Clinical trial results:
One-, Three-, Five-, and Ten-Year Data on the Long-Term Immunogenicity of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) in Adults and Adolescents (11-64 years)

Summary

EudraCT number	2015-005845-30
Trial protocol	Outside EU/EEA
Global end of trial date	29 August 2012

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	Td506-LT

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
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/Medical Monitor, Sanofi Pasteur, 1 570-957-1506, Dr.Johnson@sanofipasteur.com
Scientific contact	Clinical/Medical Monitor, Sanofi Pasteur, 1 570-957-1506, Dr.Johnson@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	29 August 2012
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 August 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Long-term follow-up study to describe the profile of antibody levels after booster vaccination with Tdap vaccine or Td vaccine at 1-month, 1-, 3-, and 5-years postvaccination and Tdap only at 10 years post-vaccination.

Protection of trial subjects:

Subjects were vaccinated in a previous study, Td506. No vaccination was administered as part of this long-term immunogenicity study.

Background therapy:

A subset (189) of the Per-Protocol Immunogenicity (PPI) Paired Population from the Tdap vaccine group (2296 subjects) in the main study were in the 10-year follow up immunogenicity follow-up analysis. The Per-Protocol Immunogenicity (PPI) Paired Population for the 10-year follow-up analyses included subjects from the PPI-1 year, PPI-3 year, PPI-5 year, and PPI-10 year populations who provided blood samples at all 4 follow-up visits, i.e., at 1, 3, 5, and 10 years, and who did not receive any diphtheria-, tetanus-,or pertussis-containing vaccine between 1-month and 10-years after vaccination or did not report pertussis illness during this period.

Evidence for comparator:

Not applicable

Actual start date of recruitment	28 August 2002
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 189
Worldwide total number of subjects	189
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)	44
Adults (18-64 years)	145
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A subset of the Per-Protocol Immunogenicity (PPI) Paired Population from the Tdap vaccine group in the main study were in the 10-year follow up immunogenicity follow-up study.

Pre-assignment

Screening details:

A subset (189) of the Tdap vaccine group in the original study (paired per-protocol population) were included in the 10-year long-term immunogenicity analysis.

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

Arm title	Tdap Vaccine

Arm description:

A subset of subjects (paired per-protocol population) that received 1 dose of Tdap vaccine (Adacel®) in the original Td506 study.

Arm type	Experimental
Investigational medicinal product name	Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Adacel®)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

No vaccine was administered in the long-term follow-up study. (Subjects received 1 injection, 0.5 mL by intramuscular route on Day 0 in the original Td506 study)

Number of subjects in period 1	Tdap Vaccine
Started	189
Completed	189

Baseline characteristics

Reporting groups	
Reporting group title	Tdap Vaccine
Reporting group description:	
A subset of subjects (paired per-protocol population) that received 1 dose of Tdap vaccine (Adacel®) in the original Td506 study.	

Reporting group values	Tdap Vaccine	Total	
Number of subjects	189	189	
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)	44	44	
Adults (18-64 years)	145	145	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	29		
standard deviation	± 16.4	-	
Gender categorical Units: Subjects			
Female	129	129	
Male	60	60	

End points

End points reporting groups

Reporting group title	Tdap Vaccine

Reporting group description:

A subset of subjects (paired per-protocol population) that received 1 dose of Tdap vaccine (Adacel®) in the original Td506 study.

Primary: Percentage of Subjects with Seroprotection to Tetanus and Diphtheria Following Vaccination with Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL®

End point title	Percentage of Subjects with Seroprotection to Tetanus and Diphtheria Following Vaccination with Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL®[1]

End point description:

Anti-Diphtheria antibody responses were measured by the ability of the test sera to protect Vero cells from a diphtheria toxin challenge. Anti-Tetanus antibody responses were measured by an indirect enzyme-linked immunosorbent assay method. Seroprotection was defined as diphtheria and tetanus titers ≥ 0.01 IU/mL and ≥ 0.1 IU/mL.

