



## Clinical trial results:

**A phase III, open-label, randomised multicentre study to evaluate the immunogenicity and safety of a booster dose of GlaxoSmithKline Biologicals' dTpa-IPV vaccine (Boostrix Polio) compared with Sanofi Pasteur MSD's dTpa-IPV vaccine (Repevax), when co-administered with GSK Biologicals' MMR vaccine (Priorix) in 3 and 4-year-old healthy children.**

### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2009-012202-39 |
| Trial protocol           | GB             |
| Global end of trial date |                |

### Results information

|                                |               |
|--------------------------------|---------------|
| Result version number          | v1            |
| This version publication date  | 27 April 2016 |
| First version publication date | 06 June 2015  |

### Trial information

#### Trial identification

|                       |        |
|-----------------------|--------|
| Sponsor protocol code | 111763 |
|-----------------------|--------|

#### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT01245049 |
| 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, 0044 2089904466, GSKClinicalSupportHD@gsk.com |
| Scientific contact           | Clinical Trials Call Center, GlaxoSmithKline Biologicals, 0044 2089904466, GSKClinicalSupportHD@gsk.com |

Notes:

### Paediatric regulatory details

|  |                     |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP)       | Yes                 |
| EMA paediatric investigation plan number(s)                          | EMA-000500-PIP01-08 |
| 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                                       | Interim       |
| Date of interim/final analysis                       | 27 March 2012 |
| Is this the analysis of the primary completion data? | Yes           |
| Primary completion date                              | 27 March 2012 |
| Global end of trial reached?                         | No            |

Notes:

## General information about the trial

Main objective of the trial:

- To demonstrate that GSK Biologicals' dTpa-IPV vaccine is non-inferior to Sanofi Pasteur MSD's dTpa-IPV vaccine in terms of percentages of subjects with immune response to the diphtheria, tetanus and polio antigens, one month after booster vaccination.
- To demonstrate that GSK Biologicals' dTpa-IPV vaccine given as a single booster dose in this study is non-inferior to GSK Biologicals' DTPa vaccine (Infanrix) given as a primary series in the German household contact study APV-039 in terms of anti-PT, anti-FHA and anti-PRN geometric mean concentrations (GMCs), one month after booster vaccination.

Protection of trial subjects:

The vaccine was administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may have occurred following an intramuscular administration to these subjects. Firm pressure was applied to the injection site (without rubbing) for at least two minutes.

Background therapy: -

Evidence for comparator: -

|   |               |
|---|---------------|
| Actual start date of recruitment                          | 06 April 2011 |
| 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 | United Kingdom: 385 |
| Worldwide total number of subjects   | 385                 |
| EEA total number of subjects         | 385                 |

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)                     | 385 |

|                           |   |
|---------------------------|---|
| 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 trial (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>             | Boostrix Polio Group |

Arm description:

Subjects received 1 booster dose of Boostrix Polio vaccine co-administered with Priorix

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

Dosage and administration details:

1 dose of Boostrix™ Polio co-administered with Priorix™.

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

Dosage and administration details:

1 dose of Boostrix™ Polio co-administered with Priorix™.

|                  |               |
|------------------|---------------|
| <b>Arm title</b> | Repevax Group |
|------------------|---------------|

Arm description:

Subjects received 1 booster dose of Repevax vaccine co-administered with Priorix vaccine

|  |                   |
|--|-------------------|
| Arm type                               | Active comparator |
| Investigational medicinal product name | Repevax™          |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Intramuscular use |

Dosage and administration details:

1 dose of Repevax™ Polio co-administered with Priorix™.

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

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**Dosage and administration details:**

1 dose of Repevax™ co-administered with Priorix™.

| <b>Number of subjects in period 1</b> | <b>Boostrix Polio Group</b> | <b>Repevax Group</b> |
|---------------------------------------|-----------------------------|----------------------|
| Started                               | 255                         | 130                  |
| Completed                             | 254                         | 126                  |
| Not completed                         | 1                           | 4                    |
| Consent withdrawn by subject          | -                           | 1                    |
| Lost to follow-up                     | -                           | 2                    |
| Migrated/moved from study area        | -                           | 1                    |
| Lost to follow-up                     | 1                           | -                    |

## Baseline characteristics

### Reporting groups

|  |                      |
|--|----------------------|
| Reporting group title  | Boostrix Polio Group |
| Reporting group description:   |                      |
| Subjects received 1 booster dose of Boostrix Polio vaccine co-administered with Priorix  |                      |
| Reporting group title  | Repevax Group        |
| Reporting group description:   |                      |
| Subjects received 1 booster dose of Repevax vaccine co-administered with Priorix vaccine |                      |

| Reporting group values                                | Boostrix Polio Group | Repevax Group | Total |
|---|----------------------|---------------|-------|
| Number of subjects                                    | 255                  | 130           | 385   |
| Age categorical<br>Units: Subjects                    |                      |               |       |
| In utero  |                      |               | 0     |
| Preterm newborn infants<br>(gestational age < 37 wks) |                      |               | 0     |
| Newborns (0-27 days)                                  |                      |               | 0     |
| Infants and toddlers (28 days-23 months)              |                      |               | 0     |
| Children (2-11 years)                                 |                      |               | 0     |
| Adolescents (12-17 years)                             |                      |               | 0     |
| Adults (18-64 years)                                  |                      |               | 0     |
| From 65-84 years                                      |                      |               | 0     |
| 85 years and over                                     |                      |               | 0     |
| Age continuous<br>Units: years                        |                      |               |       |
| arithmetic mean                                       | 3.1                  | 3.1           |       |
| standard deviation                                    | ± 0.25               | ± 0.24        | -     |
| Gender categorical<br>Units: Subjects                 |                      |               |       |
| Female  | 123                  | 65            | 188   |
| Male  | 132                  | 65            | 197   |

## End points

### End points reporting groups

|  |                      |
|--|----------------------|
| Reporting group title  | Boostrix Polio Group |
| Reporting group description:   |                      |
| Subjects received 1 booster dose of Boostrix Polio vaccine co-administered with Priorix  |                      |
| Reporting group title  | Repevax Group        |
| Reporting group description:   |                      |
| Subjects received 1 booster dose of Repevax vaccine co-administered with Priorix vaccine |                      |

### Primary: Number of subjects with a booster response to diphtheria (D) and tetanus (T) antibodies.

|  |  |
|--|--|
| End point title  | Number of subjects with a booster response to diphtheria (D) and tetanus (T) antibodies. |
| End point description:   |  |
| Booster response was defined as: for initially seronegative subjects, antibody concentrations at least four times the assay cut-off; for initially seropositive subjects, an increase in antibody concentrations of at least four times the Pre booster vaccination concentration. |  |
| End point type   | Primary  |
| End point timeframe:   |  |
| One month after booster vaccination  |  |

| End point values            | Boostrix Polio Group | Repevax Group   |  |  |
|-----------------------------|----------------------|-----------------|--|--|
| Subject group type          | Reporting group      | Reporting group |  |  |
| Number of subjects analysed | 177                  | 90              |  |  |
| Units: Subject              |                      |                 |  |  |
| Anti-D [N=177;90]           | 176                  | 90              |  |  |
| Anti-T [N=176;90]           | 173                  | 90              |  |  |

### Statistical analyses

|   |   |
|---|---|
| Statistical analysis title              | Non-inferiority in terms of booster response to D |
| Comparison groups                       | Boostrix Polio Group v Repevax Group              |
| Number of subjects included in analysis | 267   |
| Analysis specification                  | Pre-specified                                     |
| Analysis type                           | non-inferiority <sup>[1]</sup>                    |
| Method                                  | Standardized asymptotic                           |
| Parameter estimate                      | Percentage difference                             |
| Point estimate                          | 0.56  |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -3.55   |
| upper limit                             | 3.14  |

Notes:

[1] - To assess the Non-inferiority of the Boostrix Polio Group compared to the Repevax Group in terms of booster response to diphtheria, standardized asymptotic 95% CI for the groups' difference [Repevax Group minus Boostrix Polio Group] was computed.

Non-inferiority criterion: Upper limit of the 95% CI of the groups' difference in booster response rate  $\leq 10\%$ .

|   |   |
|---|---|
| <b>Statistical analysis title</b>       | Non-inferiority in terms of booster response to T |
| Comparison groups                       | Boostrix Polio Group v Repevax Group              |
| Number of subjects included in analysis | 267   |
| Analysis specification                  | Pre-specified                                     |
| Analysis type                           | non-inferiority <sup>[2]</sup>                    |
| Parameter estimate                      | Percentage difference                             |
| Point estimate                          | 1.7   |
| Confidence interval                     |   |
| level                                   | 95 %  |
| sides                                   | 2-sided   |
| lower limit                             | -2.43   |
| upper limit                             | 4.9   |

Notes:

[2] - To assess the Non-inferiority of the Boostrix Polio Group compared to the Repevax Group in terms of booster response to tetanus, standardized asymptotic 95% CI for the groups' difference [Repevax Group minus Boostrix Polio Group] was computed.

Non-inferiority criterion: Upper limit of the 95% CI of the groups' difference in booster response rate  $\leq 10\%$

### **Primary: Concentrations for anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA) and anti-pertactin (anti-PRN).**

|                 |  |
|-----------------|--|
| End point title | Concentrations for anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA) and anti-pertactin (anti-PRN). <sup>[3]</sup> |
|-----------------|--|

End point description:

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

End point timeframe:

Before (PRE) and one month after (POST) the booster 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.

| <b>End point values</b>                  | Boostrix Polio Group | Repevax Group       |  |  |
|--|----------------------|---------------------|--|--|
| Subject group type                       | Reporting group      | Reporting group     |  |  |
| Number of subjects analysed              | 195                  | 96                  |  |  |
| Units: EU/mL                             |                      |                     |  |  |
| geometric mean (confidence interval 95%) |                      |                     |  |  |
| Anti-PT PRE [N=171;90]                   | 3.4 (3 to 3.9)       | 3.2 (2.9 to 3.6)    |  |  |
| Anti-PT POST [N=194;96]                  | 70.1 (62.2 to 79)    | 47.8 (39.9 to 57.3) |  |  |
| Anti-FHA PRE [N=174;85]                  | 12.9 (10 to 16.6)    | 10.7 (7.9 to 14.5)  |  |  |

|                          |                        |                        |  |  |
|--------------------------|------------------------|------------------------|--|--|
| Anti-FHA POST [N=195;95] | 358.3 (312.5 to 410.8) | 164.8 (138.5 to 196.1) |  |  |
| Anti-PRN PRE [N=175;91]  | 4.3 (3.8 to 5)         | 4.3 (3.7 to 5)         |  |  |
| Anti-PRN POST [N=195;94] | 151.4 (127.5 to 179.6) | 209.8 (168.5 to 261.3) |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of seropositive subjects for anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA) and anti-pertactin (anti-PRN).

|                 |  |
|-----------------|--|
| End point title | Number of seropositive subjects for anti-pertussis toxoid (anti-PT), anti-filamentous haemagglutinin (anti-FHA) and anti-pertactin (anti-PRN). |
|-----------------|--|

End point description:

A seropositive subject for anti-PT, anti-FHA and anti-PRN was a subject whose antibody concentration was  $\geq 5$  IU/ml.

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

End point timeframe:

Before (PRE) and one month after (POST) the booster vaccination.

| End point values            | Boostrix Polio Group | Repevax Group   |  |  |
|-----------------------------|----------------------|-----------------|--|--|
| Subject group type          | Reporting group      | Reporting group |  |  |
| Number of subjects analysed | 195                  | 96              |  |  |
| Units: Subject              |                      |                 |  |  |
| Anti-PT PRE [N=171;90]      | 31                   | 18              |  |  |
| Anti-PT POST [N=194;96]     | 194                  | 96              |  |  |
| Anti-FHA PRE [N=174;85]     | 112                  | 60              |  |  |
| Anti-FHA POST [N=195;95]    | 195                  | 95              |  |  |
| Anti-PRN PRE [N=175;91]     | 61                   | 37              |  |  |
| Anti-PRN POST [N=195;94]    | 194                  | 94              |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of seroprotected subjects for anti-D and anti-T.

|                 |   |
|-----------------|---|
| End point title | Number of seroprotected subjects for anti-D and anti-T. |
|-----------------|---|

End point description:

A seroprotected subject was defined a subject with antibody concentrations  $\geq 0.1$  international units per millilitre (IU/mL).

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

End point timeframe:

Before (PRE) and one month after (POST) the booster vaccination.

| <b>End point values</b>     | Boostrix Polio Group | Repevax Group   |  |  |
|-----------------------------|----------------------|-----------------|--|--|
| Subject group type          | Reporting group      | Reporting group |  |  |
| Number of subjects analysed | 195                  | 96              |  |  |
| Units: Subject              |                      |                 |  |  |
| Anti-D PRE [N=177;90]       | 136                  | 75              |  |  |
| Anti-D POST [N=195;96]      | 195                  | 96              |  |  |
| Anti-T PRE [N=177;90]       | 116                  | 63              |  |  |
| Anti-T POST [N=194;96]      | 194                  | 96              |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Concentrations for anti-D and anti-T.

|                 |                                       |
|-----------------|---------------------------------------|
| End point title | Concentrations for anti-D and anti-T. |
|-----------------|---------------------------------------|

End point description:

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

End point timeframe:

Before (PRE) and one month after (POST) the booster vaccination.

| <b>End point values</b>                  | Boostrix Polio Group   | Repevax Group             |  |  |
|--|------------------------|---------------------------|--|--|
| Subject group type                       | Reporting group        | Reporting group           |  |  |
| Number of subjects analysed              | 195                    | 96                        |  |  |
| Units: IU/mL                             |                        |                           |  |  |
| geometric mean (confidence interval 95%) |                        |                           |  |  |
| Anti-D PRE [N=177;90]                    | 0.228 (0.194 to 0.267) | 0.259 (0.209 to 0.32)     |  |  |
| Anti-D POST [N=195;96]                   | 8.113 (7.259 to 9.068) | 11.948 (10.003 to 14.271) |  |  |
| Anti-T PRE [N=177;90]                    | 0.209 (0.173 to 0.253) | 0.241 (0.184 to 0.315)    |  |  |
| Anti-T POST [N=194;96]                   | 6.787 (5.961 to 7.727) | 9.194 (7.565 to 11.175)   |  |  |

### Statistical analyses

No statistical analyses for this end point

**Secondary: Number of seroconverted subjects for anti-measles.**

|                 |  |
|-----------------|--|
| End point title | Number of seroconverted subjects for anti-measles. |
|-----------------|--|

End point description:

A converted subject was defined an initially seronegative subject with antibody concentrations  $\geq 150$  milli-international units per millilitre (mIU/mL).

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

End point timeframe:

Before (PRE) and one month after (POST) the booster vaccination.

| End point values            | Boostrix Polio Group | Repevax Group   |  |  |
|-----------------------------|----------------------|-----------------|--|--|
| Subject group type          | Reporting group      | Reporting group |  |  |
| Number of subjects analysed | 4                    | 2               |  |  |
| Units: Subject              |                      |                 |  |  |
| Anti-measles PRE [N=4;2]    | 0                    | 0               |  |  |
| Anti-measles POST [N=4;2]   | 4                    | 2               |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Concentrations for anti-measles**

|                 |                                 |
|-----------------|---------------------------------|
| End point title | Concentrations for anti-measles |
|-----------------|---------------------------------|

End point description:

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

End point timeframe:

Before (PRE) and one month after (POST) the booster vaccination.

| End point values                         | Boostrix Polio Group     | Repevax Group           |  |  |
|--|--------------------------|-------------------------|--|--|
| Subject group type                       | Reporting group          | Reporting group         |  |  |
| Number of subjects analysed              | 4                        | 2                       |  |  |
| Units: mIU/mL                            |                          |                         |  |  |
| geometric mean (confidence interval 95%) |                          |                         |  |  |
| Anti-measles PRE [N=4;2]                 | 75 (75 to 75)            | 75 (75 to 75)           |  |  |
| Anti-measles POST [N=4;2]                | 1937.2 (597.6 to 6279.9) | 2662.6 (0.9 to 7909745) |  |  |

**Statistical analyses**

No statistical analyses for this end point

### Secondary: Number of seroconverted subjects for anti-mumps.

|  |  |
|--|--|
| End point title  | Number of seroconverted subjects for anti-mumps. |
| End point description:<br>A converted subject was defined an initially seronegative subject with antibody concentrations $\geq 231$ units per millilitre (U/mL). |  |
| End point type   | Secondary  |
| End point timeframe:<br>Before (PRE) and one month after (POST) the booster vaccination.   |  |

| End point values            | Boostrix Polio Group | Repevax Group   |  |  |
|-----------------------------|----------------------|-----------------|--|--|
| Subject group type          | Reporting group      | Reporting group |  |  |
| Number of subjects analysed | 16                   | 7               |  |  |
| Units: Subjects             |                      |                 |  |  |
| Anti-mumps PRE [N=16;7]     | 0                    | 0               |  |  |
| Anti-mumps POST [N=11;6]    | 11                   | 6               |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Concentrations for anti-mumps

|  |                               |
|--|-------------------------------|
| End point title  | Concentrations for anti-mumps |
| End point description:   |                               |
| End point type   | Secondary                     |
| End point timeframe:<br>Before (PRE) and one month after (POST) the booster vaccination. |                               |

| End point values                         | Boostrix Polio Group    | Repevax Group             |  |  |
|--|-------------------------|---------------------------|--|--|
| Subject group type                       | Reporting group         | Reporting group           |  |  |
| Number of subjects analysed              | 16                      | 7                         |  |  |
| Units: U/mL                              |                         |                           |  |  |
| geometric mean (confidence interval 95%) |                         |                           |  |  |
| Anti-mumps PRE [N=16;7]                  | 115.5 (115.5 to 115.5)  | 115.5 (115.5 to 115.5)    |  |  |
| Anti-mumps POST [N=11;6]                 | 4131.9 (2453 to 6959.7) | 3671.2 (1642.9 to 8203.7) |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with a booster response to PT, FHA and PRN antibodies.

|                 |   |
|-----------------|---|
| End point title | Number of subjects with a booster response to PT, FHA and PRN antibodies. |
|-----------------|---|

End point description:

Booster response was defined as: for initially seronegative subjects, antibody concentrations at least four times the assay cut-off; for initially seropositive subjects, an increase in antibody concentrations of at least four times the Pre booster vaccination concentration.

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

End point timeframe:

One month after the booster vaccination.

| End point values            | Boostrix Polio Group | Repevax Group   |  |  |
|-----------------------------|----------------------|-----------------|--|--|
| Subject group type          | Reporting group      | Reporting group |  |  |
| Number of subjects analysed | 175                  | 90              |  |  |
| Units: Subjects             |                      |                 |  |  |
| Anti-PT [N=170;90]          | 154                  | 73              |  |  |
| Anti-FHA [N=174;85]         | 165                  | 79              |  |  |
| Anti-PRN [N= 175;89]        | 169                  | 89              |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with solicited local symptoms.

|                 |   |
|-----------------|---|
| End point title | Number of subjects with solicited local symptoms. |
|-----------------|---|

End point description:

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

End point timeframe:

During the 4-day (Days 0-3) follow-up period after booster vaccination.

| End point values            | Boostrix Polio Group | Repevax Group   |  |  |
|-----------------------------|----------------------|-----------------|--|--|
| Subject group type          | Reporting group      | Reporting group |  |  |
| Number of subjects analysed | 255                  | 125             |  |  |
| Units: Subjects             |                      |                 |  |  |
| Pain [N=255;125]            | 134                  | 72              |  |  |
| Redness [N=255;125]         | 156                  | 77              |  |  |
| Swelling [N=255;125]        | 99                   | 54              |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with solicited general symptoms.

|                 |   |
|-----------------|---|
| End point title | Number of subjects with solicited general symptoms. |
|-----------------|---|

End point description:

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

End point timeframe:

During the 4-day (Days 0-3) follow-up period after booster vaccination.

| End point values             | Boostrix Polio Group | Repevax Group   |  |  |
|------------------------------|----------------------|-----------------|--|--|
| Subject group type           | Reporting group      | Reporting group |  |  |
| Number of subjects analysed  | 255                  | 125             |  |  |
| Units: Subjects              |                      |                 |  |  |
| Drowsiness [N=255;125]       | 77                   | 39              |  |  |
| Irritability [N=255;125]     | 107                  | 49              |  |  |
| Loss of appetite [N=255;125] | 67                   | 30              |  |  |
| Temperature [N=255;125]      | 18                   | 9               |  |  |

### Statistical analyses

No statistical analyses for this end point

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

|                 |   |
|-----------------|---|
| End point title | Number of subjects with unsolicited adverse events (AEs). |
|-----------------|---|

End point description:

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

End point timeframe:

During the 31-day (Days 0-30) follow-up period after booster vaccination.

| <b>End point values</b>     | Boostrix Polio Group | Repevax Group   |  |  |
|-----------------------------|----------------------|-----------------|--|--|
| Subject group type          | Reporting group      | Reporting group |  |  |
| Number of subjects analysed | 255                  | 130             |  |  |
| Units: Subjects             |                      |                 |  |  |
| AEs [N=255;130]             | 88                   | 36              |  |  |

### Statistical analyses

No statistical analyses for this end point

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

|                 |  |
|-----------------|--|
| End point title | Number of subjects with serious adverse events (SAEs). |
|-----------------|--|

End point description:

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

End point timeframe:

During the entire study period.

| <b>End point values</b>     | Boostrix Polio Group | Repevax Group   |  |  |
|-----------------------------|----------------------|-----------------|--|--|
| Subject group type          | Reporting group      | Reporting group |  |  |
| Number of subjects analysed | 225                  | 130             |  |  |
| Units: Subjects             |                      |                 |  |  |
| SAEs [N=255;130]            | 1                    | 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- (Day 0-Day 3) after vaccination
- Unsolicited adverse events: during the 31 day (Day 0-Day 30) after vaccination
- Serious adverse event from the booster dose up to study end

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 14.1 |
|--------------------|------|

### Reporting groups

|                       |                      |
|-----------------------|----------------------|
| Reporting group title | Boostrix Polio Group |
|-----------------------|----------------------|

Reporting group description:

Subjects received 1 booster dose of Boostrix Polio vaccine co-administered with Priorix

|                       |               |
|-----------------------|---------------|
| Reporting group title | Repevax Group |
|-----------------------|---------------|

Reporting group description:

Subjects received 1 booster dose of Repevax vaccine co-administered with Priorix vaccine

| Serious adverse events                            | Boostrix Polio Group | Repevax Group   |  |
|---|----------------------|-----------------|--|
| Total subjects affected by serious adverse events |                      |                 |  |
| subjects affected / exposed                       | 1 / 255 (0.39%)      | 0 / 130 (0.00%) |  |
| number of deaths (all causes)                     | 0                    | 0               |  |
| number of deaths resulting from adverse events    | 0                    | 0               |  |
| Respiratory, thoracic and mediastinal disorders   |                      |                 |  |
| Pneumonia   |                      |                 |  |
| subjects affected / exposed                       | 1 / 255 (0.39%)      | 0 / 130 (0.00%) |  |
| occurrences causally related to treatment / all   | 0 / 1                | 0 / 0           |  |
| deaths causally related to treatment / all        | 0 / 0                | 0 / 0           |  |

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

| Non-serious adverse events                            | Boostrix Polio Group | Repevax Group     |  |
|---|----------------------|-------------------|--|
| Total subjects affected by non-serious adverse events |                      |                   |  |
| subjects affected / exposed                           | 156 / 255 (61.18%)   | 77 / 130 (59.23%) |  |
| General disorders and administration site conditions  |                      |                   |  |
| Pain  |                      |                   |  |
| alternative assessment type: Systematic               |                      |                   |  |

|  |                    |                   |
|--|--------------------|-------------------|
| subjects affected / exposed                | 134 / 255 (52.55%) | 72 / 130 (55.38%) |
| occurrences (all)                          | 134                | 72                |
| Redness                                    |                    |                   |
| alternative assessment type:<br>Systematic |                    |                   |
| subjects affected / exposed                | 156 / 255 (61.18%) | 77 / 130 (59.23%) |
| occurrences (all)                          | 156                | 77                |
| Swelling                                   |                    |                   |
| subjects affected / exposed                | 99 / 255 (38.82%)  | 54 / 130 (41.54%) |
| occurrences (all)                          | 99                 | 54                |
| Drowsiness                                 |                    |                   |
| alternative assessment type:<br>Systematic |                    |                   |
| subjects affected / exposed                | 77 / 255 (30.20%)  | 39 / 130 (30.00%) |
| occurrences (all)                          | 77                 | 39                |
| Irritability                               |                    |                   |
| alternative assessment type:<br>Systematic |                    |                   |
| subjects affected / exposed                | 107 / 255 (41.96%) | 49 / 130 (37.69%) |
| occurrences (all)                          | 107                | 49                |
| Loss of appetite                           |                    |                   |
| alternative assessment type:<br>Systematic |                    |                   |
| subjects affected / exposed                | 67 / 255 (26.27%)  | 30 / 130 (23.08%) |
| occurrences (all)                          | 67                 | 30                |
| Temperature/(Axillary)                     |                    |                   |
| alternative assessment type:<br>Systematic |                    |                   |
| subjects affected / exposed                | 18 / 255 (7.06%)   | 9 / 130 (6.92%)   |
| occurrences (all)                          | 18                 | 9                 |

## **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