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
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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
Arm title	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.

Arm title	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.

Arm title	TdaP2-IPV Adolescents

Arm description:

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:

0.5 mL, intramuscular, 1 injection on Day 0.

Arm title	TdaP3-IPV Adolescents

Arm description:

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:

0.5 mL, intramuscular, 1 injection on Day 0.

Arm title	Td/aP Adults

Arm 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).

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:

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:

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:

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

Arm title	TdaP/IPV Adults

Arm description:

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:

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:

0.5 mL, subcutaneous, l injection at Month 1.

Arm title	TdaP/aP Adults

Arm 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).

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:

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 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).

Arm title	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.

Arm title	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.

Arm title	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.

Number of subjects in period 1	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	-	-	-

Number of subjects in period 1	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	-	-	-

Number of subjects in period 1	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	-	-

Number of subjects in period 1	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:	
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.	

Reporting group values	Td-mIPV Adolescents	TdaP1-IPV Adolescents	TdaP2-IPV Adolescents
Number of subjects	117	118	117
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	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			
Units: years			
arithmetic mean	13.9	14.01	13.97
standard deviation	± 0.96	± 1.06	± 1.04
Gender categorical			
Units: Subjects			
Female	55	63	54
Male	62	55	63

Reporting group values	TdaP3-IPV Adolescents	Td/aP Adults	TdaP/IPV Adults
Number of subjects	116	126	126
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	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			
Units: years			
arithmetic mean	13.91	37.93	38.13
standard deviation	± 1	± 9.55	± 9.09
Gender categorical			
Units: Subjects			
Female	57	82	81
Male	59	44	45

Reporting group values	TdaP/aP Adults	TdaP1-IPV Adults	TdaP2-IPV Adults
Number of subjects	122	126	121
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	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			
Units: years			
arithmetic mean	38.28	37.89	38.29
standard deviation	± 8.7	± 8.69	± 8.95
Gender categorical			
Units: Subjects			
Female	91	93	82
Male	31	33	39

Reporting group values	TdaP3-IPV Adults	Total	
Number of subjects	125	1214	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 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			
Units: years			
arithmetic mean	38.55		
standard deviation	± 8.18	-	
Gender categorical			
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®[1][2]
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 ≥ 0.01 IU/mL for Diphtheria and ≥ 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.

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	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®[3]

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 ≥ 0.01 IU/mL for Diphtheria and ≥ 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.

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	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

End point values	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®[4]

End point description:

Anti-Poliovirus types 1, 2, and 3 titers were measured by a neutralization assay. Seroprotection was defined as post-vaccination titers ≥ 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®[5]

End point description:

Anti-Poliovirus types 1, 2, and 3 titers were measured by a neutralization assay. Seroprotection was defined as post-vaccination titers ≥ 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

End point values	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)				
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[6]

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.

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: 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)	0 (0 to 0)	0 (0 to 0)	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)	0 (0 to 0)	0 (0 to 0)	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)	0 (0 to 0)	0 (0 to 0)	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[7]

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 Td/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 (705.07 to 1586.63)	1026.41 (767.42 to 1372.82)	1026.41 (767.42 to 1372.82)	1690.74 (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 (10223.31 to 20364.35)	14428.83 (10223.31 to 20364.35)	16475.84 (12303.16 to 22063.71)
Poliovirus 2; 6 months post-vaccination	1722.16 (636.15 to 4662.16)	6562.36 (3309.05 to 13014.21)	6562.36 (3309.05 to 13014.21)	5792.62 (2701.43 to 12420.99)
Poliovirus 2; 1 year post-vaccination	1217.75 (586.65 to 2527.76)	4350.47 (2124.32 to 8909.49)	4350.47 (2124.32 to 8909.49)	5612.96 (2549.3 to 12358.39)
Poliovirus 2; 3 years post-vaccination	2345.46 (1404.56 to 3916.64)	3337.48 (2451.11 to 4544.38)	3337.48 (2451.11 to 4544.38)	1961.17 (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 (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 (31201.8 to 59916.2)	43237.64 (31201.8 to 59916.2)	68917.4 (52375.57 to 90683.66)
Poliovirus 3; 6 months post-vaccination	5467.5 (973.38 to 30711.21)	9152.82 (4204.96 to 19922.67)	9152.82 (4204.96 to 19922.67)	16384 (7916.91 to 33906.6)
Poliovirus 3; 1 year post-vaccination	3774.53 (849.34 to 16774.21)	6437.01 (2672.5 to 15504.22)	6437.01 (2672.5 to 15504.22)	12733.7 (7893.64 to 20541.47)
Poliovirus 3; 3 years post-vaccination	2896.31 (1385.48 to 6054.66)	3208.6 (2180.34 to 4721.78)	3208.6 (2180.34 to 4721.78)	4216.02 (2868.98 to 6195.52)
Poliovirus 3; 5 years post-vaccination	1907.77 (988.71 to 3681.15)	2081.67 (1503.43 to 2882.31)	2081.67 (1503.43 to 2882.31)	3104.18 (2092.54 to 4604.89)

End point values	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%)				
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 (1844.13 to 4999.74)	3726.58 (2203.82 to 6301.52)		
Poliovirus 3; 5 years post-vaccination	1829.52 (1209.08 to 2768.35)	2252.73 (1395.48 to 3636.59)		

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Adolescents Subjects with Pertussis ≥ 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 ≥ 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®[8]

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 ≥ 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 ≥ 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 ≥ 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®[9]

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 ≥ 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.

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	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

End point values	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®[10]

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.

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%)				
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)

End point values	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[1]	
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