End point type	Primary

End point timeframe:

Day 0 (pre-vaccination) and 1 month and 1, 3, 5, 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 vaccine groups from the primary series for the long term follow-up period.

End point values	Tdap Vaccine			
Subject group type	Reporting group			
Number of subjects analysed	62[2]			
Units: Percentage of subjects				
number (not applicable)				
Diphtheria; ≥ 0.01 IU/mL; 11-17 yrs; Pre-injection	100			
Diphtheria; ≥ 0.01 IU/mL; 18-64 yrs; Pre-injection	91.9			
Diphtheria; ≥ 0.01 IU/mL;11-17 yrs;1 mth;Post-inj.	100			
Diphtheria; ≥ 0.01 IU/mL;18-64 yrs;1 mth;Post-inj.	98.4			
Diphtheria; ≥ 0.01 IU/mL;11-17 yrs;1 yr;Post-inj.	100			
Diphtheria; ≥ 0.01 IU/mL;18-64 yrs;1 yr;Post-inj.	98.4			
Diphtheria; ≥ 0.01 IU/mL;11-17 yrs;3 yrs;Post-inj.	100			
Diphtheria; ≥ 0.01 IU/mL;18-64 yrs;3 yrs;Post-inj.	98.4			
Diphtheria; ≥ 0.01 IU/mL;11-17 yrs;5 yrs;Post-inj.	100			
Diphtheria; ≥ 0.01 IU/mL;18-64 yrs;5 yrs;Post-inj.	98.4			

Diphtheria;≥ 0.01 IU/mL;11-17 yrs;10 yrs;Post-inj.	100			
Diphtheria;≥ 0.01 IU/mL;18-64 yrs;10 yrs;Post-inj.	98.4			
Tetanus; ≥ 0.01 IU/mL; 11-17 yrs; Pre-injection	100			
Tetanus; ≥ 0.01 IU/mL; 18-64 yrs; Pre-injection	100			
Tetanus; ≥ 0.01 IU/mL; 11-17 yrs; 1 mth Post-inj.	100			
Tetanus; ≥ 0.01 IU/mL; 18-64 yrs; 1 mth Post-inj.	100			
Tetanus; ≥ 0.01 IU/mL; 11-17 yrs; 1 year Post-inj.	100			
Tetanus; ≥ 0.01 IU/mL; 18-64 yrs; 1 year Post-inj.	100			
Tetanus; ≥ 0.01 IU/mL; 11-17 yrs; 3 yrs Post-inj.	100			
Tetanus; ≥ 0.01 IU/mL; 18-64 yrs; 3 yrs Post-inj.	100			
Tetanus; ≥ 0.01 IU/mL; 11-17 yrs; 5 yrs Post-inj.	100			
Tetanus; ≥ 0.01 IU/mL; 18-64 yrs; 5 yrs Post-inj.	100			
Tetanus; ≥ 0.01 IU/mL; 11-17 yrs; 10 yrs Post-inj.	100			
Tetanus; ≥ 0.01 IU/mL; 18-64 yrs; 10 yrs Post-inj.	100			
Diphtheria; ≥ 0.1 IU/mL; 11-17 yrs; Pre-injection	70.6			
Diphtheria; ≥ 0.1 IU/mL; 18-64 yrs; Pre-injection	64.5			
Diphtheria; ≥ 0.1 IU/mL; 11-17 yrs;1 mth;Post-inj.	100			
Diphtheria; ≥ 0.1 IU/mL; 18-64 yrs;1 mth;Post-inj.	98.4			
Diphtheria; ≥ 0.1 IU/mL; 11-17 yrs;1 yr;Post-inj.	100			
Diphtheria; ≥ 0.1 IU/mL; 18-64 yrs;1 yr;Post-inj.	93.5			
Diphtheria; ≥ 0.1 IU/mL; 11-17 yrs;3 yrs;Post-inj.	100			
Diphtheria; ≥ 0.1 IU/mL; 18-64 yrs;3 yrs;Post-inj.	88.7			
Diphtheria; ≥ 0.1 IU/mL; 11-17 yrs;5 yrs;Post-inj.	88.2			
Diphtheria; ≥ 0.1 IU/mL; 18-64 yrs;5 yrs;Post-inj.	90.3			
Diphtheria; ≥ 0.1 IU/mL;11-17 yrs;10 yrs;Post-inj.	94.1			
Diphtheria; ≥ 0.1 IU/mL;18-64 yrs;10 yrs;Post-inj.	85.5			
Tetanus; ≥ 0.1 IU/mL; 11-17 yrs; Pre-injection	100			
Tetanus; ≥ 0.1 IU/mL; 18-64 yrs; Pre-injection	100			
Tetanus; ≥ 0.1 IU/mL; 11-17 yrs; 1 mth; Post-inj.	100			
Tetanus; ≥ 0.1 IU/mL; 18-64 yrs; 1 mth; Post-inj.	100			
Tetanus; ≥ 0.1 IU/mL; 11-17 yrs; 1 year; Post-inj.	100			

