



## Clinical trial results:

**A phase IIIb, 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-MSDs DTPa-IPV (Tetravac), when co-administered with MMRV (Priorix Tetra) in 5 to 6-year-old healthy children.**

### Summary

|                          |                  |
|--------------------------|------------------|
| EudraCT number           | 2008-006124-64   |
| Trial protocol           | IT               |
| Global end of trial date | 18 November 2009 |

### Results information

|                                |                  |
|--------------------------------|------------------|
| Result version number          | v1               |
| This version publication date  | 02 May 2016      |
| First version publication date | 20 February 2015 |

### Trial information

#### Trial identification

|                       |        |
|-----------------------|--------|
| Sponsor protocol code | 111815 |
|-----------------------|--------|

#### Additional study identifiers

|                                    |   |
|------------------------------------|---|
| ISRCTN number                      | - |
| ClinicalTrials.gov id (NCT number) | - |
| 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, 044 2089-904466, GSKClinicalSupportHD@gsk.com |
| Scientific contact           | Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, 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                                       | Final            |
| Date of interim/final analysis                       | 29 June 2010     |
| Is this the analysis of the primary completion data? | Yes              |
| Primary completion date                              | 18 November 2009 |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 18 November 2009 |
| Was the trial ended prematurely?                     | 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-MSDs DTPa-IPV vaccine, in terms of seroprotection rates against diphtheria, tetanus and poliovirus types 1, 2 and 3, one month after vaccination.

Protection of trial subjects:

As with all injectable vaccines, appropriate medical treatment was always readily available in case of anaphylactic reactions following the administration of the vaccine. For this reason, the vaccinee remained under medical supervision for 30 minutes after vaccination

Background therapy: -

Evidence for comparator: -

|   |               |
|---|---------------|
| Actual start date of recruitment                          | 15 April 2009 |
| Long term follow-up planned                               | No            |
| Independent data monitoring committee (IDMC) involvement? | Yes           |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |            |
|--------------------------------------|------------|
| Country: Number of subjects enrolled | Italy: 303 |
| Worldwide total number of subjects   | 303        |
| EEA total number of subjects         | 303        |

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)                     | 303 |
| 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>                       | Boostrix Group    |
| Arm description: -                     |                   |
| 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:

Single dose, intramuscular administration.

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

Dosage and administration details:

Single dose, subcutaneously.

|  |                   |
|--|-------------------|
| <b>Arm title</b>                       | Tetravac Group    |
| Arm description: -                     |                   |
| Arm type                               | Active comparator |
| Investigational medicinal product name | Priorix Tetra     |
| Investigational medicinal product code |                   |
| Other name                             |                   |
| Pharmaceutical forms                   | Injection         |
| Routes of administration               | Subcutaneous use  |

Dosage and administration details:

Single dose, subcutaneously.

|  |          |
|--|----------|
| Investigational medicinal product name | Tetravac |
| Investigational medicinal product code |          |
| Other name                             |          |

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

Dosage and administration details:

Single dose, intramuscular administration.

| <b>Number of subjects in period 1</b> | Boostrix Group | Tetravac Group |
|---------------------------------------|----------------|----------------|
| Started                               | 151            | 152            |
| Completed                             | 150            | 152            |
| Not completed                         | 1              | 0              |
| Consent withdrawn by subject          | 1              | -              |

## Baseline characteristics

### Reporting groups

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

|                                |
|--------------------------------|
| Reporting group description: - |
|--------------------------------|

|                       |                |
|-----------------------|----------------|
| Reporting group title | Tetravac Group |
|-----------------------|----------------|

|                                |
|--------------------------------|
| Reporting group description: - |
|--------------------------------|

| Reporting group values                                | Boostrix Group | Tetravac Group | Total |
|---|----------------|----------------|-------|
| Number of subjects                                    | 151            | 152            | 303   |
| 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<br>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                        |                |                |       |
| geometric mean  | 5              | 5              |       |
| standard deviation                                    | ± 0.14         | ± 0.14         | -     |
| Gender categorical<br>Units: Subjects                 |                |                |       |
| Female  | 81             | 68             | 149   |
| Male  | 70             | 84             | 154   |

## End points

### End points reporting groups

|                                |                |
|--------------------------------|----------------|
| Reporting group title          | Boostrix Group |
| Reporting group description: - |                |
| Reporting group title          | Tetravac Group |
| Reporting group description: - |                |

### Primary: Anti-diphtheria (anti-D) and anti-tetanus (anti-T) antibody concentrations

|                 |   |
|-----------------|---|
| End point title | Anti-diphtheria (anti-D) and anti-tetanus (anti-T) antibody concentrations <sup>[1]</sup> |
|-----------------|---|

End point description:

|                             |         |
|-----------------------------|---------|
| End point type              | Primary |
| End point timeframe:        |         |
| At 1 Month post-vaccination |         |

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                         | Boostrix Group            | Tetravac Group           |  |  |
|--|---------------------------|--------------------------|--|--|
| Subject group type                       | Reporting group           | Reporting group          |  |  |
| Number of subjects analysed              | 139                       | 144                      |  |  |
| Units: IU/mL                             |                           |                          |  |  |
| geometric mean (confidence interval 95%) |                           |                          |  |  |
| Anti-D                                   | 9.207 (8.057 to 10.522)   | 21.393 (19.165 to 23.88) |  |  |
| Anti-T                                   | 12.527 (10.957 to 14.323) | 11.07 (9.872 to 12.413)  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Primary: Anti-poliovirus types 1, 2 and 3 antibody titres

|                 |   |
|-----------------|---|
| End point title | Anti-poliovirus types 1, 2 and 3 antibody titres <sup>[2]</sup> |
|-----------------|---|

End point description:

|                             |         |
|-----------------------------|---------|
| End point type              | Primary |
| End point timeframe:        |         |
| At 1 Month post-vaccination |         |

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                         | Boostrix Group            | Tetravac Group            |  |  |
|--|---------------------------|---------------------------|--|--|
| Subject group type                       | Reporting group           | Reporting group           |  |  |
| Number of subjects analysed              | 139                       | 144                       |  |  |
| Units: Titers                            |                           |                           |  |  |
| geometric mean (confidence interval 95%) |                           |                           |  |  |
| Anti-poliovirus type 1                   | 1145.6 (978.7 to 1340.9)  | 948 (817.5 to 1099.4)     |  |  |
| Anti-poliovirus type 2                   | 1076.4 (908.7 to 1274.9)  | 1315.3 (1123.1 to 1540.3) |  |  |
| Anti-poliovirus type 3                   | 1937.8 (1631.4 to 2301.8) | 1657.3 (1385.5 to 1982.6) |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of subjects with anti-diphtheria (anti-D) and anti-tetanus (anti-T) antibody concentrations above 0.1 IU/mL.

|                 |  |
|-----------------|--|
| End point title | Number of subjects with anti-diphtheria (anti-D) and anti-tetanus (anti-T) antibody concentrations above 0.1 IU/mL. <sup>[3]</sup> |
|-----------------|--|

End point description:

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

End point timeframe:

At 1 Month post-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            | Boostrix Group  | Tetravac Group  |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 139             | 144             |  |  |
| Units: Subjects             |                 |                 |  |  |
| Anti-D                      | 139             | 144             |  |  |
| Anti-T                      | 139             | 144             |  |  |

## Statistical analyses

No statistical analyses for this end point

**Primary: Number of subjects with anti-poliovirus types 1, 2 and 3 antibody titres above 8**

|                 |   |
|-----------------|---|
| End point title | Number of subjects with anti-poliovirus types 1, 2 and 3 antibody titres above 8 <sup>[4]</sup> |
|-----------------|---|

End point description:

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

End point timeframe:

At 1 Month post-vaccination

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            | Boostrix Group  | Tetravac Group  |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 139             | 144             |  |  |
| Units: Subjects             |                 |                 |  |  |
| Anti-poliovirus type 1      | 139             | 144             |  |  |
| Anti-poliovirus type 2      | 139             | 144             |  |  |
| Anti-poliovirus type 3      | 138             | 144             |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Anti-pertussis toxoid (anti-PT), anti-filamentous hemagglutinin (anti-FHA) and anti-pertactin (anti-PRN) antibody concentrations**

|                 |  |
|-----------------|--|
| End point title | Anti-pertussis toxoid (anti-PT), anti-filamentous hemagglutinin (anti-FHA) and anti-pertactin (anti-PRN) antibody concentrations |
|-----------------|--|

End point description:

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

End point timeframe:

At 1 Month post-vaccination

| End point values                         | Boostrix Group      | Tetravac Group      |  |  |
|--|---------------------|---------------------|--|--|
| Subject group type                       | Reporting group     | Reporting group     |  |  |
| Number of subjects analysed              | 139                 | 144                 |  |  |
| Units: EL.U/mL                           |                     |                     |  |  |
| geometric mean (confidence interval 95%) |                     |                     |  |  |
| Anti-PT                                  | 59.8 (52.2 to 68.5) | 75.9 (65.7 to 87.7) |  |  |



|          |                        |                      |  |  |
|----------|------------------------|----------------------|--|--|
| Anti-FHA | 556.2 (491.4 to 629.5) | 613.5 (547 to 688.2) |  |  |
| Anti-PRN | 354.8 (280.2 to 449.4) | 7.8 (6.5 to 9.2)     |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects with anti-D and anti-T antibody concentrations $\geq 1.0$ IU/mL

|                 |  |
|-----------------|--|
| End point title | Number of subjects with anti-D and anti-T antibody concentrations $\geq 1.0$ IU/mL |
|-----------------|--|

End point description:

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

End point timeframe:

At 1 Month post-vaccination

| End point values            | Boostrix Group  | Tetravac Group  |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 139             | 144             |  |  |
| Units: Subjects             |                 |                 |  |  |
| Anti-D                      | 138             | 137             |  |  |
| Anti-T                      | 144             | 143             |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects with anti-measles, anti-mumps, anti-rubella and anti-varicella antibody titres above the cut-off values

|                 |  |
|-----------------|--|
| End point title | Number of subjects with anti-measles, anti-mumps, anti-rubella and anti-varicella antibody titres above the cut-off values |
|-----------------|--|

End point description:

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

End point timeframe:

At 1 Month post-vaccination

| End point values            | Boostrix Group  | Tetravac Group  |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 139             | 146             |  |  |
| Units: Subjects             |                 |                 |  |  |
| Anti- measles               | 139             | 146             |  |  |
| Anti-mumps                  | 139             | 144             |  |  |
| Anti-rubella                | 139             | 146             |  |  |
| Anti- varicella             | 135             | 140             |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Anti-PT, anti-FHA and anti-PRN antibody concentrations

|                 |  |
|-----------------|--|
| End point title | Anti-PT, anti-FHA and anti-PRN antibody concentrations |
|-----------------|--|

End point description:

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

End point timeframe:

At 1 Month post-vaccination

| End point values                         | Boostrix Group         | Tetravac Group       |  |  |
|--|------------------------|----------------------|--|--|
| Subject group type                       | Reporting group        | Reporting group      |  |  |
| Number of subjects analysed              | 139                    | 144                  |  |  |
| Units: EL.U/mL                           |                        |                      |  |  |
| geometric mean (confidence interval 95%) |                        |                      |  |  |
| Anti-PT                                  | 59.8 (52.2 to 68.5)    | 75.9 (65.7 to 87.7)  |  |  |
| Anti-FHA                                 | 556.2 (491.4 to 629.5) | 613.5 (547 to 688.2) |  |  |
| Anti-PRN                                 | 354.8 (280.2 to 449.4) | 7.8 (6.5 to 9.2)     |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Anti-measles, anti-mumps, anti-rubella and anti-varicella antibody titres

|                 |   |
|-----------------|---|
| End point title | Anti-measles, anti-mumps, anti-rubella and anti-varicella antibody titres |
|-----------------|---|

End point description:

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

End point timeframe:  
At 1 Month post-vaccination

| End point values                         | Boostrix Group            | Tetravac Group            |  |  |
|--|---------------------------|---------------------------|--|--|
| Subject group type                       | Reporting group           | Reporting group           |  |  |
| Number of subjects analysed              | 139                       | 146                       |  |  |
| Units: EL.U/mL                           |                           |                           |  |  |
| geometric mean (confidence interval 95%) |                           |                           |  |  |
| Anti- measles                            | 2743.9 (2411.4 to 3122.2) | 2863 (2534.6 to 3233.9)   |  |  |
| Anti-mumps                               | 4141.3 (3590.5 to 4776.5) | 3837.6 (3275.1 to 4496.7) |  |  |
| Anti-rubella                             | 154.5 (141.3 to 168.9)    | 162.5 (145.8 to 181)      |  |  |
| Anti- varicella                          | 856.7 (671.8 to 1092.4)   | 909.9 (721 to 1148.2)     |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with booster responses for anti-diphtheria and anti-tetanus antibody concentrations

|                 |  |
|-----------------|--|
| End point title | Number of subjects with booster responses for anti-diphtheria and anti-tetanus antibody concentrations |
|-----------------|--|

End point description:

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

End point timeframe:

At 1 Month post-vaccination

| End point values            | Boostrix Group  | Tetravac Group  |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 136             | 143             |  |  |
| Units: Subjects             |                 |                 |  |  |
| Anti-D                      | 130             | 136             |  |  |
| Anti-T                      | 137             | 142             |  |  |

### Statistical analyses

No statistical analyses for this end point

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**Secondary: Number of subjects with booster responses for anti-poliovirus types 1, 2 and 3 antibody concentrations**

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|                 |  |
|-----------------|--|
| End point title | Number of subjects with booster responses for anti-poliovirus types 1, 2 and 3 antibody concentrations |
|-----------------|--|

End point description:

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

End point timeframe:

At 1 Month post-vaccination

---

| End point values            | Boostrix Group  | Tetravac Group  |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 139             | 144             |  |  |
| Units: Subjects             |                 |                 |  |  |
| Anti-poliovirus type 1      | 115             | 112             |  |  |
| Anti-poliovirus type 2      | 113             | 112             |  |  |
| Anti-poliovirus type 3      | 126             | 127             |  |  |

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**Statistical analyses**

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No statistical analyses for this end point

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**Secondary: Number of subjects with booster responses for anti-PT, anti-FHA and anti-PRN antibody concentrations**

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|                 |  |
|-----------------|--|
| End point title | Number of subjects with booster responses for anti-PT, anti-FHA and anti-PRN antibody concentrations |
|-----------------|--|

End point description:

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

End point timeframe:

At 1 Month post-vaccination

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| End point values            | Boostrix Group  | Tetravac Group  |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 137             | 143             |  |  |
| Units: Subjects             |                 |                 |  |  |
| Anti-PT                     | 123             | 130             |  |  |
| Anti-FHA                    | 129             | 134             |  |  |
| Anti-PRN                    | 129             | 0               |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of seroconverted subjects for anti-measles, anti-mumps, anti-rubella and anti-varicella

|                 |  |
|-----------------|--|
| End point title | Number of seroconverted subjects for anti-measles, anti-mumps, anti-rubella and anti-varicella |
|-----------------|--|

End point description:

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

End point timeframe:

At 1 Month post-vaccination

| End point values            | Boostrix Group  | Tetravac Group  |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 36              | 34              |  |  |
| Units: Subjects             |                 |                 |  |  |
| Anti- measles               | 2               | 1               |  |  |
| Anti-mumps                  | 13              | 12              |  |  |
| Anti-rubella                | 0               | 0               |  |  |
| Anti- varicella             | 35              | 32              |  |  |

## Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period

| End point values            | Boostrix Group  | Tetravac Group  |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 151             | 152             |  |  |
| Units: Subjects             |                 |                 |  |  |
| Pain                        | 96              | 96              |  |  |
| Redness                     | 58              | 66              |  |  |
| Swelling                    | 55              | 62              |  |  |

### Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period

| End point values            | Boostrix Group  | Tetravac Group  |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 151             | 152             |  |  |
| Units: Subjects             |                 |                 |  |  |
| Fatigue                     | 40              | 36              |  |  |
| Gastrointestinal            | 23              | 15              |  |  |
| Headache                    | 18              | 20              |  |  |
| Temperature                 | 32              | 30              |  |  |

### Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

End point timeframe:

During the 31 days (Days 0-30) post-vaccination period

| <b>End point values</b>     | Boostrix Group  | Tetravac Group  |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 151             | 152             |  |  |
| Units: Subjects             |                 |                 |  |  |
| Subjects with any AE(s)     | 23              | 20              |  |  |

### 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 whole study period

| <b>End point values</b>     | Boostrix Group  | Tetravac Group  |  |  |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type          | Reporting group | Reporting group |  |  |
| Number of subjects analysed | 151             | 152             |  |  |
| Units: Subjects             |                 |                 |  |  |
| Subjects with any SAE(s)    | 0               | 0               |  |  |

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms: 4-day follow-up period after vaccination (Day 0 - Day 3); Unsolicited AEs: 31-day follow-up period after vaccination (Day 0 - Day 30); SAEs: throughout the study.

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

### Dictionary used

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

|                    |    |
|--------------------|----|
| Dictionary version | 13 |
|--------------------|----|

### Reporting groups

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

Reporting group description: -

|                       |                |
|-----------------------|----------------|
| Reporting group title | Tetravac Group |
|-----------------------|----------------|

Reporting group description: -

| Serious adverse events                            | Boostrix Group  | Tetravac Group  |  |
|---|-----------------|-----------------|--|
| Total subjects affected by serious adverse events |                 |                 |  |
| subjects affected / exposed                       | 0 / 151 (0.00%) | 0 / 152 (0.00%) |  |
| number of deaths (all causes)                     | 0               | 0               |  |
| number of deaths resulting from adverse events    |                 |                 |  |

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

| Non-serious adverse events                            | Boostrix Group    | Tetravac Group    |  |
|---|-------------------|-------------------|--|
| Total subjects affected by non-serious adverse events |                   |                   |  |
| subjects affected / exposed                           | 96 / 151 (63.58%) | 96 / 152 (63.16%) |  |
| General disorders and administration site conditions  |                   |                   |  |
| Pain  |                   |                   |  |
| alternative assessment type: Systematic               |                   |                   |  |
| subjects affected / exposed                           | 96 / 151 (63.58%) | 96 / 152 (63.16%) |  |
| occurrences (all)                                     | 96                | 96                |  |
| Gastrointestinal                                      |                   |                   |  |
| alternative assessment type: Systematic               |                   |                   |  |
| subjects affected / exposed                           | 23 / 151 (15.23%) | 15 / 152 (9.87%)  |  |
| occurrences (all)                                     | 23                | 15                |  |
| Headache  |                   |                   |  |



|   |                         |                         |  |
|---|-------------------------|-------------------------|--|
| alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)  | 18 / 151 (11.92%)<br>18 | 20 / 152 (13.16%)<br>20 |  |
| Temperature<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                           | 32 / 151 (21.19%)<br>32 | 30 / 152 (19.74%)<br>30 |  |
| Gastrointestinal disorders<br>Redness<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all) | 58 / 151 (38.41%)<br>58 | 66 / 152 (43.42%)<br>66 |  |
| Swelling<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                              | 55 / 151 (36.42%)<br>55 | 62 / 152 (40.79%)<br>62 |  |
| Fatigue<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                               | 40 / 151 (26.49%)<br>40 | 36 / 152 (23.68%)<br>36 |  |

## **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