



## Clinical trial results:

**An open-label primary vaccination study to assess the safety and reactogenicity of GlaxoSmithKline Biologicals' combined diphtheria-tetanus-acellular pertussis-inactivated poliovirus-Haemophilus influenzae type b (DTPa-IPV/Hib) vaccine administered as a three-dose primary vaccination course at 2-3-4 or 3-4-5 months of age in healthy infants in China.**

### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2015-001513-27 |
| Trial protocol           | Outside EU/EEA |
| Global end of trial date | 12 April 2010  |

### Results information

|                                |                                                                                                                                             |
|--------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Result version number          | v3 (current)                                                                                                                                |
| This version publication date  | 20 May 2023                                                                                                                                 |
| First version publication date | 04 July 2015                                                                                                                                |
| Version creation reason        | <ul style="list-style-type: none"><li>• Correction of full data set</li></ul> Correction of full data set and alignment between registries. |

### Trial information

#### Trial identification

|                       |        |
|-----------------------|--------|
| Sponsor protocol code | 112065 |
|-----------------------|--------|

#### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT00964028 |
| WHO universal trial number (UTN)   | -           |

Notes:

### Sponsors

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

Notes:

### Paediatric regulatory details

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

Notes:

## Results analysis stage

|                                                      |               |
|------------------------------------------------------|---------------|
| Analysis stage                                       | Final         |
| Date of interim/final analysis                       | 23 July 2010  |
| Is this the analysis of the primary completion data? | Yes           |
| Primary completion date                              | 12 April 2010 |
| Global end of trial reached?                         | Yes           |
| Global end of trial date                             | 12 April 2010 |
| Was the trial ended prematurely?                     | No            |

Notes:

## General information about the trial

Main objective of the trial:

To assess the safety and reactogenicity of the study vaccine administered as a three-dose primary vaccination course.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

|                                                           |                  |
|-----------------------------------------------------------|------------------|
| Actual start date of recruitment                          | 01 December 2009 |
| 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 | China: 50 |
| Worldwide total number of subjects   | 50        |
| EEA total number of subjects         | 0         |

Notes:

### Subjects enrolled per age group

|                                           |    |
|-------------------------------------------|----|
| In utero                                  | 0  |
| Preterm newborn - gestational age < 37 wk | 0  |
| Newborns (0-27 days)                      | 0  |
| Infants and toddlers (28 days-23 months)  | 50 |
| Children (2-11 years)                     | 0  |
| Adolescents (12-17 years)                 | 0  |
| Adults (18-64 years)                      | 0  |

|                     |   |
|---------------------|---|
| From 65 to 84 years | 0 |
| 85 years and over   | 0 |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

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

### Period 1

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

### Arms

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

|                  |                                 |
|------------------|---------------------------------|
| <b>Arm title</b> | Infanrix-IPV/Hib M2-M3-M4 Group |
|------------------|---------------------------------|

Arm description:

Healthy male or female subjects between and including 60 and 90 days of age at the time of the first vaccination, received 3 doses of Infanrix-IPV/Hib vaccine at 2, 3 and 4 months of age (M2-M3-M4), administered intramuscularly into the upper right side of the thigh.

|                                        |                   |
|----------------------------------------|-------------------|
| Arm type                               | Experimental      |
| Investigational medicinal product name | Infanrix-IPV/Hib  |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

The vaccine was administered intramuscularly into the upper right side of the thigh, at 2, 3, 4 months of age.

|                  |                                 |
|------------------|---------------------------------|
| <b>Arm title</b> | Infanrix-IPV/Hib M3-M4-M5 Group |
|------------------|---------------------------------|

Arm description:

Healthy male or female subjects between and including 60 and 90 days of age at the time of the first vaccination, received 3 doses of Infanrix-IPV/Hib vaccine at 3, 4 and 5 months of age (M3-M4-M5), administered intramuscularly into the upper right side of the thigh.

|                                        |                   |
|----------------------------------------|-------------------|
| Arm type                               | Experimental      |
| Investigational medicinal product name | Infanrix-IPV/Hib  |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

The vaccine was administered intramuscularly into the upper right side of the thigh, at 3, 4, 5 months of age.

| <b>Number of subjects in period 1</b> | Infanrix-IPV/Hib M2-M3-M4 Group | Infanrix-IPV/Hib M3-M4-M5 Group |
|---------------------------------------|---------------------------------|---------------------------------|
| Started                               | 25                              | 25                              |
| Completed                             | 25                              | 24                              |
| Not completed                         | 0                               | 1                               |
| Consent withdrawn by subject          | -                               | 1                               |

## Baseline characteristics

### Reporting groups

|                       |                                 |
|-----------------------|---------------------------------|
| Reporting group title | Infanrix-IPV/Hib M2-M3-M4 Group |
|-----------------------|---------------------------------|

Reporting group description:

Healthy male or female subjects between and including 60 and 90 days of age at the time of the first vaccination, received 3 doses of Infanrix-IPV/Hib vaccine at 2, 3 and 4 months of age (M2-M3-M4), administered intramuscularly into the upper right side of the thigh.

|                       |                                 |
|-----------------------|---------------------------------|
| Reporting group title | Infanrix-IPV/Hib M3-M4-M5 Group |
|-----------------------|---------------------------------|

Reporting group description:

Healthy male or female subjects between and including 60 and 90 days of age at the time of the first vaccination, received 3 doses of Infanrix-IPV/Hib vaccine at 3, 4 and 5 months of age (M3-M4-M5), administered intramuscularly into the upper right side of the thigh.

| Reporting group values                             | Infanrix-IPV/Hib M2-M3-M4 Group | Infanrix-IPV/Hib M3-M4-M5 Group | Total |
|----------------------------------------------------|---------------------------------|---------------------------------|-------|
| Number of subjects                                 | 25                              | 25                              | 50    |
| Age categorical                                    |                                 |                                 |       |
| Units: Subjects                                    |                                 |                                 |       |
| In utero                                           | 0                               | 0                               | 0     |
| Preterm newborn infants (gestational age < 37 wks) | 0                               | 0                               | 0     |
| Newborns (0-27 days)                               | 0                               | 0                               | 0     |
| Infants and toddlers (28 days-23 months)           | 25                              | 25                              | 50    |
| Children (2-11 years)                              | 0                               | 0                               | 0     |
| Adolescents (12-17 years)                          | 0                               | 0                               | 0     |
| Adults (18-64 years)                               | 0                               | 0                               | 0     |
| From 65-84 years                                   | 0                               | 0                               | 0     |
| 85 years and over                                  | 0                               | 0                               | 0     |
| Age continuous                                     |                                 |                                 |       |
| Units: weeks                                       |                                 |                                 |       |
| arithmetic mean                                    | 10.1                            | 14.2                            |       |
| standard deviation                                 | ± 1.36                          | ± 1.18                          | -     |
| Gender categorical                                 |                                 |                                 |       |
| Units: Subjects                                    |                                 |                                 |       |
| Female                                             | 7                               | 11                              | 18    |
| Male                                               | 18                              | 14                              | 32    |
| Race/Ethnicity                                     |                                 |                                 |       |
| Units: Subjects                                    |                                 |                                 |       |
| Asian-East Asian heritage                          | 24                              | 25                              | 49    |
| Asian-Japanese heritage                            | 1                               | 0                               | 1     |

## End points

### End points reporting groups

|                                                                                                                                                                                                                                                                                                             |                                 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|
| Reporting group title                                                                                                                                                                                                                                                                                       | Infanrix-IPV/Hib M2-M3-M4 Group |
| Reporting group description:<br>Healthy male or female subjects between and including 60 and 90 days of age at the time of the first vaccination, received 3 doses of Infanrix-IPV/Hib vaccine at 2, 3 and 4 months of age (M2-M3-M4), administered intramuscularly into the upper right side of the thigh. |                                 |
| Reporting group title                                                                                                                                                                                                                                                                                       | Infanrix-IPV/Hib M3-M4-M5 Group |
| Reporting group description:<br>Healthy male or female subjects between and including 60 and 90 days of age at the time of the first vaccination, received 3 doses of Infanrix-IPV/Hib vaccine at 3, 4 and 5 months of age (M3-M4-M5), administered intramuscularly into the upper right side of the thigh. |                                 |

### Primary: Number of subjects with any solicited local symptoms

|                                                                                                                                                                   |                                                                     |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|
| End point title                                                                                                                                                   | Number of subjects with any solicited local symptoms <sup>[1]</sup> |
| End point description:<br>Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of any local symptom regardless of intensity grade. |                                                                     |
| End point type                                                                                                                                                    | Primary                                                             |
| End point timeframe:<br>During the 4-day (Day 0-Day 3) follow-up period after each dose and across doses                                                          |                                                                     |

Notes:

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

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values                    | Infanrix-IPV/Hib M2-M3-M4 Group | Infanrix-IPV/Hib M3-M4-M5 Group |  |  |
|-------------------------------------|---------------------------------|---------------------------------|--|--|
| Subject group type                  | Reporting group                 | Reporting group                 |  |  |
| Number of subjects analysed         | 25                              | 25                              |  |  |
| Units: Subjects                     |                                 |                                 |  |  |
| Any pain Dose 1 [N=25;25]           | 4                               | 2                               |  |  |
| Any redness Dose 1 [N=25;25]        | 2                               | 0                               |  |  |
| Any swelling Dose 1 [N=25;25]       | 1                               | 0                               |  |  |
| Any pain Dose 2 [N=25;24]           | 1                               | 1                               |  |  |
| Any redness Dose 2 [N=25;24]        | 2                               | 0                               |  |  |
| Any swelling Dose 2 [N=25;24]       | 1                               | 0                               |  |  |
| Any pain Dose 3 [N=25;24]           | 2                               | 1                               |  |  |
| Any redness Dose 3 [N=25;24]        | 2                               | 0                               |  |  |
| Any swelling Dose 3 [N=25;24]       | 0                               | 0                               |  |  |
| Any pain Across doses [N=25;25]     | 4                               | 3                               |  |  |
| Any redness Across doses [N=25;25]  | 4                               | 0                               |  |  |
| Any swelling Across doses [N=25;25] | 2                               | 0                               |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of subjects with any solicited general symptoms

|                 |                                                                       |
|-----------------|-----------------------------------------------------------------------|
| End point title | Number of subjects with any solicited general symptoms <sup>[2]</sup> |
|-----------------|-----------------------------------------------------------------------|

End point description:

Assessed solicited general symptoms were drowsiness, irritability, loss of appetite and fever [defined as axillary temperature equal to or above 37.0 degrees Celsius (°C)]. Any = occurrence of any general symptom regardless of intensity grade or relationship to vaccination.

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

End point timeframe:

During the 4-day (Day 0-Day 3) follow-up period after each dose and across doses

Notes:

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

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values                               | Infanrix-<br>IPV/Hib M2-<br>M3-M4 Group | Infanrix-<br>IPV/Hib M3-<br>M4-M5 Group |  |  |
|------------------------------------------------|-----------------------------------------|-----------------------------------------|--|--|
| Subject group type                             | Reporting group                         | Reporting group                         |  |  |
| Number of subjects analysed                    | 25                                      | 25                                      |  |  |
| Units: Subjects                                |                                         |                                         |  |  |
| Any Drowsiness Dose 1 [N=25;25]                | 9                                       | 1                                       |  |  |
| Any Irritability Dose 1 [N=25;25]              | 9                                       | 5                                       |  |  |
| Any Loss of appetite Dose 1 [N=25;25]          | 7                                       | 1                                       |  |  |
| Any Fever Dose 1 [N=25;25]                     | 8                                       | 8                                       |  |  |
| Any Drowsiness Dose 2 [N=25;24]                | 3                                       | 5                                       |  |  |
| Any Irritability Dose 2 [N=25;24]              | 6                                       | 3                                       |  |  |
| Any Loss of appetite Dose 2 [N=25;24]          | 3                                       | 3                                       |  |  |
| Any Fever Dose 2 [N=25;24]                     | 5                                       | 5                                       |  |  |
| Any Drowsiness Dose 3 [N=25;24]                | 2                                       | 0                                       |  |  |
| Any Irritability Dose 3 [N=25;24]              | 5                                       | 4                                       |  |  |
| Any Loss of appetite Dose 3 [N=25;24]          | 3                                       | 1                                       |  |  |
| Any Fever Dose 3 [N=25;24]                     | 7                                       | 3                                       |  |  |
| Any Drowsiness Across doses<br>[N=25;25]       | 12                                      | 5                                       |  |  |
| Any Irritability Across doses [N=25;25]        | 15                                      | 8                                       |  |  |
| Any Loss of appetite Across doses<br>[N=25;25] | 9                                       | 4                                       |  |  |
| Any Fever Across doses [N=25;25]               | 13                                      | 12                                      |  |  |

### Statistical analyses

No statistical analyses for this end point

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

|                 |                                                                         |
|-----------------|-------------------------------------------------------------------------|
| End point title | Number of subjects with unsolicited adverse events (AEs) <sup>[3]</sup> |
|-----------------|-------------------------------------------------------------------------|

End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom

with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination.

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

End point timeframe:

During the 31-day (Day 0–30) follow-up period after each vaccination

Notes:

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

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values            | Infanrix-<br>IPV/Hib M2-<br>M3-M4 Group | Infanrix-<br>IPV/Hib M3-<br>M4-M5 Group |  |  |
|-----------------------------|-----------------------------------------|-----------------------------------------|--|--|
| Subject group type          | Reporting group                         | Reporting group                         |  |  |
| Number of subjects analysed | 25                                      | 25                                      |  |  |
| Units: Subjects             |                                         |                                         |  |  |
| AEs                         | 16                                      | 1                                       |  |  |

## Statistical analyses

No statistical analyses for this end point

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

|                 |                                                                      |
|-----------------|----------------------------------------------------------------------|
| End point title | Number of subjects with serious adverse events (SAEs) <sup>[4]</sup> |
|-----------------|----------------------------------------------------------------------|

End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

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

End point timeframe:

During the whole study period (from Day 0 until Month 3 or Month 4)

Notes:

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

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

| End point values            | Infanrix-<br>IPV/Hib M2-<br>M3-M4 Group | Infanrix-<br>IPV/Hib M3-<br>M4-M5 Group |  |  |
|-----------------------------|-----------------------------------------|-----------------------------------------|--|--|
| Subject group type          | Reporting group                         | Reporting group                         |  |  |
| Number of subjects analysed | 25                                      | 25                                      |  |  |
| Units: Subjects             |                                         |                                         |  |  |
| SAEs                        | 0                                       | 0                                       |  |  |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Solicited local and general symptoms: during the 4-day (Days 0-3) post-vaccination period. Unsolicited AEs: during the 31-day (Days 0-30) post-vaccination period. SAEs: during the entire study period (from Day 0 until Month 3/4).

|                 |            |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

### Dictionary used

|                    |        |
|--------------------|--------|
| Dictionary name    | MedDRA |
| Dictionary version | 13.0   |

### Reporting groups

|                       |                                 |
|-----------------------|---------------------------------|
| Reporting group title | Infanrix-IPV/Hib M3-M4-M5 Group |
|-----------------------|---------------------------------|

Reporting group description:

Healthy male or female subjects between and including 60 and 90 days of age at the time of the first vaccination, received 3 doses of Infanrix-IPV/Hib vaccine at 3, 4 and 5 months of age (M3-M4-M5), administered intramuscularly into the upper right side of the thigh.

|                       |                                 |
|-----------------------|---------------------------------|
| Reporting group title | Infanrix-IPV/Hib M2-M3-M4 Group |
|-----------------------|---------------------------------|

Reporting group description:

Healthy male or female subjects between and including 60 and 90 days of age at the time of the first vaccination, received 3 doses of Infanrix-IPV/Hib vaccine at 2, 3 and 4 months of age (M2-M3-M4), administered intramuscularly into the upper right side of the thigh.

| Serious adverse events                            | Infanrix-IPV/Hib M3-M4-M5 Group | Infanrix-IPV/Hib M2-M3-M4 Group |  |
|---------------------------------------------------|---------------------------------|---------------------------------|--|
| Total subjects affected by serious adverse events |                                 |                                 |  |
| subjects affected / exposed                       | 0 / 25 (0.00%)                  | 0 / 25 (0.00%)                  |  |
| number of deaths (all causes)                     | 0                               | 0                               |  |
| number of deaths resulting from adverse events    | 0                               | 0                               |  |

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

| Non-serious adverse events                            | Infanrix-IPV/Hib M3-M4-M5 Group | Infanrix-IPV/Hib M2-M3-M4 Group |  |
|-------------------------------------------------------|---------------------------------|---------------------------------|--|
| Total subjects affected by non-serious adverse events |                                 |                                 |  |
| subjects affected / exposed                           | 16 / 25 (64.00%)                | 23 / 25 (92.00%)                |  |
| General disorders and administration site conditions  |                                 |                                 |  |
| Pyrexia                                               |                                 |                                 |  |
| alternative assessment type: Non-systematic           |                                 |                                 |  |
| subjects affected / exposed                           | 0 / 25 (0.00%)                  | 5 / 25 (20.00%)                 |  |
| occurrences (all)                                     | 0                               | 5                               |  |
| Pain                                                  |                                 |                                 |  |

|                                                                                                                                                                                                                                                                                                                                  |                                                               |                                                                   |  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|-------------------------------------------------------------------|--|
| <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                                                                                                                                                                                                                                                      | <p>3 / 25 (12.00%)</p> <p>3</p>                               | <p>4 / 25 (16.00%)</p> <p>4</p>                                   |  |
| <p>Redness</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                                                                                                                                                                                                                                       | <p>0 / 25 (0.00%)</p> <p>0</p>                                | <p>4 / 25 (16.00%)</p> <p>4</p>                                   |  |
| <p>Swelling</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                                                                                                                                                                                                                                      | <p>0 / 25 (0.00%)</p> <p>0</p>                                | <p>2 / 25 (8.00%)</p> <p>2</p>                                    |  |
| <p>Drowsiness</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                                                                                                                                                                                                                                    | <p>5 / 25 (20.00%)</p> <p>5</p>                               | <p>12 / 25 (48.00%)</p> <p>12</p>                                 |  |
| <p>Irritability</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                                                                                                                                                                                                                                  | <p>8 / 25 (32.00%)</p> <p>8</p>                               | <p>15 / 25 (60.00%)</p> <p>15</p>                                 |  |
| <p>Loss of appetite</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                                                                                                                                                                                                                              | <p>4 / 25 (16.00%)</p> <p>4</p>                               | <p>9 / 25 (36.00%)</p> <p>9</p>                                   |  |
| <p>Fever</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                                                                                                                                                                                                                                         | <p>12 / 25 (48.00%)</p> <p>12</p>                             | <p>13 / 25 (52.00%)</p> <p>13</p>                                 |  |
| <p>Gastrointestinal disorders</p> <p>Diarrhoea</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>                                                                                                                                                                | <p>0 / 25 (0.00%)</p> <p>0</p>                                | <p>4 / 25 (16.00%)</p> <p>4</p>                                   |  |
| <p>Infections and infestations</p> <p>Upper respiratory tract infection</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>Nasopharyngitis</p> <p>alternative assessment type: Non-systematic</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> | <p>1 / 25 (4.00%)</p> <p>1</p> <p>0 / 25 (0.00%)</p> <p>0</p> | <p>10 / 25 (40.00%)</p> <p>10</p> <p>4 / 25 (16.00%)</p> <p>4</p> |  |



## 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