Tetanus; ≥ 0.1 IU/mL; 18-64 yrs; 1 year; Post-inj.	100			
Tetanus; ≥ 0.1 IU/mL; 11-17 yrs; 3 yrs; Post-inj.	100			
Tetanus; ≥ 0.1 IU/mL; 18-64 yrs; 3 yrs; Post-inj.	98.4			
Tetanus; ≥ 0.1 IU/mL; 11-17 yrs; 5 yrs; Post-inj.	100			
Tetanus; ≥ 0.1 IU/mL; 18-64 yrs; 5 yrs; Post-inj.	98.4			
Tetanus; ≥ 0.1 IU/mL; 11-17 yrs; 10 yrs; Post-inj.	100			
Tetanus; ≥ 0.1 IU/mL; 18-64 yrs; 10 yrs; Post-inj.	100			

Notes:

[2] - N represents the PPI Paired population subset.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Summary of Geometric Mean Concentrations of Anti-Tetanus and Anti-Diphtheria Titers Following Vaccination with Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL®

End point title	Summary of Geometric Mean Concentrations of Anti-Tetanus and Anti-Diphtheria Titers Following Vaccination with Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL®

End point description:

Anti-Diphtheria antibody responses were measured by the ability of the test sera to protect Vero cells from a diphtheria toxin challenge. Anti-Tetanus antibody responses were measured by an indirect enzyme-linked immunosorbent assay method.

End point type	Other pre-specified

End point timeframe:

Day 0 (pre-vaccination) and 1 month and 1, 3, 5, 10 years post-vaccination

End point values	Tdap Vaccine			
Subject group type	Reporting group			
Number of subjects analysed	62[3]			
Units: Titers (1/dil)				
geometric mean (confidence interval 95%)				
Diphtheria; 11-17 years; Pre-injection	0.17 (0.09 to 0.32)			
Diphtheria; 18-64 years; Pre-injection	0.18 (0.11 to 0.29)			
Diphtheria; 11-17 years; 1 month Post-injection	6.03 (4.08 to 8.89)			
Diphtheria; 18-64 years; 1 month Post-injection	3.74 (2.41 to 5.81)			
Diphtheria; 11-17 years; 1 year Post-injection	2.27 (1.34 to 3.82)			
Diphtheria; 18-64 years; 1 year Post-injection	1.34 (0.89 to 2.02)			

Diphtheria; 11-17 years; 3 years Post-injection	0.85 (0.53 to 1.37)			
Diphtheria; 18-64 years; 3 years Post-injection	0.55 (0.39 to 0.79)			
Diphtheria; 11-17 years; 5 years Post-injection	1 (0.46 to 2.18)			
Diphtheria; 18-64 years; 5 years Post-injection	0.59 (0.4 to 0.87)			
Diphtheria; 11-17 years; 10 years Post-injection	0.82 (0.44 to 1.53)			
Diphtheria; 18-64 years; 10 years Post-injection	0.43 (0.29 to 0.62)			
Tetanus; 11-17 years; Pre-injection	1.19 (0.71 to 2.01)			
Tetanus; 18-64 years; Pre-injection	1.68 (1.32 to 2.15)			
Tetanus; 11-17 years; 1 month Post-injection	12.82 (9.14 to 17.98)			
Tetanus; 18-64 years; 1 month Post-injection	8.96 (7.65 to 10.5)			
Tetanus; 11-17 years; 1 year Post-injection	5.46 (4.27 to 6.98)			
Tetanus; 18-64 years; 1 year Post-injection	4.1 (3.51 to 4.79)			
Tetanus; 11-17 years; 3 years Post-injection	3.47 (2.55 to 4.73)			
Tetanus; 18-64 years; 3 years Post-injection	3.31 (2.78 to 3.93)			
Tetanus; 11-17 years; 5 years Post-injection	2.5 (1.78 to 3.53)			
Tetanus; 18-64 years; 5 years Post-injection	2.49 (2.08 to 2.97)			
Tetanus; 11-17 years; 10 years Post-injection	2.08 (1.42 to 3.03)			
Tetanus; 18-64 years; 10 years Post-injection	3 (2.53 to 3.56)			

Notes:

[3] - N represents the PPI Paired population subset.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Summary of Geometric Mean of Anti-Pertussis Titers Following Vaccination with Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL®

End point title	Summary of Geometric Mean of Anti-Pertussis Titers Following Vaccination with Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL®

End point description:

Anti-Pertussis Toxoid (PT), anti-Filamentous hemagglutinin (FHA), anti-Fimbriae (FIM), and anti-Pertactin (PRN) immunoglobulin antibody titers were determined by an indirect ELISA method.

End point type	Other pre-specified

End point timeframe:

Day 0 (pre-vaccination) and 1 month and 1, 3, 5, 10 years post-vaccination

End point values	Tdap Vaccine			
Subject group type	Reporting group			
Number of subjects analysed	62[4]			
Units: Titers (1/dil)				
geometric mean (confidence interval 95%)				
PT; 11-17 years; Pre-injection	15.42 (7.1 to 33.48)			
PT; 18-64 years; Pre-injection	9.92 (7.45 to 13.21)			
PT; 11-17 years; 1 month Post-injection	318.34 (199.39 to 508.23)			
PT; 18-64 years; 1 month Post-injection	136.61 (104.68 to 178.27)			
PT; 11-17 years; 1 year Post-injection	93.28 (48.36 to 179.93)			
PT; 18-64 years; 1 year Post-injection	58.85 (43.89 to 78.91)			
PT; 11-17 years; 3 years Post-injection	52.22 (27.19 to 100.3)			
PT; 18-64 years; 3 years Post-injection	46.26 (34.07 to 62.82)			
PT; 11-17 years; 5 years Post-injection	11.63 (5.56 to 24.32)			
PT; 18-64 years; 5 years Post-injection	14.68 (11.43 to 18.84)			
PT; 11-17 years; 10 years Post-injection	18.4 (7.31 to 46.3)			
PT; 18-64 years; 10 years Post-injection	11.9 (9.11 to 15.54)			
FHA; 11-17 years; Pre-injection	20.79 (9.16 to 47.19)			
FHA; 18-64 years; Pre-injection	14.91 (12 to 18.52)			
FHA; 11-17 years; 1 month Post-injection	209.85 (146.27 to 301.07)			
FHA; 18-64 years; 1 month Post-injection	172 (139.91 to 211.44)			
FHA; 11-17 years; 1 year Post-injection	87.43 (60.95 to 125.43)			
FHA; 18-64 years; 1 year Post-injection	81.92 (65.97 to 101.71)			
FHA; 11-17 years; 3 years Post-injection	56.42 (38.75 to 82.15)			
FHA; 18-64 years; 3 years Post-injection	56.83 (44.84 to 72.01)			
FHA; 11-17 years; 5 years Post-injection	37.35 (26.48 to 52.69)			
FHA; 18-64 years; 5 years Post-injection	35.1 (29.42 to 41.87)			
FHA; 11-17 years; 10 years Post-injection	39.15 (28.03 to 54.67)			
FHA; 18-64 years; 10 years Post-injection	37.95 (31.26 to 46.08)			
PRN; 11-17 years; Pre-injection	10.46 (4.42 to 24.73)			
PRN; 18-64 years; Pre-injection	8.36 (5.93 to 11.78)			

PRN; 11-17 years; 1 month Post-injection	402.73 (238.34 to 680.49)			
PRN; 18-64 years; 1 month Post-injection	420.9 (308.31 to 574.61)			
PRN; 11-17 years; 1 year Post-injection	129.91 (84.26 to 200.28)			
PRN; 18-64 years; 1 year Post-injection	172.85 (126.71 to 235.8)			
PRN; 11-17 years; 3 years Post-injection	88.55 (56.21 to 139.49)			
PRN; 18-64 years; 3 years Post-injection	128.78 (95.3 to 174.03)			
PRN; 11-17 years; 5 years Post-injection	49.88 (28.63 to 86.9)			
PRN; 18-64 years; 5 years Post-injection	78.5 (57.26 to 107.62)			
PRN; 11-17 years; 10 years Post-injection	67.05 (34.34 to 130.91)			
PRN; 18-64 years; 10 years Post-injection	78.59 (58.37 to 105.82)			
FIM; 11-17 years; Pre-injection	25.98 (14.37 to 46.97)			
FIM; 18-64 years; Pre-injection	27.35 (20.18 to 37.06)			
FIM; 11-17 years; 1 month Post-injection	1627.76 (1078.93 to 2455.75)			
FIM; 18-64 years; 1 month Post-injection	749.07 (545.32 to 1028.95)			
FIM; 11-17 years; 1 year Post-injection	653.13 (322.49 to 1322.75)			
FIM; 18-64 years; 1 year Post-injection	296.74 (217.99 to 403.92)			
FIM; 11-17 years; 3 years Post-injection	344.71 (193 to 615.64)			
FIM; 18-64 years; 3 years Post-injection	179.82 (132.58 to 243.88)			
FIM; 11-17 years; 5 years Post-injection	269.75 (162.47 to 447.86)			
FIM; 18-64 years; 5 years Post-injection	166.43 (122.72 to 225.7)			
FIM; 11-17 years; 10 years Post-injection	215.55 (129.09 to 359.91)			
FIM; 18-64 years; 10 years Post-injection	118.43 (91.88 to 152.65)			

Notes:

[4] - N represents the PPI Paired population subset.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Subjects with Seropositivity to Pertussis antigens Following Vaccination with Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL®

End point title	Percentage of Subjects with Seropositivity to Pertussis antigens Following Vaccination with Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (Tdap) - ADACEL®

End point description:

Anti-Pertussis Toxoid (PT), anti-Filamentous hemagglutinin (FHA), anti-Fimbriae (FIM), and anti-Pertactin (PRN) immunoglobulin antibody titers were determined by an indirect ELISA method. Seropositivity ≥ 4X lower limit of quantitation (LLOQ) was ≥ 16 EU/mL for PT, FIM, and PRN and ≥ 12 EU/mL for FHA.

End point type	Other pre-specified

End point timeframe:

Day 0 (pre-vaccination) and 1 month and 1, 3, 5, 10 years post-vaccination

End point values	Tdap Vaccine			
Subject group type	Reporting group			
Number of subjects analysed	62[5]			
Units: Percentage of subjects				
number (not applicable)				
PT; 11-17 years; Pre-injection	41.2			
PT; 18-64 years; Pre-injection	35.5			
PT; 11-17 years; 1 month Post-injection	100			
PT; 18-64 years; 1 month Post-injection	95.2			
PT; 11-17 years; 1 year Post-injection	82.4			
PT; 18-64 years; 1 year Post-injection	82.3			
PT; 11-17 years; 3 years Post-injection	88.2			
PT; 18-64 years; 3 years Post-injection	79			
PT; 11-17 years; 5 years Post-injection	35.3			
PT; 18-64 years; 5 years Post-injection	56.5			
PT; 11-17 years; 10 years Post-injection	54.5			
PT; 18-64 years; 10 years Post-injection	43.1			
FHA; 11-17 years; Pre-injection	52.9			
FHA; 18-64 years; Pre-injection	62.9			
FHA; 11-17 years; 1 month Post-injection	100			
FHA; 18-64 years; 1 month Post-injection	100			
FHA; 11-17 years; 1 year Post-injection	100			
FHA; 18-64 years; 1 year Post-injection	98.4			
FHA; 11-17 years; 3 years Post-injection	100			
FHA; 18-64 years; 3 years Post-injection	96.8			
FHA; 11-17 years; 5 years Post-injection	94.1			
FHA; 18-64 years; 5 years Post-injection	93.5			
FHA; 11-17 years; 10 years Post-injection	100			
FHA; 18-64 years; 10 years Post-injection	95.2			

PRN; 11-17 years; Pre-injection	47.1			
PRN; 18-64 years; Pre-injection	41.9			
PRN; 11-17 years; 1 month Post-injection	100			
PRN; 18-64 years; 1 month Post-injection	98.4			
PRN; 11-17 years; 1 year Post-injection	100			
PRN; 18-64 years; 1 year Post-injection	98.4			
PRN; 11-17 years; 3 years Post-injection	100			
PRN; 18-64 years; 3 years Post-injection	96.8			
PRN; 11-17 years; 5 years Post-injection	82.4			
PRN; 18-64 years; 5 years Post-injection	85.5			
PRN; 11-17 years; 10 years Post-injection	88.2			
PRN; 18-64 years; 10 years Post-injection	85.5			
FIM; 11-17 years; Pre-injection	23.5			
FIM; 18-64 years; Pre-injection	27.4			
FIM; 11-17 years; 1 month Post-injection	100			
FIM; 18-64 years; 1 month Post-injection	98.4			
FIM; 11-17 years; 1 year Post-injection	94.1			
FIM; 18-64 years; 1 year Post-injection	88.7			
FIM; 11-17 years; 3 years Post-injection	88.2			
FIM; 18-64 years; 3 years Post-injection	79			
FIM; 11-17 years; 5 years Post-injection	100			
FIM; 18-64 years; 5 years Post-injection	95.2			
FIM; 11-17 years; 10 years Post-injection	100			
FIM; 18-64 years; 10 years Post-injection	95.2			

Notes:

[5] - N represents the PPI Paired population subset.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

This long-term immunogenicity study was a follow-up to study Td506 which evaluated the safety and immunogenicity of Tdap compared to Td vaccine. 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 long-term immunogenicity study was a follow-up to study Td506 which evaluated the safety and immunogenicity of Tdap compared to Td vaccine. 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 July 2001	Involved study design changes to increase the safety database, subject follow-up duration, and included administrative changes for clarification.
30 April 2002	Added the long-term follow up for 1 year.
10 June 2004	Planned long-term follow up for 3 years and 5 years.
30 September 2005	Planned long-term follow up for 10 years.
15 June 2006	Updated study personnel throughout the protocol.
11 July 2011	Involved study design changes to increase the safety database, subject follow-up duration, and included administrative changes for clarification.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported