



## Clinical trial results:

**Immunogenicity and Safety of the sanofi pasteur's DTacP-IPV Combined Vaccine (TETRAXIM™) given as a booster dose at 4 to 6 years of life in children previously vaccinated with PENTAXIM™ in the study E2I34**

### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2015-005403-87 |
| Trial protocol           | Outside EU/EEA |
| Global end of trial date | 31 May 2010    |

### Results information

|                                |              |
|--------------------------------|--------------|
| Result version number          | v1 (current) |
| This version publication date  | 09 June 2016 |
| First version publication date | 09 June 2016 |

### Trial information

#### Trial identification

|                       |       |
|-----------------------|-------|
| Sponsor protocol code | E2I57 |
|-----------------------|-------|

#### Additional study identifiers

|                                    |                 |
|------------------------------------|-----------------|
| ISRCTN number                      | -               |
| ClinicalTrials.gov id (NCT number) | NCT01031303     |
| WHO universal trial number (UTN)   | U1111-1112-2680 |

Notes:

### Sponsors

|                              |                                                                                             |
|------------------------------|---------------------------------------------------------------------------------------------|
| Sponsor organisation name    | Sanofi Pasteur, SA                                                                          |
| Sponsor organisation address | 2, avenue Pont Pasteur, Lyon cedex 07, France, F-69367                                      |
| Public contact               | Medical Team Leader, Sanofi Pasteur, SA, 33 4 37 65 67 99, Emmanuel.vidor@sanofipasteur.com |
| Scientific contact           | Medical Team Leader, Sanofi Pasteur, SA, 33 4 37 65 67 99, Emmanuel.vidor@sanofipasteur.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                       | 16 September 2010 |
| Is this the analysis of the primary completion data? | No                |
| Global end of trial reached?                         | Yes               |
| Global end of trial date                             | 31 May 2010       |
| Was the trial ended prematurely?                     | No                |

Notes:

## General information about the trial

Main objective of the trial:

To assess immunogenicity in terms of seroprotection rates (Diphtheria, Tetanus, Polio types 1, 2 and 3) and seroconversion/vaccine response rates to acellular Pertussis antigens (PT, FHA) of sanofi pasteur's DTaP-IPV (Tetraxim™) vaccine, one month after the booster dose given at 4 to 6 years of age.

Protection of trial subjects:

Only subjects that met all the study inclusion and none of the exclusion criteria were randomized and vaccinated in the study. Vaccinations were performed by qualified and trained study personnel. Subjects with allergy to any of the vaccine components were not vaccinated. After vaccination, subjects were kept under clinical observation for 30 minutes to ensure their safety. Appropriate medical equipment were available on site in case of any immediate allergic reactions.

Background therapy:

Subjects were vaccinated with PENTAXIM™ in a previous Study, 2015-005352-10 .

Evidence for comparator:

Not applicable.

|                                                           |                  |
|-----------------------------------------------------------|------------------|
| Actual start date of recruitment                          | 19 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 | Thailand: 123 |
| Worldwide total number of subjects   | 123           |
| 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)  | 0   |
| Children (2-11 years)                     | 123 |
| 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:

Study subjects were enrolled from 19 December 2009 to 31 March 2010 at 2 clinical centers in Thailand.

### Pre-assignment

Screening details:

Subjects who received Sanofi Pasteur's DTacP-IPV//PRP~T vaccine (Pentaxim™) as a 3-dose primary vaccination (at 2, 4, and 6 months of age) in parallel with a recombinant hepatitis B vaccination received at birth, 2 and 6 months of age in the study E2I34 are eligible for the booster dose study.

### Period 1

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

Blinding implementation details:

Not applicable

### Arms

|           |             |
|-----------|-------------|
| Arm title | Study Group |
|-----------|-------------|

Arm description:

Subjects received a booster dose of study vaccine DTacP-IPV vaccine (TETRAXIM™) at 4 to 6 years of age (at visit 1).

|                                        |                            |
|----------------------------------------|----------------------------|
| Arm type                               | Experimental               |
| Investigational medicinal product name | DTacP-IPV combined vaccine |
| Investigational medicinal product code |                            |
| Other name                             | TETRAXIM™                  |
| Pharmaceutical forms                   | Suspension for injection   |
| Routes of administration               | Intramuscular use          |

Dosage and administration details:

0.5 mL, Intramuscular into the right deltoid region

| Number of subjects in period 1 | Study Group |
|--------------------------------|-------------|
| Started                        | 123         |
| Completed                      | 123         |

## Baseline characteristics

### Reporting groups

|                       |               |
|-----------------------|---------------|
| Reporting group title | Overall Study |
|-----------------------|---------------|

Reporting group description: -

| Reporting group values                                | Overall Study | Total |  |
|-------------------------------------------------------|---------------|-------|--|
| Number of subjects                                    | 123           | 123   |  |
| Age categorical                                       |               |       |  |
| Units: Subjects                                       |               |       |  |
| In utero                                              | 0             | 0     |  |
| Preterm newborn infants<br>(gestational age < 37 wks) | 0             | 0     |  |
| Newborns (0-27 days)                                  | 0             | 0     |  |
| Infants and toddlers (28 days-23<br>months)           | 0             | 0     |  |
| Children (2-11 years)                                 | 123           | 123   |  |
| Adolescents (12-17 years)                             | 0             | 0     |  |
| Adults (18-64 years)                                  | 0             | 0     |  |
| From 65-84 years                                      | 0             | 0     |  |
| 85 years and over                                     | 0             | 0     |  |
| Age continuous                                        |               |       |  |
| Units: years                                          |               |       |  |
| arithmetic mean                                       | 4.2           |       |  |
| standard deviation                                    | ± 0.1         | -     |  |
| Gender categorical                                    |               |       |  |
| Units: Subjects                                       |               |       |  |
| Female                                                | 50            | 50    |  |
| Male                                                  | 73            | 73    |  |

## End points

### End points reporting groups

|                                                                                                                      |             |
|----------------------------------------------------------------------------------------------------------------------|-------------|
| Reporting group title                                                                                                | Study Group |
| Reporting group description:                                                                                         |             |
| Subjects received a booster dose of study vaccine DTacP-IPV vaccine (TETRAXIM™) at 4 to 6 years of age (at visit 1). |             |

### Primary: Percentage of Subjects with Seroprotection, Seroconversion/Vaccine Response After Booster Vaccination with DTacP-IPV Combined Vaccine (TETRAXIM™) Following Primary PENTAXIM™ Vaccination in a Previous Study (2015-005352-10).

|                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title                                                                                                                                                                                                                                                                       | Percentage of Subjects with Seroprotection, Seroconversion/Vaccine Response After Booster Vaccination with DTacP-IPV Combined Vaccine (TETRAXIM™) Following Primary PENTAXIM™ Vaccination in a Previous Study (2015-005352-10). <sup>[1]</sup> |
| End point description:                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                |
| Anti-diphtheria (D) and Anti-poliovirus (IPV) types 1, 2, and 3 antibodies were measured by a toxin neutralization test. Anti-Tetanus (T), anti-Pertussis toxoid (PT) and anti-Filamentous Haemagglutinin (FHA) antibodies were measured by enzyme-linked immunosorbent assay (ELISA) |                                                                                                                                                                                                                                                |
| End point type                                                                                                                                                                                                                                                                        | Primary                                                                                                                                                                                                                                        |
| End point timeframe:                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                |
| Day 30 post-booster 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: Descriptive analyses were performed based on the booster vaccine administered in the study.

| End point values                                 | Study Group     |  |  |  |
|--------------------------------------------------|-----------------|--|--|--|
| Subject group type                               | Reporting group |  |  |  |
| Number of subjects analysed                      | 123             |  |  |  |
| Units: Percentage of Subjects                    |                 |  |  |  |
| number (not applicable)                          |                 |  |  |  |
| Anti-Diphtheria                                  | 100             |  |  |  |
| Anti-Tetanus                                     | 100             |  |  |  |
| Anti-Polio 1                                     | 100             |  |  |  |
| Anti-Polio 1 (subjects got OPV, N = 11)          | 100             |  |  |  |
| Anti-Polio 1 (subjects did not get OPV, N = 112) | 100             |  |  |  |
| Anti-Polio 2                                     | 100             |  |  |  |
| Anti-Polio 2 (subjects got OPV, N = 11)          | 100             |  |  |  |
| Anti-Polio 2 (subjects did not get OPV, N = 112) | 100             |  |  |  |
| Anti-Polio 3                                     | 100             |  |  |  |
| Anti-Polio 3 (subjects got OPV, N = 11)          | 100             |  |  |  |
| Anti-Polio 3 (subjects did not get OPV, N = 112) | 100             |  |  |  |
| Anti-Pertussis toxoid                            | 97.6            |  |  |  |
| Anti-Filamentous Haemagglutinin                  | 92.6            |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### **Secondary: Geometric Mean Titers of Antibodies Against Vaccine Antigens Before and After Booster Vaccination with DTacP-IPV Combined Vaccine (TETRAXIM™) Following Primary PENTAXIM™ Vaccination in a Previous Study (2015-005352-10).**

|                 |                                                                                                                                                                                                                             |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Geometric Mean Titers of Antibodies Against Vaccine Antigens Before and After Booster Vaccination with DTacP-IPV Combined Vaccine (TETRAXIM™) Following Primary PENTAXIM™ Vaccination in a Previous Study (2015-005352-10). |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### End point description:

Anti-diphtheria (D) and Anti-poliovirus (IPV) types 1, 2, and 3 antibodies were measured by a toxin neutralization test. Anti-Tetanus (T), anti-Pertussis toxoid (PT) and anti-Filamentous Haemagglutinin (FHA) antibodies were measured by enzyme-linked immunosorbent assay (ELISA)

|                                                   |           |
|---------------------------------------------------|-----------|
| End point type                                    | Secondary |
| End point timeframe:                              |           |
| Day 0 Pre-vaccination and Day 30 Post-vaccination |           |

| End point values                                   | Study Group            |  |  |  |
|----------------------------------------------------|------------------------|--|--|--|
| Subject group type                                 | Reporting group        |  |  |  |
| Number of subjects analysed                        | 123                    |  |  |  |
| Units: Titers                                      |                        |  |  |  |
| geometric mean (confidence interval 95%)           |                        |  |  |  |
| Anti-Diphtheria Antibody (Day 0 Pre-vaccination)   | 0.149 (0.109 to 0.204) |  |  |  |
| Anti-Diphtheria Antibody (Day 30 Post-vaccination) | 7.81 (6.47 to 9.43)    |  |  |  |
| Anti-Tetanus Antibody (Day 0 Pre-vaccination)      | 0.654 (0.556 to 0.769) |  |  |  |
| Anti-Tetanus Antibody (Day 30 Post-vaccination)    | 7.72 (6.83 to 8.72)    |  |  |  |
| Anti-Polio 1 Antibody (Day 0 Pre-vaccination)      | 583 (467 to 729)       |  |  |  |
| Anti-Polio 1 Antibody (Day 30 Post-vaccination)    | 3013 (2631 to 3450)    |  |  |  |
| Anti-Polio 2 Antibody (Day 0 Pre-vaccination)      | 714 (566 to 900)       |  |  |  |
| Anti-Polio 2 Antibody (Day 30 Post-vaccination)    | 3430 (2969 to 3963)    |  |  |  |
| Anti-Polio 3 Antibody (Day 0 Pre-vaccination)      | 481 (374 to 619)       |  |  |  |
| Anti-Polio 3 Antibody (Day 30 Post-vaccination)    | 3837 (3261 to 4515)    |  |  |  |

|                                                   |                     |  |  |  |
|---------------------------------------------------|---------------------|--|--|--|
| Anti-Pertussis Antibody (Day 0 Pre-vaccination)   | 10.9 (9.11 to 13.1) |  |  |  |
| Anti-Pertussis Antibody (Day 30 Post-vaccination) | 190 (168 to 216)    |  |  |  |
| Anti-FHA Antibody (Day 0 Pre-vaccination)         | 24.3 (19.7 to 29.9) |  |  |  |
| Anti-FHA Antibody (Day 30 Post-vaccination)       | 356 (314 to 405)    |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Geometric Mean Titer Ratios of Antibodies Against Vaccine Antigens Before and After Booster Vaccination with DTacP-IPV Combined Vaccine (TETRAXIM™) Following Primary PENTAXIM™ Vaccination in a Previous Study (2015-005352-10).

|                 |                                                                                                                                                                                                                                   |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Geometric Mean Titer Ratios of Antibodies Against Vaccine Antigens Before and After Booster Vaccination with DTacP-IPV Combined Vaccine (TETRAXIM™) Following Primary PENTAXIM™ Vaccination in a Previous Study (2015-005352-10). |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Anti-diphtheria (D) and Anti-poliovirus (IPV) types 1, 2, and 3 antibodies were measured by a toxin neutralization test. Anti-Tetanus (T), anti-Pertussis toxoid (PT) and anti-Filamentous Haemagglutinin (FHA) antibodies were measured by enzyme-linked immunosorbent assay (ELISA)

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

End point timeframe:

Day 0 (pre-vaccination) and Day 30 Post-vaccination

| End point values                         | Study Group         |  |  |  |
|------------------------------------------|---------------------|--|--|--|
| Subject group type                       | Reporting group     |  |  |  |
| Number of subjects analysed              | 123                 |  |  |  |
| Units: Titer Ratios                      |                     |  |  |  |
| geometric mean (confidence interval 95%) |                     |  |  |  |
| Anti-Diphtheria                          | 52.5 (42.5 to 64.9) |  |  |  |
| Anti-Tetanus                             | 11.6 (10 to 13.5)   |  |  |  |
| Anti-Polio 1                             | 5.14 (4.08 to 6.46) |  |  |  |
| Anti-Polio 2                             | 4.77 (3.82 to 5.96) |  |  |  |
| Anti-Polio 3                             | 8.26 (6.33 to 10.8) |  |  |  |
| Anti-Pertussis toxoid                    | 17.4 (15.1 to 20)   |  |  |  |
| Anti-Filamentous Haemagglutinin          | 14.6 (12.3 to 17.3) |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects with Solicited Injection-site and Systemic Reactions After A Booster Vaccination with DTacP-IPV Combined Vaccine (TETRAXIM™) Following Primary PENTAXIM™ Vaccination in a Previous Study (2015-005352-10)

|                 |                                                                                                                                                                                                                                  |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Percentage of Subjects with Solicited Injection-site and Systemic Reactions After A Booster Vaccination with DTacP-IPV Combined Vaccine (TETRAXIM™) Following Primary PENTAXIM™ Vaccination in a Previous Study (2015-005352-10) |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

End point description:

Solicited injection site reactions: Pain, Erythema, and Swelling. Solicited systemic reactions: Fever (temperature), Headache, Malaise, Myalgia, and Asthenia

Grade 3 injection-site Pain, Incapacitating, preventing the performance of usual activities; Erythema and Swelling,  $\geq 5$  cm; Fever,  $\geq 39.0^{\circ}\text{C}$ ; Headache, Malaise, and Myalgia, Significant, prevents daily activity.

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

End point timeframe:

Day 0 up to Day 7 post-vaccination

| End point values                | Study Group     |  |  |  |
|---------------------------------|-----------------|--|--|--|
| Subject group type              | Reporting group |  |  |  |
| Number of subjects analysed     | 123             |  |  |  |
| Units: Percentage of Subjects   |                 |  |  |  |
| number (not applicable)         |                 |  |  |  |
| Injection-site Pain             | 75.6            |  |  |  |
| Grade 3 Injection-site Pain     | 0.8             |  |  |  |
| Injection-site Erythema         | 48.8            |  |  |  |
| Grade 3 Injection-site Erythema | 4.1             |  |  |  |
| Injection-site Swelling         | 36.6            |  |  |  |
| Grade 3 Injection-site Swelling | 2.4             |  |  |  |
| Fever                           | 10.6            |  |  |  |
| Grade 3 Fever                   | 0.8             |  |  |  |
| Headache                        | 24.4            |  |  |  |
| Grade 3 Headache                | 0               |  |  |  |
| Malaise                         | 32.5            |  |  |  |
| Grade 3 Malaise                 | 0               |  |  |  |
| Myalgia                         | 43.9            |  |  |  |
| Grade 3 Myalgia                 | 0               |  |  |  |

## Statistical analyses

No statistical analyses for this end point

### **Other pre-specified: Geometric Mean Titers of Antibodies Against Poliovirus Antigens Before and After Booster Vaccination with DTacP-IPV Combined Vaccine (TETRAXIM™) Following Primary PENTAXIM™ Vaccination in OPV and non-OPV Recipients in a Previous Study.**

|                 |                                                                                                                                                                                                                                             |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Geometric Mean Titers of Antibodies Against Poliovirus Antigens Before and After Booster Vaccination with DTacP-IPV Combined Vaccine (TETRAXIM™) Following Primary PENTAXIM™ Vaccination in OPV and non-OPV Recipients in a Previous Study. |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### End point description:

Geometric Mean Titers were determined in subjects who received Oral Polio Vaccine (OPV), and those who did not received Oral Polio Vaccine (N/A)

Anti-poliovirus (IPV) types 1, 2, and 3 antibodies was measured by a toxin neutralization test.

|                |                     |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

#### End point timeframe:

Day 0 (pre-vaccination) and Day 30 Post-vaccination.

| End point values                         | Study Group         |  |  |  |
|------------------------------------------|---------------------|--|--|--|
| Subject group type                       | Reporting group     |  |  |  |
| Number of subjects analysed              | 123 <sup>[2]</sup>  |  |  |  |
| Units: Titers                            |                     |  |  |  |
| geometric mean (confidence interval 95%) |                     |  |  |  |
| Anti-Polio 1 (Day 0, + OPV)              | 563 (296 to 1070)   |  |  |  |
| Anti-Polio 1 (Day 30, + OPV)             | 2719 (1752 to 4221) |  |  |  |
| Anti-Polio 1 (Day 0, N/A)                | 586 (461 to 744)    |  |  |  |
| Anti-Polio 1 (Day 30, N/A)               | 3043 (2634 to 3516) |  |  |  |
| Anti-Polio 2 (Day 0, + OPV)              | 875 (406 to 1885)   |  |  |  |
| Anti-Polio 2 (Day 30, + OPV)             | 3285 (1835 to 5881) |  |  |  |
| Anti-Polio 2 (Day 0, N/A)                | 700 (547 to 895)    |  |  |  |
| Anti-Polio 2 (Day 30, N/A)               | 3444 (2961 to 4006) |  |  |  |
| Anti-Polio 3 (Day 0, + OPV)              | 724 (315 to 1666)   |  |  |  |
| Anti-Polio 3 (Day 30, + OPV)             | 2896 (1758 to 4772) |  |  |  |
| Anti-Polio 3 (Day 0, N/A)                | 462 (354 to 603)    |  |  |  |
| Anti-Polio 3 (Day 30, N/A)               | 3945 (3318 to 4692) |  |  |  |

#### Notes:

[2] - N = 11 for subject who received OPV (+ OPV)

N = 112 for subject who did not receive OPV (N/A)

## Statistical analyses

No statistical analyses for this end point

### Other pre-specified: Geometric Mean Titer Ratios of Antibodies Against Poliovirus Antigens Before and After Booster Vaccination with DTacP-IPV Combined Vaccine (TETRAXIM™) Following Primary PENTAXIM™ Vaccination in OPV and non-OPV Recipients in a Previous Study.

|                 |                                                                                                                                                                                                                                                   |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| End point title | Geometric Mean Titer Ratios of Antibodies Against Poliovirus Antigens Before and After Booster Vaccination with DTacP-IPV Combined Vaccine (TETRAXIM™) Following Primary PENTAXIM™ Vaccination in OPV and non-OPV Recipients in a Previous Study. |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### End point description:

Geometric Mean Titers were determined in subjects who received Oral Polio Vaccine (OPV), and those who did not received Oral Polio Vaccine (N/A)

Anti-poliovirus (IPV) types 1, 2, and 3 antibodies were measured by a toxin neutralization test.

|                |                     |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

#### End point timeframe:

Day 0 (pre-vaccination) and Day 30 post-vaccination.

| End point values                         | Study Group         |  |  |  |
|------------------------------------------|---------------------|--|--|--|
| Subject group type                       | Reporting group     |  |  |  |
| Number of subjects analysed              | 123 <sup>[3]</sup>  |  |  |  |
| Units: Titer Ratios                      |                     |  |  |  |
| geometric mean (confidence interval 95%) |                     |  |  |  |
| Anti-polio 1 (Day 30 + OPV)              | 4.83 (1.91 to 12.2) |  |  |  |
| Anti-polio 1 (Day 30, N/A)               | 5.17 (4.07 to 6.57) |  |  |  |
| Anti-polio 2 (Day 30 + OPV)              | 3.76 (1.79 to 7.89) |  |  |  |
| Anti-polio 2 (Day 30 , N/A)              | 4.88 (3.85 to 6.19) |  |  |  |
| Anti-polio 3 (Day 30 + OPV)              | 4 (1.55 to 10.3)    |  |  |  |
| Anti-polio 2 (Day 30, N/A)               | 8.88 (6.72 to 11.7) |  |  |  |

Notes:

[3] - N = 11 for subject who received OPV (+ OPV)

N = 112 for subject who did not receive OPV (N/A)

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Adverse events were reported from Day 0 up to Day 30 post-vaccination

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 13.1 |
|--------------------|------|

### Reporting groups

|                       |             |
|-----------------------|-------------|
| Reporting group title | Study Group |
|-----------------------|-------------|

Reporting group description:

Subjects received a booster dose of study vaccine DTacP-IPV vaccine (TETRAXIM™) at 4 to 6 years of age (at visit 1).

| Serious adverse events                            | Study Group     |  |  |
|---------------------------------------------------|-----------------|--|--|
| Total subjects affected by serious adverse events |                 |  |  |
| subjects affected / exposed                       | 1 / 123 (0.81%) |  |  |
| number of deaths (all causes)                     | 0               |  |  |
| number of deaths resulting from adverse events    | 0               |  |  |
| Infections and infestations                       |                 |  |  |
| Nasopharyngitis                                   |                 |  |  |
| subjects affected / exposed                       | 1 / 123 (0.81%) |  |  |
| occurrences causally related to treatment / all   | 0 / 1           |  |  |
| deaths causally related to treatment / all        | 0 / 0           |  |  |

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

| Non-serious adverse events                            | Study Group       |  |  |
|-------------------------------------------------------|-------------------|--|--|
| Total subjects affected by non-serious adverse events |                   |  |  |
| subjects affected / exposed                           | 93 / 123 (75.61%) |  |  |
| Nervous system disorders                              |                   |  |  |
| Headache                                              |                   |  |  |
| alternative assessment type: Systematic               |                   |  |  |
| subjects affected / exposed                           | 30 / 123 (24.39%) |  |  |
| occurrences (all)                                     | 30                |  |  |
| General disorders and administration site conditions  |                   |  |  |

|                                                                                                                                                              |                         |  |  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--|--|
| Injection site Pain<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                        | 93 / 123 (75.61%)<br>93 |  |  |
| Injection-site Erythema<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                    | 60 / 123 (48.78%)<br>60 |  |  |
| Injection-site Swelling<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                    | 45 / 123 (36.59%)<br>45 |  |  |
| Fever<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                                      | 13 / 123 (10.57%)<br>13 |  |  |
| Malaise<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all)                                                    | 40 / 123 (32.52%)<br>40 |  |  |
| Musculoskeletal and connective tissue disorders<br>Myalgia<br>alternative assessment type:<br>Systematic<br>subjects affected / exposed<br>occurrences (all) | 54 / 123 (43.90%)<br>54 |  |  |
| Infections and infestations<br>Upper respiratory tract infection<br>subjects affected / exposed<br>occurrences (all)                                         | 28 / 123 (22.76%)<br>30 |  |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date            | Amendment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 29 October 2009 | This amendment was issued before the commencement of the trial to change the site of the intramuscular injection of the vaccine from anterolateral aspect of the right thigh to the right deltoid region.                                                                                                                                                                                                                                                                                                                                                                                      |
| 13 January 2010 | Protocol updated to allow inclusion of subjects that received or were to receive Oral Polio Vaccine (OPV) as part of the National Immunization Days (that occurred at the same time as study period in Thailand)<br>In the section on "Population used in the Analyses" the following text was added<br>"In addition, anti polio 1, 2, and 3 antibody titers will be analyzed on the subset of subjects who did not receive OPV as part of the National Immunization Days campaign, as well as on the subset of subjects who received OPV as part of the National Immunization Days campaign." |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported