



## Clinical trial results:

### Six-Month, One-Year, Three-Year, Five-Year and Ten-Year Data on the Long-Term Immunogenicity of Td-mIPV, Tdap-vIPV, Td, aP and Tdap in Adolescents and Adults

#### Summary

|                          |                  |
|--------------------------|------------------|
| EudraCT number           | 2015-005197-38   |
| Trial protocol           | Outside EU/EEA   |
| Global end of trial date | 09 February 2009 |

#### Results information

|                                |               |
|--------------------------------|---------------|
| Result version number          | v1 (current)  |
| This version publication date  | 16 April 2016 |
| First version publication date | 16 April 2016 |

#### Trial information

##### Trial identification

|                       |           |
|-----------------------|-----------|
| Sponsor protocol code | TD9707-LT |
|-----------------------|-----------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT00712959 |
| WHO universal trial number (UTN)   | -           |

Notes:

##### Sponsors

|                              |  |
|------------------------------|--|
| Sponsor organisation name    | Sanofi Pasteur Limited   |
| Sponsor organisation address | 1755 Steeles Ave. West, Toronto, Canada, M2R 3T4   |
| Public contact               | Clinical Team Leader, Sanofi Pasteur Limited, 1 416-667-2273, Miggi.Tomovici@sanofipasteur.com |
| Scientific contact           | Clinical Team Leader, Sanofi Pasteur Limited, 1 416-667-2273, Miggi.Tomovici@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? | Yes |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No  |

Notes:

## Results analysis stage

|  |                  |
|--|------------------|
| Analysis stage                                       | Final            |
| Date of interim/final analysis                       | 09 February 2009 |
| Is this the analysis of the primary completion data? | No               |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 09 February 2009 |
| Was the trial ended prematurely?                     | No               |

Notes:

## General information about the trial

Main objective of the trial:

1) To describe the antibody levels for tetanus, diphtheria, pertussis and poliovirus types 1, 2 and 3 at pre-vaccination, 1 month, 6 months, 1 year, 3 years, 5 years and 10 years after vaccination with Td-mIPV, Tdap-vIPV (vero), Td, aP and Tdap.

Protection of trial subjects:

Subjects were vaccinated in a previous study, Td9707. No vaccination was administered as part of this study.

Background therapy:

In Td9707, adolescents received either Td-mIPV Vaccine at Visit 1 followed by aP Vaccine 1 month later (Visit 2) or one of the three lots of the Tdap-vIPV Vaccine. Adults received separate injections (1 month apart) of Td and aP, Tdap and vIPV Vaccines, or Tdap and aP Vaccines, or they received one of the three lots of the Tdap-vIPV Vaccine at Visit 1. Subjects in groups that did not receive vIPV as a component of the study vaccine were offered vIPV vaccination at their last study visit (Visit 3). For the long-term immunogenicity follow-up study, subjects in all study groups were recalled for serology at 6 months, 1, 3, 5, and 10 years post-vaccination.

Evidence for comparator:

Not applicable

|   |                |
|---|----------------|
| Actual start date of recruitment                          | 05 August 1998 |
| 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 | Canada: 1214 |
| Worldwide total number of subjects   | 1214         |
| 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)     | 0   |
| Adolescents (12-17 years) | 468 |
| Adults (18-64 years)      | 746 |
| From 65 to 84 years       | 0   |
| 85 years and over         | 0   |

## Subject disposition

### Recruitment

Recruitment details:

The study subjects were enrolled in the long-term immunogenicity study from 5 August 1998 to 9 February 2009 at 4 clinic centers in Canada.

### Pre-assignment

Screening details:

A total of 1214 subjects who met all inclusion and none of the exclusion criteria were enrolled in the original Td9707 study; 1207 subjects were included in the long-term follow-up immunogenicity study.

### Period 1

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

Blinding implementation details:

Not applicable

### Arms

|                              |                     |
|------------------------------|---------------------|
| Are arms mutually exclusive? | Yes                 |
| <b>Arm title</b>             | Td-mIPV Adolescents |

Arm description:

Adolescents who received Td-mIPV on Day 0 followed by aP 1 month later.

|  |   |
|--|---|
| Arm type                               | Experimental  |
| Investigational medicinal product name | Tetanus Toxoid and Reduced Diphtheria Toxoid Adsorbed and Inactivated Poliovirus Vaccine (live virus grown on MRC-5 diploid cells); Td-mIPV Vaccine |
| Investigational medicinal product code |   |
| Other name                             |   |
| Pharmaceutical forms                   | Suspension for injection  |
| Routes of administration               | Intramuscular use   |

Dosage and administration details:

0.5 mL, intramuscular, 1 injection on Day 0.

|  |  |
|--|--|
| Investigational medicinal product name | Adult formulation of the 5-component Pertussis Vaccine; aP |
| Investigational medicinal product code |  |
| Other name                             |  |
| Pharmaceutical forms                   | Suspension for injection                                   |
| Routes of administration               | Intramuscular use  |

Dosage and administration details:

0.5 mL, intramuscular, 1 injection on Day 30.

|                  |                       |
|------------------|-----------------------|
| <b>Arm title</b> | TdaP1-IPV Adolescents |
|------------------|-----------------------|

Arm description:

Adolescents received 1 injection of TdaP1-IPV Lot 15001-11 on Day 0.

|  |  |
|--|--|
| Arm type                               | Experimental   |
| Investigational medicinal product name | TdaP Adsorbed Vaccine combined with inactivated poliovirus vaccine derived from Vero cell culture; TdcP1-IPV Adsorbed Vaccine Lot 15001-11 |
| Investigational medicinal product code |  |
| Other name                             |  |
| Pharmaceutical forms                   | Suspension for injection   |
| Routes of administration               | Intramuscular use  |

**Dosage and administration details:**

0.5 mL, intramuscular, 1 injection on Day 0.

|  |  |
|--|--|
| <b>Arm title</b>   | TdaP2-IPV Adolescents  |
| Arm description:<br>Adolescents received 1 injection of TdaP2-IPV Lot 15002-11 on Day 0.   |  |
| Arm type   | Experimental   |
| Investigational medicinal product name   | TdaP Adsorbed Vaccine combined with inactivated poliovirus vaccine derived from Vero cell culture; TdcP2-IPV Adsorbed Vaccine Lot 15002-11 |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Suspension for injection   |
| Routes of administration   | Intramuscular use  |
| Dosage and administration details:<br>0.5 mL, intramuscular, 1 injection on Day 0.   |  |
| <b>Arm title</b>   | TdaP3-IPV Adolescents  |
| Arm description:<br>Adolescents received 1 injection of TdaP3-IPV Lot 15003-11 on Day 0.   |  |
| Arm type   | Experimental   |
| Investigational medicinal product name   | TdaP Adsorbed Vaccine combined with inactivated poliovirus vaccine derived from Vero cell culture; TdcP3-IPV Adsorbed Vaccine Lot 15003-11 |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Suspension for injection   |
| Routes of administration   | Intramuscular use  |
| Dosage and administration details:<br>0.5 mL, intramuscular, 1 injection on Day 0.   |  |
| <b>Arm title</b>   | Td/aP Adults   |
| Arm description:<br>Adults received 1 injection of Tetanus and Diphtheria Toxoids Adsorbed Vaccine (Td Adsorbed Vaccine; Td) on Day 0 and 1 injection of Adult formulation of the 5-component Pertussis Vaccine (aP) 1 month later. An injection of Inactivated Poliovirus Vaccine was optional 1 month post-aP vaccination (Visit 3). |  |
| Arm type   | Experimental   |
| Investigational medicinal product name   | Adult formulation of the 5-component Pertussis Vaccine (aP)  |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Suspension for injection   |
| Routes of administration   | Intramuscular use  |
| Dosage and administration details:<br>0.5 mL, intramuscular, 1 injection at Month 1.   |  |
| Investigational medicinal product name   | Tetanus and Diphtheria Toxoids Adsorbed Vaccine (Td Adsorbed Vaccine; Td)  |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Suspension for injection   |
| Routes of administration   | Intramuscular use  |
| Dosage and administration details:<br>0.5 mL, intramuscular, 1 injection on Day 0.   |  |

|  |  |
|--|--|
| Investigational medicinal product name   | Inactivated Poliovirus Vaccine derived from Vero cell culture (IPV)  |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Suspension for injection   |
| Routes of administration   | Subcutaneous use   |
| Dosage and administration details:<br>0.5 mL, subcutaneous, optional injection at 1 month post-aP vaccination (Visit 3).   |  |
| <b>Arm title</b>   | Tdap/IPV Adults  |
| Arm description:<br>Adults received 1 injection of Tdap on Day 0 and 1 injection of IPV 1 month later.   |  |
| Arm type   | Experimental   |
| Investigational medicinal product name   | Td Adsorbed Vaccine combined with aP Vaccine (Tdap Adsorbed Vaccine) |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Suspension for injection   |
| Routes of administration   | Intramuscular use  |
| Dosage and administration details:<br>0.5 mL, intramuscular, 1 injection on Day 0.   |  |
| Investigational medicinal product name   | Inactivated Poliovirus Vaccine derived from Vero cell culture (IPV)  |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Suspension for injection   |
| Routes of administration   | Subcutaneous use   |
| Dosage and administration details:<br>0.5 mL, subcutaneous, 1 injection at Month 1.  |  |
| <b>Arm title</b>   | Tdap/aP Adults   |
| Arm description:<br>Adults received 1 injection of Tdap on Day 0 and 1 injection of aP one month later. An injection of Inactivated Poliovirus Vaccine was optional 1 month post-aP vaccination (Visit 3). |  |
| Arm type   | Experimental   |
| Investigational medicinal product name   | Td Adsorbed Vaccine combined with aP Vaccine (Tdap Adsorbed Vaccine) |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Suspension for injection   |
| Routes of administration   | Intramuscular use  |
| Dosage and administration details:<br>0.5 mL, intramuscular, 1 injection on Day 0.   |  |
| Investigational medicinal product name   | Adult formulation of the 5-component Pertussis Vaccine (aP)          |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Suspension for injection   |
| Routes of administration   | Intramuscular use  |
| Dosage and administration details:<br>0.5 mL, intramuscular, 1 injection at Month 1.   |  |
| Investigational medicinal product name   | Inactivated Poliovirus Vaccine derived from Vero cell culture (IPV)  |
| Investigational medicinal product code   |  |
| Other name   |  |
| Pharmaceutical forms   | Suspension for injection   |

|                          |                  |
|--------------------------|------------------|
| Routes of administration | Subcutaneous use |
|--------------------------|------------------|

Dosage and administration details:

0.5 mL, subcutaneous, optional injection at 1 month post-aP vaccination (Visit 3).

|                  |                  |
|------------------|------------------|
| <b>Arm title</b> | TdaP1-IPV Adults |
|------------------|------------------|

Arm description:

Adults received 1 injection of TdaP1-IPV Lot 15001-11 on Day 0.

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

|  |  |
|--|--|
| Investigational medicinal product name | TdaP Adsorbed Vaccine combined with inactivated poliovirus vaccine derived from Vero cell culture; TdcP1-IPV Adsorbed Vaccine Lot 15001-11 |
|--|--|

|  |  |
|--|--|
| Investigational medicinal product code |  |
|--|--|

|            |  |
|------------|--|
| Other name |  |
|------------|--|

|                      |                          |
|----------------------|--------------------------|
| Pharmaceutical forms | Suspension for injection |
|----------------------|--------------------------|

|                          |                   |
|--------------------------|-------------------|
| Routes of administration | Intramuscular use |
|--------------------------|-------------------|

Dosage and administration details:

0.5 mL, intramuscular, 1 injection on Day 0.

|                  |                  |
|------------------|------------------|
| <b>Arm title</b> | TdaP2-IPV Adults |
|------------------|------------------|

Arm description:

Adults received 1 injection of TdaP2-IPV Lot 15002-11 on Day 0.

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

|  |  |
|--|--|
| Investigational medicinal product name | TdaP Adsorbed Vaccine combined with inactivated poliovirus vaccine derived from Vero cell culture; TdcP2-IPV Adsorbed Vaccine Lot 15002-11 |
|--|--|

|  |  |
|--|--|
| Investigational medicinal product code |  |
|--|--|

|            |  |
|------------|--|
| Other name |  |
|------------|--|

|                      |                          |
|----------------------|--------------------------|
| Pharmaceutical forms | Suspension for injection |
|----------------------|--------------------------|

|                          |                   |
|--------------------------|-------------------|
| Routes of administration | Intramuscular use |
|--------------------------|-------------------|

Dosage and administration details:

0.5 mL, intramuscular, 1 injection on Day 0.

|                  |                  |
|------------------|------------------|
| <b>Arm title</b> | TdaP3-IPV Adults |
|------------------|------------------|

Arm description:

Adults received 1 injection of TdaP3-IPV Lot 15003-11 on Day 0.

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

|  |  |
|--|--|
| Investigational medicinal product name | TdaP Adsorbed Vaccine combined with inactivated poliovirus vaccine derived from Vero cell culture; TdcP3-IPV Adsorbed Vaccine Lot 15003-11 |
|--|--|

|  |  |
|--|--|
| Investigational medicinal product code |  |
|--|--|

|            |  |
|------------|--|
| Other name |  |
|------------|--|

|                      |                          |
|----------------------|--------------------------|
| Pharmaceutical forms | Suspension for injection |
|----------------------|--------------------------|

|                          |                   |
|--------------------------|-------------------|
| Routes of administration | Intramuscular use |
|--------------------------|-------------------|

Dosage and administration details:

0.5 mL, intramuscular, 1 injection on Day 0.

| <b>Number of subjects in period 1</b> | Td-mIPV Adolescents | TdaP1-IPV Adolescents | TdaP2-IPV Adolescents |
|---------------------------------------|---------------------|-----------------------|-----------------------|
| Started                               | 117                 | 118                   | 117                   |
| Completed                             | 117                 | 118                   | 115                   |
| Not completed                         | 0                   | 0                     | 2                     |
| Consent withdrawn by subject          | -                   | -                     | 2                     |
| Unable to obtain blood/serum sample   | -                   | -                     | -                     |
| Failed to meet inclusion criteria     | -                   | -                     | -                     |
| Unable to obtain serum sample         | -                   | -                     | -                     |
| Due to nature of bilateral hip pain   | -                   | -                     | -                     |
| Tetanus in < 5 years prior to study   | -                   | -                     | -                     |
| Not eligible; Td boost within 5 years | -                   | -                     | -                     |
| Lost to follow-up                     | -                   | -                     | -                     |
| Pregnancy                             | -                   | -                     | -                     |

| <b>Number of subjects in period 1</b> | TdaP3-IPV Adolescents | Td/aP Adults | TdaP/IPV Adults |
|---------------------------------------|-----------------------|--------------|-----------------|
| Started                               | 116                   | 126          | 126             |
| Completed                             | 116                   | 121          | 121             |
| Not completed                         | 0                     | 5            | 5               |
| Consent withdrawn by subject          | -                     | 4            | 2               |
| Unable to obtain blood/serum sample   | -                     | -            | 2               |
| Failed to meet inclusion criteria     | -                     | -            | -               |
| Unable to obtain serum sample         | -                     | -            | -               |
| Due to nature of bilateral hip pain   | -                     | -            | -               |
| Tetanus in < 5 years prior to study   | -                     | -            | -               |
| Not eligible; Td boost within 5 years | -                     | -            | -               |
| Lost to follow-up                     | -                     | 1            | 1               |
| Pregnancy                             | -                     | -            | -               |

| <b>Number of subjects in period 1</b> | TdaP/aP Adults | TdaP1-IPV Adults | TdaP2-IPV Adults |
|---------------------------------------|----------------|------------------|------------------|
| Started                               | 122            | 126              | 121              |
| Completed                             | 117            | 124              | 121              |
| Not completed                         | 5              | 2                | 0                |
| Consent withdrawn by subject          | 3              | -                | -                |
| Unable to obtain blood/serum sample   | -              | -                | -                |
| Failed to meet inclusion criteria     | -              | -                | -                |
| Unable to obtain serum sample         | -              | 1                | -                |
| Due to nature of bilateral hip pain   | 1              | -                | -                |
| Tetanus in < 5 years prior to study   | -              | -                | -                |
| Not eligible; Td boost within 5 years | -              | -                | -                |

|                   |   |   |   |
|-------------------|---|---|---|
| Lost to follow-up | - | 1 | - |
| Pregnancy         | 1 | - | - |

| <b>Number of subjects in period 1</b> | TdaP3-IPV Adults |
|---------------------------------------|------------------|
| Started                               | 125              |
| Completed                             | 121              |
| Not completed                         | 4                |
| Consent withdrawn by subject          | 1                |
| Unable to obtain blood/serum sample   | -                |
| Failed to meet inclusion criteria     | 1                |
| Unable to obtain serum sample         | -                |
| Due to nature of bilateral hip pain   | -                |
| Tetanus in < 5 years prior to study   | 1                |
| Not eligible; Td boost within 5 years | 1                |
| Lost to follow-up                     | -                |
| Pregnancy                             | -                |

## Baseline characteristics

### Reporting groups

|  |                       |
|--|-----------------------|
| Reporting group title  | Td-mIPV Adolescents   |
| Reporting group description:<br>Adolescents who received Td-mIPV on Day 0 followed by aP 1 month later.  |                       |
| Reporting group title  | TdaP1-IPV Adolescents |
| Reporting group description:<br>Adolescents received 1 injection of TdaP1-IPV Lot 15001-11 on Day 0.   |                       |
| Reporting group title  | TdaP2-IPV Adolescents |
| Reporting group description:<br>Adolescents received 1 injection of TdaP2-IPV Lot 15002-11 on Day 0.   |                       |
| Reporting group title  | TdaP3-IPV Adolescents |
| Reporting group description:<br>Adolescents received 1 injection of TdaP3-IPV Lot 15003-11 on Day 0.   |                       |
| Reporting group title  | Td/aP Adults          |
| Reporting group description:<br>Adults received 1 injection of Tetanus and Diphtheria Toxoids Adsorbed Vaccine (Td Adsorbed Vaccine; Td) on Day 0 and 1 injection of Adult formulation of the 5-component Pertussis Vaccine (aP) 1 month later. An injection of Inactivated Poliovirus Vaccine was optional 1 month post-aP vaccination (Visit 3). |                       |
| Reporting group title  | TdaP/IPV Adults       |
| Reporting group description:<br>Adults received 1 injection of TdaP on Day 0 and 1 injection of IPV 1 month later.   |                       |
| Reporting group title  | TdaP/aP Adults        |
| Reporting group description:<br>Adults received 1 injection of TdaP on Day 0 and 1 injection of aP one month later. An injection of Inactivated Poliovirus Vaccine was optional 1 month post-aP vaccination (Visit 3).   |                       |
| Reporting group title  | TdaP1-IPV Adults      |
| Reporting group description:<br>Adults received 1 injection of TdaP1-IPV Lot 15001-11 on Day 0.  |                       |
| Reporting group title  | TdaP2-IPV Adults      |
| Reporting group description:<br>Adults received 1 injection of TdaP2-IPV Lot 15002-11 on Day 0.  |                       |
| Reporting group title  | TdaP3-IPV Adults      |
| Reporting group description:<br>Adults received 1 injection of TdaP3-IPV Lot 15003-11 on Day 0.  |                       |

| Reporting group values                                | Td-mIPV Adolescents | TdaP1-IPV Adolescents | TdaP2-IPV Adolescents |
|---|---------------------|-----------------------|-----------------------|
| Number of subjects                                    | 117                 | 118                   | 117                   |
| Age categorical<br>Units: Subjects                    |                     |                       |                       |
| In utero  | 0                   | 0                     | 0                     |
| Preterm newborn infants<br>(gestational age < 37 wks) | 0                   | 0                     | 0                     |
| Newborns (0-27 days)                                  | 0                   | 0                     | 0                     |
| Infants and toddlers (28 days-23 months)              | 0                   | 0                     | 0                     |
| Children (2-11 years)                                 | 0                   | 0                     | 0                     |
| Adolescents (12-17 years)                             | 117                 | 118                   | 117                   |
| Adults (18-64 years)                                  | 0                   | 0                     | 0                     |

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

|                                       |        |        |        |
|---------------------------------------|--------|--------|--------|
| Age continuous<br>Units: years        |        |        |        |
| arithmetic mean                       | 13.9   | 14.01  | 13.97  |
| standard deviation                    | ± 0.96 | ± 1.06 | ± 1.04 |
| Gender categorical<br>Units: Subjects |        |        |        |
| Female                                | 55     | 63     | 54     |
| Male                                  | 62     | 55     | 63     |

| <b>Reporting group values</b>                      | TdaP3-IPV Adolescents | Td/aP Adults | TdaP/IPV Adults |
|--|-----------------------|--------------|-----------------|
| Number of subjects                                 | 116                   | 126          | 126             |
| Age categorical<br>Units: Subjects                 |                       |              |                 |
| In utero   | 0                     | 0            | 0               |
| Preterm newborn infants (gestational age < 37 wks) | 0                     | 0            | 0               |
| Newborns (0-27 days)                               | 0                     | 0            | 0               |
| Infants and toddlers (28 days-23 months)           | 0                     | 0            | 0               |
| Children (2-11 years)                              | 0                     | 0            | 0               |
| Adolescents (12-17 years)                          | 116                   | 0            | 0               |
| Adults (18-64 years)                               | 0                     | 126          | 126             |
| From 65-84 years                                   | 0                     | 0            | 0               |
| 85 years and over                                  | 0                     | 0            | 0               |
| Age continuous<br>Units: years                     |                       |              |                 |
| arithmetic mean                                    | 13.91                 | 37.93        | 38.13           |
| standard deviation                                 | ± 1                   | ± 9.55       | ± 9.09          |
| Gender categorical<br>Units: Subjects              |                       |              |                 |
| Female   | 57                    | 82           | 81              |
| Male   | 59                    | 44           | 45              |

| <b>Reporting group values</b>                      | TdaP/aP Adults | TdaP1-IPV Adults | TdaP2-IPV Adults |
|--|----------------|------------------|------------------|
| Number of subjects                                 | 122            | 126              | 121              |
| Age categorical<br>Units: Subjects                 |                |                  |                  |
| In utero   | 0              | 0                | 0                |
| Preterm newborn infants (gestational age < 37 wks) | 0              | 0                | 0                |
| Newborns (0-27 days)                               | 0              | 0                | 0                |
| Infants and toddlers (28 days-23 months)           | 0              | 0                | 0                |
| Children (2-11 years)                              | 0              | 0                | 0                |
| Adolescents (12-17 years)                          | 0              | 0                | 0                |
| Adults (18-64 years)                               | 122            | 126              | 121              |
| From 65-84 years                                   | 0              | 0                | 0                |
| 85 years and over                                  | 0              | 0                | 0                |

|   |                |                 |                 |
|---|----------------|-----------------|-----------------|
| Age continuous<br>Units: years<br>arithmetic mean<br>standard deviation | 38.28<br>± 8.7 | 37.89<br>± 8.69 | 38.29<br>± 8.95 |
| Gender categorical<br>Units: Subjects                                   |                |                 |                 |
| Female  | 91             | 93              | 82              |
| Male  | 31             | 33              | 39              |

| <b>Reporting group values</b>   | TdaP3-IPV Adults | Total |  |
|---|------------------|-------|--|
| Number of subjects  | 125              | 1214  |  |
| Age categorical<br>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)   | 0                | 0     |  |
| Adolescents (12-17 years)   | 0                | 468   |  |
| Adults (18-64 years)  | 125              | 746   |  |
| From 65-84 years  | 0                | 0     |  |
| 85 years and over   | 0                | 0     |  |
| Age continuous<br>Units: years<br>arithmetic mean<br>standard deviation | 38.55<br>± 8.18  | -     |  |
| Gender categorical<br>Units: Subjects                                   |                  |       |  |
| Female  | 85               | 743   |  |
| Male  | 40               | 471   |  |

## End points

### End points reporting groups

|                              |  |
|------------------------------|--|
| Reporting group title        | Td-mIPV Adolescents  |
| Reporting group description: | Adolescents who received Td-mIPV on Day 0 followed by aP 1 month later.  |
| Reporting group title        | Tdap1-IPV Adolescents  |
| Reporting group description: | Adolescents received 1 injection of Tdap1-IPV Lot 15001-11 on Day 0.   |
| Reporting group title        | Tdap2-IPV Adolescents  |
| Reporting group description: | Adolescents received 1 injection of Tdap2-IPV Lot 15002-11 on Day 0.   |
| Reporting group title        | Tdap3-IPV Adolescents  |
| Reporting group description: | Adolescents received 1 injection of Tdap3-IPV Lot 15003-11 on Day 0.   |
| Reporting group title        | Td/aP Adults   |
| Reporting group description: | Adults received 1 injection of Tetanus and Diphtheria Toxoids Adsorbed Vaccine (Td Adsorbed Vaccine; Td) on Day 0 and 1 injection of Adult formulation of the 5-component Pertussis Vaccine (aP) 1 month later. An injection of Inactivated Poliovirus Vaccine was optional 1 month post-aP vaccination (Visit 3). |
| Reporting group title        | Tdap/IPV Adults  |
| Reporting group description: | Adults received 1 injection of Tdap on Day 0 and 1 injection of IPV 1 month later.   |
| Reporting group title        | Tdap/aP Adults   |
| Reporting group description: | Adults received 1 injection of Tdap on Day 0 and 1 injection of aP one month later. An injection of Inactivated Poliovirus Vaccine was optional 1 month post-aP vaccination (Visit 3).   |
| Reporting group title        | Tdap1-IPV Adults   |
| Reporting group description: | Adults received 1 injection of Tdap1-IPV Lot 15001-11 on Day 0.  |
| Reporting group title        | Tdap2-IPV Adults   |
| Reporting group description: | Adults received 1 injection of Tdap2-IPV Lot 15002-11 on Day 0.  |
| Reporting group title        | Tdap3-IPV Adults   |
| Reporting group description: | Adults received 1 injection of Tdap3-IPV Lot 15003-11 on Day 0.  |

### **Primary: Percentage of Adolescent Subjects with Seroprotection to Tetanus and Diphtheria Following Vaccination with Td-mIPV, or Tdap-vIPV, or Td, or aP or Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL®**

|                        |   |
|------------------------|---|
| End point title        | Percentage of Adolescent Subjects with Seroprotection to Tetanus and Diphtheria Following Vaccination with Td-mIPV, or Tdap-vIPV, or Td, or aP or Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL® <sup>[1][2]</sup>   |
| End point description: | Anti-Diphtheria antibody responses were measured by a micrometabolic inhibition test. Anti-Tetanus antibody responses were measured by an enzyme-linked immunosorbent assay (ELISA). Seroprotection was defined as post-vaccination antibody titers $\geq 0.01$ IU/mL for Diphtheria and $\geq 0.01$ EU/mL for Tetanus. |
| End point type         | Primary   |

End point timeframe:

Pre-vaccination, 1 and 6 months post-vaccination, and 1, 3, 5, and 10 years 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: Descriptive analyses were performed based on the study groups and the study vaccine administered for this outcome.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is reporting data for only the adolescent subjects; data for adult subjects were reported in a separate outcome.

| <b>End point values</b>               | Td-mIPV Adolescents | TdaP1-IPV Adolescents | TdaP2-IPV Adolescents | TdaP3-IPV Adolescents |
|---------------------------------------|---------------------|-----------------------|-----------------------|-----------------------|
| Subject group type                    | Reporting group     | Reporting group       | Reporting group       | Reporting group       |
| Number of subjects analysed           | 117                 | 118                   | 115                   | 116                   |
| Units: Percentage of subjects         |                     |                       |                       |                       |
| number (not applicable)               |                     |                       |                       |                       |
| Diphtheria; Pre-vaccination           | 93.2                | 95.8                  | 95.7                  | 94                    |
| Diphtheria; 1 month post-vaccination  | 99.1                | 99.2                  | 100                   | 100                   |
| Diphtheria; 6 months post-vaccination | 100                 | 100                   | 100                   | 100                   |
| Diphtheria; 1 year post-vaccination   | 100                 | 100                   | 100                   | 100                   |
| Diphtheria; 3 years post-vaccination  | 100                 | 97.6                  | 100                   | 100                   |
| Diphtheria; 5 years post-vaccination  | 100                 | 94.7                  | 93.9                  | 100                   |
| Diphtheria; 10 years post-vaccination | 100                 | 97.7                  | 100                   | 100                   |
| Tetanus; Pre-vaccination              | 100                 | 100                   | 100                   | 100                   |
| Tetanus; 1 month post-vaccination     | 100                 | 100                   | 100                   | 100                   |
| Tetanus; 6 months post-vaccination    | 100                 | 100                   | 100                   | 100                   |
| Tetanus; 1 year post-vaccination      | 100                 | 100                   | 100                   | 100                   |
| Tetanus; 3 years post-vaccination     | 100                 | 100                   | 100                   | 100                   |
| Tetanus; 5 years post-vaccination     | 100                 | 100                   | 100                   | 100                   |
| Tetanus; 10 years post-vaccination    | 100                 | 100                   | 100                   | 100                   |

## Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Percentage of Adult Subjects with Seroprotection to Tetanus and Diphtheria Following Vaccination with Td-mIPV, or Tdap-vIPV, or Td, or aP, or Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL®

|                 |  |
|-----------------|--|
| End point title | Percentage of Adult Subjects with Seroprotection to Tetanus and Diphtheria Following Vaccination with Td-mIPV, or Tdap-vIPV, or Td, or aP, or Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL® <sup>[3]</sup> |
|-----------------|--|

End point description:

Anti-Diphtheria antibody responses were measured by a micrometabolic inhibition test. Anti-Tetanus antibody responses were measured by an enzyme-linked immunosorbent assay (ELISA). Seroprotection was defined as post-vaccination antibody titers  $\geq 0.01$  IU/mL for Diphtheria and  $\geq 0.01$  EU/mL for Tetanus. The data of Tdap/IPV Adults and Tdap/aP Adults were combined for this analysis. The collective total (N) for the analysis was 240, the cumulative data are presented for each group in the table for this outcome.

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

End point timeframe:

Pre-vaccination, 1 and 6 months post-vaccination, and 1, 3, 5, and 10 years post-vaccination

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint is reporting data for only the adult subjects; data for adolescent subjects were reported in a separate outcome.

| <b>End point values</b>               | Td/aP Adults    | TdaP/IPV Adults | TdaP/aP Adults  | TdaP1-IPV Adults |
|---------------------------------------|-----------------|-----------------|-----------------|------------------|
| Subject group type                    | Reporting group | Reporting group | Reporting group | Reporting group  |
| Number of subjects analysed           | 122             | 126             | 122             | 124              |
| Units: Percentage of subjects         |                 |                 |                 |                  |
| number (not applicable)               |                 |                 |                 |                  |
| Diphtheria; Pre-vaccination           | 82.8            | 77.5            | 77.5            | 80.6             |
| Diphtheria; 1 month post-vaccination  | 98.4            | 97.9            | 97.9            | 98.4             |
| Diphtheria; 6 months post-vaccination | 100             | 100             | 100             | 100              |
| Diphtheria; 1 year post-vaccination   | 100             | 100             | 100             | 100              |
| Diphtheria; 3 years post-vaccination  | 95.7            | 89.7            | 89.7            | 95.8             |
| Diphtheria; 5 years post-vaccination  | 81.8            | 77.8            | 77.8            | 75               |
| Diphtheria; 10 years post-vaccination | 80              | 87              | 87              | 80.6             |
| Tetanus; Pre-vaccination              | 99.2            | 99.2            | 99.2            | 98.4             |
| Tetanus; 1 month post-vaccination     | 100             | 100             | 100             | 100              |
| Tetanus; 6 months post-vaccination    | 100             | 100             | 100             | 100              |
| Tetanus; 1 year post-vaccination      | 100             | 100             | 100             | 100              |
| Tetanus; 3 years post-vaccination     | 97.8            | 100             | 100             | 100              |
| Tetanus; 5 years post-vaccination     | 100             | 100             | 100             | 100              |
| Tetanus; 10 years post-vaccination    | 100             | 100             | 100             | 100              |

| <b>End point values</b>               | TdaP2-IPV Adults | TdaP3-IPV Adults |  |  |
|---------------------------------------|------------------|------------------|--|--|
| Subject group type                    | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed           | 121              | 121              |  |  |
| Units: Percentage of subjects         |                  |                  |  |  |
| number (not applicable)               |                  |                  |  |  |
| Diphtheria; Pre-vaccination           | 74.4             | 76               |  |  |
| Diphtheria; 1 month post-vaccination  | 94.2             | 95.9             |  |  |
| Diphtheria; 6 months post-vaccination | 91.7             | 90.9             |  |  |
| Diphtheria; 1 year post-vaccination   | 81.8             | 90               |  |  |
| Diphtheria; 3 years post-vaccination  | 88.6             | 90.7             |  |  |
| Diphtheria; 5 years post-vaccination  | 78.6             | 84.6             |  |  |
| Diphtheria; 10 years post-vaccination | 92.6             | 81               |  |  |
| Tetanus; Pre-vaccination              | 99.2             | 100              |  |  |
| Tetanus; 1 month post-vaccination     | 100              | 100              |  |  |
| Tetanus; 6 months post-vaccination    | 100              | 100              |  |  |
| Tetanus; 1 year post-vaccination      | 100              | 100              |  |  |
| Tetanus; 3 years post-vaccination     | 100              | 100              |  |  |
| Tetanus; 5 years post-vaccination     | 100              | 100              |  |  |
| Tetanus; 10 years post-vaccination    | 96.3             | 100              |  |  |

## Statistical analyses

No statistical analyses for this end point

### Other pre-specified: Percentage of Adolescent Subjects with Seroprotection to Vaccine Poliovirus Following Vaccination with Td-mIPV, or Tdap-vIPV, or Td, or aP, or Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL®

|                 |   |
|-----------------|---|
| End point title | Percentage of Adolescent Subjects with Seroprotection to Vaccine Poliovirus Following Vaccination with Td-mIPV, or Tdap-vIPV, or Td, or aP, or Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL® <sup>[4]</sup> |
|-----------------|---|

End point description:

Anti-Poliovirus types 1, 2, and 3 titers were measured by a neutralization assay. Seroprotection was defined as post-vaccination titers  $\geq$  1:8 dilutions.

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

End point timeframe:

Pre-vaccination, 1 and 6 months post-vaccination, and 1, 3, 5, and 10 years post-vaccination

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is reporting data for only the adolescent subjects; data for adult subjects were reported in a separate outcome.

| End point values                        | Td-mIPV Adolescents | Tdap1-IPV Adolescents | Tdap2-IPV Adolescents | Tdap3-IPV Adolescents |
|---|---------------------|-----------------------|-----------------------|-----------------------|
| Subject group type                      | Reporting group     | Reporting group       | Reporting group       | Reporting group       |
| Number of subjects analysed             | 117                 | 116                   | 115                   | 116                   |
| Units: Percentage of subjects           |                     |                       |                       |                       |
| number (not applicable)                 |                     |                       |                       |                       |
| Poliovirus 1; Pre-vaccination           | 96.6                | 97.4                  | 95.7                  | 94                    |
| Poliovirus 1; 1 month post-vaccination  | 100                 | 99.1                  | 100                   | 100                   |
| Poliovirus 1; 6 months post-vaccination | 100                 | 95.7                  | 100                   | 100                   |
| Poliovirus 1; 1 year post-vaccination   | 100                 | 95.2                  | 100                   | 100                   |
| Poliovirus 1; 3 years post-vaccination  | 100                 | 100                   | 100                   | 100                   |
| Poliovirus 1; 5 years post-vaccination  | 100                 | 100                   | 100                   | 100                   |
| Poliovirus 2; Pre-vaccination           | 99.1                | 98.3                  | 97.4                  | 98.3                  |
| Poliovirus 2; 1 month post-vaccination  | 100                 | 100                   | 100                   | 100                   |
| Poliovirus 2; 6 months post-vaccination | 100                 | 100                   | 100                   | 100                   |
| Poliovirus 2; 1 year post-vaccination   | 100                 | 100                   | 100                   | 100                   |
| Poliovirus 2; 3 years post-vaccination  | 100                 | 100                   | 100                   | 100                   |
| Poliovirus 2; 5 years post-vaccination  | 100                 | 100                   | 100                   | 100                   |
| Poliovirus 3; Pre-vaccination           | 96.6                | 90.5                  | 89.6                  | 96.6                  |
| Poliovirus 3; 1 month post-vaccination  | 100                 | 100                   | 100                   | 100                   |
| Poliovirus 3; 6 months post-vaccination | 100                 | 100                   | 100                   | 100                   |
| Poliovirus 3; 1 year post-vaccination   | 100                 | 95.2                  | 100                   | 100                   |
| Poliovirus 3; 3 years post-vaccination  | 100                 | 100                   | 100                   | 100                   |

|  |     |      |     |     |
|--|-----|------|-----|-----|
| Poliovirus 3; 5 years post-vaccination | 100 | 94.7 | 100 | 100 |
|--|-----|------|-----|-----|

## Statistical analyses

No statistical analyses for this end point

### Other pre-specified: Percentage of Adult Subjects with Seroprotection to Vaccine Poliovirus Following Vaccination with Td-mIPV, or Tdap-vIPV, or Td, or aP or Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL®

|                 |   |
|-----------------|---|
| End point title | Percentage of Adult Subjects with Seroprotection to Vaccine Poliovirus Following Vaccination with Td-mIPV, or Tdap-vIPV, or Td, or aP or Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL® <sup>[5]</sup> |
|-----------------|---|

End point description:

Anti-Poliovirus types 1, 2, and 3 titers were measured by a neutralization assay. Seroprotection was defined as post-vaccination titers  $\geq$  1:8 dilutions. The data of Tdap/IPV Adults and Tdap/aP Adults were combined for this analysis. The collective total (N) for the analysis was 238, the cumulative data are presented for each group in the table for this outcome.

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

End point timeframe:

Pre-vaccination, 1 and 6 months post-vaccination, and 1, 3, 5, and 10 years post-vaccination

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint is reporting data for only the adult subjects; data for adolescent subjects were reported in a separate outcome.

| End point values                        | Td/aP Adults    | Tdap/IPV Adults | Tdap/aP Adults  | Tdap1-IPV Adults |
|---|-----------------|-----------------|-----------------|------------------|
| Subject group type                      | Reporting group | Reporting group | Reporting group | Reporting group  |
| Number of subjects analysed             | 121             | 126             | 122             | 124              |
| Units: Percentage of subjects           |                 |                 |                 |                  |
| number (not applicable)                 |                 |                 |                 |                  |
| Poliovirus 1; Pre-vaccination           | 99.2            | 98.7            | 98.7            | 98.4             |
| Poliovirus 1; 1 month post-vaccination  | 0               | 100             | 100             | 100              |
| Poliovirus 1; 6 months post-vaccination | 100             | 100             | 100             | 100              |
| Poliovirus 1; 1 year post-vaccination   | 100             | 100             | 100             | 100              |
| Poliovirus 1; 3 years post-vaccination  | 97.8            | 100             | 100             | 100              |
| Poliovirus 1; 5 years post-vaccination  | 100             | 98.8            | 98.8            | 100              |
| Poliovirus 2; Pre-vaccination           | 99.2            | 99.6            | 99.6            | 100              |
| Poliovirus 2; 1 month post-vaccination  | 0               | 100             | 100             | 100              |
| Poliovirus 2; 6 months post-vaccination | 100             | 100             | 100             | 100              |
| Poliovirus 2; 1 year post-vaccination   | 100             | 100             | 100             | 100              |
| Poliovirus 2; 3 years post-vaccination  | 100             | 100             | 100             | 100              |
| Poliovirus 2; 5 years post-vaccination  | 97.7            | 98.8            | 98.8            | 100              |
| Poliovirus 3; Pre-vaccination           | 98.3            | 98.7            | 98.7            | 99.2             |
| Poliovirus 3; 1 month post-vaccination  | 0               | 100             | 100             | 100              |
| Poliovirus 3; 6 months post-vaccination | 100             | 100             | 100             | 100              |
| Poliovirus 3; 1 year post-vaccination   | 100             | 100             | 100             | 100              |
| Poliovirus 3; 3 years post-vaccination  | 97.8            | 100             | 100             | 100              |

|  |      |     |     |     |
|--|------|-----|-----|-----|
| Poliovirus 3; 5 years post-vaccination | 97.7 | 100 | 100 | 100 |
|--|------|-----|-----|-----|

| <b>End point values</b>                 | Tdap2-IPV<br>Adults | Tdap3-IPV<br>Adults |  |  |
|---|---------------------|---------------------|--|--|
| Subject group type                      | Reporting group     | Reporting group     |  |  |
| Number of subjects analysed             | 121                 | 121                 |  |  |
| Units: Percentage of subjects           |                     |                     |  |  |
| number (not applicable)                 |                     |                     |  |  |
| Poliovirus 1; Pre-vaccination           | 99.2                | 98.3                |  |  |
| Poliovirus 1; 1 month post-vaccination  | 100                 | 100                 |  |  |
| Poliovirus 1; 6 months post-vaccination | 100                 | 100                 |  |  |
| Poliovirus 1; 1 year post-vaccination   | 100                 | 100                 |  |  |
| Poliovirus 1; 3 years post-vaccination  | 100                 | 100                 |  |  |
| Poliovirus 1; 5 years post-vaccination  | 100                 | 100                 |  |  |
| Poliovirus 2; Pre-vaccination           | 99.2                | 100                 |  |  |
| Poliovirus 2; 1 month post-vaccination  | 100                 | 100                 |  |  |
| Poliovirus 2; 6 months post-vaccination | 100                 | 100                 |  |  |
| Poliovirus 2; 1 year post-vaccination   | 100                 | 100                 |  |  |
| Poliovirus 2; 3 years post-vaccination  | 100                 | 100                 |  |  |
| Poliovirus 2; 5 years post-vaccination  | 100                 | 100                 |  |  |
| Poliovirus 3; Pre-vaccination           | 100                 | 97.5                |  |  |
| Poliovirus 3; 1 month post-vaccination  | 100                 | 100                 |  |  |
| Poliovirus 3; 6 months post-vaccination | 100                 | 100                 |  |  |
| Poliovirus 3; 1 year post-vaccination   | 100                 | 100                 |  |  |
| Poliovirus 3; 3 years post-vaccination  | 100                 | 100                 |  |  |
| Poliovirus 3; 5 years post-vaccination  | 100                 | 100                 |  |  |

## Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Geometric Mean Titers of Antibodies for Diphtheria, Tetanus, Pertussis and Poliovirus Antibodies in Adolescents After Td-mIPV, or Tdap-vIPV, or Td, or aP or Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL

|                 |  |
|-----------------|--|
| End point title | Geometric Mean Titers of Antibodies for Diphtheria, Tetanus, Pertussis and Poliovirus Antibodies in Adolescents After Td-mIPV, or Tdap-vIPV, or Td, or aP or Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL <sup>[6]</sup> |
|-----------------|--|

End point description:

Anti-Diphtheria antibody responses were measured by a micrometabolic inhibition test. Anti-Tetanus and Anti-Pertussis (Pertussis Toxoid, Filamentous hemagglutinin, Pertactin, and Fimbriae types 2 and 3) antibody responses were measured by an enzyme-linked immunosorbent assay (ELISA). Anti-Poliovirus types 1, 2, and 3 titers were measured by a neutralization assay.

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

End point timeframe:

Pre-vaccination, 1 and 6 months post-vaccination, and 1, 3, 5, and 10 years post-vaccination

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Descriptive analyses were performed based on the study groups and the study vaccine administered for this outcome.

| <b>End point values</b>                             | Td-mIPV Adolescents       | TdaP1-IPV Adolescents     | TdaP2-IPV Adolescents     | TdaP3-IPV Adolescents     |
|---|---------------------------|---------------------------|---------------------------|---------------------------|
| Subject group type                                  | Reporting group           | Reporting group           | Reporting group           | Reporting group           |
| Number of subjects analysed                         | 117                       | 118                       | 117                       | 116                       |
| Units: Titers (1/dil)                               |                           |                           |                           |                           |
| geometric mean (confidence interval 95%)            |                           |                           |                           |                           |
| Diphtheria; Pre-vaccination                         | 0.18 (0.13 to 0.24)       | 0.11 (0.08 to 0.14)       | 0.11 (0.08 to 0.14)       | 0.11 (0.08 to 0.15)       |
| Diphtheria; 1 month post-vaccination                | 3.56 (2.77 to 4.58)       | 1.96 (1.48 to 2.59)       | 1.97 (1.53 to 2.55)       | 1.94 (1.55 to 2.44)       |
| Diphtheria; 6 months post-vaccination               | 0.66 (0.34 to 1.31)       | 0.74 (0.43 to 1.3)        | 0.49 (0.22 to 1.07)       | 0.33 (0.15 to 0.7)        |
| Diphtheria; 1 year post-vaccination                 | 0.43 (0.22 to 0.83)       | 0.58 (0.31 to 1.07)       | 0.31 (0.15 to 0.66)       | 0.22 (0.11 to 0.46)       |
| Diphtheria; 3 years post-vaccination                | 0.62 (0.36 to 1.07)       | 0.5 (0.26 to 0.96)        | 0.74 (0.4 to 1.36)        | 0.91 (0.49 to 1.68)       |
| Diphtheria; 5 years post-vaccination                | 0.6 (0.37 to 0.99)        | 0.26 (0.14 to 0.49)       | 0.31 (0.16 to 0.61)       | 0.46 (0.27 to 0.8)        |
| Diphtheria; 10 years post-vaccination               | 0.21 (0.12 to 0.35)       | 0.22 (0.13 to 0.36)       | 0.2 (0.11 to 0.37)        | 0.26 (0.17 to 0.4)        |
| Tetanus; Pre-vaccination                            | 0.64 (0.53 to 0.78)       | 0.7 (0.57 to 0.87)        | 0.61 (0.49 to 0.75)       | 0.59 (0.48 to 0.72)       |
| Tetanus; 1 month post-vaccination                   | 18.28 (15.44 to 21.64)    | 20.07 (17.04 to 23.63)    | 16.2 (13.67 to 19.2)      | 17.61 (14.82 to 20.93)    |
| Tetanus; 6 months post-vaccination                  | 9.72 (5.78 to 16.35)      | 6.89 (4.73 to 10.04)      | 7.95 (5.4 to 11.71)       | 4.24 (2.62 to 6.89)       |
| Tetanus; 1 year post-vaccination                    | 5.3 (2.86 to 9.84)        | 4.38 (3.06 to 6.28)       | 4.45 (2.98 to 6.65)       | 2.95 (1.86 to 4.66)       |
| Tetanus; 3 years post-vaccination                   | 2.65 (1.91 to 3.68)       | 2.14 (1.54 to 2.96)       | 2.22 (1.65 to 2.98)       | 3.53 (2.8 to 4.44)        |
| Tetanus; 5 years post-vaccination                   | 2.08 (1.4 to 3.09)        | 1.44 (1.04 to 1.99)       | 1.49 (1.12 to 1.98)       | 2.46 (1.89 to 3.2)        |
| Tetanus; 10 years post-vaccination                  | 1.41 (0.93 to 2.15)       | 0.99 (0.65 to 1.53)       | 1.28 (0.93 to 1.77)       | 1.52 (1.07 to 2.16)       |
| Pertussis toxoid; Pre-vaccination                   | 11.98 (9.4 to 15.26)      | 10.07 (7.95 to 12.76)     | 14.24 (11.25 to 18.03)    | 12.42 (9.85 to 15.66)     |
| Pertussis toxoid; 1 month post-vaccination          | 350.95 (304.91 to 403.95) | 173.06 (143.65 to 208.5)  | 185.84 (153.64 to 224.79) | 143.63 (121.11 to 170.34) |
| Pertussis toxoid; 6 months post-vaccination         | 157.43 (104.66 to 236.81) | 82.63 (52.98 to 128.87)   | 115.7 (67.19 to 199.25)   | 71.51 (46.7 to 109.49)    |
| Pertussis toxoid; 1 year post-vaccination           | 140.16 (91.83 to 213.92)  | 83.93 (56.56 to 124.56)   | 100.17 (59.44 to 168.8)   | 74.16 (50.03 to 109.92)   |
| Pertussis toxoid; 3 years post-vaccination          | 76.71 (55.54 to 105.94)   | 55.14 (41.14 to 73.91)    | 56.51 (38.94 to 82)       | 56.49 (42.35 to 75.36)    |
| Pertussis toxoid; 5 years post-vaccination          | 74.28 (51.17 to 107.82)   | 53.45 (39.66 to 72.03)    | 53.06 (39.33 to 71.58)    | 57.08 (43.87 to 74.27)    |
| Pertussis toxoid; 10 years post-vaccination         | 18.07 (9.78 to 33.41)     | 14.35 (10.72 to 19.22)    | 21.81 (12.24 to 38.87)    | 16.83 (10.58 to 26.75)    |
| Filamentous hemagglutinin; Pre-vaccination          | 26.71 (21.31 to 33.48)    | 23.8 (18.46 to 30.7)      | 25.79 (20.07 to 33.13)    | 23.29 (18.65 to 29.08)    |
| Filamentous hemagglutinin; 1 month post-vaccination | 432.06 (374.55 to 498.39) | 252.42 (210.17 to 303.16) | 215.7 (183.85 to 253.07)  | 269.75 (231.03 to 314.96) |

|  |                                 |                               |                               |                                 |
|--|---------------------------------|-------------------------------|-------------------------------|---------------------------------|
| Filamentous hemagglutinin;6 month post-vaccination | 189.05 (109.33 to 326.88)       | 91.7 (64.03 to 131.32)        | 164.35 (110.83 to 243.72)     | 123.22 (84.58 to 179.51)        |
| Filamentous hemagglutinin; 1 year post-vaccination | 139.45 (100.09 to 194.28)       | 85.2 (64.08 to 113.28)        | 125.14 (93.06 to 168.28)      | 92.37 (63.62 to 134.13)         |
| Filamentous hemagglutinin;3 years post-vaccination | 77.49 (60.22 to 99.72)          | 71.5 (52.4 to 97.56)          | 57.86 (44.36 to 75.47)        | 66.92 (48.83 to 91.71)          |
| Filamentous hemagglutinin;5 years post-vaccination | 60.37 (46.27 to 78.77)          | 57.54 (42.83 to 77.31)        | 45.9 (35.45 to 59.43)         | 55.07 (40.89 to 74.17)          |
| Filamentous hemagglutinin;10 year post-vaccination | 43.53 (28.47 to 66.54)          | 30.26 (21.85 to 41.89)        | 34.5 (23.45 to 50.76)         | 30.26 (20.83 to 43.98)          |
| Pertactin; Pre-vaccination                         | 5.47 (4 to 7.49)                | 5.24 (3.85 to 7.14)           | 5.5 (3.93 to 7.68)            | 4.87 (3.64 to 6.51)             |
| Pertactin; 1 month post-vaccination                | 189.64 (153.92 to 233.63)       | 272.33 (208.06 to 356.44)     | 258.67 (194.65 to 343.74)     | 203.11 (157.08 to 262.63)       |
| Pertactin; 6 months post-vaccination               | 94.58 (52.03 to 171.92)         | 130.67 (72.22 to 236.44)      | 185 (106.53 to 321.25)        | 106.78 (61.19 to 186.36)        |
| Pertactin; 1 year post-vaccination                 | 87.97 (51.1 to 151.46)          | 123.26 (72.5 to 209.55)       | 138.29 (81.9 to 233.52)       | 85.29 (57.54 to 126.43)         |
| Pertactin; 3 years post-vaccination                | 53.13 (37.43 to 75.43)          | 52.15 (33.65 to 80.82)        | 51.12 (30.69 to 85.13)        | 47.68 (30.71 to 74.02)          |
| Pertactin; 5 years post-vaccination                | 48.76 (33.7 to 70.55)           | 42.26 (28.33 to 63.05)        | 41.73 (27.38 to 63.61)        | 42.66 (28.06 to 64.85)          |
| Pertactin; 10 years post-vaccination               | 22.55 (14.89 to 34.16)          | 27.43 (17.45 to 43.11)        | 28.9 (15.87 to 52.62)         | 28.95 (17.84 to 46.98)          |
| Fimbriae; Pre-vaccination                          | 43.88 (34.39 to 55.99)          | 30.95 (22.93 to 41.78)        | 47.86 (35.87 to 63.87)        | 38.26 (29.78 to 49.16)          |
| Fimbriae; 1 month post-vaccination                 | 2997.39 (2471.45 to 3635.27)    | 1374.6 (1094.61 to 1726.2)    | 1178.17 (969.28 to 1432.07)   | 1026.2 (846.52 to 1244.02)      |
| Fimbriae; 6 months post-vaccination                | 1403.36 (861.19 to 2286.86)     | 521.86 (332.36 to 819.38)     | 416.44 (246.89 to 702.43)     | 441.87 (273.54 to 713.79)       |
| Fimbriae; 1 year post-vaccination                  | 1002.54 (607.77 to 1653.73)     | 510.41 (318.77 to 817.29)     | 318.22 (187.89 to 538.96)     | 376.78 (224.94 to 631.12)       |
| Fimbriae; 3 years post-vaccination                 | 449.39 (318.4 to 634.26)        | 215.63 (155.37 to 299.26)     | 252.82 (174.14 to 367.07)     | 219.77 (170.49 to 283.3)        |
| Fimbriae; 5 years post-vaccination                 | 361.33 (232.47 to 561.64)       | 197.84 (137.21 to 285.26)     | 218.1 (159.44 to 298.34)      | 211.77 (163.87 to 273.67)       |
| Fimbriae; 10 years post-vaccination                | 228.26 (121.34 to 429.38)       | 128.82 (98.91 to 167.79)      | 179.95 (109.46 to 295.83)     | 106.58 (82.8 to 137.2)          |
| Poliovirus 1; Pre-vaccination                      | 84.55 (64.2 to 111.35)          | 128 (95.3 to 171.93)          | 93.56 (68.43 to 127.92)       | 122.03 (88.83 to 167.63)        |
| Poliovirus 1; 1 month post-vaccination             | 18336.02 (13812.49 to 24340.99) | 13055.9 (9656.92 to 17651.23) | 12416.75 (9811.5 to 15713.78) | 18244.48 (14064.25 to 23667.17) |
| Poliovirus 1; 6 months post-vaccination            | 8466.91 (4109.86 to 17443.04)   | 3856.41 (1469.86 to 10117.92) | 1845.76 (931.05 to 3659.11)   | 2686.11 (1312.92 to 5495.54)    |
| Poliovirus 1; 1 year post-vaccination              | 7342.75 (3232.91 to 16677.26)   | 3145.44 (984.75 to 10047.06)  | 1024 (429.9 to 2439.11)       | 1303.18 (737.89 to 2301.56)     |
| Poliovirus 1; 3 years post-vaccination             | 2639.14 (1664.56 to 4184.33)    | 1342.07 (907.75 to 1984.19)   | 1762.96 (1180.81 to 2632.1)   | 2702.35 (1882.91 to 3878.41)    |
| Poliovirus 1; 5 years post-vaccination             | 3071.67 (2004.91 to 4706.02)    | 1657.77 (1211.07 to 2269.24)  | 1767.97 (1232.73 to 2535.62)  | 2901.46 (2073.62 to 4059.79)    |

|   |                                 |                                 |                                 |                                 |
|---|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| Poliovirus 1; 10 years post-vaccination | 0 (0 to 0)                      |
| Poliovirus 2; Pre-vaccination           | 152.9 (126.24 to 185.18)        | 246.98 (187.38 to 325.54)       | 209.83 (156.9 to 280.61)        | 245.51 (177.04 to 340.47)       |
| Poliovirus 2; 1 month post-vaccination  | 27924.25 (22493.75 to 34665.79) | 31238.43 (24053.34 to 40569.83) | 35868.62 (27819.46 to 46246.7)  | 45950.77 (35136.01 to 60094.27) |
| Poliovirus 2; 6 months post-vaccination | 12173.27 (6348.64 to 23341.74)  | 3974.4 (1902.2 to 8304)         | 4544.8 (2154.82 to 9585.56)     | 5372.23 (3039 to 9496.81)       |
| Poliovirus 2; 1 year post-vaccination   | 7342.75 (3790.18 to 14225.17)   | 3709.84 (1984.99 to 6933.49)    | 2194.99 (1020.88 to 4719.43)    | 3974.4 (2160.65 to 7310.71)     |
| Poliovirus 2; 3 years post-vaccination  | 8914.58 (5899.7 to 13470.14)    | 4382.57 (2870.58 to 6690.96)    | 5033.33 (3202.86 to 7909.94)    | 8051.27 (6047.82 to 10718.39)   |
| Poliovirus 2; 5 years post-vaccination  | 4592.47 (3049.45 to 6916.26)    | 3304.91 (2201.29 to 4961.84)    | 2984.06 (1989.15 to 4476.61)    | 4749.27 (3310.9 to 6812.51)     |
| Poliovirus 2; 10 years post-vaccination | 0 (0 to 0)                      |
| Poliovirus 3; Pre-vaccination           | 40.32 (31.7 to 51.27)           | 47.76 (34.7 to 65.73)           | 47.63 (34.56 to 65.66)          | 65.16 (49.32 to 86.08)          |
| Poliovirus 3; 1 month post-vaccination  | 37551.46 (28146.46 to 50099.08) | 53807.41 (36689.54 to 78911.78) | 57286.05 (39802.05 to 82450.31) | 57120.62 (40030.6 to 81506.79)  |
| Poliovirus 3; 6 months post-vaccination | 8921.64 (4292.5 to 18542.96)    | 3630.84 (1243.15 to 10604.52)   | 4389.98 (1486.2 to 12967.31)    | 7712.82 (3197.67 to 18603.43)   |
| Poliovirus 3; 1 year post-vaccination   | 5484.15 (2292.97 to 13116.57)   | 2415.48 (764.64 to 7630.48)     | 3565.78 (1227.87 to 10355.09)   | 4221.32 (2020.38 to 8819.91)    |
| Poliovirus 3; 3 years post-vaccination  | 4236.86 (2750.81 to 6525.73)    | 2970.7 (1799.06 to 4905.35)     | 3945.37 (2439.09 to 6381.89)    | 3444.31 (2006.98 to 5911.01)    |
| Poliovirus 3; 5 years post-vaccination  | 2249.11 (1597.69 to 3166.13)    | 1152.9 (574.32 to 2314.35)      | 2190.84 (1509.2 to 3180.35)     | 1433.84 (932.95 to 2203.65)     |
| Poliovirus 3; 10 years post-vaccination | 0 (0 to 0)                      |

## Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Geometric Mean Titers for Diphtheria, Tetanus, and Poliovirus Antibodies in Adults After Vaccination with Td-mIPV, or Tdap-vIPV, or Td, or aP, or Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL

|                 |   |
|-----------------|---|
| End point title | Geometric Mean Titers for Diphtheria, Tetanus, and Poliovirus Antibodies in Adults After Vaccination with Td-mIPV, or Tdap-vIPV, or Td, or aP, or Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL <sup>[7]</sup> |
|-----------------|---|

### End point description:

Anti-Diphtheria antibody responses were measured by a micrometabolic inhibition test. Anti-Tetanus antibody responses were measured by an enzyme-linked immunosorbent assay (ELISA). Anti-Poliovirus types 1, 2, and 3 titers were measured by a neutralization assay. The data of Tdap/IPV Adults and Tdap/aP Adults were combined for this analysis. The collective total (N) for the analysis was 240, the cumulative data are presented for each group in the table for this outcome. Data was not collected for Tdap/aP Adults for Poliovirus 1, 2, and 3 at 1 month post-vaccination or for any of the groups for Poliovirus

1, 2, and 3 at 10 years post-vaccination.

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

End point timeframe:

Pre-vaccination, 1 and 6 months post-vaccination, and 1, 3, 5, and 10 years post-vaccination

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint is reporting data for only the adult subjects; data for adolescent subjects were reported in a separate outcome.

| End point values                         | Td/aP Adults                 | TdaP/IPV Adults              | TdaP/aP Adults               | TdaP1-IPV Adults              |
|--|------------------------------|------------------------------|------------------------------|-------------------------------|
| Subject group type                       | Reporting group              | Reporting group              | Reporting group              | Reporting group               |
| Number of subjects analysed              | 126                          | 126                          | 122                          | 126                           |
| Units: Titers (1/dil)                    |                              |                              |                              |                               |
| geometric mean (confidence interval 95%) |                              |                              |                              |                               |
| Diphtheria; Pre-vaccination              | 0.05 (0.04 to 0.07)          | 0.04 (0.04 to 0.06)          | 0.04 (0.04 to 0.06)          | 0.05 (0.03 to 0.06)           |
| Diphtheria; 1 month post-vaccination     | 0.95 (0.71 to 1.28)          | 0.75 (0.6 to 0.95)           | 0.75 (0.6 to 0.95)           | 0.58 (0.44 to 0.77)           |
| Diphtheria; 6 months post-vaccination    | 0.4 (0.2 to 0.82)            | 0.54 (0.31 to 0.93)          | 0.54 (0.31 to 0.93)          | 0.38 (0.18 to 0.81)           |
| Diphtheria; 1 year post-vaccination      | 0.23 (0.12 to 0.44)          | 0.34 (0.19 to 0.6)           | 0.34 (0.19 to 0.6)           | 0.32 (0.14 to 0.74)           |
| Diphtheria; 3 years post-vaccination     | 0.15 (0.09 to 0.25)          | 0.1 (0.06 to 0.14)           | 0.1 (0.06 to 0.14)           | 0.11 (0.07 to 0.19)           |
| Diphtheria; 5 years post-vaccination     | 0.06 (0.03 to 0.1)           | 0.04 (0.03 to 0.07)          | 0.04 (0.03 to 0.07)          | 0.03 (0.02 to 0.06)           |
| Diphtheria; 10 years post-vaccination    | 0.04 (0.02 to 0.08)          | 0.05 (0.03 to 0.09)          | 0.05 (0.03 to 0.09)          | 0.05 (0.02 to 0.1)            |
| Tetanus; Pre-vaccination                 | 1.14 (0.91 to 1.43)          | 1.1 (0.94 to 1.29)           | 1.1 (0.94 to 1.29)           | 1.1 (0.88 to 1.39)            |
| Tetanus; 1 month post-vaccination        | 15.24 (12.76 to 18.21)       | 16.59 (14.88 to 18.49)       | 16.59 (14.88 to 18.49)       | 12.83 (11.06 to 14.88)        |
| Tetanus; 6 months post-vaccination       | 6.19 (4.39 to 8.74)          | 7.33 (5.55 to 9.68)          | 7.33 (5.55 to 9.68)          | 4.32 (2.84 to 6.57)           |
| Tetanus; 1 year post-vaccination         | 4.59 (2.96 to 7.12)          | 4.3 (2.99 to 6.17)           | 4.3 (2.99 to 6.17)           | 3.25 (2.28 to 4.63)           |
| Tetanus; 3 years post-vaccination        | 2.25 (1.44 to 3.52)          | 2.54 (2.08 to 3.11)          | 2.54 (2.08 to 3.11)          | 2.57 (1.94 to 3.4)            |
| Tetanus; 5 years post-vaccination        | 2.16 (1.55 to 2.99)          | 1.94 (1.5 to 2.51)           | 1.94 (1.5 to 2.51)           | 1.87 (1.42 to 2.46)           |
| Tetanus; 10 years post-vaccination       | 1.45 (0.96 to 2.19)          | 1.61 (1.28 to 2.03)          | 1.61 (1.28 to 2.03)          | 1.51 (1 to 2.29)              |
| Poliovirus 1; Pre-vaccination            | 325.63 (245.26 to 432.35)    | 316.65 (258.22 to 388.29)    | 316.65 (258.22 to 388.29)    | 350.1 (258.22 to 474.66)      |
| Poliovirus 1; 1 month post-vaccination   | 0 (0 to 0)                   | 6427.31 (5063.35 to 8158.69) | 6427.31 (5063.35 to 8158.69) | 9315.93 (7201.87 to 12050.56) |
| Poliovirus 1; 6 months post-vaccination  | 3649.12 (1308.37 to 10177.6) | 3104.19 (1682.38 to 5727.57) | 3104.19 (1682.38 to 5727.57) | 5160.64 (1690.13 to 15757.46) |
| Poliovirus 1; 1 year post-vaccination    | 2048 (848.79 to 4941.52)     | 3122.95 (1526.44 to 6389.27) | 3122.95 (1526.44 to 6389.27) | 3611 (1056.71 to 12339.52)    |
| Poliovirus 1; 3 years post-vaccination   | 1104.13 (669.1 to 1822.01)   | 1198.71 (909.52 to 1579.86)  | 1198.71 (909.52 to 1579.86)  | 1933.05 (1295.72 to 2883.87)  |

|   |                                 |                                    |                                    |                                    |
|---|---------------------------------|------------------------------------|------------------------------------|------------------------------------|
| Poliovirus 1; 5 years post-vaccination  | 1057.68<br>(705.07 to 1586.63)  | 1026.41<br>(767.42 to 1372.82)     | 1026.41<br>(767.42 to 1372.82)     | 1690.74<br>(1165.31 to 2453.09)    |
| Poliovirus 2; Pre-vaccination           | 414.21 (322.6 to 531.83)        | 432.17 (357.11 to 520.58)          | 432.17 (357.11 to 520.58)          | 440.27 (333.35 to 581.5)           |
| Poliovirus 2; 1 month post-vaccination  | 0 (0 to 0)                      | 14428.83<br>(10223.31 to 20364.35) | 14428.83<br>(10223.31 to 20364.35) | 16475.84<br>(12303.16 to 22063.71) |
| Poliovirus 2; 6 months post-vaccination | 1722.16<br>(636.15 to 4662.16)  | 6562.36<br>(3309.05 to 13014.21)   | 6562.36<br>(3309.05 to 13014.21)   | 5792.62<br>(2701.43 to 12420.99)   |
| Poliovirus 2; 1 year post-vaccination   | 1217.75<br>(586.65 to 2527.76)  | 4350.47<br>(2124.32 to 8909.49)    | 4350.47<br>(2124.32 to 8909.49)    | 5612.96<br>(2549.3 to 12358.39)    |
| Poliovirus 2; 3 years post-vaccination  | 2345.46<br>(1404.56 to 3916.64) | 3337.48<br>(2451.11 to 4544.38)    | 3337.48<br>(2451.11 to 4544.38)    | 1961.17<br>(1380.85 to 2785.38)    |
| Poliovirus 2; 5 years post-vaccination  | 1307 (788.25 to 2167.14)        | 1428.7 (1016.3 to 2008.45)         | 1428.7 (1016.3 to 2008.45)         | 1149.83<br>(795.27 to 1662.48)     |
| Poliovirus 3; Pre-vaccination           | 229.6 (169.28 to 311.4)         | 190.76 (154.85 to 235.01)          | 190.76 (154.85 to 235.01)          | 239.39 (174.47 to 328.47)          |
| Poliovirus 3; 1 month post-vaccination  | 0 (0 to 0)                      | 43237.64<br>(31201.8 to 59916.2)   | 43237.64<br>(31201.8 to 59916.2)   | 68917.4<br>(52375.57 to 90683.66)  |
| Poliovirus 3; 6 months post-vaccination | 5467.5 (973.38 to 30711.21)     | 9152.82<br>(4204.96 to 19922.67)   | 9152.82<br>(4204.96 to 19922.67)   | 16384<br>(7916.91 to 33906.6)      |
| Poliovirus 3; 1 year post-vaccination   | 3774.53<br>(849.34 to 16774.21) | 6437.01<br>(2672.5 to 15504.22)    | 6437.01<br>(2672.5 to 15504.22)    | 12733.7<br>(7893.64 to 20541.47)   |
| Poliovirus 3; 3 years post-vaccination  | 2896.31<br>(1385.48 to 6054.66) | 3208.6<br>(2180.34 to 4721.78)     | 3208.6<br>(2180.34 to 4721.78)     | 4216.02<br>(2868.98 to 6195.52)    |
| Poliovirus 3; 5 years post-vaccination  | 1907.77<br>(988.71 to 3681.15)  | 2081.67<br>(1503.43 to 2882.31)    | 2081.67<br>(1503.43 to 2882.31)    | 3104.18<br>(2092.54 to 4604.89)    |

| <b>End point values</b>                  | TdaP2-IPV<br>Adults | TdaP3-IPV<br>Adults |  |  |
|--|---------------------|---------------------|--|--|
| Subject group type                       | Reporting group     | Reporting group     |  |  |
| Number of subjects analysed              | 121                 | 125                 |  |  |
| Units: Titers (1/dil)                    |                     |                     |  |  |
| geometric mean (confidence interval 95%) |                     |                     |  |  |
| Diphtheria; Pre-vaccination              | 0.04 (0.03 to 0.05) | 0.05 (0.03 to 0.07) |  |  |
| Diphtheria; 1 month post-vaccination     | 0.4 (0.28 to 0.57)  | 0.45 (0.32 to 0.63) |  |  |
| Diphtheria; 6 months post-vaccination    | 0.23 (0.05 to 1.1)  | 0.22 (0.06 to 0.87) |  |  |
| Diphtheria; 1 year post-vaccination      | 0.11 (0.02 to 0.56) | 0.15 (0.03 to 0.7)  |  |  |
| Diphtheria; 3 years post-vaccination     | 0.1 (0.05 to 0.18)  | 0.12 (0.07 to 0.22) |  |  |
| Diphtheria; 5 years post-vaccination     | 0.04 (0.02 to 0.08) | 0.06 (0.03 to 0.13) |  |  |

|   |                                 |                                 |  |  |
|---|---------------------------------|---------------------------------|--|--|
| Diphtheria; 10 years post-vaccination   | 0.07 (0.04 to 0.12)             | 0.06 (0.02 to 0.18)             |  |  |
| Tetanus; Pre-vaccination                | 1.02 (0.81 to 1.28)             | 1.12 (0.9 to 1.39)              |  |  |
| Tetanus; 1 month post-vaccination       | 12.08 (10.21 to 14.29)          | 10.89 (9.62 to 12.34)           |  |  |
| Tetanus; 6 months post-vaccination      | 3.51 (1.84 to 6.68)             | 4.21 (2.41 to 7.34)             |  |  |
| Tetanus; 1 year post-vaccination        | 2.79 (1.37 to 5.66)             | 3.26 (1.76 to 6.06)             |  |  |
| Tetanus; 3 years post-vaccination       | 2.2 (1.46 to 3.3)               | 2.27 (1.71 to 3.01)             |  |  |
| Tetanus; 5 years post-vaccination       | 1.97 (1.38 to 2.83)             | 2.02 (1.44 to 2.83)             |  |  |
| Tetanus; 10 years post-vaccination      | 1.46 (0.75 to 2.83)             | 1.3 (0.61 to 2.76)              |  |  |
| Poliovirus 1; Pre-vaccination           | 333.18 (243.68 to 455.56)       | 416.59 (315.96 to 549.26)       |  |  |
| Poliovirus 1; 1 month post-vaccination  | 8774.94 (6716.74 to 11463.82)   | 7960.69 (6105.39 to 10379.78)   |  |  |
| Poliovirus 1; 6 months post-vaccination | 3068.53 (1312.34 to 7174.89)    | 2896.31 (961.2 to 8727.24)      |  |  |
| Poliovirus 1; 1 year post-vaccination   | 2474.17 (1046 to 5852.31)       | 4096 (1243.76 to 13489.08)      |  |  |
| Poliovirus 1; 3 years post-vaccination  | 1642.66 (1070.48 to 2520.68)    | 1805.5 (1166.8 to 2793.82)      |  |  |
| Poliovirus 1; 5 years post-vaccination  | 1483.77 (1062.04 to 2072.97)    | 1259.77 (863.81 to 1837.23)     |  |  |
| Poliovirus 2; Pre-vaccination           | 433.63 (325.66 to 577.4)        | 402.51 (303.86 to 533.19)       |  |  |
| Poliovirus 2; 1 month post-vaccination  | 17449.63 (12865.7 to 23666.77)  | 16012.85 (12413.14 to 20656.44) |  |  |
| Poliovirus 2; 6 months post-vaccination | 3251 (1155.69 to 9145.15)       | 3649.12 (1548.6 to 8598.8)      |  |  |
| Poliovirus 2; 1 year post-vaccination   | 2048 (608.09 to 6897.53)        | 5042.77 (1641.71 to 15489.67)   |  |  |
| Poliovirus 2; 3 years post-vaccination  | 2323.07 (1519.39 to 3551.85)    | 2359.96 (1538.64 to 3619.7)     |  |  |
| Poliovirus 2; 5 years post-vaccination  | 1168.54 (802.22 to 1702.15)     | 1146.14 (723.98 to 1814.47)     |  |  |
| Poliovirus 3; Pre-vaccination           | 260.44 (187.7 to 361.36)        | 256 (175.95 to 372.47)          |  |  |
| Poliovirus 3; 1 month post-vaccination  | 48653.23 (35443.25 to 66786.67) | 65912.5 (47693.21 to 91091.74)  |  |  |
| Poliovirus 3; 6 months post-vaccination | 9741.98 (3305.66 to 28710.21)   | 6501.99 (2731.22 to 15478.78)   |  |  |
| Poliovirus 3; 1 year post-vaccination   | 8724.82 (3325.35 to 22891.57)   | 5042.77 (1920.88 to 13238.45)   |  |  |

|  |                                    |                                    |  |  |
|--|------------------------------------|------------------------------------|--|--|
| Poliovirus 3; 3 years post-vaccination | 3036.48<br>(1844.13 to<br>4999.74) | 3726.58<br>(2203.82 to<br>6301.52) |  |  |
| Poliovirus 3; 5 years post-vaccination | 1829.52<br>(1209.08 to<br>2768.35) | 2252.73<br>(1395.48 to<br>3636.59) |  |  |

## Statistical analyses

No statistical analyses for this end point

### Other pre-specified: Percentage of Adolescents Subjects with Pertussis $\geq$ 1xLLOQ Following Vaccination with Td-mIPV, or Tdap-vIPV, or Td, or aP, or Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL®

|                 |   |
|-----------------|---|
| End point title | Percentage of Adolescents Subjects with Pertussis $\geq$ 1xLLOQ Following Vaccination with Td-mIPV, or Tdap-vIPV, or Td, or aP, or Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL® <sup>[8]</sup> |
|-----------------|---|

End point description:

Anti-Pertussis (Pertussis Toxoid, Filamentous hemagglutinin, Pertactin, and Fimbriae types 2 and 3) antibody responses were measured by an enzyme-linked immunosorbent assay (ELISA). Subjects with Pertussis titers  $\geq$  LLOQ defined as 5 EU/mL for Pertussis toxoid, 3 EU/mL for Filamentous hemagglutinin and Pertactin, and 17 EU/mL for Fimbriae types 2 and 3 for all time points, except for 10 year post-vaccination; 4 EU/mL for Pertussis toxoid, Fimbriae types 2 and 3, and Pertactin and 3 EU/mL for Filamentous hemagglutinin for 10 year post-vaccination.

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

End point timeframe:

Pre-vaccination, 1 and 6 months post-vaccination, and 1, 3, 5, and 10 years post-vaccination

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint is reporting data for only the adolescent subjects; data for adult subjects were reported in a separate outcome.

| End point values                                    | Td-mIPV Adolescents | TdaP1-IPV Adolescents | TdaP2-IPV Adolescents | TdaP3-IPV Adolescents |
|---|---------------------|-----------------------|-----------------------|-----------------------|
| Subject group type                                  | Reporting group     | Reporting group       | Reporting group       | Reporting group       |
| Number of subjects analysed                         | 117                 | 118                   | 117                   | 116                   |
| Units: Percentage of subjects                       |                     |                       |                       |                       |
| number (not applicable)                             |                     |                       |                       |                       |
| Pertussis toxoid; Pre-vaccination                   | 75.9                | 70.1                  | 79.1                  | 74.1                  |
| Pertussis toxoid; 1 month post-vaccination          | 100                 | 99.1                  | 100                   | 99.1                  |
| Pertussis toxoid; 6 months post-vaccination         | 100                 | 100                   | 100                   | 95.7                  |
| Pertussis toxoid; 1 year post-vaccination           | 100                 | 100                   | 100                   | 95.7                  |
| Pertussis toxoid; 3 years post-vaccination          | 100                 | 97.5                  | 94.6                  | 97.5                  |
| Pertussis toxoid; 5 years post-vaccination          | 100                 | 97.3                  | 100                   | 100                   |
| Pertussis toxoid; 10 years post-vaccination         | 85.7                | 89.7                  | 88                    | 84.8                  |
| Filamentous hemagglutinin; Pre-vaccination          | 96.6                | 93.2                  | 93.9                  | 94                    |
| Filamentous hemagglutinin; 1 month post-vaccination | 100                 | 100                   | 100                   | 100                   |

|  |      |      |      |      |
|--|------|------|------|------|
| Filamentous hemagglutinin;6 month post-vaccination | 100  | 100  | 100  | 100  |
| Filamentous hemagglutinin; 1 year post-vaccination | 100  | 100  | 100  | 100  |
| Filamentous hemagglutinin;3 years post-vaccination | 100  | 97.5 | 100  | 100  |
| Filamentous hemagglutinin;5 years post-vaccination | 100  | 97.3 | 100  | 100  |
| Filamentous hemagglutinin;10 year post-vaccination | 100  | 97.6 | 96.7 | 100  |
| Pertactin; Pre-vaccination                         | 62.4 | 62.7 | 59.1 | 56   |
| Pertactin; 1 month post-vaccination                | 100  | 99.2 | 100  | 100  |
| Pertactin; 6 months post-vaccination               | 100  | 100  | 100  | 100  |
| Pertactin; 1 year post-vaccination                 | 100  | 100  | 100  | 100  |
| Pertactin; 3 years post-vaccination                | 100  | 100  | 100  | 97.5 |
| Pertactin; 5 years post-vaccination                | 100  | 100  | 100  | 100  |
| Pertactin; 10 years post-vaccination               | 96.3 | 88.1 | 83.3 | 94.3 |
| Fimbriae; Pre-vaccination                          | 79.5 | 66.9 | 78.3 | 76.7 |
| Fimbriae; 1 month post-vaccination                 | 100  | 100  | 100  | 100  |
| Fimbriae; 6 months post-vaccination                | 100  | 100  | 100  | 100  |
| Fimbriae; 1 year post-vaccination                  | 100  | 100  | 100  | 95.7 |
| Fimbriae; 3 years post-vaccination                 | 100  | 97.5 | 97.3 | 100  |
| Fimbriae; 5 years post-vaccination                 | 97.1 | 94.6 | 100  | 100  |
| Fimbriae; 10 years post-vaccination                | 96.3 | 100  | 100  | 100  |

## Statistical analyses

No statistical analyses for this end point

### Other pre-specified: Percentage of Adult Subjects with Pertussis $\geq$ 1xLLOQ Following Vaccination with Td-mIPV, or Tdap-vIPV, or Td, or aP, or Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL®

|                 |   |
|-----------------|---|
| End point title | Percentage of Adult Subjects with Pertussis $\geq$ 1xLLOQ Following Vaccination with Td-mIPV, or Tdap-vIPV, or Td, or aP, or Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL® <sup>[9]</sup> |
|-----------------|---|

#### End point description:

Anti-Pertussis (Pertussis Toxoid, Filamentous hemagglutinin, Pertactin, and Fimbriae types 2 and 3) antibody responses were measured by an enzyme-linked immunosorbent assay (ELISA). Subjects with Pertussis titers  $\geq$  LLOQ defined as 5 EU/mL for Pertussis toxoid, 3 EU/mL for Filamentous hemagglutinin and Pertactin, and 17 EU/mL for Fimbriae types 2 and 3 for all time points, except for 10 year post-vaccination; 4 EU/mL for Pertussis toxoid, Fimbriae types 2 and 3, and Pertactin and 3 EU/mL for Filamentous hemagglutinin for 10 year post-vaccination. The data of Tdap/IPV Adults and Tdap/aP Adults were combined for this analysis. The collective total (N) for the analysis was 55 at year 10, the cumulative data are presented for each group in the table for this outcome.

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

#### End point timeframe:

10 years post-vaccination

#### Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint is reporting data for only the adult subjects; data for adolescent subjects were reported in a separate outcome.

| <b>End point values</b>                             | Td/aP Adults    | Tdap/IPV Adults | Tdap/aP Adults  | Tdap1-IPV Adults |
|---|-----------------|-----------------|-----------------|------------------|
| Subject group type                                  | Reporting group | Reporting group | Reporting group | Reporting group  |
| Number of subjects analysed                         | 30              | 55              | 55              | 31               |
| Units: Percentage of subjects                       |                 |                 |                 |                  |
| number (not applicable)                             |                 |                 |                 |                  |
| Pertussis toxoid; 10 years post-vaccination         | 100             | 89.6            | 89.6            | 88.5             |
| Filamentous hemagglutinin; 10 year post-vaccination | 100             | 100             | 100             | 100              |
| Pertactin; 10 years post-vaccination                | 86.7            | 98.2            | 98.2            | 93.5             |
| Fimbriae; 10 years post-vaccination                 | 100             | 100             | 100             | 96.8             |

| <b>End point values</b>                             | Tdap2-IPV Adults | Tdap3-IPV Adults |  |  |
|---|------------------|------------------|--|--|
| Subject group type                                  | Reporting group  | Reporting group  |  |  |
| Number of subjects analysed                         | 27               | 21               |  |  |
| Units: Percentage of subjects                       |                  |                  |  |  |
| number (not applicable)                             |                  |                  |  |  |
| Pertussis toxoid; 10 years post-vaccination         | 95.2             | 90               |  |  |
| Filamentous hemagglutinin; 10 year post-vaccination | 100              | 100              |  |  |
| Pertactin; 10 years post-vaccination                | 92.6             | 95.2             |  |  |
| Fimbriae; 10 years post-vaccination                 | 100              | 100              |  |  |

## Statistical analyses

No statistical analyses for this end point

## Other pre-specified: Summary of Geometric Mean Titers for Pertussis Antibodies in Adult Subjects Following Vaccination with Td-mIPV, or Tdap-vIPV, or Td, or aP, or Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL®

|                 |  |
|-----------------|--|
| End point title | Summary of Geometric Mean Titers for Pertussis Antibodies in Adult Subjects Following Vaccination with Td-mIPV, or Tdap-vIPV, or Td, or aP, or Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL® <sup>[10]</sup> |
|-----------------|--|

End point description:

Anti-Pertussis (Pertussis Toxoid, Filamentous hemagglutinin, Pertactin, and Fimbriae types 2 and 3) antibody responses were measured by an enzyme-linked immunosorbent assay (ELISA).

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

End point timeframe:

Pre-vaccination, 1 and 6 months post-vaccination, and 1, 3, 5, and 10 years post-vaccination

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint is reporting data for only the adult subjects; data for adolescent subjects were reported in a separate outcome.

| <b>End point values</b>                            | Td/aP Adults                | TdaP/IPV Adults            | TdaP/aP Adults             | TdaP1-IPV Adults           |
|--|-----------------------------|----------------------------|----------------------------|----------------------------|
| Subject group type                                 | Reporting group             | Reporting group            | Reporting group            | Reporting group            |
| Number of subjects analysed                        | 126                         | 126                        | 122                        | 126                        |
| Units: Titers (1/dil)                              |                             |                            |                            |                            |
| geometric mean (confidence interval 95%)           |                             |                            |                            |                            |
| Pertussis toxoid; Pre-vaccination                  | 11.21 (8.88 to 14.15)       | 11.86 (9.46 to 14.86)      | 10.05 (8.19 to 12.32)      | 9.71 (7.76 to 12.15)       |
| Pertussis toxoid; 1 month post-vaccination         | 170.87 (143.34 to 203.7)    | 124.53 (102.13 to 151.85)  | 137.89 (114.51 to 166.04)  | 124.9 (104 to 150)         |
| Pertussis toxoid; 6 months post-vaccination        | 55.84 (30.26 to 103.05)     | 30.68 (18.1 to 52)         | 90.95 (67.62 to 122.31)    | 49.51 (23.87 to 102.7)     |
| Pertussis toxoid; 1 year post-vaccination          | 51.57 (27.66 to 96.16)      | 31.36 (15.45 to 63.65)     | 97.81 (69.37 to 137.91)    | 67.89 (41.95 to 109.87)    |
| Pertussis toxoid; 3 years post-vaccination         | 45.51 (35.99 to 57.55)      | 39.29 (28.92 to 53.37)     | 63.42 (47.18 to 85.25)     | 42.09 (34.04 to 52.06)     |
| Pertussis toxoid; 5 years post-vaccination         | 47.49 (37.44 to 60.22)      | 45.42 (34.28 to 60.2)      | 56.16 (42.86 to 73.58)     | 43.9 (34.51 to 55.85)      |
| Pertussis toxoid; 10 years post-vaccination        | 18.19 (13.93 to 23.75)      | 12.24 (7.89 to 18.98)      | 25.86 (15.23 to 43.9)      | 17.49 (11.07 to 27.64)     |
| Filamentous hemagglutinin; Pre-vaccination         | 21.34 (16.74 to 27.2)       | 21.04 (16.76 to 26.42)     | 21.43 (17.51 to 26.24)     | 22.62 (17.96 to 28.49)     |
| Filamentous hemagglutinin;1 month post-vaccination | 385.08 (326.51 to 454.15)   | 360.16 (305.34 to 424.81)  | 333.39 (283.49 to 392.09)  | 246.8 (212.16 to 287.1)    |
| Filamentous hemagglutinin;6 month post-vaccination | 147.85 (70.64 to 309.43)    | 62.71 (44.88 to 87.62)     | 166.74 (110.67 to 251.22)  | 70.2 (47.16 to 104.49)     |
| Filamentous hemagglutinin; 1 year post-vaccination | 120.35 (64.97 to 222.94)    | 63.61 (41.91 to 96.54)     | 148.02 (114.19 to 191.87)  | 82.93 (55.71 to 123.44)    |
| Filamentous hemagglutinin;3 years post-vaccination | 67.17 (52.28 to 86.29)      | 71.68 (58.25 to 88.21)     | 87.03 (67.77 to 111.76)    | 55.21 (42.94 to 70.98)     |
| Filamentous hemagglutinin;5 years post-vaccination | 55.71 (44.27 to 70.1)       | 62.04 (51.53 to 74.69)     | 70.85 (56.16 to 89.37)     | 46.46 (36.42 to 59.28)     |
| Filamentous hemagglutinin;10 year post-vaccination | 44.12 (31.97 to 60.89)      | 33.33 (25.21 to 44.07)     | 59.23 (41.51 to 84.52)     | 33.17 (23.28 to 47.26)     |
| Pertactin; Pre-vaccination                         | 5.49 (4.11 to 7.34)         | 5.77 (4.15 to 8.03)        | 4.26 (3.19 to 5.7)         | 4.81 (3.51 to 6.61)        |
| Pertactin; 1 month post-vaccination                | 187.19 (137.04 to 255.68)   | 292.38 (222.9 to 383.53)   | 213.81 (155.87 to 293.29)  | 231.44 (172.06 to 311.32)  |
| Pertactin; 6 months post-vaccination               | 142.41 (50.42 to 402.2)     | 148.11 (56.09 to 391.11)   | 265.86 (115.37 to 612.67)  | 78.22 (29.84 to 205.03)    |
| Pertactin; 1 year post-vaccination                 | 83.85 (35.81 to 196.35)     | 102.31 (36.42 to 287.4)    | 200.85 (90.29 to 446.77)   | 60.28 (25.78 to 140.95)    |
| Pertactin; 3 years post-vaccination                | 65.79 (39.83 to 108.66)     | 69.7 (45.83 to 105.98)     | 74.81 (49.4 to 113.28)     | 71.11 (44.3 to 114.13)     |
| Pertactin; 5 years post-vaccination                | 49.89 (30.76 to 80.93)      | 58.95 (40.03 to 86.82)     | 53.87 (36.73 to 79)        | 58.98 (37.62 to 92.47)     |
| Pertactin; 10 years post-vaccination               | 24.39 (13.95 to 42.66)      | 27.9 (17 to 45.78)         | 28.98 (15.65 to 53.68)     | 32.28 (19.23 to 54.19)     |
| Fimbriae; Pre-vaccination                          | 21.07 (15.06 to 29.49)      | 20.66 (15.08 to 28.3)      | 18.89 (14.05 to 25.39)     | 23.07 (17.52 to 30.38)     |
| Fimbriae; 1 month post-vaccination                 | 1044.54 (851.74 to 1280.98) | 803.56 (571.19 to 1130.45) | 966.48 (747.74 to 1249.21) | 851.04 (644.03 to 1124.59) |

|                                     |                           |                          |                            |                           |
|-------------------------------------|---------------------------|--------------------------|----------------------------|---------------------------|
| Fimbriae; 6 months post-vaccination | 412.35 (189.93 to 895.25) | 172.46 (83.52 to 356.12) | 640.02 (386.87 to 1058.83) | 156.76 (43.98 to 558.66)  |
| Fimbriae; 1 year post-vaccination   | 333.4 (173.9 to 639.17)   | 129.08 (49.84 to 334.29) | 598.59 (391.63 to 914.91)  | 187.27 (57.36 to 611.38)  |
| Fimbriae; 3 years post-vaccination  | 204.28 (141.99 to 293.91) | 143.11 (91.12 to 224.76) | 262.4 (167.53 to 410.99)   | 210.66 (151.16 to 293.59) |
| Fimbriae; 5 years post-vaccination  | 180.76 (129.47 to 252.36) | 139.55 (91.67 to 212.45) | 198.54 (138.8 to 283.99)   | 179.95 (132.27 to 244.81) |
| Fimbriae; 10 years post-vaccination | 204.04 (134.44 to 309.66) | 117.03 (70.21 to 195.07) | 234.26 (152.57 to 359.7)   | 117.98 (79.5 to 175.08)   |

| <b>End point values</b>                            | TdaP2-IPV Adults          | TdaP3-IPV Adults          |  |  |
|--|---------------------------|---------------------------|--|--|
| Subject group type                                 | Reporting group           | Reporting group           |  |  |
| Number of subjects analysed                        | 121                       | 125                       |  |  |
| Units: Titers (1/dil)                              |                           |                           |  |  |
| geometric mean (confidence interval 95%)           |                           |                           |  |  |
| Pertussis toxoid; Pre-vaccination                  | 10.66 (8.59 to 13.24)     | 10.1 (8.03 to 12.7)       |  |  |
| Pertussis toxoid; 1 month post-vaccination         | 123.01 (104.01 to 145.47) | 92.46 (77.88 to 109.76)   |  |  |
| Pertussis toxoid; 6 months post-vaccination        | 80.29 (47.71 to 135.13)   | 58.37 (37.48 to 90.88)    |  |  |
| Pertussis toxoid; 1 year post-vaccination          | 82.3 (50 to 135.45)       | 72.45 (42.91 to 122.32)   |  |  |
| Pertussis toxoid; 3 years post-vaccination         | 43.21 (29.39 to 63.54)    | 36.18 (26.36 to 49.66)    |  |  |
| Pertussis toxoid; 5 years post-vaccination         | 40.76 (30.26 to 54.9)     | 34.62 (24.77 to 48.37)    |  |  |
| Pertussis toxoid; 10 years post-vaccination        | 21.51 (12.99 to 35.62)    | 14.18 (8.46 to 23.76)     |  |  |
| Filamentous hemagglutinin; Pre-vaccination         | 19.57 (16.01 to 23.92)    | 18.95 (15.39 to 23.33)    |  |  |
| Filamentous hemagglutinin;1 month post-vaccination | 221.21 (185.99 to 263.1)  | 246.88 (207.89 to 293.19) |  |  |
| Filamentous hemagglutinin;6 month post-vaccination | 81.15 (63.32 to 104)      | 83.69 (54.78 to 127.86)   |  |  |
| Filamentous hemagglutinin; 1 year post-vaccination | 92.25 (71.97 to 118.25)   | 105.13 (74.35 to 148.64)  |  |  |
| Filamentous hemagglutinin;3 years post-vaccination | 58.61 (44.75 to 76.76)    | 64.52 (49.36 to 84.32)    |  |  |
| Filamentous hemagglutinin;5 years post-vaccination | 55.01 (43.08 to 70.24)    | 60.43 (47.39 to 77.07)    |  |  |
| Filamentous hemagglutinin;10 year post-vaccination | 36.38 (24.81 to 53.35)    | 42.49 (28.1 to 64.26)     |  |  |
| Pertactin; Pre-vaccination                         | 4.16 (3 to 5.78)          | 4.96 (3.67 to 6.71)       |  |  |
| Pertactin; 1 month post-vaccination                | 219.62 (162.84 to 296.21) | 177.64 (135.49 to 232.9)  |  |  |

|                                      |                           |                           |  |  |
|--------------------------------------|---------------------------|---------------------------|--|--|
| Pertactin; 6 months post-vaccination | 177.46 (79.79 to 394.7)   | 72.44 (26.1 to 201.05)    |  |  |
| Pertactin; 1 year post-vaccination   | 117.54 (55.9 to 247.16)   | 75.91 (25.1 to 229.55)    |  |  |
| Pertactin; 3 years post-vaccination  | 65.61 (41.91 to 102.72)   | 79.47 (54.08 to 116.78)   |  |  |
| Pertactin; 5 years post-vaccination  | 47.43 (30.23 to 74.43)    | 62.4 (43.51 to 89.51)     |  |  |
| Pertactin; 10 years post-vaccination | 37.39 (20.48 to 68.27)    | 27.96 (15.24 to 51.3)     |  |  |
| Fimbriae; Pre-vaccination            | 22.54 (16.57 to 30.66)    | 18.93 (13.67 to 26.22)    |  |  |
| Fimbriae; 1 month post-vaccination   | 724.61 (561.38 to 935.3)  | 461.68 (363.26 to 586.77) |  |  |
| Fimbriae; 6 months post-vaccination  | 466.05 (241.63 to 898.9)  | 316.27 (168.73 to 592.8)  |  |  |
| Fimbriae; 1 year post-vaccination    | 370.49 (193.93 to 707.78) | 358.2 (192.57 to 666.28)  |  |  |
| Fimbriae; 3 years post-vaccination   | 165.84 (110.42 to 249.09) | 135.38 (89.11 to 205.68)  |  |  |
| Fimbriae; 5 years post-vaccination   | 144.74 (100.22 to 209.02) | 108.1 (73.93 to 158.06)   |  |  |
| Fimbriae; 10 years post-vaccination  | 167.23 (112.19 to 249.28) | 103.57 (59.81 to 179.36)  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

---

### Adverse events information<sup>[1]</sup>

---

Timeframe for reporting adverse events:

This was a long-term immunogenicity follow-up study of subjects who participated in a previous study, Td9707. No vaccines were administered in this study and adverse event data were also not collected

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

---

### Dictionary used

---

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

---

|                    |    |
|--------------------|----|
| Dictionary version | 10 |
|--------------------|----|

---

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

---

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: This was a long-term immunogenicity follow-up study of subjects who participated in a previous study, Td9707. No vaccines were administered in this study and adverse event data were also not collected.

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date        | Amendment   |
|-------------|---|
| 23 May 2001 | Added details regarding the long-term follow up serology studies, including the collection of additional blood samples and the time of visit for each blood test. |

Notes:

---

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported

---

### Online references

<http://www.ncbi.nlm.nih.gov/pubmed/10783014>

<http://www.ncbi.nlm.nih.gov/pubmed/17945400>