statistical analysis title</b> | Swelling (Mild) |
|-----------------------------------|-----------------|

Statistical analysis description:

Swelling (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 194                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| P-value                                 | = 0.687                                    |
| Method                                  | Fisher exact                               |

|                                   |                     |
|-----------------------------------|---------------------|
| <b>Statistical analysis title</b> | Swelling (Moderate) |
|-----------------------------------|---------------------|

Statistical analysis description:

Swelling (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between

13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 194                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| P-value                                 | = 0.671                                   |
| Method                                  | Fisher exact                              |

|                                   |                     |
|-----------------------------------|---------------------|
| <b>Statistical analysis title</b> | Swelling (Moderate) |
|-----------------------------------|---------------------|

Statistical analysis description:

Swelling (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 128                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| P-value                                 | = 0.253                                  |
| Method                                  | Fisher exact                             |

|                                   |                     |
|-----------------------------------|---------------------|
| <b>Statistical analysis title</b> | Swelling (Moderate) |
|-----------------------------------|---------------------|

Statistical analysis description:

Swelling (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 194                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| P-value                                 | = 0.074                                    |
| Method                                  | Fisher exact                               |

|                                   |                   |
|-----------------------------------|-------------------|
| <b>Statistical analysis title</b> | Swelling (Severe) |
|-----------------------------------|-------------------|

Statistical analysis description:

Swelling (Severe): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 194                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| P-value                                 | = 0.323                                   |
| Method                                  | Fisher exact                              |

|                                   |                   |
|-----------------------------------|-------------------|
| <b>Statistical analysis title</b> | Swelling (Severe) |
|-----------------------------------|-------------------|

**Statistical analysis description:**

Swelling (Severe): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 128                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| P-value                                 | = 0.489                                  |
| Method                                  | Fisher exact                             |

|                                   |               |
|-----------------------------------|---------------|
| <b>Statistical analysis title</b> | Redness (Any) |
|-----------------------------------|---------------|

**Statistical analysis description:**

Redness (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 194                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| P-value                                 | = 0.607                                   |
| Method                                  | Fisher exact                              |

|                                   |               |
|-----------------------------------|---------------|
| <b>Statistical analysis title</b> | Redness (Any) |
|-----------------------------------|---------------|

**Statistical analysis description:**

Redness (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 128                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| P-value                                 | = 0.549                                  |
| Method                                  | Fisher exact                             |

|                                   |               |
|-----------------------------------|---------------|
| <b>Statistical analysis title</b> | Redness (Any) |
|-----------------------------------|---------------|

**Statistical analysis description:**

Redness (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 194                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| P-value                                 | = 0.864                                    |
| Method                                  | Fisher exact                               |

|                                                                                                                                        |                                           |
|----------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                      | Redness (Mild)                            |
| Statistical analysis description:                                                                                                      |                                           |
| Redness (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC. |                                           |
| Comparison groups                                                                                                                      | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis                                                                                                | 194                                       |
| Analysis specification                                                                                                                 | Pre-specified                             |
| Analysis type                                                                                                                          | superiority                               |
| P-value                                                                                                                                | = 0.859                                   |
| Method                                                                                                                                 | Fisher exact                              |

|                                                                                                                                       |                                          |
|---------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                     | Redness (Mild)                           |
| Statistical analysis description:                                                                                                     |                                          |
| Redness (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC. |                                          |
| Comparison groups                                                                                                                     | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis                                                                                               | 128                                      |
| Analysis specification                                                                                                                | Pre-specified                            |
| Analysis type                                                                                                                         | superiority                              |
| P-value                                                                                                                               | = 0.836                                  |
| Method                                                                                                                                | Fisher exact                             |

|                                                                                                                                         |                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                       | Redness (Mild)                             |
| Statistical analysis description:                                                                                                       |                                            |
| Redness (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC. |                                            |
| Comparison groups                                                                                                                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis                                                                                                 | 194                                        |
| Analysis specification                                                                                                                  | Pre-specified                              |
| Analysis type                                                                                                                           | superiority                                |
| P-value                                                                                                                                 | > 0.99                                     |
| Method                                                                                                                                  | Fisher exact                               |

|                                                                                                                                            |                                           |
|--------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                          | Redness (Moderate)                        |
| Statistical analysis description:                                                                                                          |                                           |
| Redness (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC. |                                           |
| Comparison groups                                                                                                                          | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis                                                                                                    | 194                                       |
| Analysis specification                                                                                                                     | Pre-specified                             |
| Analysis type                                                                                                                              | superiority                               |
| P-value                                                                                                                                    | = 0.297                                   |
| Method                                                                                                                                     | Fisher exact                              |

|                                                                                                                                                                                |                                          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                              | Redness (Moderate)                       |
| Statistical analysis description:<br>Redness (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC. |                                          |
| Comparison groups                                                                                                                                                              | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis                                                                                                                                        | 128                                      |
| Analysis specification                                                                                                                                                         | Pre-specified                            |
| Analysis type                                                                                                                                                                  | superiority                              |
| P-value                                                                                                                                                                        | = 0.145                                  |
| Method                                                                                                                                                                         | Fisher exact                             |

|                                                                                                                                                                                  |                                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                | Redness (Moderate)                         |
| Statistical analysis description:<br>Redness (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC. |                                            |
| Comparison groups                                                                                                                                                                | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis                                                                                                                                          | 194                                        |
| Analysis specification                                                                                                                                                           | Pre-specified                              |
| Analysis type                                                                                                                                                                    | superiority                                |
| P-value                                                                                                                                                                          | = 0.517                                    |
| Method                                                                                                                                                                           | Fisher exact                               |

|                                                                                                                                                                               |                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                             | Redness (Severe)                          |
| Statistical analysis description:<br>Redness (Severe): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC. |                                           |
| Comparison groups                                                                                                                                                             | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis                                                                                                                                       | 194                                       |
| Analysis specification                                                                                                                                                        | Pre-specified                             |
| Analysis type                                                                                                                                                                 | superiority                               |
| P-value                                                                                                                                                                       | = 0.323                                   |
| Method                                                                                                                                                                        | Fisher exact                              |

|                                                                                                                                                                              |                                          |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                            | Redness (Severe)                         |
| Statistical analysis description:<br>Redness (Severe): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC. |                                          |
| Comparison groups                                                                                                                                                            | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |



|                                         |               |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 128           |
| Analysis specification                  | Pre-specified |
| Analysis type                           | superiority   |
| P-value                                 | = 0.489       |
| Method                                  | Fisher exact  |

### Primary: Percentage of Subjects With Prespecified Systemic Events

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                          |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Percentage of Subjects With Prespecified Systemic Events |
| End point description:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                          |
| Systemic events (any fever greater than or equals to [ $\geq$ ]38 degree celsius [C], vomiting, diarrhea, and fatigue) were reported using electronic diary. Fever categorized as $\geq$ 38 to less than or equals to ( $\leq$ )39 degree C; $>39$ to $\leq 40$ degree C; $>40$ degree C. Vomiting: mild (1-2 times/day ); moderate ( $>2$ times/day); severe (requires intravenous hydration). Diarrhea: mild (2-3 loose stools/day); moderate (4-5 stools/day); severe ( $\geq 6$ loose stools/day). Fatigue: mild (does not interfere with activity); moderate (some interference with activity); severe (prevents daily routine activity). Subjects may be reported in more than 1 category. Safety population: all subjects who received the single dose of 13vPnC vaccination. n = number of subjects reporting yes for at least 1 day or no for all days, for each group, respectively. |                                                          |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Primary                                                  |
| End point timeframe:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                          |
| Seven days after vaccination                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                          |

| End point values                                      | 13vPnC/13vPnC/13vPnC | 7vPnC/7vPnC/13vPnC | 7vPnC/13vPnC/13vPnC |  |
|-------------------------------------------------------|----------------------|--------------------|---------------------|--|
| Subject group type                                    | Reporting group      | Reporting group    | Reporting group     |  |
| Number of subjects analysed                           | 130                  | 64                 | 64                  |  |
| Units: percentage of subjects                         |                      |                    |                     |  |
| number (not applicable)                               |                      |                    |                     |  |
| Fever $\geq 38$ to $\leq 39$ degree C (n= 93, 49, 46) | 15.1                 | 28.6               | 19.6                |  |
| Fever $>39$ to $\leq 40$ degree C (n= 92, 43, 46)     | 2.2                  | 4.7                | 2.2                 |  |
| Fever $>40$ degree C (n= 90, 43, 45)                  | 0                    | 0                  | 2.2                 |  |
| Vomiting: Any (n= 91, 44, 45)                         | 3.3                  | 9.1                | 6.7                 |  |
| Vomiting: Mild (n= 91, 44, 45)                        | 3.3                  | 9.1                | 6.7                 |  |
| Vomiting: Moderate (n= 90, 43, 45)                    | 0                    | 0                  | 0                   |  |
| Vomiting: Severe (n= 90, 43, 45)                      | 0                    | 0                  | 0                   |  |
| Diarrhea: Any (n= 90, 45, 47)                         | 8.9                  | 17.8               | 8.5                 |  |
| Diarrhea: Mild (n= 90, 45, 47)                        | 8.9                  | 17.8               | 8.5                 |  |
| Diarrhea: Moderate (n= 90, 43, 45)                    | 1.1                  | 0                  | 0                   |  |
| Diarrhea: Severe (n= 90, 43, 45)                      | 0                    | 0                  | 0                   |  |
| Fatigue: Any (n= 103, 54, 48)                         | 40.8                 | 51.9               | 31.3                |  |
| Fatigue: Mild (n= 100, 49, 48)                        | 34                   | 34.7               | 20.8                |  |
| Fatigue: Moderate (n= 96, 49, 46)                     | 16.7                 | 30.6               | 15.2                |  |
| Fatigue: Severe (n= 92, 43, 45)                       | 3.3                  | 2.3                | 2.2                 |  |

## Statistical analyses

|                                                                                                                                                                                                               |                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                             | Fever ( $\geq 38$ degree C to $\leq 39$ degree C) |
| Statistical analysis description:<br>Fever ( $\geq 38$ degree C to $\leq 39$ degree C): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC |                                                   |
| Comparison groups                                                                                                                                                                                             | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC         |
| Number of subjects included in analysis                                                                                                                                                                       | 194                                               |
| Analysis specification                                                                                                                                                                                        | Pre-specified                                     |
| Analysis type                                                                                                                                                                                                 | superiority                                       |
| P-value                                                                                                                                                                                                       | = 0.075                                           |
| Method                                                                                                                                                                                                        | Fisher exact                                      |

|                                                                                                                                                                                                              |                                                   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                            | Fever ( $\geq 38$ degree C to $\leq 39$ degree C) |
| Statistical analysis description:<br>Fever ( $\geq 38$ degree C to $\leq 39$ degree C): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC |                                                   |
| Comparison groups                                                                                                                                                                                            | 7vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC          |
| Number of subjects included in analysis                                                                                                                                                                      | 128                                               |
| Analysis specification                                                                                                                                                                                       | Pre-specified                                     |
| Analysis type                                                                                                                                                                                                | superiority                                       |
| P-value                                                                                                                                                                                                      | = 0.345                                           |
| Method                                                                                                                                                                                                       | Fisher exact                                      |

|                                                                                                                                                                                                                |                                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                              | Fever ( $\geq 38$ degree C to $\leq 39$ degree C) |
| Statistical analysis description:<br>Fever ( $\geq 38$ degree C to $\leq 39$ degree C): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC |                                                   |
| Comparison groups                                                                                                                                                                                              | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                        | 194                                               |
| Analysis specification                                                                                                                                                                                         | Pre-specified                                     |
| Analysis type                                                                                                                                                                                                  | superiority                                       |
| P-value                                                                                                                                                                                                        | = 0.628                                           |
| Method                                                                                                                                                                                                         | Fisher exact                                      |

|                                                                                                                                                                                                                |                                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                              | Fever ( $\geq 39$ degree C to $\leq 40$ degree C) |
| Statistical analysis description:<br>Fever ( $\geq 39$ degree C to $\leq 40$ degree C): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC. |                                                   |
| Comparison groups                                                                                                                                                                                              | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC         |

|                                         |               |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 194           |
| Analysis specification                  | Pre-specified |
| Analysis type                           | superiority   |
| P-value                                 | = 0.592       |
| Method                                  | Fisher exact  |

|                                   |                                                   |
|-----------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b> | Fever ( $\geq 39$ degree C to $\leq 40$ degree C) |
|-----------------------------------|---------------------------------------------------|

Statistical analysis description:

Fever ( $\geq 39$  degree C to  $\leq 40$  degree C): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 128                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| P-value                                 | = 0.608                                  |
| Method                                  | Fisher exact                             |

|                                   |                                                   |
|-----------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b> | Fever ( $\geq 39$ degree C to $\leq 40$ degree C) |
|-----------------------------------|---------------------------------------------------|

Statistical analysis description:

Fever ( $\geq 39$  degree C to  $\leq 40$  degree C): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 194                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| P-value                                 | > 0.99                                     |
| Method                                  | Fisher exact                               |

|                                   |                         |
|-----------------------------------|-------------------------|
| <b>Statistical analysis title</b> | Fever ( $>40$ degree C) |
|-----------------------------------|-------------------------|

Statistical analysis description:

Fever ( $>40$  degree C): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 128                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| P-value                                 | > 0.99                                   |
| Method                                  | Fisher exact                             |

|                                   |                         |
|-----------------------------------|-------------------------|
| <b>Statistical analysis title</b> | Fever ( $>40$ degree C) |
|-----------------------------------|-------------------------|

Statistical analysis description:

Fever ( $>40$  degree C): Fisher exact test, 2-sided was used. Pairwise comparison was made between

13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 194                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| P-value                                 | = 0.333                                    |
| Method                                  | Fisher exact                               |

|                                   |                |
|-----------------------------------|----------------|
| <b>Statistical analysis title</b> | Vomiting (Any) |
|-----------------------------------|----------------|

Statistical analysis description:

Vomiting (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 194                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| P-value                                 | = 0.215                                   |
| Method                                  | Fisher exact                              |

|                                   |                |
|-----------------------------------|----------------|
| <b>Statistical analysis title</b> | Vomiting (Any) |
|-----------------------------------|----------------|

Statistical analysis description:

Vomiting (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 128                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| P-value                                 | = 0.714                                  |
| Method                                  | Fisher exact                             |

|                                   |                |
|-----------------------------------|----------------|
| <b>Statistical analysis title</b> | Vomiting (Any) |
|-----------------------------------|----------------|

Statistical analysis description:

Vomiting (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 194                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| P-value                                 | = 0.397                                    |
| Method                                  | Fisher exact                               |

|                                   |                 |
|-----------------------------------|-----------------|
| <b>Statistical analysis title</b> | Vomiting (Mild) |
|-----------------------------------|-----------------|

Statistical analysis description:

Vomiting (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 194                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| P-value                                 | = 0.215                                   |
| Method                                  | Fisher exact                              |

|                                   |                 |
|-----------------------------------|-----------------|
| <b>Statistical analysis title</b> | Vomiting (Mild) |
|-----------------------------------|-----------------|

Statistical analysis description:

Vomiting (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 128                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| P-value                                 | = 0.714                                  |
| Method                                  | Fisher exact                             |

|                                   |                 |
|-----------------------------------|-----------------|
| <b>Statistical analysis title</b> | Vomiting (Mild) |
|-----------------------------------|-----------------|

Statistical analysis description:

Vomiting (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 194                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| P-value                                 | = 0.397                                    |
| Method                                  | Fisher exact                               |

|                                   |                |
|-----------------------------------|----------------|
| <b>Statistical analysis title</b> | Diarrhea (Any) |
|-----------------------------------|----------------|

Statistical analysis description:

Diarrhea (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 194                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| P-value                                 | = 0.161                                    |
| Method                                  | Fisher exact                               |

|                                                                                                                                       |                                          |
|---------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                     | Diarrhea (Any)                           |
| Statistical analysis description:                                                                                                     |                                          |
| Diarrhea (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC. |                                          |
| Comparison groups                                                                                                                     | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis                                                                                               | 128                                      |
| Analysis specification                                                                                                                | Pre-specified                            |
| Analysis type                                                                                                                         | superiority                              |
| P-value                                                                                                                               | = 0.226                                  |
| Method                                                                                                                                | Fisher exact                             |

|                                                                                                                                         |                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                       | Diarrhea (Any)                             |
| Statistical analysis description:                                                                                                       |                                            |
| Diarrhea (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC. |                                            |
| Comparison groups                                                                                                                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis                                                                                                 | 194                                        |
| Analysis specification                                                                                                                  | Pre-specified                              |
| Analysis type                                                                                                                           | superiority                                |
| P-value                                                                                                                                 | > 0.99                                     |
| Method                                                                                                                                  | Fisher exact                               |

|                                                                                                                                         |                                           |
|-----------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                       | Diarrhea (Mild)                           |
| Statistical analysis description:                                                                                                       |                                           |
| Diarrhea (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC. |                                           |
| Comparison groups                                                                                                                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis                                                                                                 | 194                                       |
| Analysis specification                                                                                                                  | Pre-specified                             |
| Analysis type                                                                                                                           | superiority                               |
| P-value                                                                                                                                 | = 0.161                                   |
| Method                                                                                                                                  | Fisher exact                              |

|                                                                                                                                        |                                          |
|----------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                      | Diarrhea (Mild)                          |
| Statistical analysis description:                                                                                                      |                                          |
| Diarrhea (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC. |                                          |
| Comparison groups                                                                                                                      | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis                                                                                                | 128                                      |
| Analysis specification                                                                                                                 | Pre-specified                            |
| Analysis type                                                                                                                          | superiority                              |
| P-value                                                                                                                                | = 0.226                                  |
| Method                                                                                                                                 | Fisher exact                             |

|                                                                                                                                          |                                            |
|------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                        | Diarrhea (Mild)                            |
| Statistical analysis description:                                                                                                        |                                            |
| Diarrhea (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC. |                                            |
| Comparison groups                                                                                                                        | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis                                                                                                  | 194                                        |
| Analysis specification                                                                                                                   | Pre-specified                              |
| Analysis type                                                                                                                            | superiority                                |
| P-value                                                                                                                                  | > 0.99                                     |
| Method                                                                                                                                   | Fisher exact                               |

|                                                                                                                                             |                                           |
|---------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                           | Diarrhea (Moderate)                       |
| Statistical analysis description:                                                                                                           |                                           |
| Diarrhea (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC. |                                           |
| Comparison groups                                                                                                                           | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis                                                                                                     | 194                                       |
| Analysis specification                                                                                                                      | Pre-specified                             |
| Analysis type                                                                                                                               | superiority                               |
| P-value                                                                                                                                     | > 0.99                                    |
| Method                                                                                                                                      | Fisher exact                              |

|                                                                                                                                              |                                            |
|----------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                            | Diarrhea (Moderate)                        |
| Statistical analysis description:                                                                                                            |                                            |
| Diarrhea (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC. |                                            |
| Comparison groups                                                                                                                            | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis                                                                                                      | 194                                        |
| Analysis specification                                                                                                                       | Pre-specified                              |
| Analysis type                                                                                                                                | superiority                                |
| P-value                                                                                                                                      | > 0.99                                     |
| Method                                                                                                                                       | Fisher exact                               |

|                                                                                                                                       |                                           |
|---------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                     | Fatigue (Any)                             |
| Statistical analysis description:                                                                                                     |                                           |
| Fatigue (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC. |                                           |
| Comparison groups                                                                                                                     | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |

|                                         |               |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 194           |
| Analysis specification                  | Pre-specified |
| Analysis type                           | superiority   |
| P-value                                 | = 0.237       |
| Method                                  | Fisher exact  |

|                                   |               |
|-----------------------------------|---------------|
| <b>Statistical analysis title</b> | Fatigue (Any) |
|-----------------------------------|---------------|

Statistical analysis description:

Fatigue (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 128                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| P-value                                 | = 0.045                                  |
| Method                                  | Fisher exact                             |

|                                   |               |
|-----------------------------------|---------------|
| <b>Statistical analysis title</b> | Fatigue (Any) |
|-----------------------------------|---------------|

Statistical analysis description:

Fatigue (Any): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 194                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| P-value                                 | = 0.285                                    |
| Method                                  | Fisher exact                               |

|                                   |                |
|-----------------------------------|----------------|
| <b>Statistical analysis title</b> | Fatigue (Mild) |
|-----------------------------------|----------------|

Statistical analysis description:

Fatigue (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 194                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| P-value                                 | > 0.99                                    |
| Method                                  | Fisher exact                              |

|                                   |                |
|-----------------------------------|----------------|
| <b>Statistical analysis title</b> | Fatigue (Mild) |
|-----------------------------------|----------------|

Statistical analysis description:

Fatigue (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between



7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 128                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| P-value                                 | = 0.174                                  |
| Method                                  | Fisher exact                             |

|                                   |                |
|-----------------------------------|----------------|
| <b>Statistical analysis title</b> | Fatigue (Mild) |
|-----------------------------------|----------------|

Statistical analysis description:

Fatigue (Mild): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 194                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| P-value                                 | = 0.125                                    |
| Method                                  | Fisher exact                               |

|                                   |                    |
|-----------------------------------|--------------------|
| <b>Statistical analysis title</b> | Fatigue (Moderate) |
|-----------------------------------|--------------------|

Statistical analysis description:

Fatigue (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 194                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| P-value                                 | = 0.058                                   |
| Method                                  | Fisher exact                              |

|                                   |                    |
|-----------------------------------|--------------------|
| <b>Statistical analysis title</b> | Fatigue (Moderate) |
|-----------------------------------|--------------------|

Statistical analysis description:

Fatigue (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 128                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| P-value                                 | = 0.092                                  |
| Method                                  | Fisher exact                             |

|                                   |                    |
|-----------------------------------|--------------------|
| <b>Statistical analysis title</b> | Fatigue (Moderate) |
|-----------------------------------|--------------------|

Statistical analysis description:

Fatigue (Moderate): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 194                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| P-value                                 | > 0.99                                     |
| Method                                  | Fisher exact                               |

|                                   |                  |
|-----------------------------------|------------------|
| <b>Statistical analysis title</b> | Fatigue (Severe) |
|-----------------------------------|------------------|

Statistical analysis description:

Fatigue (Severe): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/7vPnC/13vPnC.

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 194                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| P-value                                 | > 0.99                                    |
| Method                                  | Fisher exact                              |

|                                   |                  |
|-----------------------------------|------------------|
| <b>Statistical analysis title</b> | Fatigue (Severe) |
|-----------------------------------|------------------|

Statistical analysis description:

Fatigue (Severe): Fisher exact test, 2-sided was used. Pairwise comparison was made between 7vPnC/7vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 128                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| P-value                                 | > 0.99                                   |
| Method                                  | Fisher exact                             |

|                                   |                  |
|-----------------------------------|------------------|
| <b>Statistical analysis title</b> | Fatigue (Severe) |
|-----------------------------------|------------------|

Statistical analysis description:

Fatigue (Severe): Fisher exact test, 2-sided was used. Pairwise comparison was made between 13vPnC/13vPnC/13vPnC and 7vPnC/13vPnC/13vPnC.

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 194                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| P-value                                 | > 0.99                                     |
| Method                                  | Fisher exact                               |

## Secondary: Serotype-specific Pneumococcal IgG GMC Prior to Single Dose of 13vPnC Vaccine

|                 |                                                                               |
|-----------------|-------------------------------------------------------------------------------|
| End point title | Serotype-specific Pneumococcal IgG GMC Prior to Single Dose of 13vPnC Vaccine |
|-----------------|-------------------------------------------------------------------------------|

End point description:

IgG GMC to the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) were determined in the blood samples of all the subjects using a standardized anti-pneumococcal IgG enzymelinked immunosorbent assay (ELISA). CIs for GMC are back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Evaluable immunogenicity population: eligible subjects, randomized, blood drawn within required timeframes, at least 1 valid and determinate assay result for proposed analysis, received no prohibited vaccines, no major protocol violations.

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

End point timeframe:

Up to 7 days before vaccination

| End point values                         | 13vPnC/13vPnC/13vPnC | 7vPnC/7vPnC/13vPnC  | 7vPnC/13vPnC/13vPnC |  |
|------------------------------------------|----------------------|---------------------|---------------------|--|
| Subject group type                       | Reporting group      | Reporting group     | Reporting group     |  |
| Number of subjects analysed              | 120 <sup>[4]</sup>   | 57 <sup>[5]</sup>   | 58 <sup>[6]</sup>   |  |
| Units: mcg/mL                            |                      |                     |                     |  |
| geometric mean (confidence interval 95%) |                      |                     |                     |  |
| Serotype 4                               | 0.17 (0.15 to 0.21)  | 0.23 (1.43 to 3.11) | 0.18 (0.15 to 0.22) |  |
| Serotype 6B                              | 2.86 (2.35 to 3.48)  | 4.1 (1.19 to 2.05)  | 3.21 (2.37 to 4.36) |  |
| Serotype 9V                              | 0.72 (0.6 to 0.85)   | 0.92 (0.09 to 0.2)  | 0.71 (0.58 to 0.87) |  |
| Serotype 14                              | 0.77 (0.61 to 0.98)  | 0.74 (0.29 to 0.75) | 0.59 (0.42 to 0.83) |  |
| Serotype 18C                             | 0.21 (0.17 to 0.25)  | 0.36 (0.89 to 1.41) | 0.23 (0.18 to 0.28) |  |
| Serotype 19F                             | 2.22 (1.67 to 2.95)  | 2.11 (1.5 to 2.38)  | 1.44 (1.04 to 2.02) |  |
| Serotype 23F                             | 1.26 (1 to 1.58)     | 1.56 (0.15 to 0.3)  | 1.18 (0.92 to 1.52) |  |
| Serotype 1                               | 0.35 (0.29 to 0.43)  | 0.14 (2.6 to 4.41)  | 0.28 (0.23 to 0.34) |  |
| Serotype 3                               | 0.5 (0.35 to 0.71)   | 0.47 (0.18 to 0.3)  | 0.42 (0.3 to 0.58)  |  |
| Serotype 5                               | 1.28 (1.07 to 1.53)  | 1.12 (2.96 to 5.68) | 1.41 (1.19 to 1.67) |  |
| Serotype 6A                              | 4.05 (3.25 to 5.04)  | 1.89 (0.72 to 1.17) | 2.47 (1.91 to 3.21) |  |
| Serotype 7F                              | 0.65 (0.55 to 0.78)  | 0.21 (0.52 to 1.06) | 0.77 (0.62 to 0.96) |  |
| Serotype 19A                             | 6.16 (4.88 to 7.79)  | 3.38 (0.28 to 0.47) | 4.63 (3.43 to 6.26) |  |

Notes:

[4] - N= number of subjects with determinate IgG antibody concentration to serotype.

[5] - N= number of subjects with determinate IgG antibody concentration to serotype.

[6] - N= number of subjects with determinate IgG antibody concentration to serotype.

## Statistical analyses

|                                                                                                                                                                                                                              |                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                            | 4: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                            |                                               |
| Serotype 4: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                            | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC     |
| Number of subjects included in analysis                                                                                                                                                                                      | 177                                           |
| Analysis specification                                                                                                                                                                                                       | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                                | superiority                                   |
| Parameter estimate                                                                                                                                                                                                           | GMC ratio                                     |
| Point estimate                                                                                                                                                                                                               | 0.75                                          |
| Confidence interval                                                                                                                                                                                                          |                                               |
| level                                                                                                                                                                                                                        | 95 %                                          |
| sides                                                                                                                                                                                                                        | 2-sided                                       |
| lower limit                                                                                                                                                                                                                  | 0.56                                          |
| upper limit                                                                                                                                                                                                                  | 1                                             |

|                                                                                                                                                                                                                               |                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 4: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                 |
| Serotype 4: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                             | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                       | 178                                             |
| Analysis specification                                                                                                                                                                                                        | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                 | superiority                                     |
| Parameter estimate                                                                                                                                                                                                            | GMC ratio                                       |
| Point estimate                                                                                                                                                                                                                | 0.96                                            |
| Confidence interval                                                                                                                                                                                                           |                                                 |
| level                                                                                                                                                                                                                         | 95 %                                            |
| sides                                                                                                                                                                                                                         | 2-sided                                         |
| lower limit                                                                                                                                                                                                                   | 0.73                                            |
| upper limit                                                                                                                                                                                                                   | 1.28                                            |

|                                                                                                                                                                                                                             |                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                           | 4: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                           |                                               |
| Serotype 4: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                           | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                     | 115                                           |
| Analysis specification                                                                                                                                                                                                      | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                               | superiority                                   |
| Parameter estimate                                                                                                                                                                                                          | GMC ratio                                     |
| Point estimate                                                                                                                                                                                                              | 1.29                                          |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.92    |
| upper limit         | 1.79    |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 6B: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 6B: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 0.7                                       |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.49                                      |
| upper limit                             | 1                                         |

|                                   |                                                  |
|-----------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b> | 6B: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|--------------------------------------------------|

Statistical analysis description:

Serotype 6B: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMC ratio                                  |
| Point estimate                          | 0.89                                       |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.62                                       |
| upper limit                             | 1.27                                       |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 6B: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 6B: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMC ratio                                |
| Point estimate                          | 1.27                                     |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.84                                     |
| upper limit                             | 1.94                                     |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 9V: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 9V: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 0.78                                      |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.58                                      |
| upper limit                             | 1.03                                      |

|                                   |                                                  |
|-----------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b> | 9V: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|--------------------------------------------------|

Statistical analysis description:

Serotype 9V: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMC ratio                                  |
| Point estimate                          | 1.01                                       |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.76                                       |
| upper limit                             | 1.33                                       |

|                                                                                                                                                                                                                                                                   |                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                 | 9V: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 9V: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                |
| Comparison groups                                                                                                                                                                                                                                                 | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                                                           | 115                                            |
| Analysis specification                                                                                                                                                                                                                                            | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                                                     | superiority                                    |
| Parameter estimate                                                                                                                                                                                                                                                | GMC ratio                                      |
| Point estimate                                                                                                                                                                                                                                                    | 1.29                                           |
| Confidence interval                                                                                                                                                                                                                                               |                                                |
| level                                                                                                                                                                                                                                                             | 95 %                                           |
| sides                                                                                                                                                                                                                                                             | 2-sided                                        |
| lower limit                                                                                                                                                                                                                                                       | 0.93                                           |
| upper limit                                                                                                                                                                                                                                                       | 1.8                                            |

|                                                                                                                                                                                                                                                                    |                                                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                  | 14: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 14: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                                |
| Comparison groups                                                                                                                                                                                                                                                  | 7vPnC/7vPnC/13vPnC v 13vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                                                            | 177                                            |
| Analysis specification                                                                                                                                                                                                                                             | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                                                      | superiority                                    |
| Parameter estimate                                                                                                                                                                                                                                                 | GMC ratio                                      |
| Point estimate                                                                                                                                                                                                                                                     | 1.04                                           |
| Confidence interval                                                                                                                                                                                                                                                |                                                |
| level                                                                                                                                                                                                                                                              | 95 %                                           |
| sides                                                                                                                                                                                                                                                              | 2-sided                                        |
| lower limit                                                                                                                                                                                                                                                        | 0.69                                           |
| upper limit                                                                                                                                                                                                                                                        | 1.58                                           |

|                                                                                                                                                                                                                                                                     |                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                   | 14: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 14: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                  |
| Comparison groups                                                                                                                                                                                                                                                   | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |

|                                         |               |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 178           |
| Analysis specification                  | Pre-specified |
| Analysis type                           | superiority   |
| Parameter estimate                      | GMC ratio     |
| Point estimate                          | 1.3           |
| Confidence interval                     |               |
| level                                   | 95 %          |
| sides                                   | 2-sided       |
| lower limit                             | 0.86          |
| upper limit                             | 1.97          |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 14: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 14: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMC ratio                                |
| Point estimate                          | 1.25                                     |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.77                                     |
| upper limit                             | 2.03                                     |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 18C: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 18C: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 0.58                                      |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.42                                      |
| upper limit                             | 0.78                                      |



|                                                                                                                                                                                                                                 |                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                               | 18C: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                               |                                                   |
| Serotype 18C: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                   |
| Comparison groups                                                                                                                                                                                                               | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                                         | 178                                               |
| Analysis specification                                                                                                                                                                                                          | Pre-specified                                     |
| Analysis type                                                                                                                                                                                                                   | superiority                                       |
| Parameter estimate                                                                                                                                                                                                              | GMC ratio                                         |
| Point estimate                                                                                                                                                                                                                  | 0.91                                              |
| Confidence interval                                                                                                                                                                                                             |                                                   |
| level                                                                                                                                                                                                                           | 95 %                                              |
| sides                                                                                                                                                                                                                           | 2-sided                                           |
| lower limit                                                                                                                                                                                                                     | 0.67                                              |
| upper limit                                                                                                                                                                                                                     | 1.23                                              |

|                                                                                                                                                                                                                               |                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 18C: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                 |
| Serotype 18C: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                             | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                                       | 115                                             |
| Analysis specification                                                                                                                                                                                                        | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                 | superiority                                     |
| Parameter estimate                                                                                                                                                                                                            | GMC ratio                                       |
| Point estimate                                                                                                                                                                                                                | 1.58                                            |
| Confidence interval                                                                                                                                                                                                           |                                                 |
| level                                                                                                                                                                                                                         | 95 %                                            |
| sides                                                                                                                                                                                                                         | 2-sided                                         |
| lower limit                                                                                                                                                                                                                   | 1.11                                            |
| upper limit                                                                                                                                                                                                                   | 2.25                                            |

|                                                                                                                                                                                                                                |                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                              | 19F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                              |                                                 |
| Serotype 19F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                              | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                        | 177                                             |
| Analysis specification                                                                                                                                                                                                         | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                  | superiority                                     |
| Parameter estimate                                                                                                                                                                                                             | GMC ratio                                       |
| Point estimate                                                                                                                                                                                                                 | 1.05                                            |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.66    |
| upper limit         | 1.68    |

|                                   |                                                   |
|-----------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b> | 19F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|---------------------------------------------------|

Statistical analysis description:

Serotype 19F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMC ratio                                  |
| Point estimate                          | 1.54                                       |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.97                                       |
| upper limit                             | 2.44                                       |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 19F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 19F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMC ratio                                |
| Point estimate                          | 1.46                                     |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.85                                     |
| upper limit                             | 2.51                                     |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 23F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 23F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 0.8                                       |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.56                                      |
| upper limit                             | 1.15                                      |

|                                   |                                                   |
|-----------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b> | 23F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|---------------------------------------------------|

Statistical analysis description:

Serotype 23F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMC ratio                                  |
| Point estimate                          | 1.06                                       |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.74                                       |
| upper limit                             | 1.52                                       |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 23F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 23F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMC ratio                                |
| Point estimate                          | 1.32                                     |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.87                                     |
| upper limit                             | 2.01                                     |

|                                                                                                                                                                                                                              |                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                            | 1: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                            |                                               |
| Serotype 1: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                            | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC     |
| Number of subjects included in analysis                                                                                                                                                                                      | 177                                           |
| Analysis specification                                                                                                                                                                                                       | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                                | superiority                                   |
| Parameter estimate                                                                                                                                                                                                           | GMC ratio                                     |
| Point estimate                                                                                                                                                                                                               | 2.59                                          |
| Confidence interval                                                                                                                                                                                                          |                                               |
| level                                                                                                                                                                                                                        | 95 %                                          |
| sides                                                                                                                                                                                                                        | 2-sided                                       |
| lower limit                                                                                                                                                                                                                  | 1.8                                           |
| upper limit                                                                                                                                                                                                                  | 3.73                                          |

|                                                                                                                                                                                                                               |                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 1: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                 |
| Serotype 1: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                             | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                       | 178                                             |
| Analysis specification                                                                                                                                                                                                        | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                 | superiority                                     |
| Parameter estimate                                                                                                                                                                                                            | GMC ratio                                       |
| Point estimate                                                                                                                                                                                                                | 1.26                                            |
| Confidence interval                                                                                                                                                                                                           |                                                 |
| level                                                                                                                                                                                                                         | 95 %                                            |
| sides                                                                                                                                                                                                                         | 2-sided                                         |
| lower limit                                                                                                                                                                                                                   | 0.88                                            |
| upper limit                                                                                                                                                                                                                   | 1.79                                            |

|                                                                                                                                                                                                                             |                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                           | 1: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                           |                                               |
| Serotype 1: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                           | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |

|                                         |               |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 115           |
| Analysis specification                  | Pre-specified |
| Analysis type                           | superiority   |
| Parameter estimate                      | GMC ratio     |
| Point estimate                          | 0.49          |
| Confidence interval                     |               |
| level                                   | 95 %          |
| sides                                   | 2-sided       |
| lower limit                             | 0.32          |
| upper limit                             | 0.74          |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 3: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 3: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 1.06                                      |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.61                                      |
| upper limit                             | 1.87                                      |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 3: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 3: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMC ratio                                  |
| Point estimate                          | 1.19                                       |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.68                                       |
| upper limit                             | 2.09                                       |

|                                                                                                                                                                                                                             |                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                           | 3: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                           |                                               |
| Serotype 3: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                           | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                     | 115                                           |
| Analysis specification                                                                                                                                                                                                      | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                               | superiority                                   |
| Parameter estimate                                                                                                                                                                                                          | GMC ratio                                     |
| Point estimate                                                                                                                                                                                                              | 1.12                                          |
| Confidence interval                                                                                                                                                                                                         |                                               |
| level                                                                                                                                                                                                                       | 95 %                                          |
| sides                                                                                                                                                                                                                       | 2-sided                                       |
| lower limit                                                                                                                                                                                                                 | 0.59                                          |
| upper limit                                                                                                                                                                                                                 | 2.15                                          |

|                                                                                                                                                                                                                              |                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                            | 5: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                            |                                               |
| Serotype 5: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                            | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC     |
| Number of subjects included in analysis                                                                                                                                                                                      | 177                                           |
| Analysis specification                                                                                                                                                                                                       | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                                | superiority                                   |
| Parameter estimate                                                                                                                                                                                                           | GMC ratio                                     |
| Point estimate                                                                                                                                                                                                               | 1.15                                          |
| Confidence interval                                                                                                                                                                                                          |                                               |
| level                                                                                                                                                                                                                        | 95 %                                          |
| sides                                                                                                                                                                                                                        | 2-sided                                       |
| lower limit                                                                                                                                                                                                                  | 0.87                                          |
| upper limit                                                                                                                                                                                                                  | 1.52                                          |

|                                                                                                                                                                                                                               |                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 5: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                 |
| Serotype 5: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                             | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                       | 178                                             |
| Analysis specification                                                                                                                                                                                                        | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                 | superiority                                     |
| Parameter estimate                                                                                                                                                                                                            | GMC ratio                                       |
| Point estimate                                                                                                                                                                                                                | 0.91                                            |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.69    |
| upper limit         | 1.2     |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 5: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 5: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMC ratio                                |
| Point estimate                          | 0.79                                     |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.57                                     |
| upper limit                             | 1.1                                      |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 6A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 6A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 2.14                                      |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 1.52                                      |
| upper limit                             | 3.02                                      |

|                                   |                                                  |
|-----------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b> | 6A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|--------------------------------------------------|

Statistical analysis description:

Serotype 6A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMC ratio                                  |
| Point estimate                          | 1.64                                       |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 1.16                                       |
| upper limit                             | 2.3                                        |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 6A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 6A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMC ratio                                |
| Point estimate                          | 0.76                                     |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.51                                     |
| upper limit                             | 1.14                                     |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 7F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 7F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 3.11                                      |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 2.23                                      |
| upper limit                             | 4.33                                      |



|                                                                                                                                                                                                                                                                     |                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                   | 7F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 7F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                  |
| Comparison groups                                                                                                                                                                                                                                                   | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                                                             | 178                                              |
| Analysis specification                                                                                                                                                                                                                                              | Pre-specified                                    |
| Analysis type                                                                                                                                                                                                                                                       | superiority                                      |
| Parameter estimate                                                                                                                                                                                                                                                  | GMC ratio                                        |
| Point estimate                                                                                                                                                                                                                                                      | 0.84                                             |
| Confidence interval                                                                                                                                                                                                                                                 |                                                  |
| level                                                                                                                                                                                                                                                               | 95 %                                             |
| sides                                                                                                                                                                                                                                                               | 2-sided                                          |
| lower limit                                                                                                                                                                                                                                                         | 0.61                                             |
| upper limit                                                                                                                                                                                                                                                         | 1.17                                             |

|                                                                                                                                                                                                                                                                   |                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                 | 7F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 7F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                |
| Comparison groups                                                                                                                                                                                                                                                 | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                                                           | 115                                            |
| Analysis specification                                                                                                                                                                                                                                            | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                                                     | superiority                                    |
| Parameter estimate                                                                                                                                                                                                                                                | GMC ratio                                      |
| Point estimate                                                                                                                                                                                                                                                    | 0.27                                           |
| Confidence interval                                                                                                                                                                                                                                               |                                                |
| level                                                                                                                                                                                                                                                             | 95 %                                           |
| sides                                                                                                                                                                                                                                                             | 2-sided                                        |
| lower limit                                                                                                                                                                                                                                                       | 0.19                                           |
| upper limit                                                                                                                                                                                                                                                       | 0.4                                            |

|                                                                                                                                                                                                                                                                     |                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                   | 19A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 19A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                                                                   | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC       |

|                                         |               |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 177           |
| Analysis specification                  | Pre-specified |
| Analysis type                           | superiority   |
| Parameter estimate                      | GMC ratio     |
| Point estimate                          | 1.82          |
| Confidence interval                     |               |
| level                                   | 95 %          |
| sides                                   | 2-sided       |
| lower limit                             | 1.25          |
| upper limit                             | 2.66          |

|                                                                                                                                                                                                                                 |                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                               | 19A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                               |                                                   |
| Serotype 19A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                   |
| Comparison groups                                                                                                                                                                                                               | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                                         | 178                                               |
| Analysis specification                                                                                                                                                                                                          | Pre-specified                                     |
| Analysis type                                                                                                                                                                                                                   | superiority                                       |
| Parameter estimate                                                                                                                                                                                                              | GMC ratio                                         |
| Point estimate                                                                                                                                                                                                                  | 1.33                                              |
| Confidence interval                                                                                                                                                                                                             |                                                   |
| level                                                                                                                                                                                                                           | 95 %                                              |
| sides                                                                                                                                                                                                                           | 2-sided                                           |
| lower limit                                                                                                                                                                                                                     | 0.91                                              |
| upper limit                                                                                                                                                                                                                     | 1.94                                              |

|                                                                                                                                                                                                                               |                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 19A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                 |
| Serotype 19A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                             | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                                       | 115                                             |
| Analysis specification                                                                                                                                                                                                        | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                 | superiority                                     |
| Parameter estimate                                                                                                                                                                                                            | GMC ratio                                       |
| Point estimate                                                                                                                                                                                                                | 0.73                                            |
| Confidence interval                                                                                                                                                                                                           |                                                 |
| level                                                                                                                                                                                                                         | 95 %                                            |
| sides                                                                                                                                                                                                                         | 2-sided                                         |
| lower limit                                                                                                                                                                                                                   | 0.47                                            |
| upper limit                                                                                                                                                                                                                   | 1.13                                            |

## Secondary: Serotype-specific Pneumococcal IgG GMC at 4 to 7 Days After the Single Dose of 13vPnC Vaccine

|                 |                                                                                               |
|-----------------|-----------------------------------------------------------------------------------------------|
| End point title | Serotype-specific Pneumococcal IgG GMC at 4 to 7 Days After the Single Dose of 13vPnC Vaccine |
|-----------------|-----------------------------------------------------------------------------------------------|

End point description:

IgG GMC to the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) were determined in the blood samples of all the subjects using a standardized anti-pneumococcal IgG ELISA. CIs for GMC are back transformations of a CI based on the Student t distribution for the mean logarithm of the concentrations. Evaluable immunogenicity population: eligible subjects, randomized, blood drawn within required timeframes, at least 1 valid and determinate assay result for proposed analysis, received no prohibited vaccines, no major protocol violations.

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

End point timeframe:

Four to seven days after vaccination

| End point values                         | 13vPnC/13vPnC/13vPnC  | 7vPnC/7vPnC/13vPnC    | 7vPnC/13vPnC/13vPnC   |  |
|------------------------------------------|-----------------------|-----------------------|-----------------------|--|
| Subject group type                       | Reporting group       | Reporting group       | Reporting group       |  |
| Number of subjects analysed              | 44 <sup>[7]</sup>     | 18 <sup>[8]</sup>     | 22 <sup>[9]</sup>     |  |
| Units: mcg/mL                            |                       |                       |                       |  |
| geometric mean (confidence interval 95%) |                       |                       |                       |  |
| Serotype 4                               | 2.96 (1.67 to 5.24)   | 4.66 (2.01 to 10.82)  | 3.85 (3.5 to 11.26)   |  |
| Serotype 6B                              | 17.78 (12.5 to 25.3)  | 19.15 (8.84 to 41.48) | 16.26 (3.51 to 18.23) |  |
| Serotype 9V                              | 3.49 (2.39 to 5.09)   | 3.15 (1.75 to 5.66)   | 3.2 (0.94 to 1.72)    |  |
| Serotype 14                              | 5.55 (3.32 to 9.3)    | 5.67 (2.29 to 13.99)  | 4.52 (5.29 to 18.19)  |  |
| Serotype 18C                             | 2.31 (1.36 to 3.91)   | 3.34 (1.66 to 6.72)   | 2.51 (3.95 to 13.78)  |  |
| Serotype 19F                             | 11.7 (7.21 to 19)     | 6.88 (2.98 to 15.86)  | 8.51 (1.72 to 5.51)   |  |
| Serotype 23F                             | 5.24 (3.49 to 7.87)   | 5.82 (2.97 to 11.4)   | 6.28 (7.12 to 15.5)   |  |
| Serotype 1                               | 4.24 (2.48 to 7.26)   | 0.56 (0.27 to 1.18)   | 8 (1.7 to 8.74)       |  |
| Serotype 3                               | 1.24 (0.79 to 1.95)   | 1.12 (0.56 to 2.25)   | 1.24 (8.1 to 32.66)   |  |
| Serotype 5                               | 6 (4.16 to 8.66)      | 1.43 (0.99 to 2.06)   | 9.81 (1.86 to 5.5)    |  |
| Serotype 6A                              | 13.86 (9.69 to 19.83) | 4.46 (2.18 to 9.12)   | 7.37 (2.14 to 9.52)   |  |
| Serotype 7F                              | 3.55 (2.35 to 5.36)   | 1.23 (0.69 to 2.21)   | 3.08 (1.33 to 4.73)   |  |
| Serotype 19A                             | 13.07 (9.63 to 17.74) | 5.09 (3.17 to 8.19)   | 10.5 (4.38 to 16.55)  |  |

Notes:

[7] - N= number of subjects with determinate IgG antibody concentration to serotype.

[8] - N= number of subjects with determinate IgG antibody concentration to serotype.

[9] - N= number of subjects with determinate IgG antibody concentration to serotype.

## Statistical analyses

|                                                                                                                                                                                                                              |                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                            | 4: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                            |                                               |
| Serotype 4: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                            | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC     |
| Number of subjects included in analysis                                                                                                                                                                                      | 62                                            |
| Analysis specification                                                                                                                                                                                                       | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                                | superiority                                   |
| Parameter estimate                                                                                                                                                                                                           | GMC ratio                                     |
| Point estimate                                                                                                                                                                                                               | 0.63                                          |
| Confidence interval                                                                                                                                                                                                          |                                               |
| level                                                                                                                                                                                                                        | 95 %                                          |
| sides                                                                                                                                                                                                                        | 2-sided                                       |
| lower limit                                                                                                                                                                                                                  | 0.23                                          |
| upper limit                                                                                                                                                                                                                  | 1.76                                          |

|                                                                                                                                                                                                                               |                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 4: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                 |
| Serotype 4: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                             | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                       | 66                                              |
| Analysis specification                                                                                                                                                                                                        | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                 | superiority                                     |
| Parameter estimate                                                                                                                                                                                                            | GMC ratio                                       |
| Point estimate                                                                                                                                                                                                                | 0.77                                            |
| Confidence interval                                                                                                                                                                                                           |                                                 |
| level                                                                                                                                                                                                                         | 95 %                                            |
| sides                                                                                                                                                                                                                         | 2-sided                                         |
| lower limit                                                                                                                                                                                                                   | 0.3                                             |
| upper limit                                                                                                                                                                                                                   | 1.99                                            |

|                                                                                                                                                                                                                             |                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                           | 4: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                           |                                               |
| Serotype 4: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                           | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                     | 40                                            |
| Analysis specification                                                                                                                                                                                                      | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                               | superiority                                   |
| Parameter estimate                                                                                                                                                                                                          | GMC ratio                                     |
| Point estimate                                                                                                                                                                                                              | 1.21                                          |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.38    |
| upper limit         | 3.86    |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 6B: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 6B: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 62                                        |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 0.93                                      |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.43                                      |
| upper limit                             | 1.99                                      |

|                                   |                                                  |
|-----------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b> | 6B: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|--------------------------------------------------|

Statistical analysis description:

Serotype 6B: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 66                                         |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMC ratio                                  |
| Point estimate                          | 1.09                                       |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.54                                       |
| upper limit                             | 2.22                                       |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 6B: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 6B: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 40                                       |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMC ratio                                |
| Point estimate                          | 1.18                                     |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.5                                      |
| upper limit                             | 2.79                                     |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 9V: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 9V: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 62                                        |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 1.11                                      |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.56                                      |
| upper limit                             | 2.19                                      |

|                                   |                                                  |
|-----------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b> | 9V: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|--------------------------------------------------|

Statistical analysis description:

Serotype 9V: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 66                                         |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMC ratio                                  |
| Point estimate                          | 1.09                                       |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.58                                       |
| upper limit                             | 2.06                                       |

|                                                                                                                                                                                                                                                                   |                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                 | 9V: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 9V: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                |
| Comparison groups                                                                                                                                                                                                                                                 | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                                                           | 40                                             |
| Analysis specification                                                                                                                                                                                                                                            | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                                                     | superiority                                    |
| Parameter estimate                                                                                                                                                                                                                                                | GMC ratio                                      |
| Point estimate                                                                                                                                                                                                                                                    | 0.98                                           |
| Confidence interval                                                                                                                                                                                                                                               |                                                |
| level                                                                                                                                                                                                                                                             | 95 %                                           |
| sides                                                                                                                                                                                                                                                             | 2-sided                                        |
| lower limit                                                                                                                                                                                                                                                       | 0.46                                           |
| upper limit                                                                                                                                                                                                                                                       | 2.13                                           |

|                                                                                                                                                                                                                                                                    |                                                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                  | 14: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 14: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                                |
| Comparison groups                                                                                                                                                                                                                                                  | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                                                            | 62                                             |
| Analysis specification                                                                                                                                                                                                                                             | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                                                      | superiority                                    |
| Parameter estimate                                                                                                                                                                                                                                                 | GMC ratio                                      |
| Point estimate                                                                                                                                                                                                                                                     | 0.98                                           |
| Confidence interval                                                                                                                                                                                                                                                |                                                |
| level                                                                                                                                                                                                                                                              | 95 %                                           |
| sides                                                                                                                                                                                                                                                              | 2-sided                                        |
| lower limit                                                                                                                                                                                                                                                        | 0.38                                           |
| upper limit                                                                                                                                                                                                                                                        | 2.55                                           |

|                                                                                                                                                                                                                                                                     |                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                   | 14: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 14: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                  |
| Comparison groups                                                                                                                                                                                                                                                   | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |

|                                         |               |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 66            |
| Analysis specification                  | Pre-specified |
| Analysis type                           | superiority   |
| Parameter estimate                      | GMC ratio     |
| Point estimate                          | 1.23          |
| Confidence interval                     |               |
| level                                   | 95 %          |
| sides                                   | 2-sided       |
| lower limit                             | 0.5           |
| upper limit                             | 3             |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 14: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 14: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 40                                       |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMC ratio                                |
| Point estimate                          | 1.25                                     |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.42                                     |
| upper limit                             | 3.72                                     |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 18C: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 18C: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 62                                        |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 0.69                                      |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.29                                      |
| upper limit                             | 1.68                                      |



|                                                                                                                                                                                                                                 |                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                               | 18C: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                               |                                                   |
| Serotype 18C: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                   |
| Comparison groups                                                                                                                                                                                                               | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                                         | 66                                                |
| Analysis specification                                                                                                                                                                                                          | Pre-specified                                     |
| Analysis type                                                                                                                                                                                                                   | superiority                                       |
| Parameter estimate                                                                                                                                                                                                              | GMC ratio                                         |
| Point estimate                                                                                                                                                                                                                  | 0.92                                              |
| Confidence interval                                                                                                                                                                                                             |                                                   |
| level                                                                                                                                                                                                                           | 95 %                                              |
| sides                                                                                                                                                                                                                           | 2-sided                                           |
| lower limit                                                                                                                                                                                                                     | 0.4                                               |
| upper limit                                                                                                                                                                                                                     | 2.1                                               |

|                                                                                                                                                                                                                               |                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 18C: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                 |
| Serotype 18C: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                             | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                                       | 40                                              |
| Analysis specification                                                                                                                                                                                                        | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                 | superiority                                     |
| Parameter estimate                                                                                                                                                                                                            | GMC ratio                                       |
| Point estimate                                                                                                                                                                                                                | 1.33                                            |
| Confidence interval                                                                                                                                                                                                           |                                                 |
| level                                                                                                                                                                                                                         | 95 %                                            |
| sides                                                                                                                                                                                                                         | 2-sided                                         |
| lower limit                                                                                                                                                                                                                   | 0.49                                            |
| upper limit                                                                                                                                                                                                                   | 3.64                                            |

|                                                                                                                                                                                                                                |                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                              | 19F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                              |                                                 |
| Serotype 19F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                              | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                        | 62                                              |
| Analysis specification                                                                                                                                                                                                         | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                  | superiority                                     |
| Parameter estimate                                                                                                                                                                                                             | GMC ratio                                       |
| Point estimate                                                                                                                                                                                                                 | 1.7                                             |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.7     |
| upper limit         | 4.12    |

|                                   |                                                   |
|-----------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b> | 19F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|---------------------------------------------------|

Statistical analysis description:

Serotype 19F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 66                                         |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMC ratio                                  |
| Point estimate                          | 1.37                                       |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.6                                        |
| upper limit                             | 3.14                                       |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 19F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 19F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 40                                       |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMC ratio                                |
| Point estimate                          | 0.81                                     |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.3                                      |
| upper limit                             | 2.21                                     |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 23F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 23F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 62                                        |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 0.9                                       |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.43                                      |
| upper limit                             | 1.89                                      |

|                                   |                                                   |
|-----------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b> | 23F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|---------------------------------------------------|

Statistical analysis description:

Serotype 23F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 66                                         |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMC ratio                                  |
| Point estimate                          | 0.83                                       |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.42                                       |
| upper limit                             | 1.67                                       |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 23F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 23F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 40                                       |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMC ratio                                |
| Point estimate                          | 0.93                                     |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.4                                      |
| upper limit                             | 2.16                                     |

|                                                                                                                                                                                                                              |                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                            | 1: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                            |                                               |
| Serotype 1: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                            | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC     |
| Number of subjects included in analysis                                                                                                                                                                                      | 62                                            |
| Analysis specification                                                                                                                                                                                                       | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                                | superiority                                   |
| Parameter estimate                                                                                                                                                                                                           | GMC ratio                                     |
| Point estimate                                                                                                                                                                                                               | 7.53                                          |
| Confidence interval                                                                                                                                                                                                          |                                               |
| level                                                                                                                                                                                                                        | 95 %                                          |
| sides                                                                                                                                                                                                                        | 2-sided                                       |
| lower limit                                                                                                                                                                                                                  | 2.86                                          |
| upper limit                                                                                                                                                                                                                  | 19.78                                         |

|                                                                                                                                                                                                                               |                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 1: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                 |
| Serotype 1: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                             | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                       | 66                                              |
| Analysis specification                                                                                                                                                                                                        | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                 | superiority                                     |
| Parameter estimate                                                                                                                                                                                                            | GMC ratio                                       |
| Point estimate                                                                                                                                                                                                                | 0.53                                            |
| Confidence interval                                                                                                                                                                                                           |                                                 |
| level                                                                                                                                                                                                                         | 95 %                                            |
| sides                                                                                                                                                                                                                         | 2-sided                                         |
| lower limit                                                                                                                                                                                                                   | 0.22                                            |
| upper limit                                                                                                                                                                                                                   | 1.31                                            |

|                                                                                                                                                                                                                             |                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                           | 1: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                           |                                               |
| Serotype 1: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                           | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |

|                                         |               |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 40            |
| Analysis specification                  | Pre-specified |
| Analysis type                           | superiority   |
| Parameter estimate                      | GMC ratio     |
| Point estimate                          | 0.07          |
| Confidence interval                     |               |
| level                                   | 95 %          |
| sides                                   | 2-sided       |
| lower limit                             | 0.02          |
| upper limit                             | 0.21          |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 3: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 3: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 62                                        |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 1.11                                      |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.53                                      |
| upper limit                             | 2.3                                       |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 3: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 3: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 66                                         |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMC ratio                                  |
| Point estimate                          | 1                                          |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.5                                        |
| upper limit                             | 1.97                                       |

|                                                                                                                                                                                                                             |                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                           | 3: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                           |                                               |
| Serotype 3: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                           | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                     | 40                                            |
| Analysis specification                                                                                                                                                                                                      | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                               | superiority                                   |
| Parameter estimate                                                                                                                                                                                                          | GMC ratio                                     |
| Point estimate                                                                                                                                                                                                              | 0.9                                           |
| Confidence interval                                                                                                                                                                                                         |                                               |
| level                                                                                                                                                                                                                       | 95 %                                          |
| sides                                                                                                                                                                                                                       | 2-sided                                       |
| lower limit                                                                                                                                                                                                                 | 0.39                                          |
| upper limit                                                                                                                                                                                                                 | 2.07                                          |

|                                                                                                                                                                                                                              |                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                            | 5: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                            |                                               |
| Serotype 5: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                            | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC     |
| Number of subjects included in analysis                                                                                                                                                                                      | 62                                            |
| Analysis specification                                                                                                                                                                                                       | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                                | superiority                                   |
| Parameter estimate                                                                                                                                                                                                           | GMC ratio                                     |
| Point estimate                                                                                                                                                                                                               | 4.2                                           |
| Confidence interval                                                                                                                                                                                                          |                                               |
| level                                                                                                                                                                                                                        | 95 %                                          |
| sides                                                                                                                                                                                                                        | 2-sided                                       |
| lower limit                                                                                                                                                                                                                  | 2.18                                          |
| upper limit                                                                                                                                                                                                                  | 8.09                                          |

|                                                                                                                                                                                                                               |                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 5: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                 |
| Serotype 5: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                             | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                       | 66                                              |
| Analysis specification                                                                                                                                                                                                        | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                 | superiority                                     |
| Parameter estimate                                                                                                                                                                                                            | GMC ratio                                       |
| Point estimate                                                                                                                                                                                                                | 0.61                                            |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.33    |
| upper limit         | 1.13    |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 5: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 5: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 40                                       |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMC ratio                                |
| Point estimate                          | 0.15                                     |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.07                                     |
| upper limit                             | 0.31                                     |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 6A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 6A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 62                                        |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 3.11                                      |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 1.51                                      |
| upper limit                             | 6.4                                       |

|                                   |                                                  |
|-----------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b> | 6A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|--------------------------------------------------|

Statistical analysis description:

Serotype 6A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 7vPnC/13vPnC/13vPnC v 13vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 66                                         |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMC ratio                                  |
| Point estimate                          | 1.88                                       |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.96                                       |
| upper limit                             | 3.69                                       |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 6A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 6A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 40                                       |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMC ratio                                |
| Point estimate                          | 0.6                                      |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.27                                     |
| upper limit                             | 1.37                                     |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 7F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 7F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 62                                        |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMC ratio                                 |
| Point estimate                          | 2.88                                      |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 1.39                                      |
| upper limit                             | 5.98                                      |



|                                                                                                                                                                                                                                                                     |                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                   | 7F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 7F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                  |
| Comparison groups                                                                                                                                                                                                                                                   | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                                                             | 66                                               |
| Analysis specification                                                                                                                                                                                                                                              | Pre-specified                                    |
| Analysis type                                                                                                                                                                                                                                                       | superiority                                      |
| Parameter estimate                                                                                                                                                                                                                                                  | GMC ratio                                        |
| Point estimate                                                                                                                                                                                                                                                      | 1.15                                             |
| Confidence interval                                                                                                                                                                                                                                                 |                                                  |
| level                                                                                                                                                                                                                                                               | 95 %                                             |
| sides                                                                                                                                                                                                                                                               | 2-sided                                          |
| lower limit                                                                                                                                                                                                                                                         | 0.58                                             |
| upper limit                                                                                                                                                                                                                                                         | 2.28                                             |

|                                                                                                                                                                                                                                                                   |                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                 | 7F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 7F: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                |
| Comparison groups                                                                                                                                                                                                                                                 | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                                                           | 40                                             |
| Analysis specification                                                                                                                                                                                                                                            | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                                                     | superiority                                    |
| Parameter estimate                                                                                                                                                                                                                                                | GMC ratio                                      |
| Point estimate                                                                                                                                                                                                                                                    | 0.4                                            |
| Confidence interval                                                                                                                                                                                                                                               |                                                |
| level                                                                                                                                                                                                                                                             | 95 %                                           |
| sides                                                                                                                                                                                                                                                             | 2-sided                                        |
| lower limit                                                                                                                                                                                                                                                       | 0.17                                           |
| upper limit                                                                                                                                                                                                                                                       | 0.92                                           |

|                                                                                                                                                                                                                                                                     |                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                   | 19A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 19A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                                                                   | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC       |

|                                         |               |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 62            |
| Analysis specification                  | Pre-specified |
| Analysis type                           | superiority   |
| Parameter estimate                      | GMC ratio     |
| Point estimate                          | 2.57          |
| Confidence interval                     |               |
| level                                   | 95 %          |
| sides                                   | 2-sided       |
| lower limit                             | 1.5           |
| upper limit                             | 4.39          |

|                                   |                                                   |
|-----------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b> | 19A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|---------------------------------------------------|

Statistical analysis description:

Serotype 19A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 66                                         |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMC ratio                                  |
| Point estimate                          | 1.24                                       |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.75                                       |
| upper limit                             | 2.05                                       |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 19A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 19A: CI for the GMC ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 40                                       |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMC ratio                                |
| Point estimate                          | 0.48                                     |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.26                                     |
| upper limit                             | 0.89                                     |

## Secondary: Serotype-specific Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMT) Prior to Single Dose of 13vPnC Vaccine

|                 |                                                                                                                      |
|-----------------|----------------------------------------------------------------------------------------------------------------------|
| End point title | Serotype-specific Opsonophagocytic Activity (OPA) Geometric Mean Titers (GMT) Prior to Single Dose of 13vPnC Vaccine |
|-----------------|----------------------------------------------------------------------------------------------------------------------|

End point description:

Pneumococcal OPA GMTs for 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) were determined in the blood samples of all the subjects using a microcolony OPA (mcOPA) assay. CIs for GMT are back transformations of a CI based on the Student t distribution for the mean logarithm of the titers. Evaluable immunogenicity population. n= number of subjects with a determinate OPA antibody titer to the given serotype. -99999 to 99999 for 13vPnC/13vPnC/13vPnC= Since all values for serotype 5 in 13v/13v/13v treatment arm was less than lower limit of quantification (LLOQ), values was set to 0.5 multiplied by (\*)limit of detection (LOD [8]) = 4. Hence variability (standard error) could not be estimated; CI was not estimable. -99999 to 99999 for 7vPnC/7vPnC/13vPnC= Since all values for serotype 5 in 7v/7v/13v treatment arm was less than LLOQ, values was set to 0.5\*LOD (8) = 4. Hence variability (standard error) could not be estimated; CI was not estimable.

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

End point timeframe:

Up to 7 days before vaccination

| End point values                         | 13vPnC/13vPnC/13vPnC | 7vPnC/7vPnC/13vPnC   | 7vPnC/13vPnC/13vPnC  |  |
|------------------------------------------|----------------------|----------------------|----------------------|--|
| Subject group type                       | Reporting group      | Reporting group      | Reporting group      |  |
| Number of subjects analysed              | 44 <sup>[10]</sup>   | 18 <sup>[11]</sup>   | 22 <sup>[12]</sup>   |  |
| Units: Geometric mean titers             |                      |                      |                      |  |
| geometric mean (confidence interval 95%) |                      |                      |                      |  |
| Serotype 4 (n= 40, 14, 19)               | 8 (4.4 to 13.1)      | 46 (7.8 to 268.5)    | 45 (10.6 to 190.6)   |  |
| Serotype 6B (n= 38, 16, 21)              | 245 (92.6 to 646.9)  | 247 (49.1 to 1241.8) | 332 (84.4 to 1304.3) |  |
| Serotype 9V (n= 40, 18, 21)              | 43 (16.3 to 111.9)   | 36 (8.6 to 149.1)    | 52 (14.6 to 187.8)   |  |
| Serotype 14 (n= 39, 16, 20)              | 98 (39.7 to 242.9)   | 40 (9.2 to 174.2)    | 49 (14.4 to 163.9)   |  |
| Serotype 18C (n= 42, 17, 19)             | 14 (6.9 to 27.7)     | 76 (15.7 to 363)     | 28 (7.2 to 109.7)    |  |
| Serotype 19F (n= 43, 17, 21)             | 48 (20.8 to 112.5)   | 49 (13 to 182.6)     | 40 (14 to 112.5)     |  |
| Serotype 23F (n= 43, 16, 21)             | 52 (22.5 to 120.3)   | 61 (13.1 to 284.3)   | 178 (54.6 to 578.7)  |  |
| Serotype 1 (n= 44, 18, 22)               | 6 (4.5 to 7.5)       | 5 (3.4 to 6.5)       | 10 (6.9 to 15)       |  |
| Serotype 3 (n= 42, 17, 21)               | 20 (11.8 to 34.6)    | 10 (4.4 to 22.2)     | 18 (12.1 to 28)      |  |
| Serotype 5 (n= 44, 18, 22)               | 4 (-99999 to 99999)  | 4 (-99999 to 99999)  | 4 (3.6 to 5.6)       |  |
| Serotype 6A (n= 44, 16, 21)              | 170 (72.8 to 395.5)  | 10 (3.4 to 31.4)     | 75 (22.3 to 253.9)   |  |
| Serotype 7F (n= 39, 16, 21)              | 60 (22.5 to 157.8)   | 47 (10 to 225.2)     | 389 (112 to 1351.1)  |  |
| Serotype 19A (n= 41, 18, 20)             | 118 (58.2 to 239.7)  | 25 (7.4 to 82)       | 124 (46.4 to 330.2)  |  |

Notes:

[10] - N= number of subjects analysed within a given treatment group.

[11] - N= number of subjects analysed within a given treatment group.

[12] - N= number of subjects analysed within a given treatment group.

## Statistical analyses

|                                                                                                                                                                                                                                                                   |                                               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                 | 4: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 4: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                                                                 | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC     |
| Number of subjects included in analysis                                                                                                                                                                                                                           | 62                                            |
| Analysis specification                                                                                                                                                                                                                                            | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                                                                     | superiority                                   |
| Parameter estimate                                                                                                                                                                                                                                                | GMT Ratio                                     |
| Point estimate                                                                                                                                                                                                                                                    | 0.2                                           |
| Confidence interval                                                                                                                                                                                                                                               |                                               |
| level                                                                                                                                                                                                                                                             | 95 %                                          |
| sides                                                                                                                                                                                                                                                             | 2-sided                                       |
| lower limit                                                                                                                                                                                                                                                       | 0.04                                          |
| upper limit                                                                                                                                                                                                                                                       | 0.73                                          |

|                                                                                                                                                                                                                                                                    |                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                  | 4: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 4: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                                                                  | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                                                            | 66                                              |
| Analysis specification                                                                                                                                                                                                                                             | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                                                      | superiority                                     |
| Parameter estimate                                                                                                                                                                                                                                                 | GMT Ratio                                       |
| Point estimate                                                                                                                                                                                                                                                     | 0.2                                             |
| Confidence interval                                                                                                                                                                                                                                                |                                                 |
| level                                                                                                                                                                                                                                                              | 95 %                                            |
| sides                                                                                                                                                                                                                                                              | 2-sided                                         |
| lower limit                                                                                                                                                                                                                                                        | 0.04                                            |
| upper limit                                                                                                                                                                                                                                                        | 0.64                                            |

|                                                                                                                                                                                                                                                                  |                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                | 4: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 4: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                                                                | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |

|                                         |               |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 40            |
| Analysis specification                  | Pre-specified |
| Analysis type                           | superiority   |
| Parameter estimate                      | GMT Ratio     |
| Point estimate                          | 1             |
| Confidence interval                     |               |
| level                                   | 95 %          |
| sides                                   | 2-sided       |
| lower limit                             | 0.19          |
| upper limit                             | 5.46          |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 6B: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 6B: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 62                                        |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMT ratio                                 |
| Point estimate                          | 1                                         |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.17                                      |
| upper limit                             | 5.85                                      |

|                                   |                                                  |
|-----------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b> | 6B: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|--------------------------------------------------|

Statistical analysis description:

Serotype 6B: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 66                                         |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMT ratio                                  |
| Point estimate                          | 0.7                                        |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.15                                       |
| upper limit                             | 3.72                                       |

|                                                                                                                                                                                                                              |                                                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                            | 6B: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                            |                                                |
| Serotype 6B: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                |
| Comparison groups                                                                                                                                                                                                            | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                      | 40                                             |
| Analysis specification                                                                                                                                                                                                       | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                | superiority                                    |
| Parameter estimate                                                                                                                                                                                                           | GMT ratio                                      |
| Point estimate                                                                                                                                                                                                               | 0.7                                            |
| Confidence interval                                                                                                                                                                                                          |                                                |
| level                                                                                                                                                                                                                        | 95 %                                           |
| sides                                                                                                                                                                                                                        | 2-sided                                        |
| lower limit                                                                                                                                                                                                                  | 0.1                                            |
| upper limit                                                                                                                                                                                                                  | 5.37                                           |

|                                                                                                                                                                                                                               |                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 9V: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                |
| Serotype 9V: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                                |
| Comparison groups                                                                                                                                                                                                             | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                       | 62                                             |
| Analysis specification                                                                                                                                                                                                        | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                 | superiority                                    |
| Parameter estimate                                                                                                                                                                                                            | GMT ratio                                      |
| Point estimate                                                                                                                                                                                                                | 1.2                                            |
| Confidence interval                                                                                                                                                                                                           |                                                |
| level                                                                                                                                                                                                                         | 95 %                                           |
| sides                                                                                                                                                                                                                         | 2-sided                                        |
| lower limit                                                                                                                                                                                                                   | 0.23                                           |
| upper limit                                                                                                                                                                                                                   | 6.25                                           |

|                                                                                                                                                                                                                                |                                                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                              | 9V: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                              |                                                  |
| Serotype 9V: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                  |
| Comparison groups                                                                                                                                                                                                              | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                        | 66                                               |
| Analysis specification                                                                                                                                                                                                         | Pre-specified                                    |
| Analysis type                                                                                                                                                                                                                  | superiority                                      |
| Parameter estimate                                                                                                                                                                                                             | GMT ratio                                        |
| Point estimate                                                                                                                                                                                                                 | 0.8                                              |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.17    |
| upper limit         | 3.92    |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 9V: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 9V: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 40                                       |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMT ratio                                |
| Point estimate                          | 0.7                                      |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.11                                     |
| upper limit                             | 4.43                                     |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 14: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 14: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 62                                        |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMT ratio                                 |
| Point estimate                          | 2.4                                       |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.48                                      |
| upper limit                             | 12.35                                     |

|                                   |                                                  |
|-----------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b> | 14: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|--------------------------------------------------|

Statistical analysis description:

Serotype 14: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 66                                         |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMT ratio                                  |
| Point estimate                          | 2                                          |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.45                                       |
| upper limit                             | 9.05                                       |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 14: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 14: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 40                                       |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMT ratio                                |
| Point estimate                          | 0.8                                      |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.13                                     |
| upper limit                             | 5.14                                     |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 18C: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 18C: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 62                                        |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMT ratio                                 |
| Point estimate                          | 0.2                                       |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.04                                      |
| upper limit                             | 0.8                                       |



|                                                                                                                                                                                                                                                                      |                                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                    | 18C: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 18C: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                   |
| Comparison groups                                                                                                                                                                                                                                                    | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                                                                              | 66                                                |
| Analysis specification                                                                                                                                                                                                                                               | Pre-specified                                     |
| Analysis type                                                                                                                                                                                                                                                        | superiority                                       |
| Parameter estimate                                                                                                                                                                                                                                                   | GMT ratio                                         |
| Point estimate                                                                                                                                                                                                                                                       | 0.5                                               |
| Confidence interval                                                                                                                                                                                                                                                  |                                                   |
| level                                                                                                                                                                                                                                                                | 95 %                                              |
| sides                                                                                                                                                                                                                                                                | 2-sided                                           |
| lower limit                                                                                                                                                                                                                                                          | 0.12                                              |
| upper limit                                                                                                                                                                                                                                                          | 2.03                                              |

|                                                                                                                                                                                                                                                                    |                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                  | 18C: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 18C: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                                                                  | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                                                                            | 40                                              |
| Analysis specification                                                                                                                                                                                                                                             | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                                                      | superiority                                     |
| Parameter estimate                                                                                                                                                                                                                                                 | GMT ratio                                       |
| Point estimate                                                                                                                                                                                                                                                     | 2.7                                             |
| Confidence interval                                                                                                                                                                                                                                                |                                                 |
| level                                                                                                                                                                                                                                                              | 95 %                                            |
| sides                                                                                                                                                                                                                                                              | 2-sided                                         |
| lower limit                                                                                                                                                                                                                                                        | 0.48                                            |
| upper limit                                                                                                                                                                                                                                                        | 14.92                                           |

|                                                                                                                                                                                                                                                                     |                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                   | 19F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 19F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                                                                   | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC       |

|                                         |               |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 62            |
| Analysis specification                  | Pre-specified |
| Analysis type                           | superiority   |
| Parameter estimate                      | GMT ratio     |
| Point estimate                          | 1             |
| Confidence interval                     |               |
| level                                   | 95 %          |
| sides                                   | 2-sided       |
| lower limit                             | 0.23          |
| upper limit                             | 4.36          |

|                                   |                                                   |
|-----------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b> | 19F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|---------------------------------------------------|

Statistical analysis description:

Serotype 19F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 66                                         |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMT ratio                                  |
| Point estimate                          | 1.2                                        |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.31                                       |
| upper limit                             | 4.84                                       |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 19F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 19F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 40                                       |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMT ratio                                |
| Point estimate                          | 1.2                                      |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.23                                     |
| upper limit                             | 6.65                                     |

|                                                                                                                                                                                                                                |                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                              | 23F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                              |                                                 |
| Serotype 23F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                              | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                        | 62                                              |
| Analysis specification                                                                                                                                                                                                         | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                  | superiority                                     |
| Parameter estimate                                                                                                                                                                                                             | GMT ratio                                       |
| Point estimate                                                                                                                                                                                                                 | 0.9                                             |
| Confidence interval                                                                                                                                                                                                            |                                                 |
| level                                                                                                                                                                                                                          | 95 %                                            |
| sides                                                                                                                                                                                                                          | 2-sided                                         |
| lower limit                                                                                                                                                                                                                    | 0.17                                            |
| upper limit                                                                                                                                                                                                                    | 4.17                                            |

|                                                                                                                                                                                                                                 |                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                               | 23F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                               |                                                   |
| Serotype 23F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                   |
| Comparison groups                                                                                                                                                                                                               | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                                         | 66                                                |
| Analysis specification                                                                                                                                                                                                          | Pre-specified                                     |
| Analysis type                                                                                                                                                                                                                   | superiority                                       |
| Parameter estimate                                                                                                                                                                                                              | GMT ratio                                         |
| Point estimate                                                                                                                                                                                                                  | 0.3                                               |
| Confidence interval                                                                                                                                                                                                             |                                                   |
| level                                                                                                                                                                                                                           | 95 %                                              |
| sides                                                                                                                                                                                                                           | 2-sided                                           |
| lower limit                                                                                                                                                                                                                     | 0.07                                              |
| upper limit                                                                                                                                                                                                                     | 1.24                                              |

|                                                                                                                                                                                                                               |                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 23F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                 |
| Serotype 23F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                             | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                                       | 40                                              |
| Analysis specification                                                                                                                                                                                                        | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                 | superiority                                     |
| Parameter estimate                                                                                                                                                                                                            | GMT ratio                                       |
| Point estimate                                                                                                                                                                                                                | 0.3                                             |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.06    |
| upper limit         | 2.08    |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 1: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 1: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 62                                        |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMT ratio                                 |
| Point estimate                          | 1.3                                       |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.79                                      |
| upper limit                             | 1.97                                      |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 1: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 1: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 66                                         |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMT ratio                                  |
| Point estimate                          | 0.6                                        |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.38                                       |
| upper limit                             | 0.88                                       |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 1: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 1: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 40                                       |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMT ratio                                |
| Point estimate                          | 0.5                                      |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.27                                     |
| upper limit                             | 0.77                                     |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 3: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 3: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 62                                        |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMT ratio                                 |
| Point estimate                          | 2                                         |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.85                                      |
| upper limit                             | 4.9                                       |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 3: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 3: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 66                                         |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMT ratio                                  |
| Point estimate                          | 1.1                                        |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.49                                       |
| upper limit                             | 2.48                                       |

|                                                                                                                                                                                                                             |                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                           | 3: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                           |                                               |
| Serotype 3: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                           | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                     | 40                                            |
| Analysis specification                                                                                                                                                                                                      | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                               | superiority                                   |
| Parameter estimate                                                                                                                                                                                                          | GMT ratio                                     |
| Point estimate                                                                                                                                                                                                              | 0.5                                           |
| Confidence interval                                                                                                                                                                                                         |                                               |
| level                                                                                                                                                                                                                       | 95 %                                          |
| sides                                                                                                                                                                                                                       | 2-sided                                       |
| lower limit                                                                                                                                                                                                                 | 0.2                                           |
| upper limit                                                                                                                                                                                                                 | 1.45                                          |

|                                                                                                                                                                                                                              |                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                            | 5: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                            |                                               |
| Serotype 5: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                            | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC     |
| Number of subjects included in analysis                                                                                                                                                                                      | 62                                            |
| Analysis specification                                                                                                                                                                                                       | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                                | superiority                                   |
| Parameter estimate                                                                                                                                                                                                           | GMT ratio                                     |
| Point estimate                                                                                                                                                                                                               | 1                                             |
| Confidence interval                                                                                                                                                                                                          |                                               |
| level                                                                                                                                                                                                                        | 95 %                                          |
| sides                                                                                                                                                                                                                        | 2-sided                                       |
| lower limit                                                                                                                                                                                                                  | 0.87                                          |
| upper limit                                                                                                                                                                                                                  | 1.15                                          |

|                                                                                                                                                                                                                               |                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 5: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                 |
| Serotype 5: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                             | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |

|                                         |               |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 66            |
| Analysis specification                  | Pre-specified |
| Analysis type                           | superiority   |
| Parameter estimate                      | GMT ratio     |
| Point estimate                          | 0.9           |
| Confidence interval                     |               |
| level                                   | 95 %          |
| sides                                   | 2-sided       |
| lower limit                             | 0.79          |
| upper limit                             | 1.03          |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 5: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 5: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 40                                       |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMT ratio                                |
| Point estimate                          | 0.9                                      |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.76                                     |
| upper limit                             | 1.06                                     |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 6A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 6A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 13vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 62                                        |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMT ratio                                 |
| Point estimate                          | 16.5                                      |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 3.56                                      |
| upper limit                             | 76.14                                     |

|                                                                                                                                                                                                                                |                                                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                              | 6A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                              |                                                  |
| Serotype 6A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                  |
| Comparison groups                                                                                                                                                                                                              | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                        | 66                                               |
| Analysis specification                                                                                                                                                                                                         | Pre-specified                                    |
| Analysis type                                                                                                                                                                                                                  | superiority                                      |
| Parameter estimate                                                                                                                                                                                                             | GMT ratio                                        |
| Point estimate                                                                                                                                                                                                                 | 2.3                                              |
| Confidence interval                                                                                                                                                                                                            |                                                  |
| level                                                                                                                                                                                                                          | 95 %                                             |
| sides                                                                                                                                                                                                                          | 2-sided                                          |
| lower limit                                                                                                                                                                                                                    | 0.56                                             |
| upper limit                                                                                                                                                                                                                    | 9.06                                             |

|                                                                                                                                                                                                                              |                                                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                            | 6A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                            |                                                |
| Serotype 6A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                |
| Comparison groups                                                                                                                                                                                                            | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                      | 40                                             |
| Analysis specification                                                                                                                                                                                                       | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                | superiority                                    |
| Parameter estimate                                                                                                                                                                                                           | GMT ratio                                      |
| Point estimate                                                                                                                                                                                                               | 0.1                                            |
| Confidence interval                                                                                                                                                                                                          |                                                |
| level                                                                                                                                                                                                                        | 95 %                                           |
| sides                                                                                                                                                                                                                        | 2-sided                                        |
| lower limit                                                                                                                                                                                                                  | 0.02                                           |
| upper limit                                                                                                                                                                                                                  | 0.78                                           |

|                                                                                                                                                                                                                               |                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 7F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                |
| Serotype 7F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                                |
| Comparison groups                                                                                                                                                                                                             | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                       | 62                                             |
| Analysis specification                                                                                                                                                                                                        | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                 | superiority                                    |
| Parameter estimate                                                                                                                                                                                                            | GMT ratio                                      |
| Point estimate                                                                                                                                                                                                                | 1.3                                            |



|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.22    |
| upper limit         | 7.07    |

|                                   |                                                  |
|-----------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b> | 7F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|--------------------------------------------------|

Statistical analysis description:

Serotype 7F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 66                                         |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMT ratio                                  |
| Point estimate                          | 0.2                                        |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.03                                       |
| upper limit                             | 0.74                                       |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 7F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 7F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 40                                       |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMT ratio                                |
| Point estimate                          | 0.1                                      |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.02                                     |
| upper limit                             | 0.84                                     |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 19A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 19A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 62                                        |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMT ratio                                 |
| Point estimate                          | 4.8                                       |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 1.35                                      |
| upper limit                             | 16.98                                     |

|                                   |                                                   |
|-----------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b> | 19A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|---------------------------------------------------|

Statistical analysis description:

Serotype 19A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 66                                         |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMT ratio                                  |
| Point estimate                          | 1                                          |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.28                                       |
| upper limit                             | 3.23                                       |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 19A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 19A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 40                                       |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMT ratio                                |
| Point estimate                          | 0.2                                      |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.05                                     |
| upper limit                             | 0.85                                     |

## Secondary: Serotype-specific OPA GMTs 1 Month After Single Dose of 13vPnC Vaccine

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                        |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Serotype-specific OPA GMTs 1 Month After Single Dose of 13vPnC Vaccine |
| End point description:<br>Serotype-specific pneumococcal OPA GMTs for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) were determined in the blood samples of all the subjects using mcOPA assay. CIs for GMT are back transformations of a CI based on the Student t distribution for the mean logarithm of the titers. Evaluable immunogenicity population. n= number of subjects with a determinate OPA antibody titer to the given serotype. |                                                                        |
| End point type                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Secondary                                                              |
| End point timeframe:<br>One month after vaccination                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                        |

| End point values                         | 13vPnC/13vPnC/13vPnC    | 7vPnC/7vPnC/13vPnC        | 7vPnC/13vPnC/13vPnC      |  |
|------------------------------------------|-------------------------|---------------------------|--------------------------|--|
| Subject group type                       | Reporting group         | Reporting group           | Reporting group          |  |
| Number of subjects analysed              | 120 <sup>[13]</sup>     | 57 <sup>[14]</sup>        | 58 <sup>[15]</sup>       |  |
| Units: Geometric mean titers             |                         |                           |                          |  |
| geometric mean (confidence interval 95%) |                         |                           |                          |  |
| Serotype 4 (n= 117, 53, 55)              | 5465 (4698.9 to 6356.4) | 5208 (4301.7 to 6304.2)   | 5487 (4236.9 to 7106.4)  |  |
| Serotype 6B (n= 117, 57, 56)             | 6684 (5638.4 to 7924.4) | 10042 (7697.5 to 13101.6) | 8983 (7006.9 to 11516.8) |  |
| Serotype 9V (n= 116, 54, 55)             | 5120 (4456.1 to 5882.6) | 4052 (3291 to 4989.7)     | 5221 (4110.4 to 6630.7)  |  |
| Serotype 14 (n= 115, 54, 55)             | 2780 (2374.7 to 3254.6) | 3079 (2450.6 to 3869.4)   | 2979 (2232.9 to 3973.4)  |  |
| Serotype 18C (n= 117, 54, 57)            | 7711 (6589.6 to 9023.3) | 7091 (5655.9 to 8889.9)   | 8431 (6740.3 to 10545.7) |  |
| Serotype 19F (n= 118, 57, 57)            | 1319 (1030.5 to 1689.5) | 1721 (1316.8 to 2250.3)   | 1914 (1350.6 to 2712.5)  |  |
| Serotype 23F (n= 118, 53, 56)            | 2427 (2063.6 to 2855)   | 2411 (1792.5 to 3242.4)   | 2673 (2091.2 to 3417.3)  |  |
| Serotype 1 (n= 119, 56, 57)              | 613 (525.2 to 715.7)    | 197 (161.4 to 239.4)      | 1212 (968 to 1516.9)     |  |
| Serotype 3 (n= 118, 56, 58)              | 244 (214.7 to 276.4)    | 173 (139.5 to 214.5)      | 291 (239.4 to 353.7)     |  |
| Serotype 5 (n= 118, 55, 54)              | 455 (358.7 to 537.9)    | 390 (281.2 to 541.8)      | 728 (545 to 972.2)       |  |
| Serotype 6A (n= 117, 55, 55)             | 5580 (4593.6 to 6777)   | 5596 (4276.6 to 7321.2)   | 5982 (4450.7 to 8041.1)  |  |
| Serotype 7F (n= 118, 56, 54)             | 4323 (3794.4 to 4925.1) | 8048 (6500.9 to 9962.2)   | 4056 (3092.2 to 5321.2)  |  |
| Serotype 19A (n= 116, 53, 54)            | 1212 (1048.1 to 1400.7) | 1249 (956.5 to 1632.3)    | 1568 (1249.7 to 1966.1)  |  |

Notes:

[13] - N= number of subjects analysed within a given treatment group

[14] - N= number of subjects analysed within a given treatment group

[15] - N= number of subjects analysed within a given treatment group

## Statistical analyses

|                                                                                                                                                                                                                                                                   |                                               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                 | 4: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 4: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                                                                 | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC     |
| Number of subjects included in analysis                                                                                                                                                                                                                           | 177                                           |
| Analysis specification                                                                                                                                                                                                                                            | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                                                                     | superiority                                   |
| Parameter estimate                                                                                                                                                                                                                                                | GMT Ratio                                     |
| Point estimate                                                                                                                                                                                                                                                    | 1                                             |
| Confidence interval                                                                                                                                                                                                                                               |                                               |
| level                                                                                                                                                                                                                                                             | 95 %                                          |
| sides                                                                                                                                                                                                                                                             | 2-sided                                       |
| lower limit                                                                                                                                                                                                                                                       | 0.8                                           |
| upper limit                                                                                                                                                                                                                                                       | 1.38                                          |

|                                                                                                                                                                                                                                                                    |                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                  | 4: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 4: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                                                                  | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                                                            | 178                                             |
| Analysis specification                                                                                                                                                                                                                                             | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                                                      | superiority                                     |
| Parameter estimate                                                                                                                                                                                                                                                 | GMT Ratio                                       |
| Point estimate                                                                                                                                                                                                                                                     | 1                                               |
| Confidence interval                                                                                                                                                                                                                                                |                                                 |
| level                                                                                                                                                                                                                                                              | 95 %                                            |
| sides                                                                                                                                                                                                                                                              | 2-sided                                         |
| lower limit                                                                                                                                                                                                                                                        | 0.76                                            |
| upper limit                                                                                                                                                                                                                                                        | 1.3                                             |

|                                                                                                                                                                                                                                                                  |                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                | 4: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 4: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                                                                | 7vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC      |

|                                         |               |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 115           |
| Analysis specification                  | Pre-specified |
| Analysis type                           | superiority   |
| Parameter estimate                      | GMT Ratio     |
| Point estimate                          | 0.9           |
| Confidence interval                     |               |
| level                                   | 95 %          |
| sides                                   | 2-sided       |
| lower limit                             | 0.69          |
| upper limit                             | 1.3           |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 6B: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 6B: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMT ratio                                 |
| Point estimate                          | 0.7                                       |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.49                                      |
| upper limit                             | 0.9                                       |

|                                   |                                                  |
|-----------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b> | 6B: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|--------------------------------------------------|

Statistical analysis description:

Serotype 6B: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 7vPnC/13vPnC/13vPnC v 13vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMT ratio                                  |
| Point estimate                          | 0.7                                        |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.55                                       |
| upper limit                             | 1.01                                       |

|                                                                                                                                                                                                                              |                                                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                            | 6B: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                            |                                                |
| Serotype 6B: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                |
| Comparison groups                                                                                                                                                                                                            | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                      | 115                                            |
| Analysis specification                                                                                                                                                                                                       | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                | superiority                                    |
| Parameter estimate                                                                                                                                                                                                           | GMT ratio                                      |
| Point estimate                                                                                                                                                                                                               | 1.1                                            |
| Confidence interval                                                                                                                                                                                                          |                                                |
| level                                                                                                                                                                                                                        | 95 %                                           |
| sides                                                                                                                                                                                                                        | 2-sided                                        |
| lower limit                                                                                                                                                                                                                  | 0.79                                           |
| upper limit                                                                                                                                                                                                                  | 1.59                                           |

|                                                                                                                                                                                                                               |                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 9V: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                |
| Serotype 9V: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                                |
| Comparison groups                                                                                                                                                                                                             | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                       | 177                                            |
| Analysis specification                                                                                                                                                                                                        | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                 | superiority                                    |
| Parameter estimate                                                                                                                                                                                                            | GMT ratio                                      |
| Point estimate                                                                                                                                                                                                                | 1.3                                            |
| Confidence interval                                                                                                                                                                                                           |                                                |
| level                                                                                                                                                                                                                         | 95 %                                           |
| sides                                                                                                                                                                                                                         | 2-sided                                        |
| lower limit                                                                                                                                                                                                                   | 0.98                                           |
| upper limit                                                                                                                                                                                                                   | 1.63                                           |

|                                                                                                                                                                                                                                |                                                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                              | 9V: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                              |                                                  |
| Serotype 9V: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                  |
| Comparison groups                                                                                                                                                                                                              | 7vPnC/13vPnC/13vPnC v 13vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                        | 178                                              |
| Analysis specification                                                                                                                                                                                                         | Pre-specified                                    |
| Analysis type                                                                                                                                                                                                                  | superiority                                      |
| Parameter estimate                                                                                                                                                                                                             | GMT ratio                                        |
| Point estimate                                                                                                                                                                                                                 | 1                                                |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.76    |
| upper limit         | 1.27    |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 9V: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 9V: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMT ratio                                |
| Point estimate                          | 0.8                                      |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.58    |
| upper limit         | 1.05    |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 14: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 14: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 13vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMT ratio                                 |
| Point estimate                          | 0.9                                       |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.67    |
| upper limit         | 1.21    |

|                                   |                                                  |
|-----------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b> | 14: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|--------------------------------------------------|

Statistical analysis description:

Serotype 14: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMT ratio                                  |
| Point estimate                          | 0.9                                        |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.7                                        |
| upper limit                             | 1.25                                       |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 14: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 14: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMT ratio                                |
| Point estimate                          | 1                                        |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.73                                     |
| upper limit                             | 1.46                                     |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 18C: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 18C: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMT ratio                                 |
| Point estimate                          | 1.1                                       |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.83                                      |
| upper limit                             | 1.43                                      |



|                                                                                                                                                                                                                                                                      |                                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                    | 18C: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 18C: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                   |
| Comparison groups                                                                                                                                                                                                                                                    | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                                                                              | 178                                               |
| Analysis specification                                                                                                                                                                                                                                               | Pre-specified                                     |
| Analysis type                                                                                                                                                                                                                                                        | superiority                                       |
| Parameter estimate                                                                                                                                                                                                                                                   | GMT ratio                                         |
| Point estimate                                                                                                                                                                                                                                                       | 0.9                                               |
| Confidence interval                                                                                                                                                                                                                                                  |                                                   |
| level                                                                                                                                                                                                                                                                | 95 %                                              |
| sides                                                                                                                                                                                                                                                                | 2-sided                                           |
| lower limit                                                                                                                                                                                                                                                          | 0.7                                               |
| upper limit                                                                                                                                                                                                                                                          | 1.2                                               |

|                                                                                                                                                                                                                                                                    |                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                  | 18C: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 18C: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                                                                  | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                                                                            | 115                                             |
| Analysis specification                                                                                                                                                                                                                                             | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                                                      | superiority                                     |
| Parameter estimate                                                                                                                                                                                                                                                 | GMT ratio                                       |
| Point estimate                                                                                                                                                                                                                                                     | 0.8                                             |
| Confidence interval                                                                                                                                                                                                                                                |                                                 |
| level                                                                                                                                                                                                                                                              | 95 %                                            |
| sides                                                                                                                                                                                                                                                              | 2-sided                                         |
| lower limit                                                                                                                                                                                                                                                        | 0.61                                            |
| upper limit                                                                                                                                                                                                                                                        | 1.15                                            |

|                                                                                                                                                                                                                                                                     |                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                   | 19F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:<br>Serotype 19F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                                                                   | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC       |

|                                         |               |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 177           |
| Analysis specification                  | Pre-specified |
| Analysis type                           | superiority   |
| Parameter estimate                      | GMT ratio     |
| Point estimate                          | 0.8           |
| Confidence interval                     |               |
| level                                   | 95 %          |
| sides                                   | 2-sided       |
| lower limit                             | 0.51          |
| upper limit                             | 1.15          |

|                                   |                                                   |
|-----------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b> | 19F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|---------------------------------------------------|

Statistical analysis description:

Serotype 19F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMT ratio                                  |
| Point estimate                          | 0.7                                        |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.46                                       |
| upper limit                             | 1.03                                       |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 19F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 19F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMT ratio                                |
| Point estimate                          | 0.9                                      |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.56                                     |
| upper limit                             | 1.44                                     |

|                                                                                                                                                                                                                                |                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                              | 23F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                              |                                                 |
| Serotype 23F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                              | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                        | 177                                             |
| Analysis specification                                                                                                                                                                                                         | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                  | superiority                                     |
| Parameter estimate                                                                                                                                                                                                             | GMT ratio                                       |
| Point estimate                                                                                                                                                                                                                 | 1                                               |
| Confidence interval                                                                                                                                                                                                            |                                                 |
| level                                                                                                                                                                                                                          | 95 %                                            |
| sides                                                                                                                                                                                                                          | 2-sided                                         |
| lower limit                                                                                                                                                                                                                    | 0.74                                            |
| upper limit                                                                                                                                                                                                                    | 1.37                                            |

|                                                                                                                                                                                                                                 |                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                               | 23F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                               |                                                   |
| Serotype 23F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                   |
| Comparison groups                                                                                                                                                                                                               | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                                         | 178                                               |
| Analysis specification                                                                                                                                                                                                          | Pre-specified                                     |
| Analysis type                                                                                                                                                                                                                   | superiority                                       |
| Parameter estimate                                                                                                                                                                                                              | GMT ratio                                         |
| Point estimate                                                                                                                                                                                                                  | 0.9                                               |
| Confidence interval                                                                                                                                                                                                             |                                                   |
| level                                                                                                                                                                                                                           | 95 %                                              |
| sides                                                                                                                                                                                                                           | 2-sided                                           |
| lower limit                                                                                                                                                                                                                     | 0.67                                              |
| upper limit                                                                                                                                                                                                                     | 1.23                                              |

|                                                                                                                                                                                                                               |                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 23F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                 |
| Serotype 23F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                             | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                                       | 115                                             |
| Analysis specification                                                                                                                                                                                                        | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                 | superiority                                     |
| Parameter estimate                                                                                                                                                                                                            | GMT ratio                                       |
| Point estimate                                                                                                                                                                                                                | 0.9                                             |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.63    |
| upper limit         | 1.29    |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 1: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 1: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMT ratio                                 |
| Point estimate                          | 3.1                                       |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 2.4                                       |
| upper limit                             | 4.06                                      |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 1: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 1: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMT ratio                                  |
| Point estimate                          | 0.5                                        |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.39                                       |
| upper limit                             | 0.66                                       |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 1: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 1: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMT ratio                                |
| Point estimate                          | 0.2                                      |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.12                                     |
| upper limit                             | 0.22                                     |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 3: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 3: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMT ratio                                 |
| Point estimate                          | 1.4                                       |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 1.11                                      |
| upper limit                             | 1.78                                      |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 3: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 3: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMT ratio                                  |
| Point estimate                          | 0.8                                        |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.66                                       |
| upper limit                             | 1.06                                       |

|                                                                                                                                                                                                                             |                                               |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                           | 3: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                           |                                               |
| Serotype 3: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                           | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                     | 115                                           |
| Analysis specification                                                                                                                                                                                                      | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                               | superiority                                   |
| Parameter estimate                                                                                                                                                                                                          | GMT ratio                                     |
| Point estimate                                                                                                                                                                                                              | 0.6                                           |
| Confidence interval                                                                                                                                                                                                         |                                               |
| level                                                                                                                                                                                                                       | 95 %                                          |
| sides                                                                                                                                                                                                                       | 2-sided                                       |
| lower limit                                                                                                                                                                                                                 | 0.45                                          |
| upper limit                                                                                                                                                                                                                 | 0.78                                          |

|                                                                                                                                                                                                                              |                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                            | 5: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                            |                                               |
| Serotype 5: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                               |
| Comparison groups                                                                                                                                                                                                            | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC     |
| Number of subjects included in analysis                                                                                                                                                                                      | 177                                           |
| Analysis specification                                                                                                                                                                                                       | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                                | superiority                                   |
| Parameter estimate                                                                                                                                                                                                           | GMT ratio                                     |
| Point estimate                                                                                                                                                                                                               | 1.2                                           |
| Confidence interval                                                                                                                                                                                                          |                                               |
| level                                                                                                                                                                                                                        | 95 %                                          |
| sides                                                                                                                                                                                                                        | 2-sided                                       |
| lower limit                                                                                                                                                                                                                  | 0.84                                          |
| upper limit                                                                                                                                                                                                                  | 1.62                                          |

|                                                                                                                                                                                                                               |                                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 5: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                 |
| Serotype 5: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                 |
| Comparison groups                                                                                                                                                                                                             | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |

|                                         |               |
|-----------------------------------------|---------------|
| Number of subjects included in analysis | 178           |
| Analysis specification                  | Pre-specified |
| Analysis type                           | superiority   |
| Parameter estimate                      | GMT ratio     |
| Point estimate                          | 0.6           |
| Confidence interval                     |               |
| level                                   | 95 %          |
| sides                                   | 2-sided       |
| lower limit                             | 0.45          |
| upper limit                             | 0.87          |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 5: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 5: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMT ratio                                |
| Point estimate                          | 0.5                                      |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.36                                     |
| upper limit                             | 0.79                                     |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 6A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 6A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | GMT ratio                                 |
| Point estimate                          | 1                                         |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | 0.71                                      |
| upper limit                             | 1.4                                       |

|                                                                                                                                                                                                                                |                                                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                              | 6A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                              |                                                  |
| Serotype 6A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                  |
| Comparison groups                                                                                                                                                                                                              | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                        | 178                                              |
| Analysis specification                                                                                                                                                                                                         | Pre-specified                                    |
| Analysis type                                                                                                                                                                                                                  | superiority                                      |
| Parameter estimate                                                                                                                                                                                                             | GMT ratio                                        |
| Point estimate                                                                                                                                                                                                                 | 0.9                                              |
| Confidence interval                                                                                                                                                                                                            |                                                  |
| level                                                                                                                                                                                                                          | 95 %                                             |
| sides                                                                                                                                                                                                                          | 2-sided                                          |
| lower limit                                                                                                                                                                                                                    | 0.66                                             |
| upper limit                                                                                                                                                                                                                    | 1.31                                             |

|                                                                                                                                                                                                                              |                                                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                            | 6A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                            |                                                |
| Serotype 6A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC). |                                                |
| Comparison groups                                                                                                                                                                                                            | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                      | 115                                            |
| Analysis specification                                                                                                                                                                                                       | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                | superiority                                    |
| Parameter estimate                                                                                                                                                                                                           | GMT ratio                                      |
| Point estimate                                                                                                                                                                                                               | 0.9                                            |
| Confidence interval                                                                                                                                                                                                          |                                                |
| level                                                                                                                                                                                                                        | 95 %                                           |
| sides                                                                                                                                                                                                                        | 2-sided                                        |
| lower limit                                                                                                                                                                                                                  | 0.63                                           |
| upper limit                                                                                                                                                                                                                  | 1.39                                           |

|                                                                                                                                                                                                                               |                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                             | 7F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                             |                                                |
| Serotype 7F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC). |                                                |
| Comparison groups                                                                                                                                                                                                             | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                       | 177                                            |
| Analysis specification                                                                                                                                                                                                        | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                 | superiority                                    |
| Parameter estimate                                                                                                                                                                                                            | GMT ratio                                      |
| Point estimate                                                                                                                                                                                                                | 0.5                                            |



|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | 0.41    |
| upper limit         | 0.7     |

|                                   |                                                  |
|-----------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b> | 7F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|--------------------------------------------------|

Statistical analysis description:

Serotype 7F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMT ratio                                  |
| Point estimate                          | 1.1                                        |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.82                                       |
| upper limit                             | 1.38                                       |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 7F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 7F: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMT ratio                                |
| Point estimate                          | 2                                        |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 1.46                                     |
| upper limit                             | 2.69                                     |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 19A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 19A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/7vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMT ratio                                |
| Point estimate                          | 1                                        |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.74                                     |
| upper limit                             | 1.28                                     |

|                                   |                                                   |
|-----------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b> | 19A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|---------------------------------------------------|

Statistical analysis description:

Serotype 19A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (13vPnC/13vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | GMT ratio                                  |
| Point estimate                          | 0.8                                        |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | 0.59                                       |
| upper limit                             | 1.02                                       |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 19A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 19A: CI for the GMT ratio was calculated by the back transformations of CI based on the Student t distribution for the mean difference of the logarithms of the measures (7vPnC/7vPnC/13vPnC - 7vPnC/13vPnC/13vPnC).

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | GMT ratio                                |
| Point estimate                          | 0.8                                      |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | 0.58                                     |
| upper limit                             | 1.1                                      |

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**Secondary: Percentage of Subjects With at Least 1/8 Serotype-specific OPA GMTs After Single Dose of 13vPnC Vaccine**

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|                 |                                                                                                         |
|-----------------|---------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects With at Least 1/8 Serotype-specific OPA GMTs After Single Dose of 13vPnC Vaccine |
|-----------------|---------------------------------------------------------------------------------------------------------|

End point description:

Percentage of subjects with at least 1/8 serotype-specific pneumococcal OPA GMTs for the 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) determined in the blood samples of all subjects. The data was not collected as planned as the additional, more stringent qualification and validation of the improved mcOPA assays used in this study did not support 1/8 for the quantitation of a serum response and thus the established LLOQ was used for the mcOPA assay.

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

End point timeframe:

One month after vaccination

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| End point values              | 13vPnC/13vPnC/13vPnC | 7vPnC/7vPnC/13vPnC | 7vPnC/13vPnC/13vPnC |  |
|-------------------------------|----------------------|--------------------|---------------------|--|
| Subject group type            | Reporting group      | Reporting group    | Reporting group     |  |
| Number of subjects analysed   | 0 <sup>[16]</sup>    | 0 <sup>[17]</sup>  | 0 <sup>[18]</sup>   |  |
| Units: percentage of subjects |                      |                    |                     |  |
| number (not applicable)       |                      |                    |                     |  |

Notes:

[16] - The data was not collected as planned, instead LLOQ was used for the mcOPA assay.

[17] - The data was not collected as planned, instead LLOQ was used for the mcOPA assay.

[18] - The data was not collected as planned, instead LLOQ was used for the mcOPA assay.

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**Statistical analyses**

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No statistical analyses for this end point

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**Secondary: Percentage of Subjects With at Least 1/2048 OPA GMTs for Serotype 7F After Single Dose of 13vPnC Vaccine**

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|                 |                                                                                                          |
|-----------------|----------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects With at Least 1/2048 OPA GMTs for Serotype 7F After Single Dose of 13vPnC Vaccine |
|-----------------|----------------------------------------------------------------------------------------------------------|

End point description:

Percentage of subjects with at least 1/2048 serotype-specific pneumococcal OPA GMTs for serotype 7F determined in the blood samples of all subjects. The data was not collected as planned as the additional, more stringent qualification and validation of the improved mcOPA assays used in this study did not support 1/2048 for serotype 7F for the quantitation of a serum response and thus the established LLOQ was used for the mcOPA assay.

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

End point timeframe:

One month after vaccination

---

| End point values              | 13vPnC/13vPnC/13vPnC | 7vPnC/7vPnC/13vPnC | 7vPnC/13vPnC/13vPnC |  |
|-------------------------------|----------------------|--------------------|---------------------|--|
| Subject group type            | Reporting group      | Reporting group    | Reporting group     |  |
| Number of subjects analysed   | 0 <sup>[19]</sup>    | 0 <sup>[20]</sup>  | 0 <sup>[21]</sup>   |  |
| Units: percentage of subjects |                      |                    |                     |  |
| number (not applicable)       |                      |                    |                     |  |

Notes:

[19] - The data was not collected as planned, instead LLOQ was used for the mcOPA assay.

[20] - The data was not collected as planned, instead LLOQ was used for the mcOPA assay.

[21] - The data was not collected as planned, instead LLOQ was used for the mcOPA assay.

## Statistical analyses

No statistical analyses for this end point

## Post-hoc: Percentage of Subjects Achieving OPA GMTs With at Least Lower Limit of Quantification (LLOQ) 1 Month After Single Dose of 13vPnC Vaccine

|                 |                                                                                                                                          |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects Achieving OPA GMTs With at Least Lower Limit of Quantification (LLOQ) 1 Month After Single Dose of 13vPnC Vaccine |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Percentage of subjects achieving OPA GMTs with at least LLOQ for 13 pneumococcal serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F) determined in blood samples of all subjects using mcOPA assay. Exact 2-sided CI based on observed proportion of subjects. LLOQ in titers for each serotype was: Pn001, 18; Pn003, 12; Pn004, 21; Pn005, 29; Pn06A, 37; Pn06B, 43; Pn7F, 210; Pn09V, 345; Pn014, 35; Pn18C, 31; Pn19A, 18; Pn19F, 48; Pn23F, 13. LOD established as lowest titer possible in assay, which was 8. OPA titers below LLOQ set to 0.5\*LOD for analysis. Evaluable immunogenicity population. n= number of subjects with a determinate OPA antibody titer to the given serotype.

|                |          |
|----------------|----------|
| End point type | Post-hoc |
|----------------|----------|

End point timeframe:

One month after vaccination

| End point values                 | 13vPnC/13vPnC/13vPnC | 7vPnC/7vPnC/13vPnC | 7vPnC/13vPnC/13vPnC |  |
|----------------------------------|----------------------|--------------------|---------------------|--|
| Subject group type               | Reporting group      | Reporting group    | Reporting group     |  |
| Number of subjects analysed      | 120 <sup>[22]</sup>  | 57 <sup>[23]</sup> | 58 <sup>[24]</sup>  |  |
| Units: percentage of subjects    |                      |                    |                     |  |
| number (confidence interval 95%) |                      |                    |                     |  |
| Serotype 4 (n= 117, 53, 55)      | 100 (96.9 to 100)    | 100 (93.3 to 100)  | 100 (93.5 to 100)   |  |
| Serotype 6B (n= 117, 57, 56)     | 100 (96.9 to 100)    | 100 (93.7 to 100)  | 100 (93.6 to 100)   |  |
| Serotype 9V (n= 116, 54, 55)     | 100 (96.9 to 100)    | 100 (93.4 to 100)  | 100 (93.5 to 100)   |  |
| Serotype 14 (n= 115, 54, 55)     | 100 (96.8 to 100)    | 100 (93.4 to 100)  | 100 (93.5 to 100)   |  |
| Serotype 18C (n= 117, 54, 57)    | 100 (96.9 to 100)    | 100 (93.4 to 100)  | 100 (93.7 to 100)   |  |
| Serotype 19F (n= 118, 57, 57)    | 98.3 (94 to 99.8)    | 100 (93.7 to 100)  | 98.2 (90.6 to 100)  |  |
| Serotype 23F (n= 118, 53, 56)    | 100 (96.9 to 100)    | 100 (93.3 to 100)  | 100 (93.6 to 100)   |  |
| Serotype 1 (n= 119, 56, 57)      | 100 (96.9 to 100)    | 100 (93.6 to 100)  | 100 (93.7 to 100)   |  |

|                               |                    |                     |                   |  |
|-------------------------------|--------------------|---------------------|-------------------|--|
| Serotype 3 (n= 118, 56, 58)   | 100 (96.9 to 100)  | 98.2 (90.4 to 100)  | 100 (93.8 to 100) |  |
| Serotype 5 (n= 118, 55, 54)   | 99.2 (95.4 to 100) | 96.4 (87.5 to 99.6) | 100 (93.4 to 100) |  |
| Serotype 6A (n= 117, 55, 55)  | 100 (96.9 to 100)  | 100 (93.5 to 100)   | 100 (93.5 to 100) |  |
| Serotype 7F (n= 118, 56, 54)  | 100 (96.9 to 100)  | 100 (93.6 to 100)   | 100 (93.4 to 100) |  |
| Serotype 19A (n= 116, 53, 54) | 100 (96.9 to 100)  | 100 (93.3 to 100)   | 100 (93.4 to 100) |  |

Notes:

[22] - N= number of subjects analysed within a given treatment group.

[23] - N= number of subjects analysed within a given treatment group.

[24] - N= number of subjects analysed within a given treatment group.

## Statistical analyses

|                                                                                                                                                                                                                                                                         |                                               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                       | 4: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                                                                       |                                               |
| Serotype 4: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI. |                                               |
| Comparison groups                                                                                                                                                                                                                                                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC     |
| Number of subjects included in analysis                                                                                                                                                                                                                                 | 177                                           |
| Analysis specification                                                                                                                                                                                                                                                  | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                                                                           | superiority                                   |
| Parameter estimate                                                                                                                                                                                                                                                      | Percent Difference                            |
| Point estimate                                                                                                                                                                                                                                                          | 0                                             |
| Confidence interval                                                                                                                                                                                                                                                     |                                               |
| level                                                                                                                                                                                                                                                                   | 95 %                                          |
| sides                                                                                                                                                                                                                                                                   | 2-sided                                       |
| lower limit                                                                                                                                                                                                                                                             | -3.5                                          |
| upper limit                                                                                                                                                                                                                                                             | 6.7                                           |

|                                                                                                                                                                                                                                                                          |                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                        | 4: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                                                                        |                                                 |
| Serotype 4: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI. |                                                 |
| Comparison groups                                                                                                                                                                                                                                                        | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                                                                  | 178                                             |
| Analysis specification                                                                                                                                                                                                                                                   | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                                                            | superiority                                     |
| Parameter estimate                                                                                                                                                                                                                                                       | Percent Difference                              |
| Point estimate                                                                                                                                                                                                                                                           | 0                                               |
| Confidence interval                                                                                                                                                                                                                                                      |                                                 |
| level                                                                                                                                                                                                                                                                    | 95 %                                            |
| sides                                                                                                                                                                                                                                                                    | 2-sided                                         |
| lower limit                                                                                                                                                                                                                                                              | -3.6                                            |
| upper limit                                                                                                                                                                                                                                                              | 6.5                                             |

|                                                                                                                                                                                                                                                                        |                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                      | 4: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                                                                      |                                               |
| Serotype 4: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI. |                                               |
| Comparison groups                                                                                                                                                                                                                                                      | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                                                                | 115                                           |
| Analysis specification                                                                                                                                                                                                                                                 | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                                                                          | superiority                                   |
| Parameter estimate                                                                                                                                                                                                                                                     | Percent Difference                            |
| Point estimate                                                                                                                                                                                                                                                         | 0                                             |
| Confidence interval                                                                                                                                                                                                                                                    |                                               |
| level                                                                                                                                                                                                                                                                  | 95 %                                          |
| sides                                                                                                                                                                                                                                                                  | 2-sided                                       |
| lower limit                                                                                                                                                                                                                                                            | -6.8                                          |
| upper limit                                                                                                                                                                                                                                                            | 6.6                                           |

|                                                                                                                                                                                                                                                                          |                                                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                        | 6B: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                                                                        |                                                |
| Serotype 6B: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI. |                                                |
| Comparison groups                                                                                                                                                                                                                                                        | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                                                                  | 177                                            |
| Analysis specification                                                                                                                                                                                                                                                   | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                                                            | superiority                                    |
| Parameter estimate                                                                                                                                                                                                                                                       | Percent Difference                             |
| Point estimate                                                                                                                                                                                                                                                           | 0                                              |
| Confidence interval                                                                                                                                                                                                                                                      |                                                |
| level                                                                                                                                                                                                                                                                    | 95 %                                           |
| sides                                                                                                                                                                                                                                                                    | 2-sided                                        |
| lower limit                                                                                                                                                                                                                                                              | -3.7                                           |
| upper limit                                                                                                                                                                                                                                                              | 6.3                                            |

|                                                                                                                                                                                                                                                                         |                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                       | 6B: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                                                                       |                                                |
| Serotype 6B: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI. |                                                |
| Comparison groups                                                                                                                                                                                                                                                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |

|                                         |                    |
|-----------------------------------------|--------------------|
| Number of subjects included in analysis | 115                |
| Analysis specification                  | Pre-specified      |
| Analysis type                           | superiority        |
| Parameter estimate                      | Percent Difference |
| Point estimate                          | 0                  |
| Confidence interval                     |                    |
| level                                   | 95 %               |
| sides                                   | 2-sided            |
| lower limit                             | -6.4               |
| upper limit                             | 6.5                |

|                                   |                                                  |
|-----------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b> | 6B: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|--------------------------------------------------|

Statistical analysis description:

Serotype 6B: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | Percent difference                         |
| Point estimate                          | 0                                          |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | -3.6                                       |
| upper limit                             | 6.4                                        |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 9V: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 9V: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI.

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | Percent Difference                        |
| Point estimate                          | 0                                         |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | -3.6                                      |
| upper limit                             | 6.6                                       |

|                                                                                                                                                                                                                                                                           |                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                         | 9V: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                                                                         |                                                  |
| Serotype 9V: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI. |                                                  |
| Comparison groups                                                                                                                                                                                                                                                         | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                                                                   | 178                                              |
| Analysis specification                                                                                                                                                                                                                                                    | Pre-specified                                    |
| Analysis type                                                                                                                                                                                                                                                             | superiority                                      |
| Parameter estimate                                                                                                                                                                                                                                                        | Percent Difference                               |
| Point estimate                                                                                                                                                                                                                                                            | 0                                                |
| Confidence interval                                                                                                                                                                                                                                                       |                                                  |
| level                                                                                                                                                                                                                                                                     | 95 %                                             |
| sides                                                                                                                                                                                                                                                                     | 2-sided                                          |
| lower limit                                                                                                                                                                                                                                                               | -3.6                                             |
| upper limit                                                                                                                                                                                                                                                               | 6.5                                              |

|                                                                                                                                                                                                                                                                         |                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                       | 9V: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                                                                       |                                                |
| Serotype 9V: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI. |                                                |
| Comparison groups                                                                                                                                                                                                                                                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                                                                 | 115                                            |
| Analysis specification                                                                                                                                                                                                                                                  | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                                                           | superiority                                    |
| Parameter estimate                                                                                                                                                                                                                                                      | Percent Difference                             |
| Point estimate                                                                                                                                                                                                                                                          | 0                                              |
| Confidence interval                                                                                                                                                                                                                                                     |                                                |
| level                                                                                                                                                                                                                                                                   | 95 %                                           |
| sides                                                                                                                                                                                                                                                                   | 2-sided                                        |
| lower limit                                                                                                                                                                                                                                                             | -6.7                                           |
| upper limit                                                                                                                                                                                                                                                             | 6.5                                            |

|                                                                                                                                                                                                                                                                          |                                                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                        | 14: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                                                                        |                                                |
| Serotype 14: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI. |                                                |
| Comparison groups                                                                                                                                                                                                                                                        | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                                                                  | 177                                            |
| Analysis specification                                                                                                                                                                                                                                                   | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                                                            | superiority                                    |
| Parameter estimate                                                                                                                                                                                                                                                       | Percent Difference                             |
| Point estimate                                                                                                                                                                                                                                                           | 0                                              |



|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | -3.7    |
| upper limit         | 6.6     |

|                                   |                                                  |
|-----------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b> | 14: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|--------------------------------------------------|

Statistical analysis description:

Serotype 14: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | Percent Difference                         |
| Point estimate                          | 0                                          |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | -3.7                                       |
| upper limit                             | 6.5                                        |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 18C: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 18C: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI.

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | Percent Difference                        |
| Point estimate                          | 0                                         |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | -3.6                                      |
| upper limit                             | 6.6                                       |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 14: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 14: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | Percent Difference                       |
| Point estimate                          | 0                                        |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | -6.7                                     |
| upper limit                             | 6.5                                      |

|                                   |                                                   |
|-----------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b> | 18C: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|---------------------------------------------------|

Statistical analysis description:

Serotype 18C: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | Percent Difference                         |
| Point estimate                          | 0                                          |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | -3.7                                       |
| upper limit                             | 6.3                                        |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 18C: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 18C: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | Percent Difference                       |
| Point estimate                          | 0                                        |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | -6.6                                     |
| upper limit                             | 6.4                                      |

|                                                                                                                                                                                                                                                                           |                                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                         | 19F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                                                                         |                                                 |
| Serotype 19F: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI. |                                                 |
| Comparison groups                                                                                                                                                                                                                                                         | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                                                                   | 177                                             |
| Analysis specification                                                                                                                                                                                                                                                    | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                                                             | superiority                                     |
| Parameter estimate                                                                                                                                                                                                                                                        | Percent Difference                              |
| Point estimate                                                                                                                                                                                                                                                            | -1.7                                            |
| Confidence interval                                                                                                                                                                                                                                                       |                                                 |
| level                                                                                                                                                                                                                                                                     | 95 %                                            |
| sides                                                                                                                                                                                                                                                                     | 2-sided                                         |
| lower limit                                                                                                                                                                                                                                                               | -6.2                                            |
| upper limit                                                                                                                                                                                                                                                               | 4.5                                             |

|                                                                                                                                                                                                                                                                            |                                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                          | 19F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                                                                          |                                                   |
| Serotype 19F: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI. |                                                   |
| Comparison groups                                                                                                                                                                                                                                                          | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                                                                                    | 178                                               |
| Analysis specification                                                                                                                                                                                                                                                     | Pre-specified                                     |
| Analysis type                                                                                                                                                                                                                                                              | superiority                                       |
| Parameter estimate                                                                                                                                                                                                                                                         | Percent Difference                                |
| Point estimate                                                                                                                                                                                                                                                             | 0.1                                               |
| Confidence interval                                                                                                                                                                                                                                                        |                                                   |
| level                                                                                                                                                                                                                                                                      | 95 %                                              |
| sides                                                                                                                                                                                                                                                                      | 2-sided                                           |
| lower limit                                                                                                                                                                                                                                                                | -4.8                                              |
| upper limit                                                                                                                                                                                                                                                                | 7.5                                               |

|                                                                                                                                                                                                                                                                          |                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                        | 19F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                                                                        |                                                 |
| Serotype 19F: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI. |                                                 |
| Comparison groups                                                                                                                                                                                                                                                        | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |

|                                         |                    |
|-----------------------------------------|--------------------|
| Number of subjects included in analysis | 115                |
| Analysis specification                  | Pre-specified      |
| Analysis type                           | superiority        |
| Parameter estimate                      | Percent Difference |
| Point estimate                          | 1.8                |
| Confidence interval                     |                    |
| level                                   | 95 %               |
| sides                                   | 2-sided            |
| lower limit                             | -4.8               |
| upper limit                             | 9.5                |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 23F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 23F: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI.

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | Percent Difference                        |
| Point estimate                          | 0                                         |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | -3.5                                      |
| upper limit                             | 6.7                                       |

|                                   |                                                   |
|-----------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b> | 23F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|---------------------------------------------------|

Statistical analysis description:

Serotype 23F: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | Percent Difference                         |
| Point estimate                          | 0                                          |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | -3.6                                       |
| upper limit                             | 6.4                                        |

|                                                                                                                                                                                                                                                                         |                                               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                       | 1: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                                                                       |                                               |
| Serotype 1: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI. |                                               |
| Comparison groups                                                                                                                                                                                                                                                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC     |
| Number of subjects included in analysis                                                                                                                                                                                                                                 | 177                                           |
| Analysis specification                                                                                                                                                                                                                                                  | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                                                                           | superiority                                   |
| Parameter estimate                                                                                                                                                                                                                                                      | Percent Difference                            |
| Point estimate                                                                                                                                                                                                                                                          | 0                                             |
| Confidence interval                                                                                                                                                                                                                                                     |                                               |
| level                                                                                                                                                                                                                                                                   | 95 %                                          |
| sides                                                                                                                                                                                                                                                                   | 2-sided                                       |
| lower limit                                                                                                                                                                                                                                                             | -3.5                                          |
| upper limit                                                                                                                                                                                                                                                             | 6.4                                           |

|                                                                                                                                                                                                                                                                          |                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                        | 23F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                                                                        |                                                 |
| Serotype 23F: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI. |                                                 |
| Comparison groups                                                                                                                                                                                                                                                        | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC        |
| Number of subjects included in analysis                                                                                                                                                                                                                                  | 115                                             |
| Analysis specification                                                                                                                                                                                                                                                   | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                                                            | superiority                                     |
| Parameter estimate                                                                                                                                                                                                                                                       | Percent Difference                              |
| Point estimate                                                                                                                                                                                                                                                           | 0                                               |
| Confidence interval                                                                                                                                                                                                                                                      |                                                 |
| level                                                                                                                                                                                                                                                                    | 95 %                                            |
| sides                                                                                                                                                                                                                                                                    | 2-sided                                         |
| lower limit                                                                                                                                                                                                                                                              | -6.7                                            |
| upper limit                                                                                                                                                                                                                                                              | 6.5                                             |

|                                                                                                                                                                                                                                                                          |                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                        | 1: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                                                                        |                                                 |
| Serotype 1: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI. |                                                 |
| Comparison groups                                                                                                                                                                                                                                                        | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                                                                  | 178                                             |
| Analysis specification                                                                                                                                                                                                                                                   | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                                                            | superiority                                     |
| Parameter estimate                                                                                                                                                                                                                                                       | Percent Difference                              |
| Point estimate                                                                                                                                                                                                                                                           | 0                                               |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | -3.6    |
| upper limit         | 6.3     |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 1: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 1: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | Percent Difference                       |
| Point estimate                          | 0                                        |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | -6.5                                     |
| upper limit                             | 6.3                                      |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 3: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 3: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI.

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | Percent Difference                        |
| Point estimate                          | 1.8                                       |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | -1.7                                      |
| upper limit                             | 9.6                                       |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 3: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 3: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 7vPnC/13vPnC/13vPnC v 13vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | Percent Difference                         |
| Point estimate                          | 0                                          |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | -3.7                                       |
| upper limit                             | 6.2                                        |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 3: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 3: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | Percent Difference                       |
| Point estimate                          | -1.8                                     |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | -9.6                                     |
| upper limit                             | 4.5                                      |

|                                   |                                               |
|-----------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b> | 5: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-----------------------------------------------|

Statistical analysis description:

Serotype 5: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI.

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | Percent Difference                        |
| Point estimate                          | 2.8                                       |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | -2                                        |
| upper limit                             | 11.3                                      |

|                                                                                                                                                                                                                                                                          |                                                 |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                        | 5: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                                                                        |                                                 |
| Serotype 5: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI. |                                                 |
| Comparison groups                                                                                                                                                                                                                                                        | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                                                                  | 178                                             |
| Analysis specification                                                                                                                                                                                                                                                   | Pre-specified                                   |
| Analysis type                                                                                                                                                                                                                                                            | superiority                                     |
| Parameter estimate                                                                                                                                                                                                                                                       | Percent Difference                              |
| Point estimate                                                                                                                                                                                                                                                           | -0.8                                            |
| Confidence interval                                                                                                                                                                                                                                                      |                                                 |
| level                                                                                                                                                                                                                                                                    | 95 %                                            |
| sides                                                                                                                                                                                                                                                                    | 2-sided                                         |
| lower limit                                                                                                                                                                                                                                                              | -4.9                                            |
| upper limit                                                                                                                                                                                                                                                              | 5.6                                             |

|                                                                                                                                                                                                                                                                        |                                               |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                      | 5: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                                                                      |                                               |
| Serotype 5: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI. |                                               |
| Comparison groups                                                                                                                                                                                                                                                      | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                                                                | 115                                           |
| Analysis specification                                                                                                                                                                                                                                                 | Pre-specified                                 |
| Analysis type                                                                                                                                                                                                                                                          | superiority                                   |
| Parameter estimate                                                                                                                                                                                                                                                     | Percent Difference                            |
| Point estimate                                                                                                                                                                                                                                                         | -3.6                                          |
| Confidence interval                                                                                                                                                                                                                                                    |                                               |
| level                                                                                                                                                                                                                                                                  | 95 %                                          |
| sides                                                                                                                                                                                                                                                                  | 2-sided                                       |
| lower limit                                                                                                                                                                                                                                                            | -12.5                                         |
| upper limit                                                                                                                                                                                                                                                            | 3.2                                           |

|                                                                                                                                                                                                                                                                           |                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                         | 6A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                                                                         |                                                  |
| Serotype 6A: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI. |                                                  |
| Comparison groups                                                                                                                                                                                                                                                         | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |



|                                         |                    |
|-----------------------------------------|--------------------|
| Number of subjects included in analysis | 178                |
| Analysis specification                  | Pre-specified      |
| Analysis type                           | superiority        |
| Parameter estimate                      | Percent Difference |
| Point estimate                          | 0                  |
| Confidence interval                     |                    |
| level                                   | 95 %               |
| sides                                   | 2-sided            |
| lower limit                             | -3.6               |
| upper limit                             | 6.5                |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 6A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 6A: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI.

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 13vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | Percent Difference                        |
| Point estimate                          | 0                                         |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | -3.6                                      |
| upper limit                             | 6.5                                       |

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b> | 6A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|------------------------------------------------|

Statistical analysis description:

Serotype 6A: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | Percent Difference                       |
| Point estimate                          | 0                                        |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | -6.6                                     |
| upper limit                             | 6.6                                      |

|                                                                                                                                                                                                                                                                          |                                                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                        | 7F: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                                                                        |                                                |
| Serotype 7F: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI. |                                                |
| Comparison groups                                                                                                                                                                                                                                                        | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC      |
| Number of subjects included in analysis                                                                                                                                                                                                                                  | 177                                            |
| Analysis specification                                                                                                                                                                                                                                                   | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                                                            | superiority                                    |
| Parameter estimate                                                                                                                                                                                                                                                       | Percent Difference                             |
| Point estimate                                                                                                                                                                                                                                                           | 0                                              |
| Confidence interval                                                                                                                                                                                                                                                      |                                                |
| level                                                                                                                                                                                                                                                                    | 95 %                                           |
| sides                                                                                                                                                                                                                                                                    | 2-sided                                        |
| lower limit                                                                                                                                                                                                                                                              | -3.6                                           |
| upper limit                                                                                                                                                                                                                                                              | 6.4                                            |

|                                                                                                                                                                                                                                                                           |                                                  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                         | 7F: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                                                                         |                                                  |
| Serotype 7F: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI. |                                                  |
| Comparison groups                                                                                                                                                                                                                                                         | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                                                                   | 178                                              |
| Analysis specification                                                                                                                                                                                                                                                    | Pre-specified                                    |
| Analysis type                                                                                                                                                                                                                                                             | superiority                                      |
| Parameter estimate                                                                                                                                                                                                                                                        | Percent Difference                               |
| Point estimate                                                                                                                                                                                                                                                            | 0                                                |
| Confidence interval                                                                                                                                                                                                                                                       |                                                  |
| level                                                                                                                                                                                                                                                                     | 95 %                                             |
| sides                                                                                                                                                                                                                                                                     | 2-sided                                          |
| lower limit                                                                                                                                                                                                                                                               | -3.5                                             |
| upper limit                                                                                                                                                                                                                                                               | 6.6                                              |

|                                                                                                                                                                                                                                                                         |                                                |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| <b>Statistical analysis title</b>                                                                                                                                                                                                                                       | 7F: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
| Statistical analysis description:                                                                                                                                                                                                                                       |                                                |
| Serotype 7F: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI. |                                                |
| Comparison groups                                                                                                                                                                                                                                                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC       |
| Number of subjects included in analysis                                                                                                                                                                                                                                 | 115                                            |
| Analysis specification                                                                                                                                                                                                                                                  | Pre-specified                                  |
| Analysis type                                                                                                                                                                                                                                                           | superiority                                    |
| Parameter estimate                                                                                                                                                                                                                                                      | Percent Difference                             |
| Point estimate                                                                                                                                                                                                                                                          | 0                                              |

|                     |         |
|---------------------|---------|
| Confidence interval |         |
| level               | 95 %    |
| sides               | 2-sided |
| lower limit         | -6.5    |
| upper limit         | 6.7     |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 19A: 13vPnC/13vPnC/13vPnC vs 7vPnC/7vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 19A: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC along with exact 2-sided 95% CI.

|                                         |                                           |
|-----------------------------------------|-------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/7vPnC/13vPnC |
| Number of subjects included in analysis | 177                                       |
| Analysis specification                  | Pre-specified                             |
| Analysis type                           | superiority                               |
| Parameter estimate                      | Percent Difference                        |
| Point estimate                          | 0                                         |
| Confidence interval                     |                                           |
| level                                   | 95 %                                      |
| sides                                   | 2-sided                                   |
| lower limit                             | -3.6                                      |
| upper limit                             | 6.7                                       |

|                                   |                                                   |
|-----------------------------------|---------------------------------------------------|
| <b>Statistical analysis title</b> | 19A: 13vPnC/13vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|---------------------------------------------------|

Statistical analysis description:

Serotype 19A: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 13vPnC/13vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

|                                         |                                            |
|-----------------------------------------|--------------------------------------------|
| Comparison groups                       | 13vPnC/13vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 178                                        |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| Parameter estimate                      | Percent Difference                         |
| Point estimate                          | 0                                          |
| Confidence interval                     |                                            |
| level                                   | 95 %                                       |
| sides                                   | 2-sided                                    |
| lower limit                             | -3.6                                       |
| upper limit                             | 6.6                                        |

|                                   |                                                 |
|-----------------------------------|-------------------------------------------------|
| <b>Statistical analysis title</b> | 19A: 7vPnC/7vPnC/13vPnC vs. 7vPnC/13vPnC/13vPnC |
|-----------------------------------|-------------------------------------------------|

Statistical analysis description:

Serotype 19A: Difference in proportion, expressed as percentage, was calculated by percentage of subjects achieving at least LLOQ in 7vPnC/7vPnC/13vPnC minus the percentage of subjects achieving at least LLOQ in 7vPnC/13vPnC/13vPnC along with exact 2-sided 95% CI.

|                                         |                                          |
|-----------------------------------------|------------------------------------------|
| Comparison groups                       | 7vPnC/7vPnC/13vPnC v 7vPnC/13vPnC/13vPnC |
| Number of subjects included in analysis | 115                                      |
| Analysis specification                  | Pre-specified                            |
| Analysis type                           | superiority                              |
| Parameter estimate                      | Percent Difference                       |
| Point estimate                          | 0                                        |
| Confidence interval                     |                                          |
| level                                   | 95 %                                     |
| sides                                   | 2-sided                                  |
| lower limit                             | -6.8                                     |
| upper limit                             | 6.6                                      |

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

AEs/SAEs: recorded from signing of informed consent form to completion of study (28-42 days post 13vPnC). Subjects recorded prespecified AEs in electronic diary: local reactions; systemic events; use of antipyretic medication (Day 1-Day 7 post 13vPnC).

Adverse event reporting additional description:

Adverse events(AEs) and Serious AEs were grouped by system organ class and summarized. AEs included solicited/unsolicited AEs collected in electronic diary(local and systemic reactions;systematic assessment) collected on case report form at each visit(nonsystematic assessment).LRs/SEs were assessed only for infant and toddler dose groups.

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

### Dictionary used

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

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

### Reporting groups

|                       |                      |
|-----------------------|----------------------|
| Reporting group title | 13vPnC/13vPnC/13vPnC |
|-----------------------|----------------------|

Reporting group description:

Single dose of 13vPnC, 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 13vPnC/13vPnC vaccine.

|                       |                    |
|-----------------------|--------------------|
| Reporting group title | 7vPnC/7vPnC/13vPnC |
|-----------------------|--------------------|

Reporting group description:

Single dose of 13vPnC vaccine, 2 years after receiving a full schedule (3 infant doses/1 toddler dose) of 7-valent pneumococcal conjugate (7vPnC)/7vPnC vaccine.

|                       |                     |
|-----------------------|---------------------|
| Reporting group title | 7vPnC/13vPnC/13vPnC |
|-----------------------|---------------------|

Reporting group description:

Single dose of 13vPnC vaccine, 2 years after receiving a full schedule of (3 infant doses/1 toddler dose) 7vPnC/13vPnC vaccine.

| Serious adverse events                            | 13vPnC/13vPnC/13vPnC | 7vPnC/7vPnC/13vPnC | 7vPnC/13vPnC/13vPnC |
|---------------------------------------------------|----------------------|--------------------|---------------------|
| Total subjects affected by serious adverse events |                      |                    |                     |
| subjects affected / exposed                       | 0 / 130 (0.00%)      | 0 / 64 (0.00%)     | 0 / 64 (0.00%)      |
| number of deaths (all causes)                     | 0                    | 0                  | 0                   |
| number of deaths resulting from adverse events    |                      |                    |                     |

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

| Non-serious adverse events                            | 13vPnC/13vPnC/13vPnC | 7vPnC/7vPnC/13vPnC | 7vPnC/13vPnC/13vPnC |
|-------------------------------------------------------|----------------------|--------------------|---------------------|
| Total subjects affected by non-serious adverse events |                      |                    |                     |
| subjects affected / exposed                           | 82 / 130 (63.08%)    | 36 / 64 (56.25%)   | 39 / 64 (60.94%)    |
| Injury, poisoning and procedural complications        |                      |                    |                     |

|                                                                                                                                                                     |                                                                                                                                                                                                                                                                           |                        |                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|----------------------|
| Radius fracture<br>subjects affected / exposed<br>occurrences (all)                                                                                                 | 0 / 130 (0.00%)<br>0                                                                                                                                                                                                                                                      | 0 / 64 (0.00%)<br>0    | 1 / 64 (1.56%)<br>1  |
| General disorders and administration site conditions<br>Injection site erythema<br>subjects affected / exposed<br>occurrences (all)                                 | 1 / 130 (0.77%)<br>1                                                                                                                                                                                                                                                      | 0 / 64 (0.00%)<br>0    | 0 / 64 (0.00%)<br>0  |
| Fever >=38 degree C but <=39 degree C                                                                                                                               | Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                        |                      |
| alternative dictionary used:<br>Systemic Event 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[1]</sup><br>occurrences (all) | 14 / 93 (15.05%)<br>14                                                                                                                                                                                                                                                    | 14 / 49 (28.57%)<br>14 | 9 / 46 (19.57%)<br>9 |
| Fever >39 degree C but <=40 degree C                                                                                                                                | Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                        |                      |
| alternative dictionary used:<br>Systemic Event 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[2]</sup><br>occurrences (all) | 2 / 92 (2.17%)<br>2                                                                                                                                                                                                                                                       | 2 / 43 (4.65%)<br>2    | 1 / 46 (2.17%)<br>1  |
| Fever >40 degree C                                                                                                                                                  | Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                        |                      |
| alternative dictionary used:<br>Systemic Event 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[3]</sup><br>occurrences (all) | 0 / 90 (0.00%)<br>0                                                                                                                                                                                                                                                       | 0 / 43 (0.00%)<br>0    | 1 / 45 (2.22%)<br>1  |
| Vomiting (Any)                                                                                                                                                      | Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                        |                      |
| alternative dictionary used:<br>Systemic Event 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[4]</sup><br>occurrences (all) | 3 / 91 (3.30%)<br>3                                                                                                                                                                                                                                                       | 4 / 44 (9.09%)<br>4    | 3 / 45 (6.67%)<br>3  |
| Vomiting (Mild)                                                                                                                                                     | Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                        |                      |
| alternative dictionary used:<br>Systemic Event 0.0                                                                                                                  |                                                                                                                                                                                                                                                                           |                        |                      |

|                                                                                                                                                                                          |                                                                                                                                                                                                                                                                           |                                   |                                   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|-----------------------------------|
| <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[5]</sup></p> <p>occurrences (all)</p>                                                             | <p>3 / 91 (3.30%)</p> <p>3</p>                                                                                                                                                                                                                                            | <p>4 / 44 (9.09%)</p> <p>4</p>    | <p>3 / 45 (6.67%)</p> <p>3</p>    |
| Diarrhea (Any)                                                                                                                                                                           | Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                                   |                                   |
| <p>alternative dictionary used:<br/>Systemic Event 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[6]</sup></p> <p>occurrences (all)</p>  | <p>8 / 90 (8.89%)</p> <p>8</p>                                                                                                                                                                                                                                            | <p>8 / 45 (17.78%)</p> <p>8</p>   | <p>4 / 47 (8.51%)</p> <p>4</p>    |
| Diarrhea (Mild)                                                                                                                                                                          | Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                                   |                                   |
| <p>alternative dictionary used:<br/>Systemic Event 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[7]</sup></p> <p>occurrences (all)</p>  | <p>8 / 90 (8.89%)</p> <p>8</p>                                                                                                                                                                                                                                            | <p>8 / 45 (17.78%)</p> <p>8</p>   | <p>4 / 47 (8.51%)</p> <p>4</p>    |
| Diarrhea (Moderate)                                                                                                                                                                      | Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                                   |                                   |
| <p>alternative dictionary used:<br/>Systemic Event 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[8]</sup></p> <p>occurrences (all)</p>  | <p>1 / 90 (1.11%)</p> <p>1</p>                                                                                                                                                                                                                                            | <p>0 / 43 (0.00%)</p> <p>0</p>    | <p>0 / 45 (0.00%)</p> <p>0</p>    |
| Fatigue (Any)                                                                                                                                                                            | Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                                   |                                   |
| <p>alternative dictionary used:<br/>Systemic Event 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[9]</sup></p> <p>occurrences (all)</p>  | <p>42 / 103 (40.78%)</p> <p>42</p>                                                                                                                                                                                                                                        | <p>28 / 54 (51.85%)</p> <p>28</p> | <p>15 / 48 (31.25%)</p> <p>15</p> |
| Fatigue (Mild)                                                                                                                                                                           | Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                                   |                                   |
| <p>alternative dictionary used:<br/>Systemic Event 0.0</p> <p>alternative assessment type:<br/>Systematic</p> <p>subjects affected / exposed<sup>[10]</sup></p> <p>occurrences (all)</p> | <p>34 / 100 (34.00%)</p> <p>34</p>                                                                                                                                                                                                                                        | <p>17 / 49 (34.69%)</p> <p>17</p> | <p>10 / 48 (20.83%)</p> <p>10</p> |
| Fatigue (Moderate)                                                                                                                                                                       | Additional description: Subjects affected and occurrences for SEs is same as                                                                                                                                                                                              |                                   |                                   |

|                                                                                                                                                                                              |                                                                                                                                                                                                                                                                           |                        |                        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|------------------------|
| data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                                                                                                                                                                                                                                                                           |                        |                        |
| alternative dictionary used:<br>Systemic Event 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[11]</sup><br>occurrences (all)                         | 16 / 96 (16.67%)<br>16                                                                                                                                                                                                                                                    | 15 / 49 (30.61%)<br>15 | 7 / 46 (15.22%)<br>7   |
| Fatigue (Severe)                                                                                                                                                                             | Additional description: Subjects affected and occurrences for SEs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                        |                        |
| alternative dictionary used:<br>Systemic Event 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[12]</sup><br>occurrences (all)                         | 3 / 92 (3.26%)<br>3                                                                                                                                                                                                                                                       | 1 / 43 (2.33%)<br>1    | 1 / 45 (2.22%)<br>1    |
| Respiratory, thoracic and mediastinal disorders                                                                                                                                              |                                                                                                                                                                                                                                                                           |                        |                        |
| Epistaxis                                                                                                                                                                                    |                                                                                                                                                                                                                                                                           |                        |                        |
| subjects affected / exposed                                                                                                                                                                  | 0 / 130 (0.00%)                                                                                                                                                                                                                                                           | 1 / 64 (1.56%)         | 0 / 64 (0.00%)         |
| occurrences (all)                                                                                                                                                                            | 0                                                                                                                                                                                                                                                                         | 1                      | 0                      |
| Oropharyngeal pain                                                                                                                                                                           |                                                                                                                                                                                                                                                                           |                        |                        |
| subjects affected / exposed                                                                                                                                                                  | 1 / 130 (0.77%)                                                                                                                                                                                                                                                           | 0 / 64 (0.00%)         | 0 / 64 (0.00%)         |
| occurrences (all)                                                                                                                                                                            | 1                                                                                                                                                                                                                                                                         | 0                      | 0                      |
| Skin and subcutaneous tissue disorders                                                                                                                                                       |                                                                                                                                                                                                                                                                           |                        |                        |
| Dermatitis allergic                                                                                                                                                                          |                                                                                                                                                                                                                                                                           |                        |                        |
| subjects affected / exposed                                                                                                                                                                  | 0 / 130 (0.00%)                                                                                                                                                                                                                                                           | 1 / 64 (1.56%)         | 0 / 64 (0.00%)         |
| occurrences (all)                                                                                                                                                                            | 0                                                                                                                                                                                                                                                                         | 1                      | 0                      |
| Pain (Any)                                                                                                                                                                                   | Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                        |                        |
| alternative dictionary used: Local<br>Reaction 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[13]</sup><br>occurrences (all)                         | 62 / 112 (55.36%)<br>62                                                                                                                                                                                                                                                   | 29 / 52 (55.77%)<br>29 | 34 / 53 (64.15%)<br>34 |
| Pain (Mild)                                                                                                                                                                                  | Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                        |                        |
| alternative dictionary used: Local<br>Reaction 0.0<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed <sup>[14]</sup><br>occurrences (all)                         | 55 / 109 (50.46%)<br>55                                                                                                                                                                                                                                                   | 25 / 51 (49.02%)<br>25 | 29 / 51 (56.86%)<br>29 |



|                     |                                                                                                                                                                                                                                                                           |                         |                        |
|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------------------|
| Pain (Moderate)     | Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                         |                        |
|                     | alternative dictionary used: Local Reaction 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed <sup>[15]</sup><br>occurrences (all)                                                                                                            | 17 / 95 (17.89%)<br>17  | 12 / 47 (25.53%)<br>12 |
| Pain (Severe)       | Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                         |                        |
|                     | alternative dictionary used: Local Reaction 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed <sup>[16]</sup><br>occurrences (all)                                                                                                            | 1 / 90 (1.11%)<br>1     | 1 / 43 (2.33%)<br>1    |
| Swelling (Any)      | Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                         |                        |
|                     | alternative dictionary used: Local Reaction 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed <sup>[17]</sup><br>occurrences (all)                                                                                                            | 40 / 101 (39.60%)<br>40 | 20 / 48 (41.67%)<br>20 |
| Swelling (Mild)     | Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                         |                        |
|                     | alternative dictionary used: Local Reaction 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed <sup>[18]</sup><br>occurrences (all)                                                                                                            | 27 / 96 (28.13%)<br>27  | 17 / 48 (35.42%)<br>17 |
| Swelling (Moderate) | Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                         |                        |
|                     | alternative dictionary used: Local Reaction 0.0<br>alternative assessment type: Systematic<br>subjects affected / exposed <sup>[19]</sup><br>occurrences (all)                                                                                                            | 24 / 97 (24.74%)<br>24  | 9 / 44 (20.45%)<br>9   |
| Swelling (Severe)   | Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                         |                        |
|                     | alternative dictionary used: Local Reaction 0.0<br>alternative assessment type: Systematic                                                                                                                                                                                |                         |                        |

|                                                 |                                                                                                                                                                                                                                                                           |                  |                  |
|-------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|------------------|
| subjects affected / exposed <sup>[20]</sup>     | 0 / 90 (0.00%)                                                                                                                                                                                                                                                            | 1 / 43 (2.33%)   | 0 / 45 (0.00%)   |
| occurrences (all)                               | 0                                                                                                                                                                                                                                                                         | 1                | 0                |
| Redness (Any)                                   | Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                  |                  |
| alternative dictionary used: Local Reaction 0.0 |                                                                                                                                                                                                                                                                           |                  |                  |
| alternative assessment type: Systematic         |                                                                                                                                                                                                                                                                           |                  |                  |
| subjects affected / exposed <sup>[21]</sup>     | 51 / 105 (48.57%)                                                                                                                                                                                                                                                         | 27 / 50 (54.00%) | 23 / 50 (46.00%) |
| occurrences (all)                               | 51                                                                                                                                                                                                                                                                        | 27               | 23               |
| Redness (Mild)                                  | Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                  |                  |
| alternative dictionary used: Local Reaction 0.0 |                                                                                                                                                                                                                                                                           |                  |                  |
| alternative assessment type: Systematic         |                                                                                                                                                                                                                                                                           |                  |                  |
| subjects affected / exposed <sup>[22]</sup>     | 39 / 101 (38.61%)                                                                                                                                                                                                                                                         | 20 / 49 (40.82%) | 18 / 48 (37.50%) |
| occurrences (all)                               | 39                                                                                                                                                                                                                                                                        | 20               | 18               |
| Redness (Moderate)                              | Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                  |                  |
| alternative dictionary used: Local Reaction 0.0 |                                                                                                                                                                                                                                                                           |                  |                  |
| alternative assessment type: Systematic         |                                                                                                                                                                                                                                                                           |                  |                  |
| subjects affected / exposed <sup>[23]</sup>     | 21 / 95 (22.11%)                                                                                                                                                                                                                                                          | 14 / 45 (31.11%) | 8 / 47 (17.02%)  |
| occurrences (all)                               | 21                                                                                                                                                                                                                                                                        | 14               | 8                |
| Redness (Severe)                                | Additional description: Subjects affected and occurrences for LRs is same as data collected through e-diaries cannot be used to distinguish one occurrence from another within a subject/vaccination. Version not captured, here 0.0 is mentioned for dictionary version. |                  |                  |
| alternative dictionary used: Local Reaction 0.0 |                                                                                                                                                                                                                                                                           |                  |                  |
| alternative assessment type: Systematic         |                                                                                                                                                                                                                                                                           |                  |                  |
| subjects affected / exposed <sup>[24]</sup>     | 0 / 90 (0.00%)                                                                                                                                                                                                                                                            | 1 / 43 (2.33%)   | 0 / 45 (0.00%)   |
| occurrences (all)                               | 0                                                                                                                                                                                                                                                                         | 1                | 0                |
| Infections and infestations                     |                                                                                                                                                                                                                                                                           |                  |                  |
| Acute tonsillitis                               |                                                                                                                                                                                                                                                                           |                  |                  |
| subjects affected / exposed                     | 1 / 130 (0.77%)                                                                                                                                                                                                                                                           | 0 / 64 (0.00%)   | 0 / 64 (0.00%)   |
| occurrences (all)                               | 1                                                                                                                                                                                                                                                                         | 0                | 0                |
| Bronchitis                                      |                                                                                                                                                                                                                                                                           |                  |                  |
| subjects affected / exposed                     | 2 / 130 (1.54%)                                                                                                                                                                                                                                                           | 0 / 64 (0.00%)   | 0 / 64 (0.00%)   |
| occurrences (all)                               | 2                                                                                                                                                                                                                                                                         | 0                | 0                |
| Ear infection                                   |                                                                                                                                                                                                                                                                           |                  |                  |

|                             |                 |                |                |
|-----------------------------|-----------------|----------------|----------------|
| subjects affected / exposed | 0 / 130 (0.00%) | 1 / 64 (1.56%) | 1 / 64 (1.56%) |
| occurrences (all)           | 0               | 1              | 1              |
| Gastroenteritis             |                 |                |                |
| subjects affected / exposed | 1 / 130 (0.77%) | 1 / 64 (1.56%) | 1 / 64 (1.56%) |
| occurrences (all)           | 1               | 1              | 1              |
| Nasopharyngitis             |                 |                |                |
| subjects affected / exposed | 3 / 130 (2.31%) | 0 / 64 (0.00%) | 0 / 64 (0.00%) |
| occurrences (all)           | 3               | 0              | 0              |
| Pharyngitis                 |                 |                |                |
| subjects affected / exposed | 2 / 130 (1.54%) | 0 / 64 (0.00%) | 1 / 64 (1.56%) |
| occurrences (all)           | 2               | 0              | 1              |
| Rhinitis                    |                 |                |                |
| subjects affected / exposed | 0 / 130 (0.00%) | 1 / 64 (1.56%) | 0 / 64 (0.00%) |
| occurrences (all)           | 0               | 1              | 0              |
| Tonsillitis                 |                 |                |                |
| subjects affected / exposed | 2 / 130 (1.54%) | 1 / 64 (1.56%) | 1 / 64 (1.56%) |
| occurrences (all)           | 2               | 1              | 1              |
| Urinary tract infection     |                 |                |                |
| subjects affected / exposed | 1 / 130 (0.77%) | 0 / 64 (0.00%) | 0 / 64 (0.00%) |
| occurrences (all)           | 1               | 0              | 0              |
| Varicella                   |                 |                |                |
| subjects affected / exposed | 2 / 130 (1.54%) | 0 / 64 (0.00%) | 1 / 64 (1.56%) |
| occurrences (all)           | 2               | 0              | 1              |
| Viral infection             |                 |                |                |
| subjects affected / exposed | 2 / 130 (1.54%) | 1 / 64 (1.56%) | 0 / 64 (0.00%) |
| occurrences (all)           | 2               | 1              | 0              |

Notes:

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

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

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

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

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

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

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

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no

[21] - The number of subjects exposed to this adverse event is less than the total number of subjects

exposed for the reporting group. These numbers are expected to be equal.

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

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

Justification: Here number of subjects exposed signifies subjects reporting yes for at least 1 day or no for all days.

[23] - 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.

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[24] - 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.

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## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported