Clinical trial results:
A phase IIIb open, controlled study to evaluate the immunogenicity, safety and reactogenicity of GlaxoSmithKline (GSK) Biologicals' 10-valent pneumococcal conjugate vaccine when given as a catch-up immunization in children older than 7 months of age or given as a 3-dose primary immunization in children before 6 months of age.

Summary

EudraCT number	2006-001482-42
Trial protocol	FI
Global end of trial date	15 November 2007

Results information

Result version number	v3 (current)
This version publication date	09 August 2022
First version publication date	14 June 2015
Version creation reason	• Correction of full data set Correction of full data set and alignment between registries.

Trial information

Trial identification

Sponsor protocol code	107058

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00345358
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 April 2008
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 November 2007
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the immunogenicity of GSK Biologicals' 10-valent pneumococcal conjugate vaccine, when given as a catch-up immunization in children older than 7 months of age (three age-groups with different schedules).

Protection of trial subjects:

All vaccines were observed closely for at least 30 minutes following the administration of vaccines, with appropriate medical treatment readily available in case of a rare anaphylactic reaction. Vaccines/products were administered by qualified and trained personnel. Vaccines/products were administered only to eligible subjects that had no contraindications to any components of the vaccines/products. Subjects were followed up for up to 31 days for adverse events after the last vaccination/product administration and during the entire study period for serious adverse events.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 September 2006
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	Finland: 600
Worldwide total number of subjects	600
EEA total number of subjects	600

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)	450
Children (2-11 years)	150
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study included a primary (PRI) phase (all groups) and a booster (BST) phase [only 10Pn less than (<)6M and 10Pn 7-11M groups].

Pre-assignment

Screening details:

At screening the following was performed: informed consent was obtained from and(&) signed by subject's parents/guardians, check for inclusion/exclusion criteria and precautions was performed as regards contraindications to vaccination, and medical history of subjects was collected. Subjects' pre-vaccination body temperature was evaluated.

Period 1

Period 1 title	Primary Vaccination Phase
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	10Pn <6M Group

Arm description:

This group consisted of subjects up to 6 months of age at first vaccination who received 3 doses of 10Pn-PD-DiT (or 10Pn) vaccine co-administered with Infanrix IPV/Hib (DTPa-IPV/Hib) at 3, 4 and 5 months of age and a booster dose of the same vaccines at 12-15 months of age. Vaccines were administrated intramuscularly in the right (10Pn-PD-DiT) or the left (DTPa-IPV/Hib) thigh or deltoid region [deltoid region only for children greater than (>)12 months of age if muscle size was adequate].

Arm type	Experimental
Investigational medicinal product name	10-valent streptococcus pneumoniae conjugate vaccine
Investigational medicinal product code	
Other name	10Pn-PD-DiT, 10Pn
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 primary doses administered at 3, 4 and 5 months of age followed by a booster dose at 12-15 months of age, all injected intramuscularly in the right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Investigational medicinal product name	DTPa-IPV/Hib
Investigational medicinal product code	
Other name	Infanrix IPV/Hib, Infanrix-Polio+Hib
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 primary doses administered at 3, 4 and 5 months of age followed by a booster dose at 12-15 months of age, all injected intramuscularly in the left right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Arm title	10Pn 7-11M Group

Arm description:

This group consisted of subjects 7 to 11 months of age at first vaccination who received 2 doses of 10Pn-PD-DiT (10Pn), one first dose at enrolment followed by a second dose one month later, and a booster dose at 12-15 months of age. The 10PN-PD-DiT vaccine was administrated intramuscularly in the right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Arm type	Experimental
Investigational medicinal product name	10-valent streptococcus pneumoniae conjugate vaccine
Investigational medicinal product code	
Other name	10Pn-PD-DiT, 10Pn
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 doses, one first dose at enrolment followed by a second dose one month later, followed by a booster dose at 12-15 months of age, injected intramuscularly in the right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Arm title	10Pn 12-23M Group

Arm description:

This group consisted of subjects 12 to 23 months inclusive at first vaccination who received 2 doses of 10Pn-PD-DiT (10Pn), one first dose at enrolment followed by a second dose 2 months later. The 10PN-PD-DiT vaccine was administrated intramuscularly in the right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Arm type	Experimental
Investigational medicinal product name	10-valent streptococcus pneumoniae conjugate vaccine
Investigational medicinal product code	
Other name	10Pn-PD-DiT, 10Pn
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 doses of 10Pn-PD-DiT (10Pn), one first dose at enrolment followed by a second dose 2 months later, injected intramuscularly in the right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Arm title	10Pn >=24M Group

Arm description:

This group consisted of subjects aged between 24 months (inclusive) to 5 years (inclusive) at vaccination who received one dose of 10Pn-PD-DiT (10Pn). The 10PN-PD-DiT vaccine was administrated intramuscularly in the right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Arm type	Experimental
Investigational medicinal product name	10-valent streptococcus pneumoniae conjugate vaccine
Investigational medicinal product code	
Other name	10Pn-PD-DiT, 10Pn
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose administered when subject’s age was between 24 months (inclusive) to 5 years of age (inclusive) at vaccination, injected intramuscularly in the right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Number of subjects in period 1	10Pn <6M Group	10Pn 7-11M Group	10Pn 12-23M Group
Started	150	150	150
Completed	145	146	142
Not completed	5	4	8
Consent withdrawn by subject	1	2	4
Adverse event, non-fatal	3	1	1
Other reason (unspecified)	-	1	1

Lost to follow-up	1	-	2

Number of subjects in period 1	10Pn >=24M Group
Started	150
Completed	148
Not completed	2
Consent withdrawn by subject	-
Adverse event, non-fatal	-
Other reason (unspecified)	-
Lost to follow-up	2

Period 2

Period 2 title	Booster Vaccination Phase
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	10Pn <6M Group

Arm description:

This group consisted of subjects up to 6 months of age at first vaccination who received 3 doses of 10Pn-PD-DiT (or 10Pn) vaccine co-administered with Infanrix IPV/Hib (DTPa-IPV/Hib) at 3, 4 and 5 months of age and a booster dose of the same vaccines at 12-15 months of age. Vaccines were administrated intramuscularly in the right (10Pn-PD-DiT) or the left (DTPa-IPV/Hib) thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Arm type	Experimental
Investigational medicinal product name	10-valent streptococcus pneumoniae conjugate vaccine
Investigational medicinal product code	
Other name	10Pn-PD-DiT, 10Pn
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 primary doses administered at 3, 4 and 5 months of age followed by a booster dose at 12-15 months of age, all injected intramuscularly in the right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Investigational medicinal product name	DTPa-IPV/Hib
Investigational medicinal product code	
Other name	Infanrix IPV/Hib, Infanrix-Polio+Hib
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 primary doses administered at 3, 4 and 5 months of age followed by a booster dose at 12-15 months of age, all injected intramuscularly in the left right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Arm title	10Pn 7-11M Group

Arm description:

This group consisted of subjects 7 to 11 months of age at first vaccination who received 2 doses of

10Pn-PD-DiT (10Pn), one first dose at enrolment followed by a second dose one month later, and a booster dose at 12-15 months of age. The 10PN-PD-DiT vaccine was administrated intramuscularly in the right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Arm type	Experimental
Investigational medicinal product name	10-valent streptococcus pneumoniae conjugate vaccine
Investigational medicinal product code	
Other name	10Pn-PD-DiT, 10Pn
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 doses, one first dose at enrolment followed by a second dose one month later, followed by a booster dose at 12-15 months of age., injected intramuscularly in the right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Number of subjects in period 2[1]	10Pn <6M Group	10Pn 7-11M Group
Started	145	145
Completed	141	145
Not completed	4	0
Consent withdrawn by subject	1	-
Lost to follow-up	3	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: One subject from the 10Pn 7-11M Group was not included in the Booster Phase of the study for not having received the booster vaccination dose.

Baseline characteristics

Reporting groups	
Reporting group title	10Pn <6M Group
Reporting group description:	
This group consisted of subjects up to 6 months of age at first vaccination who received 3 doses of 10Pn-PD-DiT (or 10Pn) vaccine co-administered with Infanrix IPV/Hib (DTPa-IPV/Hib) at 3, 4 and 5 months of age and a booster dose of the same vaccines at 12-15 months of age. Vaccines were administrated intramuscularly in the right (10Pn-PD-DiT) or the left (DTPa-IPV/Hib) thigh or deltoid region [deltoid region only for children greater than (>)12 months of age if muscle size was adequate].	
Reporting group title	10Pn 7-11M Group
Reporting group description:	
This group consisted of subjects 7 to 11 months of age at first vaccination who received 2 doses of 10Pn-PD-DiT (10Pn), one first dose at enrolment followed by a second dose one month later, and a booster dose at 12-15 months of age. The 10PN-PD-DiT vaccine was administrated intramuscularly in the right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).	
Reporting group title	10Pn 12-23M Group
Reporting group description:	
This group consisted of subjects 12 to 23 months inclusive at first vaccination who received 2 doses of 10Pn-PD-DiT (10Pn), one first dose at enrolment followed by a second dose 2 months later. The 10PN-PD-DiT vaccine was administrated intramuscularly in the right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).	
Reporting group title	10Pn >=24M Group
Reporting group description:	
This group consisted of subjects aged between 24 months (inclusive) to 5 years (inclusive) at vaccination who received one dose of 10Pn-PD-DiT (10Pn). The 10PN-PD-DiT vaccine was administrated intramuscularly in the right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).	

Reporting group values	10Pn <6M Group	10Pn 7-11M Group	10Pn 12-23M Group
Number of subjects	150	150	150
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: months			
arithmetic mean	10.8	8.3	17.9
standard deviation	± 1.09	± 1.2	± 3.19
Gender categorical Units: Subjects			
Female	66	68	76
Male	84	82	74

Reporting group values	10Pn >=24M Group	Total	
Number of subjects	150	600	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		0	
Newborns (0-27 days)		0	
Infants and toddlers (28 days-23 months)		0	
Children (2-11 years)		0	
Adolescents (12-17 years)		0	
Adults (18-64 years)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: months			
arithmetic mean	36.6		
standard deviation	± 11.87	-	
Gender categorical Units: Subjects			
Female	72	282	
Male	78	318	

End points

End points reporting groups

Reporting group title	10Pn <6M Group

Reporting group description:

This group consisted of subjects up to 6 months of age at first vaccination who received 3 doses of 10Pn-PD-DiT (or 10Pn) vaccine co-administered with Infanrix IPV/Hib (DTPa-IPV/Hib) at 3, 4 and 5 months of age and a booster dose of the same vaccines at 12-15 months of age. Vaccines were administrated intramuscularly in the right (10Pn-PD-DiT) or the left (DTPa-IPV/Hib) thigh or deltoid region [deltoid region only for children greater than (>)12 months of age if muscle size was adequate].

Reporting group title	10Pn 7-11M Group

Reporting group description:

This group consisted of subjects 7 to 11 months of age at first vaccination who received 2 doses of 10Pn-PD-DiT (10Pn), one first dose at enrolment followed by a second dose one month later, and a booster dose at 12-15 months of age. The 10PN-PD-DiT vaccine was administrated intramuscularly in the right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Reporting group title	10Pn 12-23M Group

Reporting group description:

This group consisted of subjects 12 to 23 months inclusive at first vaccination who received 2 doses of 10Pn-PD-DiT (10Pn), one first dose at enrolment followed by a second dose 2 months later. The 10PN-PD-DiT vaccine was administrated intramuscularly in the right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Reporting group title	10Pn >=24M Group

Reporting group description:

This group consisted of subjects aged between 24 months (inclusive) to 5 years (inclusive) at vaccination who received one dose of 10Pn-PD-DiT (10Pn). The 10PN-PD-DiT vaccine was administrated intramuscularly in the right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Reporting group title	10Pn <6M Group

Reporting group description:

This group consisted of subjects up to 6 months of age at first vaccination who received 3 doses of 10Pn-PD-DiT (or 10Pn) vaccine co-administered with Infanrix IPV/Hib (DTPa-IPV/Hib) at 3, 4 and 5 months of age and a booster dose of the same vaccines at 12-15 months of age. Vaccines were administrated intramuscularly in the right (10Pn-PD-DiT) or the left (DTPa-IPV/Hib) thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Reporting group title	10Pn 7-11M Group

Reporting group description:

This group consisted of subjects 7 to 11 months of age at first vaccination who received 2 doses of 10Pn-PD-DiT (10Pn), one first dose at enrolment followed by a second dose one month later, and a booster dose at 12-15 months of age. The 10PN-PD-DiT vaccine was administrated intramuscularly in the right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Primary: Number of subjects with anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations greater than or equal to (>=)0.20 microgram per milliliter (µg/mL) (Primary/full vaccination)

End point title	Number of subjects with anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations greater than or equal to (>=)0.20 microgram per milliliter (µg/mL) (Primary/full vaccination)[1]

End point description:

Anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations were assessed by 22F-inhibition Enzyme-Linked Immuno-Sorbent Assay (ELISA) method. The >=0.20 microgram per milliliter (microg/mL) cut-off corresponded to the seroprotection cut-off as regards anti-pneumococcal serotypes antibody concentrations. Seropositivity status, defined as anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations >= 0.05 microg/mL.

The analysis was performed on the Primary According-To-Protocol cohort for immunogenicity, which included all evaluable subjects with immunogenicity data available. This included subjects with assay results available for antibodies against at least one study vaccine antigen component and at least one blood sampling time point after primary vaccination.

End point type	Primary

End point timeframe:

At one month after primary (10Pn <6M & 10Pn 7-11M groups) or after the full (10Pn 12-23M & 10Pn >=24M groups) vaccination course with 10Pn, that is Month (M)3 for 10Pn <6M & 12-23M groups, M2 for 10Pn 7-11M Group, & M1

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive, no statistical hypothesis test was performed.

End point values	10Pn <6M Group	10Pn 7-11M Group	10Pn 12-23M Group	10Pn >=24M Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	131	135	133	140
Units: Subjects				
Anti-1 (N=131; 135; 133; 140)	128	135	132	135
Anti-4 (N=131; 135; 133; 140)	128	135	133	140
Anti-5(N=131; 135; 133; 138)	130	134	131	135
Anti-6B (N=131; 135; 133; 140)	95	69	108	96
Anti-7F (N=131; 135; 133; 140)	130	135	133	140
Anti-9V (N=131; 135; 133; 140)	128	129	130	132
Anti-14 (N=131; 135; 133; 139)	130	132	132	127
Anti-18C (N=131; 135; 133; 140)	127	135	133	140
Anti-19F (N=130; 135; 133; 140)	122	129	131	140
Anti-23F (N=131; 135; 133; 139)	114	95	122	93

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F (Primary/full vaccination)

End point title	Antibody concentrations against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F (Primary/full vaccination)

End point description:

Antibodies assessed for this outcome measure were those against the vaccine pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F (ANTI-1, -4, -5, -6B, -7F, -9V, -14, -18C, -19F and -23F).
Antibody concentrations were measured by 22F enzyme-linked immunosorbent assay (ELISA), expressed as geometric mean concentrations (GMCs), in micrograms per milliliter (µg/mL).
Seropositivity = Anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations >=0.05 µg/mL.
The analysis was performed on the Primary According-To-Protocol cohort for immunogenicity, which included all evaluable subjects with immunogenicity data available. This included subjects with assay results available for antibodies against at least one study vaccine antigen component and at least one blood sampling time point after primary vaccination.

End point type	Secondary

End point timeframe:

At 1 month after the administration of the primary (<6 months and 7-11 months groups) or the full (12-23 months and >= 24 months groups) vaccination course, with 10Pn-PD-DiT vaccine

End point values	10Pn <6M Group	10Pn 7-11M Group	10Pn 12-23M Group	10Pn >=24M Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	131	135	133	140
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-1 (N=131; 135; 133; 140)	1.2 (1.02 to 1.42)	1.19 (1.05 to 1.35)	1.22 (1.06 to 1.4)	0.77 (0.66 to 0.89)
Anti-4 (N=131; 135; 133; 140)	1.84 (1.57 to 2.15)	3.47 (3.03 to 3.97)	4.21 (3.77 to 4.69)	5.72 (5 to 6.54)
Anti-5(N=131; 135; 133; 138)	2.04 (1.75 to 2.37)	1.72 (1.51 to 1.96)	1.8 (1.57 to 2.06)	1.16 (0.99 to 1.36)
Anti-6B (N=131; 135; 133; 140)	0.37 (0.29 to 0.48)	0.21 (0.16 to 0.26)	0.53 (0.43 to 0.65)	0.38 (0.3 to 0.47)
Anti-7F (N=131; 135; 133; 140)	2.03 (1.76 to 2.33)	2.1 (1.83 to 2.41)	3.62 (3.22 to 4.06)	2.6 (2.25 to 3.01)
Anti-9V (N=131; 135; 133; 140)	1.33 (1.14 to 1.55)	0.91 (0.78 to 1.07)	1.5 (1.3 to 1.73)	1.01 (0.84 to 1.22)
Anti-14 (N=131; 135; 133; 139)	3 (2.61 to 3.46)	2.3 (1.95 to 2.72)	4.24 (3.64 to 4.95)	1.36 (1.06 to 1.74)
Anti-18C (N=131; 135; 133; 140)	1.84 (1.5 to 2.26)	4.82 (4.14 to 5.61)	9.2 (8.22 to 10.29)	4.65 (4.06 to 5.31)
Anti-19F (N=130; 135; 133; 140)	1.61 (1.28 to 2.02)	3.36 (2.68 to 4.2)	5.45 (4.63 to 6.41)	5.26 (4.34 to 6.39)
Anti-23F (N=131; 135; 133; 139)	0.62 (0.5 to 0.76)	0.4 (0.32 to 0.5)	0.88 (0.73 to 1.05)	0.37 (0.3 to 0.47)

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations against pneumococcal cross-reactive serotypes 6A and 19A (Primary/full vaccination)

End point title	Antibody concentrations against pneumococcal cross-reactive serotypes 6A and 19A (Primary/full vaccination)

End point description:

Antibodies assessed for this outcome measure were those against the vaccine pneumococcal serotypes 6A, 19A (ANTI-6A, -19A). Antibody concentrations were measured by 22F enzyme-linked immunosorbent assay (ELISA), expressed as geometric mean concentrations (GMCs), in micrograms per milliliter (µg/mL). Seropositivity = Anti-pneumococcal cross-reactive serotypes 6A and 19A antibody concentrations ≥ 0.05 µg/mL.
The analysis was performed on the Primary According-To-Protocol cohort for immunogenicity, which included all evaluable subjects with immunogenicity data available. This included subjects with assay results available for antibodies against at least one study vaccine antigen component and at least one blood sampling time point after primary vaccination.

End point type	Secondary

End point timeframe:

At 1 month after the administration of the primary (<6 months and 7-11 months groups) or the full (12-23 months and >= 24 months groups) vaccination course, with 10Pn-PD-DiT vaccine

End point values	10Pn <6M Group	10Pn 7-11M Group	10Pn 12-23M Group	10Pn >=24M Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	132	135	133	138
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-6A (N=132;135;133;138)	0.1 (0.08 to 0.12)	0.06 (0.05 to 0.08)	0.23 (0.18 to 0.29)	0.24 (0.19 to 0.31)
Anti-19A (N=131;135;133;138)	0.09 (0.07 to 0.11)	0.12 (0.1 to 0.15)	0.86 (0.71 to 1.05)	0.65 (0.53 to 0.82)

Statistical analyses

No statistical analyses for this end point

Secondary: Opsonophagocytic activity against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F (Primary/full vaccination)

End point title	Opsonophagocytic activity against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F (Primary/full vaccination)

End point description:

OPA titers against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F (Opsono-1, -4, -5, -6B, -7F, -9V, -14, -18C, -19F and -23F) were calculated, expressed as geometric mean titers (GMTs) and tabulated. Seropositivity = Opsonophagocytic activity against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F >= 8. Antibody titers < 8 were given an arbitrary value of half the cut-off for the purpose of GMT calculation.
The analysis was performed on the Primary According-To-Protocol cohort for immunogenicity, which included all evaluable subjects with immunogenicity data available. This included subjects with assay results available for antibodies against at least one study vaccine antigen component and at least one blood sampling time point after primary vaccination.

End point type	Secondary

End point timeframe:

At 1 month after the administration of the primary (<6 months and 7-11 months groups) or the full (12-23 months and >= 24 months groups) vaccination course, with 10Pn-PD-DiT vaccine

End point values	10Pn <6M Group	10Pn 7-11M Group	10Pn 12-23M Group	10Pn >=24M Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	48	51	41
Units: Titer				
geometric mean (confidence interval 95%)				
Opsono-1 (N=44;48;51;41)	17.3 (10.9 to 27.5)	14.8 (9.3 to 23.6)	14.2 (9 to 22.4)	17.5 (9.4 to 32.3)
Opsono-4 (N=41;46;50;36)	675.6 (475.4 to 960)	524 (361.8 to 758.9)	912.1 (617.8 to 1346.8)	2227.6 (1694 to 2929.3)
Opsono-5(N=42;46;50;39)	52.6 (33.7 to 82.2)	33.7 (21.4 to 53.3)	47.5 (30.2 to 74.8)	14.1 (9.1 to 22)

Opsono-6B (N=38;45;49;34)	296 (130.3 to 672.2)	25.4 (11.1 to 58.4)	304.3 (143.8 to 644.2)	331.7 (99.1 to 1109.8)
Opsono-7F (N=43;46;48;38)	1775.1 (1057.8 to 2978.8)	2342.5 (1555.2 to 3528.2)	4164.2 (2840.4 to 6105)	3282.2 (2105.1 to 5117.6)
Opsono-9V (N=41;44;50;37)	1281.1 (895 to 1833.7)	2209.6 (1628.6 to 2997.8)	3525.8 (2675.4 to 4646.4)	4526 (3581.7 to 5719.3)
Opsono-14 (N=42;48;51;40)	1523.3 (1028.7 to 2255.6)	1818.9 (1356.4 to 2439.2)	2277.2 (1804.9 to 2873)	1957.4 (1516.6 to 2526.3)
Opsono-18C (N=41;46;51 ;38)	181.8 (120.8 to 273.5)	971.7 (723.2 to 1305.5)	1765.3 (1330.5 to 2342.2)	2051.4 (1558.3 to 2700.5)
Opsono-19F (N=42;43;50;41)	194.7 (101.7 to 372.7)	225.6 (128.6 to 395.7)	592.7 (367.3 to 956.4)	634.3 (400.2 to 1005.4)
Opsono-23F (N=41;45;49;41)	925.8 (422.6 to 2028.3)	561.1 (273.7 to 1150.4)	1656.4 (1063.6 to 2579.6)	1575.2 (802.6 to 3091.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Opsonophagocytic activity against pneumococcal cross-reactive serotypes 6A and 19A (Primary/full vaccination)

End point title	Opsonophagocytic activity against pneumococcal cross-reactive serotypes 6A and 19A (Primary/full vaccination)

End point description:

OPA titers against pneumococcal serotypes 6A, 19A (Opsono-6A, 19A) were calculated, expressed as geometric mean titers (GMTs) and tabulated. Opsonophagocytic activity against cross-reactive pneumococcal serotypes 6A and 19A >= 8. Antibody titers < 8 were given an arbitrary value of half the cut-off for the purpose of GMT calculation.
The analysis was performed on the Primary According-To-Protocol cohort for immunogenicity, which included all evaluable subjects with immunogenicity data available. This included subjects with assay results available for antibodies against at least one study vaccine antigen component and at least one blood sampling time point after primary vaccination.

End point type	Secondary

End point timeframe:

At 1 month after the administration of the primary (<6 months and 7-11 months groups) or the full (12-23 months and >= 24 months groups) vaccination course, with 10Pn-PD-DiT vaccine

End point values	10Pn <6M Group	10Pn 7-11M Group	10Pn 12-23M Group	10Pn >=24M Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	45	50	38
Units: Titer				
geometric mean (confidence interval 95%)				
Opsono-6A (N=41;44;50;35)	14.4 (7.5 to 27.6)	39.1 (19 to 80.6)	150.7 (80.7 to 281.3)	324.6 (142.6 to 738.6)
Opsono-19 (N=43;45;49;38)	5.1 (3.9 to 6.6)	6.1 (4.2 to 8.8)	39.5 (19 to 81.9)	31.8 (14.3 to 70.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations against protein D (anti-PD) (Primary/full vaccination)

End point title	Antibody concentrations against protein D (anti-PD) (Primary/full vaccination)

End point description:

Anti-protein D (Anti-PD) antibody concentrations by Enzyme-Linked Immunosorbent Assay (ELISA) were calculated, expressed as geometric mean concentrations (GMCs) in ELISA unit per milliliter (EL.U/mL) and tabulated. Seropositivity = Anti-PD antibody concentrations >= 100 EL.U/mL. Antibody concentrations < 100 EL.U/mL were given an arbitrary value of half the cut-off for the purpose of GMC calculation.
The analysis was performed on the Primary According-To-Protocol cohort for immunogenicity, which included all evaluable subjects with immunogenicity data available. This included subjects with assay results available for antibodies against at least one study vaccine antigen component and at least one blood sampling time point after primary vaccination.

End point type	Secondary

End point timeframe:

At 1 month after the administration of the primary (<6 months and 7-11 months groups) or the full (12-23 months and >= 24 months groups) vaccination course, with 10Pn-PD-DiT vaccine

End point values	10Pn <6M Group	10Pn 7-11M Group	10Pn 12-23M Group	10Pn >=24M Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	131	135	133	139
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PD [N=131;135;133;139]	1637.7 (1430.9 to 1874.3)	654.2 (577.7 to 741)	660 (554.9 to 785.1)	224.8 (185.2 to 272.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations >= 0.20 µg/mL (Booster vaccination)

End point title	Anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations >= 0.20 µg/mL (Booster vaccination)

End point description:

Anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations were

assessed by 22F-inhibition Enzyme-Linked Immuno-Sorbent Assay (ELISA) method. The >=0.20 microgram per millilitre (microg/mL) cut-off corresponded to the seroprotection cut-off as regards anti-pneumococcal serotypes antibody concentrations. Seropositivity = Anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations >=0.05 µg/mL.
The analysis was performed on the Booster According-To-Protocol(ATP) cohort for immunogenicity, which included all evaluable subjects with immunogenicity data available (subjects from the 10Pn <6M & 7-11M groups for whom assay results were available for antibodies against at least one study vaccine antigen component after the booster vaccination).

End point type	Secondary

End point timeframe:

Before and one month after the booster dose with 10Pn for the < 6 months and 7-11 months groups

End point values	10Pn <6M Group	10Pn 7-11M Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	140	114		
Units: Subjects				
Anti-1, PRE(N=140;114)	101	102		
Anti-1, POST(N=137;114)	137	114		
Anti-4, PRE(N=140;114)	119	112		
Anti-4, POST(N=137;114)	137	114		
Anti-5, PRE(N=140;114)	123	110		
Anti-5, POST(N=137;114)	136	114		
Anti-6B, PRE(N=140;114)	108	97		
Anti-6B, POST(N=137;114)	132	110		
Anti-7F, PRE(N=140;114)	132	114		
Anti-7F, POST(N=137;114)	137	114		
Anti-9V, PRE(N=140;114)	131	108		
Anti-9V, POST(N=137;114)	137	114		
Anti-14, PRE(N=140;114)	131	113		
Anti-14, POST(N=137;114)	137	114		
Anti-18C, PRE(N=140;114)	127	114		
Anti-18C, POST(N=137;114)	137	114		
Anti-19F, PRE(N=140;114)	114	112		
Anti-19F, POST(N=137;114)	134	112		
Anti-23F, PRE(N=140;114)	116	98		
Anti-23F, POST(N=137;114)	136	110		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations (Booster vaccination)

End point title	Anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations (Booster vaccination)

End point description:

Anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations were assessed by 22F-inhibition Enzyme-Linked Immuno-Sorbent Assay (ELISA) method. The >=0.20 microgram per millilitre (microg/mL) cut-off corresponded to the seroprotection cut-off as regards anti-

pneumococcal serotypes antibody concentrations. Seropositivity status, defined as Anti-pneumococcal serotypes antibody concentrations >=0.05 µg/mL.
The analysis was performed on the Booster According-To-Protocol(ATP) cohort for immunogenicity, which included all evaluable subjects with immunogenicity data available (subjects from the 10Pn <6M & 7-11M groups for whom assay results were available for antibodies against at least one study vaccine antigen component after the booster vaccination).

End point type	Secondary

End point timeframe:

Before and one month after the booster dose with 10Pn for the < 6 months and 7-11 months groups

End point values	10Pn <6M Group	10Pn 7-11M Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	140	141		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-1, PRE(N=140;114)	0.29 (0.25 to 0.34)	0.49 (0.43 to 0.57)		
Anti-1, POST(N=137;114)	1.84 (1.59 to 2.12)	1.77 (1.55 to 2.02)		
Anti-4, PRE(N=140;114)	0.56 (0.48 to 0.66)	1.35 (1.17 to 1.57)		
Anti-4, POST(N=137;114)	2.98 (2.6 to 3.42)	3.79 (3.27 to 4.4)		
Anti-5, PRE(N=140;114)	0.51 (0.44 to 0.59)	0.8 (0.7 to 0.93)		
Anti-5, POST(N=137;114)	2.21 (1.94 to 2.53)	2.88 (2.48 to 3.34)		
Anti-6B, PRE(N=140;114)	0.41 (0.34 to 0.5)	0.48 (0.4 to 0.58)		
Anti-6B, POST(N=137;114)	1.62 (1.35 to 1.94)	1.39 (1.14 to 1.69)		
Anti-7F, PRE(N=140;114)	0.82 (0.72 to 0.94)	1.58 (1.39 to 1.8)		
Anti-7F, POST(N=137;114)	3.31 (2.92 to 3.74)	3.73 (3.24 to 4.28)		
Anti-9V, PRE(N=140;114)	0.85 (0.73 to 0.98)	0.79 (0.67 to 0.93)		
Anti-9V, POST(N=137;114)	3.41 (2.96 to 3.92)	2.13 (1.82 to 2.5)		
Anti-14, PRE(N=140;114)	1.03 (0.85 to 1.25)	2.3 (1.97 to 2.68)		
Anti-14, POST(N=137;114)	3.96 (3.39 to 4.62)	5.41 (4.71 to 6.22)		
Anti-18C, PRE(N=140;114)	0.62 (0.53 to 0.74)	2.58 (2.2 to 3.04)		
Anti-18C, POST(N=137;114)	5.28 (4.55 to 6.12)	9.4 (8.04 to 10.98)		
Anti-19F, PRE(N=140;114)	0.55 (0.44 to 0.7)	1.99 (1.65 to 2.4)		
Anti-19F, POST(N=137;114)	3.38 (2.81 to 4.06)	5.71 (4.68 to 6.97)		
Anti-23F, PRE(N=140;114)	0.48 (0.39 to 0.58)	0.57 (0.46 to 0.7)		
Anti-23F, POST(N=137;114)	2.76 (2.37 to 3.21)	1.65 (1.33 to 2.03)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations against pneumococcal cross-reactive serotypes 6A and 19A (Booster vaccination)

End point title	Antibody concentrations against pneumococcal cross-reactive serotypes 6A and 19A (Booster vaccination)

End point description:

Antibodies assessed for this outcome measure were those against the vaccine pneumococcal serotypes 6A, 19A (ANTI-6A, -19A). Antibody concentrations were measured by 22F enzyme-linked immunosorbent assay (ELISA), expressed as geometric mean concentrations (GMCs), in micrograms per milliliter (µg/mL).Seropositivity = Anti-pneumococcal cross-reactive serotypes 6A and 19A antibody concentrations >= 0.05 µg/mL.
The analysis was performed on the Booster According-To-Protocol(ATP) cohort for immunogenicity, which included all evaluable subjects with immunogenicity data available (subjects from the 10Pn <6M & 7-11M groups for whom assay results were available for antibodies against at least one study vaccine antigen component after the booster vaccination).

End point type	Secondary

End point timeframe:

Before and one month after the booster dose with 10Pn for the < 6 months and 7-11 months groups

End point values	10Pn <6M Group	10Pn 7-11M Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	140	114		
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-6A, PRE(N=140;114)	0.15 (0.12 to 0.19)	0.18 (0.14 to 0.23)		
Anti-6A, POST(N=137;114)	0.52 (0.4 to 0.68)	0.55 (0.42 to 0.73)		
Anti-19A, PRE(N=140;114)	0.1 (0.09 to 0.13)	0.26 (0.21 to 0.32)		
Anti-19A, POST(N=137;114)	0.49 (0.39 to 0.61)	0.99 (0.78 to 1.25)		

Statistical analyses

No statistical analyses for this end point

Secondary: Opsonophagocytic activity against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F (Booster vaccination)

End point title	Opsonophagocytic activity against pneumococcal serotypes 1,

	4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F (Booster vaccination)

End point description:

OPA titers against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F (Opsono-1, -4, -5, -6B, -7F, -9V, -14, -18C, -19F and -23F) were calculated, expressed as geometric mean titers (GMTs) and tabulated. Seropositivity status, defined as Opsonophagocytic activity against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F >= 8. Antibody titers < 8 were given an arbitrary value of half the cut-off for the purpose of GMT calculation.
The analysis was performed on the Booster According-To-Protocol(ATP) cohort for immunogenicity, which included all evaluable subjects with immunogenicity data available (subjects from the 10Pn <6M & 7-11M groups for whom assay results were available for antibodies against at least one study vaccine antigen component after the booster vaccination).

End point type	Secondary

End point timeframe:

Before and one month after the booster dose with 10Pn for the < 6 months and 7-11 months groups

End point values	10Pn <6M Group	10Pn 7-11M Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	51	40		
Units: Titer				
geometric mean (confidence interval 95%)				
Opsono-1, PRE(N=51;38)	6 (4.5 to 8.1)	9.9 (5.8 to 16.9)		
Opsono-1, POST(N=48;40)	188.4 (103.6 to 342.5)	234.1 (127.4 to 430.2)		
Opsono-4, PRE(N=45;37)	22.2 (12.4 to 39.9)	94 (47.7 to 185.2)		
Opsono-4, POST(N=48;38)	1486.3 (1138 to 1941)	978.3 (720.6 to 1328.1)		
Opsono-5, PRE(N=48;37)	16 (11.1 to 23.1)	25.8 (16.3 to 41)		
Opsono-5, POST(N=47;39)	143.8 (93.6 to 221)	243 (151.6 to 389.7)		
Opsono-6B, PRE(N=45;31)	59.3 (29.3 to 120.1)	122.7 (50.3 to 299.5)		
Opsono-6B, POST(N=45;40)	262 (130.3 to 526.5)	620.3 (356.5 to 1079.4)		
Opsono-7F, PRE(N=49;33)	819.6 (471.8 to 1423.8)	1380.6 (730.3 to 2609.9)		
Opsono-7F, POST(N=48;40)	4199.1 (3364.6 to 5240.6)	3726.8 (2759.4 to 5033.3)		
Opsono-9V, PRE(N=50;37)	328.2 (245.4 to 438.8)	1427 (972.7 to 2093.4)		
Opsono-9V, POST(N=48;38)	2198 (1718.6 to 2811.1)	2241.2 (1758.7 to 2856)		
Opsono-14, PRE(N=46;37)	158.6 (82.6 to 304.6)	883.8 (597.9 to 1306.2)		
Opsono-14, POST(N=48;40)	2224.7 (1674.1 to 2956.5)	1859.4 (1452.1 to 2380.9)		
Opsono-18C, PRE(N=42;33)	6.5 (4.2 to 10)	395.9 (219.9 to 712.8)		
Opsono-18C, POST(N=48;38)	650.3 (437.4 to 966.8)	1332.9 (926.3 to 1918)		

Opsono-19F, PRE(N=49;38)	18.7 (12 to 29.3)	43.3 (23.3 to 80.4)		
Opsono-19F, POST(N=47;38)	418.4 (237.8 to 736.4)	513.1 (265.8 to 990.2)		
Opsono-23F, PRE(N=49;34)	700.6 (376.5 to 1303.9)	675.8 (293.2 to 1557.4)		
Opsono-23F, POST(N=48;40)	3594.5 (2676.8 to 4826.8)	1770 (1148.4 to 2728)		

Statistical analyses

No statistical analyses for this end point

Secondary: Opsonophagocytic activity against pneumococcal cross-reactive serotypes 6A and 19A (Booster vaccination)

End point title	Opsonophagocytic activity against pneumococcal cross-reactive serotypes 6A and 19A (Booster vaccination)

End point description:

OPA titers against pneumococcal serotypes 6A, 19A (Opsono-6A, 19A) were calculated, expressed as geometric mean titers (GMTs) and tabulated. Opsonophagocytic activity against cross-reactive pneumococcal serotypes 6A and 19A >= 8. Antibody titers < 8 were given an arbitrary value of half the cut-off for the purpose of GMT calculation.
The analysis was performed on the Booster According-To-Protocol(ATP) cohort for immunogenicity, which included all evaluable subjects with immunogenicity data available (subjects from the 10Pn <6M & 7-11M groups for whom assay results were available for antibodies against at least one study vaccine antigen component after the booster vaccination).

End point type	Secondary

End point timeframe:

Before and one month after the booster dose with 10Pn for the < 6 months and 7-11 months groups

End point values	10Pn <6M Group	10Pn 7-11M Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	47	37		
Units: Titer				
geometric mean (confidence interval 95%)				
Opsono-6A, PRE(N=41;33)	31.9 (15.9 to 63.9)	140.1 (69.2 to 283.3)		
Opsono-6A, POST(N=43;36)	188.6 (96.9 to 367)	302.2 (168.7 to 541.5)		
Opsono-19A, PRE(N=47;35)	5.7 (4.2 to 7.7)	7 (3.9 to 12.6)		
Opsono-19A, POST(N=44;37)	16.1 (8.6 to 30.1)	36.8 (16.2 to 83.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations against protein D (Booster vaccination)

End point title	Antibody concentrations against protein D (Booster vaccination)

End point description:

Anti-protein D (Anti-PD) antibody concentrations by Enzyme-Linked Immunosorbent Assay (ELISA) were calculated, expressed as geometric mean concentrations (GMCs) in ELISA unit per milliliter (EL.U/mL) and tabulated. Seropositivity = Anti-PD antibody concentrations >= 100 EL.U/mL. Antibody concentrations < 100 EL.U/mL were given an arbitrary value of half the cut-off for the purpose of GMC calculation.
The analysis was performed on the Booster According-To-Protocol(ATP) cohort for immunogenicity, which included all evaluable subjects with immunogenicity data available (subjects from the 10Pn <6M & 7-11M groups for whom assay results were available for antibodies against at least one study vaccine antigen component after the booster vaccination).

End point type	Secondary

End point timeframe:

Before and one month after the booster dose with 10Pn for the < 6 months and 7-11 months groups

End point values	10Pn <6M Group	10Pn 7-11M Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	140	114		
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PD, PRE(N=140;114)	750.4 (631.2 to 892)	563.2 (475.5 to 666.9)		
Anti-PD, POST(N=135;114)	2900.7 (2481.5 to 3390.8)	1942 (1614.5 to 2335.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-diphtheria (anti-D) and anti-tetanus toxoids (anti-T) antibody concentrations (Primary vaccination)

End point title	Anti-diphtheria (anti-D) and anti-tetanus toxoids (anti-T) antibody concentrations (Primary vaccination)[2]

End point description:

Concentrations of antibodies are presented as geometric mean concentrations expressed as International units per milliliter (IU/mL). Seroprotection status, defined as: Anti-D & anti-T antibody concentrations >=0.1 IU/mL. Since only "10Pn <6M Group" had received DTPa-IPV/Hib, therefore only that group was assessed for this Outcome.
The analysis was performed on the Primary ATP cohort for immunogenicity, which included all evaluable subjects with immunogenicity data available for at least one study vaccine antigen component and at least one time point after primary vaccination. Only 10Pn <6M Group received DTPa-IPV/Hib, thus only that group was assessed for this Outcome.

End point type	Secondary

End point timeframe:

At 1 month after the administration of the primary vaccination course (Month [M]3 = POST-PRY) with DTPa-IPV/Hib vaccine when co-administered with 10Pn, for the < 6 months Group

Notes:

[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: Only subjects in the 10Pn <6M Group received the Infanrix IPV/Hib (DTPa-IPV/Hib) vaccine.

End point values	10Pn <6M Group			
Subject group type	Reporting group			
Number of subjects analysed	132			
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-D, POST-PRY (N=131)	0.961 (0.813 to 1.137)			
Anti-T, POST-PRY (N=132)	2.38 (2.131 to 2.659)			

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polyribosyl ribitol phosphate (PRP) antibody concentrations (Primary vaccination)

End point title	Anti-polyribosyl ribitol phosphate (PRP) antibody concentrations (Primary vaccination)[3]

End point description:

Concentrations of antibodies are presented as geometric mean concentrations expressed as micrograms per milliliter (µg/mL). Seroprotection status, defined as: anti-PRP antibody concentrations >=0.15 µg/mL and >= 1.0 µg/mL. Since only "10Pn <6M Group" had received DTPa-IPV/Hib, therefore only that group was assessed for this Outcome.
The analysis was performed on the Primary ATP cohort for immunogenicity, which included all evaluable subjects with immunogenicity data available for at least one study vaccine antigen component and at least one time point after primary vaccination. Only 10Pn <6M Group received DTPa-IPV/Hib, thus only that group was assessed for this Outcome.

End point type	Secondary

End point timeframe:

At 1 month after the administration of the primary vaccination course (Month [M]3 = POST-PRY) with DTPa-IPV/Hib vaccine when co-administered with 10Pn, for the < 6 months Group

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: Only subjects in the 10Pn <6M Group received the Infanrix IPV/Hib (DTPa-IPV/Hib) vaccine.

End point values	10Pn <6M Group			
Subject group type	Reporting group			
Number of subjects analysed	132			
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PRP , POST-PRY (N=132)	2.886 (2.305 to 3.615)			

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-pertussis toxoid (PT), anti-filamentous haemagglutinin (FHA) and anti-pertactin (PRN) antibody concentrations (Primary vaccination)

End point title	Anti-pertussis toxoid (PT), anti-filamentous haemagglutinin (FHA) and anti-pertactin (PRN) antibody concentrations (Primary vaccination)[4]

End point description:

Concentrations of antibodies are presented as geometric mean concentrations expressed as enzyme-linked immunosorbent assay (ELISA) unit per milliliter (EL.U/mL). Seropositivity status, defined as: Anti-PT, anti-FHA & anti-PRN antibody concentrations >= 5 EL.U/mL. Since only "10Pn <6M Group" had received DTPa-IPV/Hib, therefore only that group was assessed for this Outcome.
The analysis was performed on the Primary ATP cohort for immunogenicity, which included all evaluable subjects with immunogenicity data available for at least one study vaccine antigen component and at least one time point after primary vaccination. Only 10Pn <6M Group received DTPa-IPV/Hib, thus only that group was assessed for this Outcome.

End point type	Secondary

End point timeframe:

At 1 month after the administration of the primary vaccination course(Month [M]3 = POST-PRY) with DTPa-IPV/Hib vaccine when co-administered with 10Pn, for the < 6 months Group

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: Only subjects in the 10Pn <6M Group received the Infanrix IPV/Hib (DTPa-IPV/Hib) vaccine.

End point values	10Pn <6M Group			
Subject group type	Reporting group			
Number of subjects analysed	130			
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PT, POST-PRY (N=129)	51.5 (46.5 to 57)			
Anti-FHA, POST-PRY (N=127)	211.4 (192.7 to 231.8)			
Anti-PRN, POST-PRY (N=130)	103.2 (90.7 to 117.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polio type 1, 2 and 3 titers (Primary vaccination)

End point title	Anti-polio type 1, 2 and 3 titers (Primary vaccination)[5]

End point description:

Titers of antibodies are presented as geometric mean titers. Seroprotection status, defined as: Anti-polio type 1/2/3 titers >= 8.
The analysis was performed on the Primary ATP cohort for immunogenicity, which included all evaluable subjects with immunogenicity data available for at least one study vaccine antigen component and at least one time point after primary vaccination. Only 10Pn <6M Group received DTPa-IPV/Hib, thus only that group was assessed for this Outcome.

End point type	Secondary

End point timeframe:

At 1 month after the administration of the primary vaccination course (Month [M]3 = POST-PRY) with DTPa-IPV/Hib vaccine when co-administered with 10Pn, for the < 6 months Group

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: Only subjects in the 10Pn <6M Group received the Infanrix IPV/Hib (DTPa-IPV/Hib) vaccine.

End point values	10Pn <6M Group			
Subject group type	Reporting group			
Number of subjects analysed	17			
Units: Titer				
geometric mean (confidence interval 95%)				
Anti-Polio 1, POST-PRY (N=17)	55.5 (30 to 102.6)			
Anti-Polio 2, POST-PRY (N=16)	20.2 (9.7 to 41.9)			
Anti-Polio 3, POST-PRY (N=16)	162.3 (73.5 to 358.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Booster vaccine response to PT, FHA and PRN

End point title	Booster vaccine response to PT, FHA and PRN

End point description:

Booster vaccine response to PT, FHA and PRN, defined as appearance of antibodies in subjects who were seronegative (S-) prior to the booster dose (i.e., with concentrations < 5 EL.U/mL), and at least two-fold increase of pre-booster vaccination antibody concentrations in those who were seropositive (S+) prior to the booster dose (i.e., with concentrations >= 5 EL.U/ mL). Since only "10Pn <6M Group" had received DTPa-IPV/Hib, therefore only that group was assessed for this Outcome.
The analysis was performed on the Booster ATP cohort for immunogenicity, which included all evaluable subjects (from 10Pn <6M & 7-11M groups) for whom assay results were available for at least one study vaccine antigen after the booster vaccination. Only 10Pn <6M Group received DTPa-IPV/Hib, only that group was assessed for this Outcome.

End point type	Secondary

End point timeframe:

Before and one month after the booster dose with 10Pn

End point values	10Pn <6M Group			
Subject group type	Reporting group			
Number of subjects analysed	136			
Units: Subjects				
Anti-PT-Pre-booster status S- (N=14)	14			
Anti-PT-Pre-booster status S+ (N=121)	117			
Anti-FHA-Pre-booster status S- (N=0)	0			
Anti-FHA-Pre-booster status S+ (N=136)	131			
Anti-PRN-Pre-booster status S- (N=12)	12			
Anti-PRN-Pre-booster status S+ (N=124)	123			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited local symptoms (any and grade 3) (Primary vaccination)

End point title	Number of subjects with solicited local symptoms (any and grade 3) (Primary vaccination)

End point description:

Assessed local symptoms were pain, redness and swelling. Any = Occurrence of the specified solicited local symptom, regardless of intensity. Grade 3 Pain = Crying when limb was moved/spontaneously painful. Grade 3 Redness/Swelling = Redness/swelling at injection site larger than (>) 30 millimeters (mm). Across doses= across the 3 doses (D1, D2 and D3) of the 10Pn-PD-DiT vaccine co-administered with Infranrix in the <6 months priming group; across the 2 doses of the 10Pn-PD-DiT vaccine in the 7-11 months priming group; across the 2 doses of the 10Pn-PD-DiT vaccine in the 12-23 months priming group and in the 1 dose of 10Pn-PD-DiT vaccine in the >=24 months priming group.
The analysis was performed on the Primary Total Vaccinated cohort, which included all vaccinated subjects (e.g. all subjects who received at least one primary dose).

End point type	Secondary

End point timeframe:

Within 4-Days (Days 0-3) following the primary vaccination

End point values	10Pn <6M Group	10Pn 7-11M Group	10Pn 12-23M Group	10Pn >=24M Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	149	148	149	148
Units: Subjects				
Any Pain, D1(N=149;148;149;148)	63	52	93	102
Grade 3 Pain, D1(N=149;148;149;148)	10	5	21	24
Any Redness, D1(N=149;148;149;148)	60	83	57	65
Grade 3 Redness, D1(N=149;148;149;148)	3	9	3	9
Any Swelling, D1(N=149;148;149;148)	37	48	39	32
Grade 3 Swelling, D1(N=149;148;149;148)	5	10	6	7
Any Pain, D2(N=146;147;143;0)	51	41	84	0

Grade 3 Pain, D2(N=146;147;143;0)	0	0	12	0
Any Redness, D2(N=146;147;143;0)	66	70	52	0
Grade 3 Redness, D2(N=146;147;143;0)	0	4	2	0
Any Swelling, D2(N=146;147;143;0)	38	39	38	0
Grade 3 Swelling, D2(N=146;147;143;0)	2	6	7	0
Any Pain, D3(N=145;0;0;0)	40	0	0	0
Grade 3 Pain, D3(N=145;0;0;0)	3	0	0	0
Any Redness, D3(N=145;0;0;0)	58	0	0	0
Grade 3 Redness, D3(N=145;0;0;0)	1	0	0	0
Any Swelling, D3(N=145;0;0;0)	33	0	0	0
Grade 3 Swelling, D3(N=145;0;0;0)	2	0	0	0
Any Pain, Across(N=149;148;149;148)	89	63	113	102
Grade 3 Pain, Across(N=149;148;149;148)	13	5	29	24
Any Redness, Across(N=149;148;149;148)	90	95	79	65
Grade 3 Redness, Across(N=149;148;149;148)	4	12	4	9
Any Swelling, Across(N=149;148;149;148)	68	66	59	32
Grade 3 Swelling, Across(N=149;148;149;148)	9	14	12	7

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited local symptoms (any and grade 3) (Booster vaccination)

End point title	Number of subjects with solicited local symptoms (any and grade 3) (Booster vaccination)

End point description:

Assessed local symptoms were pain, redness and swelling. Any = Occurrence of the specified solicited local symptom, regardless of intensity. Grade 3 Pain = Crying when limb was moved/spontaneously painful. Grade 3 Redness/Swelling = Redness/swelling at injection site larger than (>) 30 millimeters (mm).
The analysis was performed on the Booster Total Vaccinated, which cohort included all subjects from the 10Pn <6M & 10Pn 7-11M groups months groups, who received the booster dose.

End point type	Secondary

End point timeframe:

Within 4-Days (Days 0-3) following the booster vaccination

End point values	10Pn <6M Group	10Pn 7-11M Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	144	145		
Units: Subjects				
Any Pain	91	64		
Grade 3 Pain	11	3		

Any Redness	80	73		
Grade 3 Redness	11	5		
Any Swelling	55	45		
Grade 3 Swelling	10	7		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited general symptoms (any and grade 3) (Booster vaccination)

End point title	Number of subjects with solicited general symptoms (any and grade 3) (Booster vaccination)

End point description:

Assessed solicited general symptoms were Drowsiness, Irritability (Irr.), Loss of appetite (Loss Appet.) and Fever (rectal temperature higher than or equal to [>=] 38.0 degrees Celsius [°C]),. Any = Occurrence of the specified solicited general symptom, regardless of intensity or relationship to vaccination. Grade 3 Drowsiness = Drowsiness that prevented normal activity. Grade 3 Irr./Fussiness (Fuss). = Crying that could not be comforted/prevented normal activity. Grade 3 Loss of appetite = Subject did not eat at all. Grade 3 Fever = Rectal temperature higher than (>) 40.0 degrees Celsius (°C).
The analysis was performed on the Booster Total Vaccinated, which cohort included all subjects from the 10Pn <6M & 10Pn 7-11M groups months groups, who received the booster dose.

End point type	Secondary

End point timeframe:

Within 4-Days (Days 0-3) following the booster vaccination

End point values	10Pn <6M Group	10Pn 7-11M Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	144	145		
Units: Subjects				
Any Drowsiness	73	57		
Grade 3 Drowsiness	3	3		
Any Fever (Rectally)	63	33		
Grade 3 Fever (Rectally)	1	0		
Any Irritability	109	71		
Grade 3 Irritability	5	3		
Any Loss of Appet.	57	35		
Grade 3 Loss of Appet.	1	3		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited Adverse Events (AEs) (Primary vaccination)

End point title	Number of subjects with unsolicited Adverse Events (AEs) (Primary vaccination)

End point description:

An unsolicited AE was defined as any untoward medical occurrence in a clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product. For the marketed products administered in the study, this also included failure to produce expected benefits (i.e. lack of efficacy), abuse or misuse of the product. Any = Occurrence of an unsolicited AE, regardless of intensity or relationship to vaccination.
The analysis was performed on the Primary Total Vaccinated cohort, which included all vaccinated subjects (e.g. all subjects who received at least one primary dose).

End point type	Secondary

End point timeframe:

Within 31-Days (Days 0-30) post primary vaccination

End point values	10Pn <6M Group	10Pn 7-11M Group	10Pn 12-23M Group	10Pn >=24M Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	150	150	150	150
Units: Subjects				
Any AEs	100	116	101	54

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited Adverse Events (AEs) (Booster vaccination)

End point title	Number of subjects with unsolicited Adverse Events (AEs) (Booster vaccination)

End point description:

An unsolicited AE was defined as any untoward medical occurrence in a clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a medicinal product. For the marketed products administered in the study, this also included failure to produce expected benefits (i.e. lack of efficacy), abuse or misuse of the product. Any = Occurrence of an unsolicited AE, regardless of intensity or relationship to vaccination.
The analysis was performed on the Booster Total Vaccinated, which cohort included all subjects from the 10Pn <6M & 10Pn 7-11M groups months groups, who received the booster dose.

End point type	Secondary

End point timeframe:

Within 31-Days (Days 0-30) following the booster vaccination

End point values	10Pn <6M Group	10Pn 7-11M Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	145	145		
Units: Subjects				
Any AEs	90	63		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with Serious Adverse Events (SAEs) (Primary vaccination)

End point title	Number of subjects with Serious Adverse Events (SAEs) (Primary vaccination)

End point description:

A SAE was defined as any medical occurrence that resulted in death, was life-threatening, required hospitalization or prolongation of hospitalization, resulted in disability/incapacity in a subject. AE(s) considered as SAE(s) also included invasive or malignant cancers, intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that did not result in hospitalisation, as per the medical or scientific judgement of the physician. Any = Occurrence of a SAE, regardless of relationship to vaccination.
The analysis was performed on the Primary Total Vaccinated cohort, which included all vaccinated subjects (e.g. all subjects who received at least one primary dose).

End point type	Secondary

End point timeframe:

During the Primary vaccination course up until start of Booster vaccination course

End point values	10Pn <6M Group	10Pn 7-11M Group	10Pn 12-23M Group	10Pn >=24M Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	150	150	150	150
Units: Subjects				
Any SAEs, Primary	17	5	2	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with Serious Adverse Events (SAEs) (Booster vaccination)

End point title	Number of subjects with Serious Adverse Events (SAEs) (Booster vaccination)

End point description:

A SAE was defined as any medical occurrence that resulted in death, was life-threatening, required hospitalization or prolongation of hospitalization, resulted in disability/incapacity in a subject. AE(s) considered as SAE(s) also included invasive or malignant cancers, intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias or convulsions that did not result in

hospitalisation, as per the medical or scientific judgement of the physician. Any = Occurrence of an SAE, regardless of relationship to vaccination.
The analysis was performed on the Booster Total Vaccinated, which cohort included all subjects from the 10Pn <6M & 10Pn 7-11M groups, who received the booster dose.

End point type	Secondary

End point timeframe:

During the booster vaccination course

End point values	10Pn <6M Group	10Pn 7-11M Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	145	145		
Units: Subjects				
Any SAEs, Booster	1	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with solicited general symptoms (Primary vaccination)

End point title	Number of subjects with solicited general symptoms (Primary vaccination)

End point description:

Assessed solicited general symptoms were Drowsiness, Irritability, Loss of appetite (Loss Appet.) and Fever (rectal temperature >=38.0 degrees Celsius [°C]). Any = Occurrence of the specified solicited general symptom, regardless of intensity or relationship to vaccination. Grade 3 Drowsiness = Drowsiness that prevented normal activity. Grade 3 Irr./Fuss. = Crying that could not be comforted/prevented normal activity. Grade 3 Loss of appetite = Subject did not eat at all. Grade 3 Fever = Rectal temperature >40.0°C. Across doses= across the 3 doses [Dose 1(D1), Dose 2(D2) and Dose 3(D3)] of the 10Pn vaccine co-administered with Infranrix in the <6 months group; across the 2 doses of the 10Pn vaccine in the 7-11 months group; across the 2 doses of the 10Pn vaccine in the 12-23 months group and in the 1 dose of 10Pn vaccine in the >=24 months group.
The analysis was performed on the Primary Total Vaccinated cohort, which included all vaccinated subjects.

End point type	Secondary

End point timeframe:

Within 4-Days (Days 0-3) following the primary vaccination

End point values	10Pn <6M Group	10Pn 7-11M Group	10Pn 12-23M Group	10Pn >=24M Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	149	148	149	148
Units: Subjects				
Drowsiness, D1(N=149;148;149;148)	101	70	63	55
Grade 3 Drowsiness, D1(N=149;148;149;148)	2	1	1	1
Any Fever (Rectally), D1(N=149;148;149;148)	54	34	30	10

Grade 3 Fever (Rectally), D1(N=149;148;149;148)	0	0	0	0
Any Irritability, D1(N=149;148;149;148)	122	90	90	62
Grade 3 Irritability, D1(N=149;148;149;148)	12	5	4	2
Any Loss of Appet, D1(N=149;148;149;148)	45	42	46	41
Grade 3 Loss of Appet., D1(N=149;148;149;148)	0	0	3	0
Any Drowsiness, D2(N=146;147;143;0)	64	51	48	0
Grade 3 Drowsiness, D2(N=146;147;143;0)	0	0	2	0
Any Fever (Rectally), D2(N=146 ;147;143;0)	60	34	24	0
Grade 3 Fever (Rectally), D2(N=146;147;143;0)	0	0	0	0
Any Irritability, D2(N=146;147;143;0)	103	78	62	0
Grade 3 Irritability, D2(N=146;147;143;0)	2	0	3	0
Any Loss of Appet., D2(N=146;147;143;0)	31	35	31	0
Grade 3 Loss of Appet., D2(N=146;147;143;0)	0	0	1	0
Any Drowsiness, D3(N=145;0;0;0)	53	0	0	0
Grade 3 Drowsiness, D3(N=145;0;0;0)	0	0	0	0
Any Fever (Rectally), D3(N=145 ;0;0;0)	40	0	0	0
Grade 3 Fever (Rectally), D3(N=145;0;0;0)	0	0	0	0
Any Irritability, D3(N=145;0;0;0)	83	0	0	0
Grade 3 Irritability, D3(N=145;0;0;0)	3	0	0	0
Any Loss of Appet., D3(N=145;0;0;0)	22	0	0	0
Grade 3 Loss of Appet., D3(N=145;0;0;0)	0	0	0	0
Any Drowsiness, Across(N=149;148;149;148)	122	92	90	55
Grade 3 Drowsiness, Across(N=149;148;149;148)	2	1	3	1
Any Fever (Rectally), Across(N=149;148;149;148)	95	55	47	10
Grade 3 Fever (Rectally),Across(N=149;148;149;148)	0	0	0	0
Any Irritability, Across(N=149;148;149;148)	143	112	107	62
Grade 3 Irritability, Across(N=149;148;149;148)	70	62	62	41
Grade 3 Loss of Appet., Across(N=149;148;149;148)	0	0	4	0

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-diphtheria (anti-D) and anti-tetanus toxoids (anti-T) antibody concentrations (Booster vaccination)

End point title	Anti-diphtheria (anti-D) and anti-tetanus toxoids (anti-T)

	antibody concentrations (Booster vaccination)

End point description:

Concentrations of antibodies are presented as geometric mean concentrations expressed as International units per milliliter (IU/mL). Seroprotection status, defined as: Anti-D & anti-T antibody concentrations >= 0.1 IU/mL. Since only "10Pn <6M Group" had received DTPa-IPV/Hib, therefore only that group was assessed for this Outcome.
The analysis was performed on the Booster ATP cohort for immunogenicity, which included all evaluable subjects (from 10Pn <6M & 7-11M groups) for whom assay results were available for at least one study vaccine antigen after the booster vaccination. Only 10Pn <6M Group received DTPa-IPV/Hib, only that group was assessed for this Outcome.

End point type	Secondary

End point timeframe:

Before (M9 = PRE-BST) and one month after the booster dose (M10 = POST-BST) with DTPa-IPV/Hib vaccine when co-administered with 10Pn, for the < 6 months Group

End point values	10Pn <6M Group			
Subject group type	Reporting group			
Number of subjects analysed	140			
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-D, PRE-BST (N=140)	0.218 (0.185 to 0.258)			
Anti-D, POST-BST (N=137)	4.093 (3.578 to 4.683)			
Anti-T, PRE-BST (N=140)	0.708 (0.616 to 0.813)			
Anti-T, POST-BST (N=137)	10.245 (9.302 to 11.283)			

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polyribosyl ribitol phosphate (PRP) antibody concentrations (Booster vaccination)

End point title	Anti-polyribosyl ribitol phosphate (PRP) antibody concentrations (Booster vaccination)

End point description:

Concentrations of antibodies are presented as geometric mean concentrations expressed as micrograms per milliliter (µg/mL). Seroprotection status, defined as: anti-PRP antibody concentrations >= 0.15 µg/mL and >= 1.0 µg/mL. Since only "10Pn <6M Group" had received DTPa-IPV/Hib, therefore only that group was assessed for this Outcome.
The analysis was performed on the Booster ATP cohort for immunogenicity, which included all evaluable subjects (from 10Pn <6M & 7-11M groups) for whom assay results were available for at least one study vaccine antigen after the booster vaccination. Only 10Pn <6M Group received DTPa-IPV/Hib, only that group was assessed for this Outcome.

End point type	Secondary

End point timeframe:

Before (M9 = PRE-BST) and one month after the booster dose (M10 = POST-BST) with DTPa-IPV/Hib vaccine when co-administered with 10Pn, for the < 6 months Group

End point values	10Pn <6M Group			
Subject group type	Reporting group			
Number of subjects analysed	140			
Units: µg/mL;				
geometric mean (confidence interval 95%)				
Anti-PRP, PRE-BST (N=140)	0.458 (0.366 to 0.573)			
Anti-PRP, POST-BST (N=136)	21.244 (16.778 to 26.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-pertussis toxoid (PT), anti-filamentous haemagglutinin (FHA) and anti-pertactin (PRN) antibody concentrations (Booster vaccination)

End point title	Anti-pertussis toxoid (PT), anti-filamentous haemagglutinin (FHA) and anti-pertactin (PRN) antibody concentrations (Booster vaccination)

End point description:

Concentrations of antibodies are presented as geometric mean concentrations expressed as enzyme-linked immunosorbent assay (ELISA) unit per milliliter (EL.U/mL). Seropositivity status, defined as: Anti-PT, anti-FHA & anti-PRN antibody concentrations >=5 EL.U/mL. Since only "10Pn <6M Group" had received DTPa-IPV/Hib, therefore only that group was assessed for this Outcome.
The analysis was performed on the Booster ATP cohort for immunogenicity, which included all evaluable subjects (from 10Pn <6M & 7-11M groups) for whom assay results were available for at least one study vaccine antigen after the booster vaccination. Only 10Pn <6M Group received DTPa-IPV/Hib, only that group was assessed for this Outcome.

End point type	Secondary

End point timeframe:

Before (M9 = PRE-BST) and one month after the booster dose (M10 = POST-BST) with DTPa-IPV/Hib vaccine when co-administered with 10Pn, for the < 6 months Group

End point values	10Pn <6M Group			
Subject group type	Reporting group			
Number of subjects analysed	140			
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PT, PRE-BST (N=140)	11.2 (9.8 to 12.7)			
Anti-PT, POST-BST (N=136)	88.6 (79.5 to 98.7)			
Anti-FHA, PRE-BST (N=140)	49.2 (43.3 to 55.9)			

Anti-FHA, POST-BST (N=137)	407.1 (368.5 to 449.8)			
Anti-PRN, PRE-BST (N=140)	17.2 (14.7 to 20.1)			
Anti-PRN, POST-BST (N=137)	276.6 (240.9 to 317.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Titers of antibodies against polio type 1, 2 and 3 (Anti-polio 1, 2 and 3) (Booster vaccination)

End point title	Titers of antibodies against polio type 1, 2 and 3 (Anti-polio 1, 2 and 3) (Booster vaccination)

End point description:

Titers of antibodies are presented as geometric mean titers. Seroprotection status, defined as: Anti-polio type 1/2/3 titers >= 8. Since only "10Pn <6M Group" had received DTPa-IPV/Hib, therefore only that group was assessed for this Outcome.
The analysis was performed on the Booster ATP cohort for immunogenicity, which included all evaluable subjects (from 10Pn <6M & 7-11M groups) for whom assay results were available for at least one study vaccine antigen after the booster vaccination. Only 10Pn <6M Group received DTPa-IPV/Hib, only that group was assessed for this Outcome.

End point type	Secondary

End point timeframe:

Before (M9 = PRE-BST) and one month after the booster dose (M10 = POST-BST) with DTPa-IPV/Hib vaccine when co-administered with 10Pn, for the < 6 months Group

End point values	10Pn <6M Group			
Subject group type	Reporting group			
Number of subjects analysed	18			
Units: Titer				
geometric mean (confidence interval 95%)				
Anti-Polio 1, PRE-BST (N=16)	19.1 (10.4 to 34.9)			
Anti-Polio 1, POST-BST (N=13)	617 (302.3 to 1259.2)			
Anti-Polio 2, PRE-BST (N=18)	14 (7.6 to 25.7)			
Anti-Polio 2, POST-BST (N=13)	498.5 (198.1 to 1254.3)			
Anti-Polio 3, PRE-BST (N=18)	20.1 (10.6 to 38.2)			
Anti-Polio 3, POST-BST (N=13)	1234.1 (688.3 to 2212.4)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited & Unsolicited AEs: During the 4 & 31-Days post PRI/BST vaccination; SAEs: during PRI and BST Phases.

Adverse event reporting additional description:

Note that 1) For 10Pn <6M Group & 10Pn 7-11M Group SAEs were reported during both PRI and BST Phases 2) The BST Phase safety follow-up is not applicable for the 10Pn 12-23M Group & 10Pn >=24M Group, as no booster doses were administered; to mark this, numbers of subjects for BST events for these groups are marked as equal to 1.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	11.0

Reporting groups

Reporting group title	10Pn <6M Group

Reporting group description:

This group consisted of subjects up to 6 months of age at first vaccination who received 3 doses of 10Pn-PD-DiT (or 10Pn) vaccine co-administered with InfanrixTM IPV/Hib (DTPa-IPV/Hib) at 3, 4 and 5 months of age and a booster dose of the same vaccines at 12-15 months of age. Vaccines were administrated intramuscularly in the right (10Pn-PD-DiT) or the left (DTPa-IPV/Hib) thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Reporting group title	10Pn 7-11M Group

Reporting group description:

This group consisted of subjects 7 to 11 months of age at first vaccination who received 2 doses of 10Pn-PD-DiT (10Pn), one first dose at enrolment followed by a second dose one month later, and a booster dose at 12-15 months of age. The 10PN-PD-DiT vaccine was administrated intramuscularly in the right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Reporting group title	10Pn 12-23M Group

Reporting group description:

This group consisted of subjects 12 to 23 months inclusive at first vaccination who received 2 doses of 10Pn-PD-DiT (10Pn), one first dose at enrolment followed by a second dose 2 months later. The 10PN-PD-DiT vaccine was administrated intramuscularly in the right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Reporting group title	10Pn >=24M Group

Reporting group description:

This group consisted of subjects aged between 24 months (inclusive) to 5 years (inclusive) at vaccination who received one dose of 10Pn-PD-DiT (10Pn). The 10PN-PD-DiT vaccine was administrated intramuscularly in the right thigh or deltoid region (deltoid region only for children >12 months of age if muscle size was adequate).

Serious adverse events	10Pn <6M Group	10Pn 7-11M Group	10Pn 12-23M Group
Total subjects affected by serious adverse events			
subjects affected / exposed	18 / 150 (12.00%)	6 / 150 (4.00%)	2 / 150 (1.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Gastrointestinal disorders			
Abdominal pain upper - PRI			
alternative assessment type: Non-			

systematic			
subjects affected / exposed	1 / 150 (0.67%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchitis chronic - PRI			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 150 (1.33%)	1 / 150 (0.67%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Psychomotor retardation - PRI			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 150 (0.67%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia - PRI			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 150 (1.33%)	2 / 150 (1.33%)	2 / 150 (1.33%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute - PRI			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 150 (2.67%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis - PRI			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 150 (0.67%)	2 / 150 (1.33%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus - PRI			
alternative assessment type: Non-			

systematic			
subjects affected / exposed	3 / 150 (2.00%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media - PRI			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	2 / 150 (1.33%)	1 / 150 (0.67%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum - PRI			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 150 (0.67%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza - PRI			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 150 (0.67%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis - PRI			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 150 (0.67%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection - PRI			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 150 (0.67%)	0 / 150 (0.00%)	0 / 150 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection - BST			
alternative assessment type: Non-systematic			

subjects affected / exposed[1]	1 / 145 (0.69%)	0 / 145 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis - BST			
alternative assessment type: Non-systematic			
subjects affected / exposed[2]	0 / 145 (0.00%)	1 / 145 (0.69%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	10Pn >=24M Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 150 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Gastrointestinal disorders			
Abdominal pain upper - PRI			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Bronchitis chronic - PRI			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Psychomotor retardation - PRI			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Pneumonia - PRI			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 150 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis acute - PRI				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 150 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis - PRI				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 150 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis rotavirus - PRI				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 150 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Otitis media - PRI				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 150 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Exanthema subitum - PRI				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 150 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza - PRI				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 150 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Respiratory syncytial virus bronchiolitis - PRI				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 150 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory syncytial virus infection - PRI				
alternative assessment type: Non-systematic				
subjects affected / exposed	0 / 150 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacterial infection - BST				
alternative assessment type: Non-systematic				
subjects affected / exposed[1]	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis - BST				
alternative assessment type: Non-systematic				
subjects affected / exposed[2]	0 / 1 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: Assessment for this event for this phase was performed solely on subjects with available results.
[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: Assessment for this event for this phase was performed solely on subjects with available results.

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

Non-serious adverse events	10Pn <6M Group	10Pn 7-11M Group	10Pn 12-23M Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	149 / 150 (99.33%)	145 / 150 (96.67%)	144 / 150 (96.00%)
General disorders and administration site conditions			
Pain			

subjects affected / exposed	114 / 150 (76.00%)	90 / 150 (60.00%)	113 / 150 (75.33%)
occurrences (all)	245	157	177
Erythema			
subjects affected / exposed	109 / 150 (72.67%)	109 / 150 (72.67%)	79 / 150 (52.67%)
occurrences (all)	266	232	112
Swelling			
subjects affected / exposed	88 / 150 (58.67%)	77 / 150 (51.33%)	59 / 150 (39.33%)
occurrences (all)	163	132	77
Somnolence			
subjects affected / exposed	130 / 150 (86.67%)	103 / 150 (68.67%)	90 / 150 (60.00%)
occurrences (all)	291	178	111
Irritability			
subjects affected / exposed	145 / 150 (96.67%)	124 / 150 (82.67%)	107 / 150 (71.33%)
occurrences (all)	426	241	152
Decreased appetite			
subjects affected / exposed	94 / 150 (62.67%)	74 / 150 (49.33%)	62 / 150 (41.33%)
occurrences (all)	155	112	77
Injection site induration			
alternative assessment type: Non-systematic			
subjects affected / exposed	16 / 150 (10.67%)	12 / 150 (8.00%)	12 / 150 (8.00%)
occurrences (all)	22	14	15
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	120 / 150 (80.00%)	87 / 150 (58.00%)	60 / 150 (40.00%)
occurrences (all)	238	138	74
Injection site haematoma			
subjects affected / exposed	9 / 150 (6.00%)	5 / 150 (3.33%)	0 / 150 (0.00%)
occurrences (all)	9	5	0
Eye disorders			
Conjunctivitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	7 / 150 (4.67%)	13 / 150 (8.67%)	4 / 150 (2.67%)
occurrences (all)	7	13	4
Gastrointestinal disorders			

Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	11 / 150 (7.33%)	16 / 150 (10.67%)	14 / 150 (9.33%)
occurrences (all)	12	21	15
Teething			
alternative assessment type: Non-systematic			
subjects affected / exposed	14 / 150 (9.33%)	22 / 150 (14.67%)	4 / 150 (2.67%)
occurrences (all)	17	28	5
Vomiting			
subjects affected / exposed	8 / 150 (5.33%)	9 / 150 (6.00%)	4 / 150 (2.67%)
occurrences (all)	8	9	4
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative assessment type: Non-systematic			
subjects affected / exposed	7 / 150 (4.67%)	20 / 150 (13.33%)	20 / 150 (13.33%)
occurrences (all)	8	22	24
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	8 / 150 (5.33%)	5 / 150 (3.33%)	4 / 150 (2.67%)
occurrences (all)	8	5	4
Infections and infestations			
Nasopharyngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	0 / 150 (0.00%)	11 / 150 (7.33%)
occurrences (all)	0	0	14
Otitis media			
alternative assessment type: Non-systematic			
subjects affected / exposed	19 / 150 (12.67%)	28 / 150 (18.67%)	20 / 150 (13.33%)
occurrences (all)	20	34	23
Rhinitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	37 / 150 (24.67%)	33 / 150 (22.00%)	18 / 150 (12.00%)
occurrences (all)	52	47	22
Upper respiratory tract infection			
alternative assessment type: Non-systematic			

subjects affected / exposed	60 / 150 (40.00%)	43 / 150 (28.67%)	21 / 150 (14.00%)
occurrences (all)	80	59	24
Ear infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)	15 / 150 (10.00%)	3 / 150 (2.00%)
occurrences (all)	0	18	3

Non-serious adverse events	10Pn >=24M Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	135 / 150 (90.00%)		
General disorders and administration site conditions			
Pain			
subjects affected / exposed	102 / 150 (68.00%)		
occurrences (all)	103		
Erythema			
subjects affected / exposed	65 / 150 (43.33%)		
occurrences (all)	66		
Swelling			
subjects affected / exposed	32 / 150 (21.33%)		
occurrences (all)	32		
Somnolence			
subjects affected / exposed	56 / 150 (37.33%)		
occurrences (all)	57		
Irritability			
subjects affected / exposed	63 / 150 (42.00%)		
occurrences (all)	64		
Decreased appetite			
subjects affected / exposed	41 / 150 (27.33%)		
occurrences (all)	42		
Injection site induration			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 150 (0.67%)		
occurrences (all)	1		
Pyrexia			
alternative assessment type: Non-systematic			

subjects affected / exposed	19 / 150 (12.67%)		
occurrences (all)	19		
Injection site haematoma			
subjects affected / exposed	2 / 150 (1.33%)		
occurrences (all)	2		
Eye disorders			
Conjunctivitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	2 / 150 (1.33%)		
occurrences (all)	2		
Gastrointestinal disorders			
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 150 (3.33%)		
occurrences (all)	5		
Teething			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	1 / 150 (0.67%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 150 (3.33%)		
occurrences (all)	6		
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 150 (0.67%)		
occurrences (all)	1		
Infections and infestations			
Nasopharyngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)		
occurrences (all)	0		

Otitis media			
alternative assessment type: Non-systematic			
subjects affected / exposed	10 / 150 (6.67%)		
occurrences (all)	11		
Rhinitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	4 / 150 (2.67%)		
occurrences (all)	4		
Upper respiratory tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	7 / 150 (4.67%)		
occurrences (all)	8		
Ear infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 150 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 June 2006	The protocol was amended to clarify in the study title that the assessment of immunogenicity, safety and reactogenicity would be done in children older than 7 months of age and in children before 6 months of age. Furthermore, because the post-licensure surveillance of Prevenar in the United States had shown a decrease and an increase in invasive pneumococcal disease caused by the cross-reactive pneumococcal serotypes 6A and 19A, respectively, it was of interest to document the immune responses (Enzyme-Linked Immuno-Sorbent Assay [ELISA] and opsonophagocytic activity [OPA]) to these cross-reactive pneumococcal serotypes. Also a higher flexibility of the distribution of replacement vial/syringe for the 10Pn-PD-DiT vaccine at the study centres was allowed as in each group all the children would receive the same vaccine.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported