



Clinical trial results:

A Phase 3, Multicenter, Randomized, Double-blind Study to Evaluate the Interchangeability of V114 and Prevnar 13™ with Respect to Safety, Tolerability, and Immunogenicity in Healthy Infants (PNEU-DIRECTION)

Summary

EudraCT number	2018-001151-12
Trial protocol	Outside EU/EEA
Global end of trial date	14 December 2020

Results information

Result version number	v2 (current)
This version publication date	14 October 2021
First version publication date	20 June 2021
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	V114-027
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03620162
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme Corp.
Sponsor organisation address	2000 Galloping Hill Road, Kenilworth, United States, 07033
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme Corp., ClinicalTrialsDisclosure@merck.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-002215-PIP01-17
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	14 December 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 December 2020
Global end of trial reached?	Yes
Global end of trial date	14 December 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The goal of this study is to evaluate the safety, tolerability, and immunogenicity of the Pneumococcal Conjugate Vaccines (PCVs) V114 and Prevnar 13™ in healthy infants switched from Prevnar 13™ to V114 during the four-dose PCV immunization schedule.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 October 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 487
Country: Number of subjects enrolled	Puerto Rico: 156
Country: Number of subjects enrolled	Thailand: 170
Country: Number of subjects enrolled	Turkey: 87
Worldwide total number of subjects	900
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	900
Children (2-11 years)	0
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: -

Pre-assignment

Screening details:

Participants were screened at Study Day 1, prior to randomization.

Period 1

Period 1 title	Period 1 (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™

Arm description:

Participants received a single 0.5 mL intramuscular (IM) injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Arm type	Active comparator
Investigational medicinal product name	Prevnar 13™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Prevnar 13™ contains the pneumococcal capsular polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 23F (2.2 mcg each) and 6B (4.4 mcg) in each 0.5 mL dose given via IM injection.

Investigational medicinal product name	RotaTeq™
Investigational medicinal product code	
Other name	V260; Trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

RotaTeq™ live, pentavalent Rotavirus vaccine given as background treatment via oral solution.

Investigational medicinal product name	Pentacel™
Investigational medicinal product code	
Other name	Trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Pentacel™ Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine, given as background treatment via IM injection in the opposite limb to V114 and Prevnar 13™ administration.

Investigational medicinal product name	RECOMBIVAX HB™
Investigational medicinal product code	
Other name	V232, HEPTAVAX™-II, HBVAXPRO; trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details: RECOMBIVAX HB™ Hepatitis B Vaccine (Recombinant), given as background treatment via IM injection in the opposite limb to V114 and Prevnar 13™ administration.	
Investigational medicinal product name	HIBERIX™
Investigational medicinal product code	
Other name	Trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details: HIBERIX™ Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate), given as background treatment via IM injection in the opposite limb to V114 and Prevnar 13™ administration.	
Investigational medicinal product name	M-M-R™ II
Investigational medicinal product code	
Other name	V205C; trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: M-M-R™ II (Measles, Mumps, and Rubella Virus Vaccine Live), given as background treatment via subcutaneous (SC) injection in the opposite limb to V114 and Prevnar 13™ administration.	
Investigational medicinal product name	VARIVAX™
Investigational medicinal product code	
Other name	V210; trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details: VARIVAX™ Varicella Virus Vaccine Live, given as background treatment via SC injection in the opposite limb to V114 and Prevnar 13™ administration.	
Arm title	Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
Arm description: Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and a single 0.5 mL IM injection of V114 on Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.	
Arm type	Experimental
Investigational medicinal product name	Prevnar 13™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details: Prevnar 13™ contains the pneumococcal capsular polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 23F (2.2 mcg each) and 6B (4.4 mcg) in each 0.5 mL dose given via IM injection.	
Investigational medicinal product name	RotaTeq™
Investigational medicinal product code	
Other name	V260; Trade names of the background vaccines may vary

	depending on where clinical supplies were sourced.
Pharmaceutical forms	Oral solution
Routes of administration	Oral use
Dosage and administration details:	
RotaTeq™ live, pentavalent Rotavirus vaccine given as background treatment via oral solution.	
Investigational medicinal product name	V114
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
V114 contains the pneumococcal capsular polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19F, 19A, 22F, 23F, 33F (2 mcg each), and serotype 6B (4 mcg) in each 0.5 mL dose given via IM injection.	
Investigational medicinal product name	M-M-R™ II
Investigational medicinal product code	
Other name	V205C; trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
M-M-R™ II (Measles, Mumps, and Rubella Virus Vaccine Live), given as background treatment via subcutaneous (SC) injection in the opposite limb to V114 and Prevnar 13™ administration.	
Investigational medicinal product name	HIBERIX™
Investigational medicinal product code	
Other name	Trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
HIBERIX™ Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate), given as background treatment via IM injection in the opposite limb to V114 and Prevnar 13™ administration.	
Investigational medicinal product name	RECOMBIVAX HB™
Investigational medicinal product code	
Other name	V232, HEPTAVAX™-II, HBVAXPRO; trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
RECOMBIVAX HB™ Hepatitis B Vaccine (Recombinant), given as background treatment via IM injection in the opposite limb to V114 and Prevnar 13™ administration.	
Investigational medicinal product name	VARIVAX™
Investigational medicinal product code	
Other name	V210; trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
VARIVAX™ Varicella Virus Vaccine Live, given as background treatment via SC injection in the opposite limb to V114 and Prevnar 13™ administration.	
Investigational medicinal product name	Pentacel™
Investigational medicinal product code	
Other name	Trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection

Routes of administration	Intramuscular use
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Dosage and administration details:

Pentacel™ Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine, given as background treatment via IM injection in the opposite limb to V114 and Prevnar 13™ administration.

Arm title	Group 3: Prevnar 13™–Prevnar 13™–V114–V114
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Arm description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2) and a single 0.5 mL IM injection of V114 on Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Arm type	Experimental
Investigational medicinal product name	RotaTeq™
Investigational medicinal product code	
Other name	V260; Trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

RotaTeq™ live, pentavalent Rotavirus vaccine given as background treatment via oral solution.

Investigational medicinal product name	V114
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

V114 contains the pneumococcal capsular polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19F, 19A, 22F, 23F, 33F (2 mcg each), and serotype 6B (4 mcg) in each 0.5 mL dose given via IM injection.

Investigational medicinal product name	Prevnar 13™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Prevnar 13™ contains the pneumococcal capsular polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 23F (2.2 mcg each) and 6B (4.4 mcg) in each 0.5 mL dose given via IM injection.

Investigational medicinal product name	VARIVAX™
Investigational medicinal product code	
Other name	V210; trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

VARIVAX™ Varicella Virus Vaccine Live, given as background treatment via SC injection in the opposite limb to V114 and Prevnar 13™ administration.

Investigational medicinal product name	Pentacel™
Investigational medicinal product code	
Other name	Trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Pentacel™ Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and

Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine, given as background treatment via IM injection in the opposite limb to V114 and Pevnar 13™ administration.

Investigational medicinal product name	M-M-R™ II
Investigational medicinal product code	
Other name	V205C; trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

M-M-R™ II (Measles, Mumps, and Rubella Virus Vaccine Live), given as background treatment via subcutaneous (SC) injection in the opposite limb to V114 and Pevnar 13™ administration.

Investigational medicinal product name	HIBERIX™
Investigational medicinal product code	
Other name	Trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

HIBERIX™ Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate), given as background treatment via IM injection in the opposite limb to V114 and Pevnar 13™ administration.

Investigational medicinal product name	RECOMBIVAX HB™
Investigational medicinal product code	
Other name	V232, HEPTAVAX™-II, HBVAXPRO; trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

RECOMBIVAX HB™ Hepatitis B Vaccine (Recombinant), given as background treatment via IM injection in the opposite limb to V114 and Pevnar 13™ administration.

Arm title	Group 4: Pevnar 13™–V114–V114–V114
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Arm description:

Participants received a single 0.5 mL IM injection of Pevnar 13™ on Day 1 (Vaccination 1) and a single 0.5 mL IM injection of V114 on Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Arm type	Experimental
Investigational medicinal product name	Pevnar 13™
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Pevnar 13™ contains the pneumococcal capsular polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 23F (2.2 mcg each) and 6B (4.4 mcg) in each 0.5 mL dose given via IM injection.

Investigational medicinal product name	V114
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

V114 contains the pneumococcal capsular polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19F, 19A, 22F, 23F, 33F (2 mcg each), and serotype 6B (4 mcg) in each 0.5 mL dose given via IM injection.

Investigational medicinal product name	RotaTeq™
Investigational medicinal product code	
Other name	V260; Trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Oral solution
Routes of administration	Oral use
Dosage and administration details:	
RotaTeq™ live, pentavalent Rotavirus vaccine given as background treatment via oral solution.	
Investigational medicinal product name	Pentacel™
Investigational medicinal product code	
Other name	Trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Pentacel™ Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine, given as background treatment via IM injection in the opposite limb to V114 and Pevnar 13™ administration.	
Investigational medicinal product name	RECOMBIVAX HB™
Investigational medicinal product code	
Other name	V232, HEPTAVAX™-II, HBVAXPRO; trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
RECOMBIVAX HB™ Hepatitis B Vaccine (Recombinant), given as background treatment via IM injection in the opposite limb to V114 and Pevnar 13™ administration.	
Investigational medicinal product name	HIBERIX™
Investigational medicinal product code	
Other name	Trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
HIBERIX™ Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate), given as background treatment via IM injection in the opposite limb to V114 and Pevnar 13™ administration.	
Investigational medicinal product name	M-M-R™ II
Investigational medicinal product code	
Other name	V205C; trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
M-M-R™ II (Measles, Mumps, and Rubella Virus Vaccine Live), given as background treatment via subcutaneous (SC) injection in the opposite limb to V114 and Pevnar 13™ administration.	
Investigational medicinal product name	VARIVAX™
Investigational medicinal product code	
Other name	V210; trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
VARIVAX™ Varicella Virus Vaccine Live, given as background treatment via SC injection in the opposite limb to V114 and Pevnar 13™ administration.	
Arm title	Group 5: V114–V114–V114–V114

Arm description:

Participants received a single 0.5 mL IM injection of V114 on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Arm type	Experimental
Investigational medicinal product name	V114
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

V114 contains the pneumococcal capsular polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19F, 19A, 22F, 23F, 33F (2 mcg each), and serotype 6B (4 mcg) in each 0.5 mL dose given via IM injection.

Investigational medicinal product name	RotaTeq™
Investigational medicinal product code	
Other name	V260; Trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Oral solution
Routes of administration	Oral use

Dosage and administration details:

RotaTeq™ live, pentavalent Rotavirus vaccine given as background treatment via oral solution.

Investigational medicinal product name	Pentacel™
Investigational medicinal product code	
Other name	Trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Pentacel™ Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed, Inactivated Poliovirus and Haemophilus b Conjugate (Tetanus Toxoid Conjugate) Vaccine, given as background treatment via IM injection in the opposite limb to V114 and Prevnar 13™ administration.

Investigational medicinal product name	RECOMBIVAX HB™
Investigational medicinal product code	
Other name	V232, HEPTAVAX™-II, HBVAXPRO; trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

RECOMBIVAX HB™ Hepatitis B Vaccine (Recombinant), given as background treatment via IM injection in the opposite limb to V114 and Prevnar 13™ administration.

Investigational medicinal product name	HIBERIX™
Investigational medicinal product code	
Other name	Trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

HIBERIX™ Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate), given as background treatment via IM injection in the opposite limb to V114 and Prevnar 13™ administration.

Investigational medicinal product name	M-M-R™ II
Investigational medicinal product code	
Other name	V205C; trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection

Routes of administration	Subcutaneous use
Dosage and administration details:	
M-M-R™ II (Measles, Mumps, and Rubella Virus Vaccine Live), given as background treatment via subcutaneous (SC) injection in the opposite limb to V114 and Pevnar 13™ administration.	
Investigational medicinal product name	VARIVAX™
Investigational medicinal product code	
Other name	V210; trade names of the background vaccines may vary depending on where clinical supplies were sourced.
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

VARIVAX™ Varicella Virus Vaccine Live, given as background treatment via SC injection in the opposite limb to V114 and Pevnar 13™ administration.

Number of subjects in period 1	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™	Group 2: Pevnar 13™–Pevnar 13™–Pevnar 13™–V114	Group 3: Pevnar 13™–Pevnar 13™–V114–V114
Started	179	181	180
Vaccination 1 (V114 or Pevnar 13™)	179	181	178
Vaccination 2 (V114 or Pevnar 13™)	176	175	166
Vaccination 3 (V114 or Pevnar 13™)	175	174	161
Vaccination 4 (V114 or Pevnar 13™)	165	168	150
Completed	164	167	147
Not completed	15	14	33
Physician decision	4	-	1
Consent withdrawn by parent/guardian	9	8	25
Lost to follow-up	2	6	7

Number of subjects in period 1	Group 4: Pevnar 13™–V114–V114–V114	Group 5: V114–V114–V114–V114
Started	180	180
Vaccination 1 (V114 or Pevnar 13™)	179	179
Vaccination 2 (V114 or Pevnar 13™)	169	173
Vaccination 3 (V114 or Pevnar 13™)	167	173
Vaccination 4 (V114 or Pevnar 13™)	162	168
Completed	160	167
Not completed	20	13
Physician decision	-	2
Consent withdrawn by parent/guardian	17	9
Lost to follow-up	3	2

Baseline characteristics

Reporting groups

Reporting group title	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™
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Reporting group description:

Participants received a single 0.5 mL intramuscular (IM) injection of Pevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Reporting group title	Group 2: Pevnar 13™–Pevnar 13™–Pevnar 13™–V114
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Reporting group description:

Participants received a single 0.5 mL IM injection of Pevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and a single 0.5 mL IM injection of V114 on Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Reporting group title	Group 3: Pevnar 13™–Pevnar 13™–V114–V114
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Reporting group description:

Participants received a single 0.5 mL IM injection of Pevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2) and a single 0.5 mL IM injection of V114 on Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Reporting group title	Group 4: Pevnar 13™–V114–V114–V114
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Reporting group description:

Participants received a single 0.5 mL IM injection of Pevnar 13™ on Day 1 (Vaccination 1) and a single 0.5 mL IM injection of V114 on Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Reporting group title	Group 5: V114–V114–V114–V114
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Reporting group description:

Participants received a single 0.5 mL IM injection of V114 on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Reporting group values	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™	Group 2: Pevnar 13™–Pevnar 13™–Pevnar 13™–V114	Group 3: Pevnar 13™–Pevnar 13™–V114–V114
Number of subjects	179	181	180
Age Categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	179	181	180
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0

Age Continuous Units: days arithmetic mean standard deviation	63.0 ± 7.8	63.6 ± 8.4	62.7 ± 9.1
Gender Categorical Units: Subjects			
Female	76	91	85
Male	103	90	95
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic Or Latino	33	47	47
Not Hispanic Or Latino	146	134	133
Unknown Or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian Or Alaska Native	1	0	0
Asian	36	34	37
Black Or African American	8	11	3
More Than One Race	19	30	26
Native Hawaiian Or Other Pacific Islander	0	0	0
White	115	106	114

Reporting group values	Group 4: Prevnar 13™-V114-V114-V114	Group 5: V114-V114-V114-V114	Total
Number of subjects	180	180	900
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	180	180	900
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: days arithmetic mean standard deviation	63.4 ± 9.3	64.0 ± 9.3	-
Gender Categorical Units: Subjects			
Female	86	88	426
Male	94	92	474
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic Or Latino	43	43	213
Not Hispanic Or Latino	136	137	686
Unknown Or Not Reported	1	0	1

Race (NIH/OMB)			
Units: Subjects			
American Indian Or Alaska Native	0	0	1
Asian	32	38	177
Black Or African American	3	9	34
More Than One Race	30	28	133
Native Hawaiian Or Other Pacific Islander	1	1	2
White	114	104	553

End points

End points reporting groups

Reporting group title	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™
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Reporting group description:

Participants received a single 0.5 mL intramuscular (IM) injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Reporting group title	Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
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Reporting group description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and a single 0.5 mL IM injection of V114 on Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Reporting group title	Group 3: Prevnar 13™–Prevnar 13™–V114–V114
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Reporting group description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2) and a single 0.5 mL IM injection of V114 on Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Reporting group title	Group 4: Prevnar 13™–V114–V114–V114
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Reporting group description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1) and a single 0.5 mL IM injection of V114 on Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Reporting group title	Group 5: V114–V114–V114–V114
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Reporting group description:

Participants received a single 0.5 mL IM injection of V114 on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™
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Subject analysis set type	Safety analysis
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Subject analysis set description:

Participants received a single 0.5 mL intramuscular (IM) injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
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Subject analysis set type	Safety analysis
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Subject analysis set description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and a single 0.5 mL IM injection of V114 on Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 3: Prevnar 13™–Prevnar 13™–V114–V114
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Subject analysis set type	Safety analysis
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Subject analysis set description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2

(Vaccination 2) and a single 0.5 mL IM injection of V114 on Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 4: Prevnar 13™–V114–V114–V114
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1) and a single 0.5 mL IM injection of V114 on Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 5: V114–V114–V114–V114
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received a single 0.5 mL IM injection of V114 on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single 0.5 mL intramuscular (IM) injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and a single 0.5 mL IM injection of V114 on Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 3: Prevnar 13™–Prevnar 13™–V114–V114
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2) and a single 0.5 mL IM injection of V114 on Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 4: Prevnar 13™–V114–V114–V114
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1) and a single 0.5 mL IM injection of V114 on Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 5: V114–V114–V114–V114
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single 0.5 mL IM injection of V114 on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants received a single 0.5 mL intramuscular (IM) injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and a single 0.5 mL IM injection of V114 on Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 3: Prevnar 13™–Prevnar 13™–V114–V114
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2) and a single 0.5 mL IM injection of V114 on Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 4: Prevnar 13™–V114–V114–V114
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1) and a single 0.5 mL IM injection of V114 on Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 5: V114–V114–V114–V114
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants received a single 0.5 mL IM injection of V114 on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants received a single 0.5 mL intramuscular (IM) injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and a single 0.5 mL IM injection of V114 on Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 3: Prevnar 13™–Prevnar 13™–V114–V114
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Subject analysis set type	Per protocol
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Subject analysis set description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2) and a single 0.5 mL IM injection of V114 on Month 4 (Vaccination 3) and Months 10-13

(Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 4: Prevnar 13™–V114–V114–V114
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1) and a single 0.5 mL IM injection of V114 on Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 5: V114–V114–V114–V114
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single 0.5 mL IM injection of V114 on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 1 + Group 2
Subject analysis set type	Per protocol

Subject analysis set description:

Group 1 participants who received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3), Months 10-13 (Vaccination 4) and Group 2 participants who received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and a single 0.5 mL IM injection of V114 on Months 10-13 (Vaccination 4), were combined across vaccination schedule. Group 1 plus Group 2 participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single 0.5 mL intramuscular (IM) injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and a single 0.5 mL IM injection of V114 on Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 5: V114–V114–V114–V114
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received a single 0.5 mL IM injection of V114 on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Subject analysis set title	Group 1 + Group 2
Subject analysis set type	Per protocol

Subject analysis set description:

Group 1 participants who received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3), Months 10-13 (Vaccination 4) and Group 2 participants who received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and a single 0.5 mL IM injection of V114 on Months 10-13 (Vaccination 4), were combined across vaccination schedule. Group 1 plus Group 2 participants

concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Primary: Percentage of Participants With a Solicited Injection-site Adverse Event (AE)

End point title	Percentage of Participants With a Solicited Injection-site Adverse Event (AE)
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End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Per protocol, the percentage of participants with solicited injection-site AEs was assessed for up to ~14 days after each vaccination. The solicited injection-site AEs assessed were erythema/redness, induration/hard lump, tenderness/pain and swelling. The analysis population included all randomized participants who got ≥ 1 dose of V114 or Prevnar 13™.

End point type	Primary
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End point timeframe:

Up to ~14 days after each vaccination

End point values	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™	Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114	Group 3: Prevnar 13™–Prevnar 13™–V114–V1 14	Group 4: Prevnar 13™–V114–V1 14–V114
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	179	181	178	179
Units: Percentage of Participants				
number (not applicable)				
Erythema/Redness	47.5	37.6	38.8	43.0
Induration/Hard lump	34.6	26.0	28.1	25.1
Tenderness/Pain	44.1	43.6	46.1	43.6
Swelling	22.9	18.8	24.7	20.7

End point values	Group 5: V114–V114–V 114–V114			
Subject group type	Subject analysis set			
Number of subjects analysed	179			
Units: Percentage of Participants				
number (not applicable)				
Erythema/Redness	44.1			
Induration/Hard lump	26.3			
Tenderness/Pain	47.5			
Swelling	22.9			

Statistical analyses

Statistical analysis title	Difference in Percentage: Erythema(Group 5 vs 1)
Comparison groups	Group 5: V114–V114–V114–V114 v Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[1]
P-value	= 0.525
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.6
upper limit	7

Notes:

[1] - Estimated differences, confidence intervals (CIs), and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Erythema(Group 4 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 4: Prevnar 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[2]
P-value	= 0.396
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.7
upper limit	5.8

Notes:

[2] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Erythema(Group 3 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 3: Prevnar 13™–Prevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[3]
P-value	= 0.097
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-8.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.8
upper limit	1.6

Notes:

[3] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Erythema(Group 2 vs 1)
Comparison groups	Group 1: Prevna 13™–Prevna 13™–Prevna 13™–Prevna 13™ v Group 2: Prevna 13™–Prevna 13™–Prevna 13™–V114
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[4]
P-value	= 0.057
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-9.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.9
upper limit	0.3

Notes:

[4] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Induration(Group 5 vs 1)
Comparison groups	Group 1: Prevna 13™–Prevna 13™–Prevna 13™–Prevna 13™ v Group 5: V114–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[5]
P-value	= 0.085
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-8.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.8
upper limit	1.2

Notes:

[5] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Induration(Group 4 vs 1)
Comparison groups	Group 1: Prevna 13™–Prevna 13™–Prevna 13™–Prevna 13™ v Group 4: Prevna 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[6]
P-value	= 0.05
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-9.5

Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.9
upper limit	0

Notes:

[6] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Induration(Group 3 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 3: Prevnar 13™–Prevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[7]
P-value	= 0.183
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-6.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.1
upper limit	3.1

Notes:

[7] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Induration(Group 2 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[8]
P-value	= 0.074
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-8.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.1
upper limit	0.8

Notes:

[8] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Tenderness(Group 5 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 5: V114–V114–V114–V114

Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[9]
P-value	= 0.525
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7
upper limit	13.6

Notes:

[9] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Tenderness(Group 4 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 4: Prevnar 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[10]
P-value	= 0.915
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.8
upper limit	9.7

Notes:

[10] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Tenderness(Group 3 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 3: Prevnar 13™–Prevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[11]
P-value	= 0.714
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.4
upper limit	12.2

Notes:

[11] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Tenderness(Group 2 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[12]
P-value	= 0.926
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.7
upper limit	9.7

Notes:

[12] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Swelling(Group 5 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 5: V114–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[13]
P-value	> 0.999
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.7
upper limit	8.7

Notes:

[13] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Swelling(Group 4 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 4: Prevnar 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[14]
P-value	= 0.609
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-2.2

Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.8
upper limit	6.4

Notes:

[14] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Swelling(Group 3 vs 1)
Comparison groups	Group 1: Plevnar 13™–Plevnar 13™–Plevnar 13™–Plevnar 13™ v Group 3: Plevnar 13™–Plevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[15]
P-value	= 0.688
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	1.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.1
upper limit	10.7

Notes:

[15] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Swelling(Group 2 vs 1)
Comparison groups	Group 1: Plevnar 13™–Plevnar 13™–Plevnar 13™–Plevnar 13™ v Group 2: Plevnar 13™–Plevnar 13™–Plevnar 13™–V114
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[16]
P-value	= 0.336
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-4.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.6
upper limit	4.3

Notes:

[16] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Primary: Percentage of Participants with a Solicited Systemic AE

End point title	Percentage of Participants with a Solicited Systemic AE
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End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. Per protocol, the percentage of participants with solicited systemic AEs was assessed for up to ~14 days after each

vaccination. The solicited systemic AEs assessed were appetite lost/decreased appetite, irritability, drowsiness/somnolence and hives or welts/urticaria. The analysis population included all randomized participants who got ≥ 1 dose of V114 or Prevnar 13™.

End point type	Primary
End point timeframe:	
Up to ~14 days after each vaccination	

End point values	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™	Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114	Group 3: Prevnar 13™–Prevnar 13™–V114–V1 14	Group 4: Prevnar 13™–V114–V1 14–V114
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	179	181	178	179
Units: Percentage of Participants				
number (not applicable)				
Appetite lost/Decreased Appetite	35.8	32.0	27.0	35.2
Irritability	67.6	60.8	62.9	68.2
Drowsiness/Somnolence	57.0	55.8	56.7	57.0
Hives/Urticaria	7.3	3.9	5.6	8.9

End point values	Group 5: V114–V114–V 114–V114			
Subject group type	Subject analysis set			
Number of subjects analysed	179			
Units: Percentage of Participants				
number (not applicable)				
Appetite lost/Decreased Appetite	34.6			
Irritability	70.4			
Drowsiness/Somnolence	60.3			
Hives/Urticaria	6.7			

Statistical analyses

Statistical analysis title	Difference in Percentage:Appetite lost(Group5 vs1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 5: V114–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[17]
P-value	= 0.825
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-1.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-11
upper limit	8.8

Notes:

[17] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage:Appetite lost(Group4 vs1)
Comparison groups	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™ v Group 4: Pevnar 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[18]
P-value	= 0.912
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.4
upper limit	9.3

Notes:

[18] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage:Appetite lost(Group3 vs1)
Comparison groups	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™ v Group 3: Pevnar 13™–Pevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[19]
P-value	= 0.074
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-8.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.3
upper limit	0.9

Notes:

[19] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage:Appetite lost(Group2 vs1)
Comparison groups	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™ v Group 2: Pevnar 13™–Pevnar 13™–Pevnar 13™–V114

Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[20]
P-value	= 0.458
Method	Miettinen & Nurminen method
Parameter estimate	Percentage of Participants
Point estimate	-3.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.4
upper limit	6.1

Notes:

[20] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage:Irritability(Group 5 vs1)
Comparison groups	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™ v Group 5: V114–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[21]
P-value	= 0.568
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.8
upper limit	12.3

Notes:

[21] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage:Irritability(Group 4 vs1)
Comparison groups	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™ v Group 4: Pevnar 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[22]
P-value	= 0.91
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.1
upper limit	10.2

Notes:

[22] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage:Irritability(Group 3 vs1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 3: Prevnar 13™–Prevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[23]
P-value	= 0.354
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-4.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.5
upper limit	5.2

Notes:

[23] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage:Irritability(Group 2 vs1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[24]
P-value	= 0.178
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-6.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.6
upper limit	3.1

Notes:

[24] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Drowsiness(Group 5 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 5: V114–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[25]
P-value	= 0.52
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	3.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.8
upper limit	13.5

Notes:

[25] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Drowsiness(Group 4 vs 1)
Comparison groups	Group 1: Prevna 13™–Prevna 13™–Prevna 13™–Prevna 13™ v Group 4: Prevna 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[26]
P-value	> 0.999
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.2
upper limit	10.2

Notes:

[26] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Drowsiness(Group 3 vs 1)
Comparison groups	Group 1: Prevna 13™–Prevna 13™–Prevna 13™–Prevna 13™ v Group 3: Prevna 13™–Prevna 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[27]
P-value	= 0.963
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.5
upper limit	10

Notes:

[27] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Drowsiness(Group 2 vs 1)
Comparison groups	Group 1: Prevna 13™–Prevna 13™–Prevna 13™–Prevna 13™ v Group 2: Prevna 13™–Prevna 13™–Prevna 13™–V114

Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[28]
P-value	= 0.821
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.4
upper limit	9

Notes:

[28] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Hives(Group 5 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 5: V114–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[29]
P-value	= 0.836
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.1
upper limit	5

Notes:

[29] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Hives(Group 4 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 4: Prevnar 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[30]
P-value	= 0.562
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.2
upper limit	7.6

Notes:

[30] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Hives(Group 3 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 3: Prevnar 13™–Prevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[31]
P-value	= 0.527
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-1.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.1
upper limit	3.7

Notes:

[31] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage: Hives(Group 2 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[32]
P-value	= 0.16
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.6
upper limit	1.5

Notes:

[32] - Estimated differences, CIs, and p-values are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Primary: Percentage of Participants with a Vaccine-related Serious Adverse Event (SAE)

End point title	Percentage of Participants with a Vaccine-related Serious Adverse Event (SAE)
End point description:	
An SAE is any untoward medical occurrence that results in death, is life-threatening, requires or prolongs existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly or birth defect, or is another important medical event deemed such by medical or scientific judgement. Relatedness of an SAE to the study vaccine was determined by the investigator. Per protocol, the percentage of participants with vaccine-related SAEs was assessed through 6 months following Vaccination 4. The analysis population included all randomized participants who got ≥1 dose of V114 or Prevnar 13™.	
End point type	Primary

End point timeframe:

Up to ~6 months after Vaccination 4 (up to ~19 months)

End point values	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™	Group 2: Pevnar 13™–Pevnar 13™–Pevnar 13™–V114	Group 3: Pevnar 13™–Pevnar 13™–V114–V1 14	Group 4: Pevnar 13™–V114–V1 14–V114
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	179	181	178	179
Units: Percentage of Participants				
number (not applicable)	0	0	0.6	0

End point values	Group 5: V114–V114–V 114–V114			
Subject group type	Subject analysis set			
Number of subjects analysed	179			
Units: Percentage of Participants				
number (not applicable)	0			

Statistical analyses

Statistical analysis title	Difference in Percentage (Group 5 vs 1)
Comparison groups	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™ v Group 5: V114–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[33]
Parameter estimate	Difference in Percentage
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	2.1

Notes:

[33] - Estimated differences and CIs are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage (Group 4 vs 1)
Comparison groups	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™ v Group 4: Pevnar 13™–V114–V114–V114

Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[34]
Parameter estimate	Difference in Percentage
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	2.1

Notes:

[34] - Estimated differences and CIs are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage (Group 3 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 3: Prevnar 13™–Prevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[35]
Parameter estimate	Difference in Percentage
Point estimate	0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	3.1

Notes:

[35] - Estimated differences and CIs are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Statistical analysis title	Difference in Percentage (Group 2 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[36]
Parameter estimate	Difference in Percentage
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	2.1

Notes:

[36] - Estimated differences and CIs are calculated based on the Miettinen & Nurminen method and are provided in accordance with the statistical analysis plan.

Primary: Geometric Mean Concentration (GMC) of Anti-Pneumococcal Polysaccharide (PnP) Immunoglobulin G (IgG) For 13 Shared Serotypes Contained in V114 and Prevnar 13™ at 30 Days Post Vaccination 4

End point title	Geometric Mean Concentration (GMC) of Anti-Pneumococcal Polysaccharide (PnP) Immunoglobulin G (IgG) For 13 Shared Serotypes Contained in V114 and Prevnar 13™ at 30 Days Post
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End point description:

The GMC of anti-PnP serotype-specific IgG for 13 shared serotypes contained in V114 and Prevnar 13™ (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F) was assessed using a pneumococcal electrochemiluminescence (PnECL) assay. Per protocol, 13 IgG serotypes in Groups 2, 3, 4 (experimental arms) were compared to Group 1 (comparator arm) at 30 days post Vaccination 4 as a pre-specified primary outcome analysis; 13 IgG serotypes in Group 5 (experimental arm) were compared to Group 1 (comparator arm) at 30 days post Vaccination 4, as a separate protocol-specified secondary outcome analysis and reported later in the record. Analysis population included all randomized participants who were compliant with the protocol, got scheduled dosing of V114 or Prevnar 13™, and had IgG GMC data available for serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F or 23F in Groups 1, 2, 3, 4 or 5 at 30 Days post Vaccination 4.

End point type	Primary
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End point timeframe:

30 Days after Vaccination 4 (Months 11-14)
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End point values	Group 1: Prevnar 13™-Prevnar 13™-Prevnar 13™-Prevnar 13™	Group 2: Prevnar 13™-Prevnar 13™-Prevnar 13™-V114	Group 3: Prevnar 13™-Prevnar 13™-V114-V1 14	Group 4: Prevnar 13™-V114-V1 14-V114
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	179	181	178	179
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype 1 (n= 147, 151, 128, 139, 147)	2.02 (1.78 to 2.30)	1.69 (1.48 to 1.93)	1.89 (1.63 to 2.18)	1.68 (1.48 to 1.91)
Serotype 3 (n=148, 151, 128, 139, 147)	0.72 (0.64 to 0.82)	0.77 (0.68 to 0.87)	0.68 (0.61 to 0.77)	0.73 (0.66 to 0.82)
Serotype 4 (n=146, 151, 128, 139, 147)	1.51 (1.30 to 1.76)	1.33 (1.14 to 1.56)	1.27 (1.10 to 1.46)	1.23 (1.08 to 1.41)
Serotype 5 (n=147, 151, 128, 138, 147)	3.66 (3.18 to 4.20)	3.39 (2.91 to 3.94)	3.82 (3.23 to 4.51)	2.90 (2.50 to 3.38)
Serotype 6A (n=146, 151, 128, 139, 147)	6.42 (5.56 to 7.42)	7.16 (6.30 to 8.15)	7.16 (6.17 to 8.30)	5.17 (4.43 to 6.03)
Serotype 6B (n=146, 151, 128, 139, 147)	6.15 (5.36 to 7.07)	7.58 (6.61 to 8.68)	6.64 (5.73 to 7.69)	6.62 (5.75 to 7.62)
Serotype 7F (n=146, 151, 128, 139, 147)	5.10 (4.43 to 5.88)	5.69 (4.93 to 6.56)	5.06 (4.33 to 5.92)	3.98 (3.47 to 4.57)
Serotype 9V (n=147, 151, 128, 139, 147)	2.93 (2.56 to 3.34)	2.76 (2.41 to 3.16)	2.57 (2.22 to 2.97)	2.46 (2.19 to 2.78)
Serotype 14 (n=146, 151, 128, 139, 147)	7.62 (6.55 to 8.86)	10.59 (9.01 to 12.44)	10.91 (9.29 to 12.81)	7.87 (6.77 to 9.16)
Serotype 18C (n=147, 151, 128, 139, 147)	2.57 (2.21 to 2.99)	3.88 (3.38 to 4.45)	3.70 (3.20 to 4.29)	2.76 (2.42 to 3.15)
Serotype 19A (n=148, 151, 128, 139, 147)	5.92 (5.15 to 6.80)	5.52 (4.88 to 6.25)	5.20 (4.42 to 6.12)	4.95 (4.27 to 5.73)
Serotype 19F (n=148, 151, 128, 139, 147)	4.78 (4.22 to 5.42)	4.88 (4.33 to 5.51)	5.02 (4.40 to 5.73)	4.60 (4.00 to 5.28)
Serotype 23F (n=146, 150, 127, 138, 146)	2.89 (2.42 to 3.44)	2.72 (2.33 to 3.18)	2.29 (1.93 to 2.70)	2.22 (1.92 to 2.56)

End point values	Group 5: V114–V114–V 114–V114			
Subject group type	Subject analysis set			
Number of subjects analysed	179			
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype 1 (n= 147, 151, 128, 139, 147)	1.46 (1.30 to 1.63)			
Serotype 3 (n=148, 151, 128, 139, 147)	0.89 (0.79 to 0.99)			
Serotype 4 (n=146, 151, 128, 139, 147)	1.35 (1.17 to 1.57)			
Serotype 5 (n=147, 151, 128, 138, 147)	2.90 (2.50 to 3.35)			
Serotype 6A (n=146, 151, 128, 139, 147)	4.43 (3.86 to 5.09)			
Serotype 6B (n=146, 151, 128, 139, 147)	5.83 (5.09 to 6.68)			
Serotype 7F (n=146, 151, 128, 139, 147)	3.43 (3.02 to 3.91)			
Serotype 9V (n=147, 151, 128, 139, 147)	2.89 (2.56 to 3.26)			
Serotype 14 (n=146, 151, 128, 139, 147)	6.57 (5.73 to 7.55)			
Serotype 18C (n=147, 151, 128, 139, 147)	2.65 (2.34 to 3.01)			
Serotype 19A (n=148, 151, 128, 139, 147)	4.66 (4.15 to 5.24)			
Serotype 19F (n=148, 151, 128, 139, 147)	4.10 (3.66 to 4.59)			
Serotype 23F (n=146, 150, 127, 138, 146)	2.11 (1.81 to 2.46)			

Statistical analyses

Statistical analysis title	GMC Ratio: Serotype 1 (Group 3 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 3: Prevnar 13™–Prevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[37]
Parameter estimate	GMC Ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.12

Notes:

[37] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 1 (Group 4 vs 1)
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Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 4: Prevnar 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[38]
Parameter estimate	GMC Ratio
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1

Notes:

[38] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 1 (Group 2 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[39]
Parameter estimate	GMC Ratio
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1

Notes:

[39] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 3 (Group 4 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 4: Prevnar 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[40]
Parameter estimate	GMC Ratio
Point estimate	1.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.19

Notes:

[40] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 3 (Group 3 vs 1)
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Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 3: Prevnar 13™–Prevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[41]
Parameter estimate	GMC Ratio
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	1.12

Notes:

[41] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 3 (Group 2 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[42]
Parameter estimate	GMC Ratio
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.9
upper limit	1.25

Notes:

[42] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 4 (Group 4 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 4: Prevnar 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[43]
Parameter estimate	GMC Ratio
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	1

Notes:

[43] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 4 (Group 3 vs 1)
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Comparison groups	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™ v Group 3: Pevnar 13™–Pevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[44]
Parameter estimate	GMC Ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	1.03

Notes:

[44] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 4 (Group 2 vs 1)
Comparison groups	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™ v Group 2: Pevnar 13™–Pevnar 13™–Pevnar 13™–V114
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[45]
Parameter estimate	GMC Ratio
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.08

Notes:

[45] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 5 (Group 3 vs 1)
Comparison groups	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™ v Group 3: Pevnar 13™–Pevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[46]
Parameter estimate	GMC Ratio
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.29

Notes:

[46] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 5 (Group 4 vs 1)
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Comparison groups	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™ v Group 4: Pevnar 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[47]
Parameter estimate	GMC Ratio
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	0.98

Notes:

[47] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 5 (Group 2 vs 1)
Comparison groups	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™ v Group 2: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™–V114
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[48]
Parameter estimate	GMC Ratio
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.75
upper limit	1.14

Notes:

[48] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 6A (Group 4 vs 1)
Comparison groups	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™ v Group 4: Pevnar 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[49]
Parameter estimate	GMC Ratio
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	0.98

Notes:

[49] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 6A (Group 3 vs 1)
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Comparison groups	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™ v Group 3: Pevnar 13™–Pevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[50]
Parameter estimate	GMC Ratio
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	1.37

Notes:

[50] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 6B (Group 4 vs 1)
Comparison groups	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™ v Group 4: Pevnar 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[51]
Parameter estimate	GMC Ratio
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.31

Notes:

[51] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 6A (Group 2 vs 1)
Comparison groups	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™ v Group 2: Pevnar 13™–Pevnar 13™–Pevnar 13™–V114
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[52]
Parameter estimate	GMC Ratio
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.36

Notes:

[52] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 6B (Group 3 vs 1)
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Comparison groups	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™ v Group 3: Pevnar 13™–Pevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[53]
Parameter estimate	GMC Ratio
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.32

Notes:

[53] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 7F (Group 4 vs 1)
Comparison groups	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™ v Group 4: Pevnar 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[54]
Parameter estimate	GMC Ratio
Point estimate	0.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	0.95

Notes:

[54] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 6B (Group 2 vs 1)
Comparison groups	Group 1: Pevnar 13™–Pevnar 13™–Pevnar 13™–Pevnar 13™ v Group 2: Pevnar 13™–Pevnar 13™–Pevnar 13™–V114
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[55]
Parameter estimate	GMC Ratio
Point estimate	1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.02
upper limit	1.49

Notes:

[55] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 7F (Group 3 vs 1)
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Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 3: Prevnar 13™–Prevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[56]
Parameter estimate	GMC Ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.21

Notes:

[56] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 7F (Group 2 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[57]
Parameter estimate	GMC Ratio
Point estimate	1.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.92
upper limit	1.35

Notes:

[57] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 9V (Group 4 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 4: Prevnar 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[58]
Parameter estimate	GMC Ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.01

Notes:

[58] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 9V (Group 3 vs 1)
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Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 3: Prevnar 13™–Prevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[59]
Parameter estimate	GMC Ratio
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.06

Notes:

[59] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 9V (Group 2 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[60]
Parameter estimate	GMC Ratio
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.79
upper limit	1.13

Notes:

[60] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 14 (Group 4 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 4: Prevnar 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[61]
Parameter estimate	GMC Ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.28

Notes:

[61] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 14 (Group 3 vs 1)
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Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 3: Prevnar 13™–Prevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[62]
Parameter estimate	GMC Ratio
Point estimate	1.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.15
upper limit	1.78

Notes:

[62] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 14 (Group 2 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[63]
Parameter estimate	GMC Ratio
Point estimate	1.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.13
upper limit	1.71

Notes:

[63] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 18C (Group 4 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 4: Prevnar 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[64]
Parameter estimate	GMC Ratio
Point estimate	1.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.3

Notes:

[64] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 18C (Group 3 vs 1)
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Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 3: Prevnar 13™–Prevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[65]
Parameter estimate	GMC Ratio
Point estimate	1.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.18
upper limit	1.76

Notes:

[65] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 18C (Group 2 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[66]
Parameter estimate	GMC Ratio
Point estimate	1.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.25
upper limit	1.83

Notes:

[66] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 19A (Group 4 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 4: Prevnar 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[67]
Parameter estimate	GMC Ratio
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.69
upper limit	1.01

Notes:

[67] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 19A (Group 3 vs 1)
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Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 3: Prevnar 13™–Prevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[68]
Parameter estimate	GMC Ratio
Point estimate	0.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.07

Notes:

[68] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 19A (Group 2 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[69]
Parameter estimate	GMC Ratio
Point estimate	0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	1.13

Notes:

[69] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 19F (Group 4 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 4: Prevnar 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[70]
Parameter estimate	GMC Ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.15

Notes:

[70] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 19F (Group 3 vs 1)
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Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 3: Prevnar 13™–Prevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[71]
Parameter estimate	GMC Ratio
Point estimate	1.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.26

Notes:

[71] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 19F (Group 2 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[72]
Parameter estimate	GMC Ratio
Point estimate	1.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.21

Notes:

[72] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 23F (Group 4 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 4: Prevnar 13™–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[73]
Parameter estimate	GMC Ratio
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.61
upper limit	0.96

Notes:

[73] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 23F (Group 3 vs 1)
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Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 3: Prevnar 13™–Prevnar 13™–V114–V114
Number of subjects included in analysis	357
Analysis specification	Pre-specified
Analysis type	other ^[74]
Parameter estimate	GMC Ratio
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.63
upper limit	0.99

Notes:

[74] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 23F (Group 2 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	other ^[75]
Parameter estimate	GMC Ratio
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	1.17

Notes:

[75] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Secondary: Group 5 Versus Group 1 + Group 2: Percentage of Participants with anti-Hepatitis B Surface Antigen (HBsAg) ≥10 mIU/mL at 30 Days Post Vaccination 3

End point title	Group 5 Versus Group 1 + Group 2: Percentage of Participants with anti-Hepatitis B Surface Antigen (HBsAg) ≥10 mIU/mL at 30 Days Post Vaccination 3
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End point description:

The concentration of anti-HBsAg was assessed using an enhanced chemiluminescence assay. The protocol-specified analysis of the percentage of participants with anti-HBsAg ≥10 mIU/mL at 30 days post vaccination 3 was conducted in participants combined across vaccine dosing schedules (Group 1 + Group 2) as well as in participants separated across vaccine dosing schedules (Group 1, Group 2). Per protocol, participants with anti-HBsAg ≥10 mIU/mL in Group 5 were compared to Group 1 + Group 2 at 30 days post Vaccination 3, as a pre-specified secondary outcome analysis. Analysis of participants with anti-HBsAg ≥10 mIU/mL was not planned to be reported in Group 3 and Group 4, per protocol. Analysis population included all randomized participants who were compliant with the protocol, got scheduled dosing of V114, Prevnar 13™ or background RECOMBIVAX HB™, and had anti-HBsAg ≥10 mIU/mL data available at 30 days post Vaccination 3.

End point type	Secondary
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End point timeframe:

30 Days after Vaccination 3 (Month 5)

End point values	Group 3: Prevnar 13™–Prevnar 13™–V114–V1 14	Group 4: Prevnar 13™–V114–V1 14–V114	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™	Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0 ^[76]	0 ^[77]	142	142
Units: Percentage of Participants				
number (not applicable)			98.6	99.3

Notes:

[76] - Analysis of participants with anti-HBsAg was not planned to be reported in Group 3 per protocol.

[77] - Analysis of participants with anti-HBsAg was not planned to be reported in Group 4 per protocol.

End point values	Group 5: V114–V114–V 114–V114	Group 1 + Group 2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	153	284		
Units: Percentage of Participants				
number (not applicable)	98.7	98.9		

Statistical analyses

Statistical analysis title	Difference in Percentage (Group 5 vs Group 1+2)
Comparison groups	Group 5: V114–V114–V114–V114 v Group 1 + Group 2
Number of subjects included in analysis	437
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[78]
P-value	< 0.001
Method	Miettinen & Nurminen method
Parameter estimate	Difference in Percentage
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.7
upper limit	2

Notes:

[78] - The statistical criterion for non-inferiority requires the lower bound of the 2-sided 95% CI for the difference in percentages (Group 5/Group 1+Group 2) to be >-10 percentage points.

Secondary: Group 5 Versus Group 1 + Group 2: Geometric Mean Titer (GMT) of Anti-Rotavirus Immunoglobulin A (IgA) at 30 Days Post Vaccination 3

End point title	Group 5 Versus Group 1 + Group 2: Geometric Mean Titer (GMT) of Anti-Rotavirus Immunoglobulin A (IgA) at 30 Days Post Vaccination 3
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End point description:

The GMT of anti-rotavirus IgA was assessed using a serum IgA enzyme linked immunosorbent assay.

The protocol specified analysis of anti-rotavirus IgA GMT at 30 days post vaccination 3 was conducted in participants combined across vaccine dosing schedules (Group 1 + Group 2) as well as in participants separated across vaccine dosing schedules (Group 1, Group 2). Per protocol, GMT of anti-rotavirus IgA in Group 5 was compared to Group 1 + Group 2 at 30 days post Vaccination 3, as a pre-specified secondary outcome analysis. Anti-rotavirus IgA GMT analysis was not planned to be reported in Group 3 and Group 4, per protocol. Analysis population included all randomized participants who were compliant with the protocol, got scheduled dosing of V114, Prevnar 13™ or background RotaTeq™, and had anti-rotavirus IgA GMT data available at 30 days post Vaccination 3.

End point type	Secondary
End point timeframe:	
30 Days after Vaccination 3 (Month 5)	

End point values	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™	Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114	Group 3: Prevnar 13™–Prevnar 13™–V114–V1 14	Group 4: Prevnar 13™–V114–V1 14–V114
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	147	143	0 ^[79]	0 ^[80]
Units: Titers				
geometric mean (confidence interval 95%)	286.5 (218.1 to 376.2)	329.5 (254.9 to 426.1)	(to)	(to)

Notes:

[79] - Anti-rotavirus IgA GMT analysis was not planned to be reported in Group 3, per protocol.

[80] - Anti-rotavirus IgA GMT analysis was not planned to be reported in Group 4, per protocol.

End point values	Group 5: V114–V114–V 114–V114	Group 1 + Group 2		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	152	290		
Units: Titers				
geometric mean (confidence interval 95%)	298.3 (228.2 to 390.0)	307.0 (254.7 to 369.9)		

Statistical analyses

Statistical analysis title	GMT Ratio (Group 5 vs Group 1+2)
Comparison groups	Group 5: V114–V114–V114–V114 v Group 1 + Group 2
Number of subjects included in analysis	442
Analysis specification	Pre-specified
Analysis type	non-inferiority ^[81]
P-value	< 0.001
Method	ANCOVA
Parameter estimate	GMT Ratio
Point estimate	0.97

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.34

Notes:

[81] - The statistical criterion for non-inferiority requires the lower bound of the 2-sided 95% CI for the GMT ratio (Group 5/Group 1+Group 2) to be >0.5.

Secondary: GMC of Anti-PnP IgG for 15 Serotypes Contained in V114 at 30 Days Post Vaccination 3

End point title	GMC of Anti-PnP IgG for 15 Serotypes Contained in V114 at 30 Days Post Vaccination 3
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End point description:

The concentration of anti-PnP serotype-specific IgG for 15 serotypes contained in V114 (13 serotypes shared with Prevnar 13™ [1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F] and 2 unique serotypes [22F, 33F]) was assessed using a PnECL assay. Per protocol, GMC of 15 IgG serotypes was assessed at 30 days post Vaccination 3. Analysis population included all randomized participants who were compliant with the protocol, got scheduled dosing of V114 or Prevnar 13™, and had IgG GMC data available for serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F, 22F or 33F in Groups 1, 2, 3, 4 or 5 at 30 Days post Vaccination 3.

End point type	Secondary
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End point timeframe:

30 Days after Vaccination 3 (Month 5)

End point values	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™	Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114	Group 3: Prevnar 13™–Prevnar 13™–V114–V1 14	Group 4: Prevnar 13™–V114–V1 14–V114
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	179	181	178	179
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype 1 (n=142, 142, 129, 138, 148)	1.93 (1.69 to 2.20)	1.99 (1.78 to 2.21)	1.86 (1.64 to 2.10)	1.35 (1.19 to 1.53)
Serotype 3 (n=142, 142, 129, 138, 147)	0.54 (0.47 to 0.61)	0.64 (0.56 to 0.73)	0.56 (0.49 to 0.63)	0.67 (0.60 to 0.76)
Serotype 4 (n=141, 139, 128, 137, 147)	1.39 (1.22 to 1.57)	1.47 (1.30 to 1.66)	1.34 (1.14 to 1.56)	1.07 (0.93 to 1.22)
Serotype 5 (n=141, 141, 128, 138, 148)	1.99 (1.69 to 2.34)	2.16 (1.87 to 2.49)	2.15 (1.83 to 2.52)	1.73 (1.50 to 1.99)
Serotype 6A (n=140, 140, 128, 138, 148)	3.07 (2.66 to 3.54)	3.22 (2.83 to 3.67)	3.26 (2.79 to 3.82)	2.05 (1.76 to 2.38)
Serotype 6B (n=138, 140, 127, 138, 147)	2.03 (1.66 to 2.49)	2.50 (2.10 to 2.99)	2.43 (2.05 to 2.88)	2.29 (1.91 to 2.76)
Serotype 7F (n=142, 142, 129, 138, 148)	3.36 (2.99 to 3.77)	3.54 (3.16 to 3.96)	3.52 (3.10 to 3.99)	2.61 (2.33 to 2.94)
Serotype 9V (n=143, 142, 128, 138, 148)	1.69 (1.48 to 1.94)	1.81 (1.60 to 2.05)	1.68 (1.44 to 1.97)	1.47 (1.28 to 1.67)
Serotype 14 (n=142, 142, 128, 138, 148)	6.57 (5.55 to 7.79)	6.18 (5.22 to 7.31)	9.32 (7.45 to 11.67)	6.71 (5.76 to 7.83)
Serotype 18C (n=142, 142, 129, 138, 148)	1.69 (1.46 to 1.95)	2.03 (1.81 to 2.28)	2.08 (1.81 to 2.38)	1.50 (1.33 to 1.71)

Serotype 19A (n=143, 142, 129, 138, 148)	2.17 (1.92 to 2.47)	2.46 (2.21 to 2.74)	2.25 (1.95 to 2.60)	1.64 (1.43 to 1.87)
Serotype 19F (n=143, 142, 128, 138, 148)	2.83 (2.51 to 3.18)	2.90 (2.61 to 3.23)	3.08 (2.72 to 3.48)	2.32 (2.06 to 2.62)
Serotype 23F (n=140, 140, 128, 135, 147)	1.32 (1.09 to 1.59)	1.72 (1.49 to 1.99)	1.22 (1.02 to 1.45)	1.33 (1.14 to 1.57)
Serotype 22F (n=138, 140, 128, 137, 148)	0.05 (0.04 to 0.05)	0.05 (0.04 to 0.06)	3.63 (2.91 to 4.52)	5.94 (5.13 to 6.88)
Serotype 33F (n=141, 139, 127, 137, 148)	0.05 (0.05 to 0.06)	0.05 (0.05 to 0.06)	0.28 (0.21 to 0.36)	0.89 (0.70 to 1.14)

End point values	Group 5: V114-V114-V 114-V114			
Subject group type	Subject analysis set			
Number of subjects analysed	179			
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype 1 (n=142, 142, 129, 138, 148)	1.27 (1.14 to 1.41)			
Serotype 3 (n=142, 142, 129, 138, 147)	1.01 (0.91 to 1.12)			
Serotype 4 (n=141, 139, 128, 137, 147)	1.40 (1.24 to 1.57)			
Serotype 5 (n=141, 141, 128, 138, 148)	1.91 (1.67 to 2.18)			
Serotype 6A (n=140, 140, 128, 138, 148)	1.82 (1.59 to 2.09)			
Serotype 6B (n=138, 140, 127, 138, 147)	2.26 (1.87 to 2.73)			
Serotype 7F (n=142, 142, 129, 138, 148)	2.41 (2.17 to 2.67)			
Serotype 9V (n=143, 142, 128, 138, 148)	2.01 (1.80 to 2.24)			
Serotype 14 (n=142, 142, 128, 138, 148)	5.50 (4.79 to 6.31)			
Serotype 18C (n=142, 142, 129, 138, 148)	1.51 (1.34 to 1.72)			
Serotype 19A (n=143, 142, 129, 138, 148)	1.63 (1.47 to 1.82)			
Serotype 19F (n=143, 142, 128, 138, 148)	2.21 (2.00 to 2.46)			
Serotype 23F (n=140, 140, 128, 135, 147)	1.46 (1.25 to 1.69)			
Serotype 22F (n=138, 140, 128, 137, 148)	5.15 (4.52 to 5.87)			
Serotype 33F (n=141, 139, 127, 137, 148)	2.22 (1.86 to 2.66)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Anti-PnP IgG Concentration ≥ 0.35 $\mu\text{g/mL}$ for 15 Serotypes Contained in V114 at 30 Days Post Vaccination 3

End point title	Percentage of Participants With Anti-PnP IgG Concentration ≥ 0.35 $\mu\text{g/mL}$ for 15 Serotypes Contained in V114 at 30 Days Post Vaccination 3
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End point description:

The concentration of anti-PnP serotype-specific IgG for 15 serotypes contained in V114 (13 serotypes shared with Prevnar 13™ [1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F] and 2 unique serotypes [22F, 33F]) was assessed using a PnECL assay. Per protocol, percentage of participants with anti-PnP IgG concentrations ≥ 0.35 $\mu\text{g/mL}$ was assessed at 30 days post Vaccination 3. Analysis population included all randomized participants who were compliant with the protocol, got scheduled dosing of V114 or Prevnar 13™, and had IgG concentration $\geq 0.35\mu\text{g/mL}$ data available for serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F, 22F or 33F in Groups 1, 2, 3, 4 or 5 at 30 Days post Vaccination 3.

End point type	Secondary
End point timeframe:	
30 Days after Vaccination 3 (Month 5)	

End point values	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™	Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114	Group 3: Prevnar 13™–Prevnar 13™–V114–V1 14	Group 4: Prevnar 13™–V114–V1 14–V114
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	179	181	178	179
Units: Percentage of Participants				
number (confidence interval 95%)				
Serotype 1 (n=142, 142, 129, 138, 148)	97.9 (94.0 to 99.6)	100 (97.4 to 100.0)	99.2 (95.8 to 100.0)	97.8 (93.8 to 99.5)
Serotype 3 (n=142, 142, 129, 138, 147)	73.2 (65.2 to 80.3)	73.9 (65.9 to 80.9)	79.1 (71.0 to 85.7)	81.9 (74.4 to 87.9)
Serotype 4 (n=141, 139, 128, 137, 147)	97.9 (93.9 to 99.6)	98.6 (94.9 to 99.8)	93.0 (87.1 to 96.7)	94.2 (88.8 to 97.4)
Serotype 5 (n=141, 141, 128, 138, 148)	97.9 (93.9 to 99.6)	99.3 (96.1 to 100.0)	97.7 (93.3 to 99.5)	97.1 (92.7 to 99.2)
Serotype 6A (n=140, 140, 128, 138, 148)	99.3 (96.1 to 100.0)	99.3 (96.1 to 100.0)	99.2 (95.7 to 100.0)	97.1 (92.7 to 99.2)
Serotype 6B (n=138, 140, 127, 138, 147)	91.3 (85.3 to 95.4)	94.3 (89.1 to 97.5)	96.1 (91.1 to 98.7)	95.7 (90.8 to 98.4)
Serotype 7F (n=142, 142, 129, 138, 148)	100 (97.4 to 100.0)	100 (97.4 to 100)	100 (97.2 to 100.0)	100 (97.4 to 100.0)
Serotype 9V (n=143, 142, 128, 138, 148)	96.5 (92.0 to 98.9)	96.5 (92.0 to 98.8)	96.1 (91.1 to 98.7)	95.7 (90.8 to 98.4)
Serotype 14 (n=142, 142, 128, 138, 148)	98.6 (95.0 to 99.8)	98.6 (95.0 to 99.8)	96.9 (92.2 to 99.1)	100 (97.4 to 100.0)
Serotype 18C (n=142, 142, 129, 138, 148)	95.8 (91.0 to 98.4)	100 (97.4 to 100.0)	99.2 (95.8 to 100.0)	97.8 (93.8 to 99.5)
Serotype 19A (n=143, 142, 129, 138, 148)	99.3 (96.2 to 100.0)	100 (97.4 to 100.0)	98.4 (94.5 to 99.8)	97.1 (92.7 to 99.2)
Serotype 19F (n=143, 142, 128, 138, 148)	99.3 (96.2 to 100.0)	99.3 (96.1 to 100.0)	99.2 (95.7 to 100.0)	100 (97.4 to 100.0)
Serotype 23F (n=140, 140, 128, 135, 147)	91.4 (85.5 to 95.5)	97.9 (93.9 to 99.6)	90.6 (84.2 to 95.1)	92.6 (86.8 to 96.4)
Serotype 22F (n=138, 140, 128, 137, 148)	2.9 (0.8 to 7.3)	1.4 (0.2 to 5.1)	93.8 (88.1 to 97.3)	99.3 (96.0 to 100.0)
Serotype 33F (n=141, 139, 127, 137, 148)	2.1 (0.4 to 6.1)	2.2 (0.4 to 6.2)	39.4 (30.8 to 48.4)	75.9 (67.9 to 82.8)

End point values	Group 5: V114–V114–V 114–V114			
Subject group type	Subject analysis set			
Number of subjects analysed	179			
Units: Percentage of Participants				
number (confidence interval 95%)				
Serotype 1 (n=142, 142, 129, 138, 148)	96.6 (92.3 to 98.9)			
Serotype 3 (n=142, 142, 129, 138, 147)	93.9 (88.7 to 97.2)			
Serotype 4 (n=141, 139, 128, 137, 147)	96.6 (92.2 to 98.9)			
Serotype 5 (n=141, 141, 128, 138, 148)	98.0 (94.2 to 99.6)			
Serotype 6A (n=140, 140, 128, 138, 148)	98.6 (95.2 to 99.8)			
Serotype 6B (n=138, 140, 127, 138, 147)	95.2 (90.4 to 98.1)			
Serotype 7F (n=142, 142, 129, 138, 148)	100 (97.5 to 100.0)			
Serotype 9V (n=143, 142, 128, 138, 148)	98.6 (95.2 to 99.8)			
Serotype 14 (n=142, 142, 128, 138, 148)	98.6 (95.2 to 99.8)			
Serotype 18C (n=142, 142, 129, 138, 148)	98.0 (94.2 to 99.6)			
Serotype 19A (n=143, 142, 129, 138, 148)	97.3 (93.2 to 99.3)			
Serotype 19F (n=143, 142, 128, 138, 148)	100 (97.5 to 100.0)			
Serotype 23F (n=140, 140, 128, 135, 147)	94.6 (89.6 to 97.6)			
Serotype 22F (n=138, 140, 128, 137, 148)	98.6 (95.2 to 99.8)			
Serotype 33F (n=141, 139, 127, 137, 148)	93.2 (87.9 to 96.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Group 5 Versus Group 1: GMC of Anti-PnP IgG For 13 Shared Serotypes Contained in V114 and Prevnar 13™ at 30 Days Post Vaccination 4

End point title	Group 5 Versus Group 1: GMC of Anti-PnP IgG For 13 Shared Serotypes Contained in V114 and Prevnar 13™ at 30 Days Post Vaccination 4
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End point description:

The GMC of anti-PnP serotype-specific IgG for 13 shared serotypes contained in V114 and Prevnar 13™ (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F) was assessed using a PnECL assay. Per protocol, GMC of 13 IgG serotypes was analysed by vaccine dosing schedules (Groups 1, 5). Per protocol, 13 IgG serotypes in Group 5 (experimental arm) were compared to Group 1 (comparator arm) at 30 days post Vaccination 4 as a pre-specified secondary outcome analysis; 13 IgG serotypes in Groups 2, 3, 4

(experimental arms) were compared to Group 1 (comparator arm) at 30 days post Vaccination 4, as a separate protocol-specified primary outcome analysis and reported earlier in the record. Analysis population included all randomized participants who were compliant with the protocol, got scheduled dosing of V114 or Prevnar 13™, and had IgG GMC data available for serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F or 23F in Groups 5 or 1 at 30 Days post Vaccination 4.

End point type	Secondary
End point timeframe:	
30 Days after Vaccination 4 (Months 11-14)	

End point values	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™	Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114	Group 3: Prevnar 13™–Prevnar 13™–V114–V1 14	Group 4: Prevnar 13™–V114–V1 14–V114
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	179	0 ^[82]	0 ^[83]	0 ^[84]
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype 1 (n=147, 147)	2.02 (1.78 to 2.30)	(to)	(to)	(to)
Serotype 3 (n=148, 147)	0.72 (0.64 to 0.82)	(to)	(to)	(to)
Serotype 4 (n=146, 147)	1.51 (1.30 to 1.76)	(to)	(to)	(to)
Serotype 5 (n=147, 147)	3.66 (3.18 to 4.20)	(to)	(to)	(to)
Serotype 6A (n=146, 147)	6.42 (5.56 to 7.42)	(to)	(to)	(to)
Serotype 6B (n=146, 147)	6.15 (5.36 to 7.07)	(to)	(to)	(to)
Serotype 7F (n=146, 147)	5.10 (4.43 to 5.88)	(to)	(to)	(to)
Serotype 9V (n=147, 147)	2.93 (2.56 to 3.34)	(to)	(to)	(to)
Serotype 14 (n=146, 147)	7.62 (6.55 to 8.86)	(to)	(to)	(to)
Serotype 18C (n=147, 147)	2.57 (2.21 to 2.99)	(to)	(to)	(to)
Serotype 19A (n=148, 147)	5.92 (5.15 to 6.80)	(to)	(to)	(to)
Serotype 19F (n=148, 147)	4.78 (4.22 to 5.42)	(to)	(to)	(to)
Serotype 23F (n=146, 146)	2.89 (2.42 to 3.44)	(to)	(to)	(to)

Notes:

[82] - Per protocol Group 2 was compared to Group 1 as a primary endpoint analysis and reported earlier.

[83] - Per protocol Group 3 was compared to Group 1 as a primary endpoint analysis and reported earlier.

[84] - Per protocol Group 4 was compared to Group 1 as a primary endpoint analysis and reported earlier.

End point values	Group 5: V114–V114–V 114–V114			
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Subject group type	Subject analysis set			
Number of subjects analysed	179			
Units: µg/mL				
geometric mean (confidence interval 95%)				
Serotype 1 (n=147, 147)	1.46 (1.30 to 1.63)			
Serotype 3 (n=148, 147)	0.89 (0.79 to 0.99)			
Serotype 4 (n=146, 147)	1.35 (1.17 to 1.57)			
Serotype 5 (n=147, 147)	2.90 (2.50 to 3.35)			
Serotype 6A (n=146, 147)	4.43 (3.86 to 5.09)			
Serotype 6B (n=146, 147)	5.83 (5.09 to 6.68)			
Serotype 7F (n=146, 147)	3.43 (3.02 to 3.91)			
Serotype 9V (n=147, 147)	2.89 (2.56 to 3.26)			
Serotype 14 (n=146, 147)	6.57 (5.73 to 7.55)			
Serotype 18C (n=147, 147)	2.65 (2.34 to 3.01)			
Serotype 19A (n=148, 147)	4.66 (4.15 to 5.24)			
Serotype 19F (n=148, 147)	4.10 (3.66 to 4.59)			
Serotype 23F (n=146, 146)	2.11 (1.81 to 2.46)			

Statistical analyses

Statistical analysis title	GMC Ratio: Serotype 1 (Group 5 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 5: V114–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[85]
Parameter estimate	GMC Ratio
Point estimate	0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	0.86

Notes:

[85] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 3 (Group 5 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 5: V114–V114–V114–V114

Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[86]
Parameter estimate	GMC Ratio
Point estimate	1.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.04
upper limit	1.44

Notes:

[86] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 4 (Group 5 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 5: V114–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[87]
Parameter estimate	GMC Ratio
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.1

Notes:

[87] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 5 (Group 5 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 5: V114–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[88]
Parameter estimate	GMC Ratio
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	0.97

Notes:

[88] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 6A (Group 5 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 5: V114–V114–V114–V114

Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[89]
Parameter estimate	GMC Ratio
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	0.84

Notes:

[89] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 6B (Group 5 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 5: V114–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[90]
Parameter estimate	GMC Ratio
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.15

Notes:

[90] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 7F (Group 5 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 5: V114–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[91]
Parameter estimate	GMC Ratio
Point estimate	0.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	0.82

Notes:

[91] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 9V (Group 5 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 5: V114–V114–V114–V114

Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[92]
Parameter estimate	GMC Ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.18

Notes:

[92] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 14 (Group 5 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 5: V114–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[93]
Parameter estimate	GMC Ratio
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	1.07

Notes:

[93] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 18C (Group 5 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 5: V114–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[94]
Parameter estimate	GMC Ratio
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.25

Notes:

[94] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 19A (Group 5 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 5: V114–V114–V114–V114

Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[95]
Parameter estimate	GMC Ratio
Point estimate	0.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.65
upper limit	0.95

Notes:

[95] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 19F (Group 5 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 5: V114–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[96]
Parameter estimate	GMC Ratio
Point estimate	0.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	1.02

Notes:

[96] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Statistical analysis title	GMC Ratio: Serotype 23F (Group 5 vs 1)
Comparison groups	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™ v Group 5: V114–V114–V114–V114
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	other ^[97]
Parameter estimate	GMC Ratio
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	0.91

Notes:

[97] - GMC ratio and CI are estimated from a serotype-specific ANCOVA model utilizing the natural log-transformed antibody concentration as the response and vaccination group and stratification factor as covariates.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Non-serious AEs (NSAEs): Up to ~14 days after each vaccination; SAEs and all-cause mortality: Up to ~6 months after Vaccination 4 (up to ~19 months)

Adverse event reporting additional description:

Safety was analyzed by the vaccine dosing schedules (Groups 1, 2, 3, 4, 5), from the first vaccination of a participant. All-cause mortality was analyzed in all randomized participants; SAEs and NSAEs were analyzed in all randomized participants who received at least dose of study vaccination V114 or Prevnar 13™.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	23.1

Reporting groups

Reporting group title	Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114
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Reporting group description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and a single 0.5 mL IM injection of V114 on Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Reporting group title	Group 3: Prevnar 13™–Prevnar 13™–V114–V114
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Reporting group description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2) and a single 0.5 mL IM injection of V114 on Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Reporting group title	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™
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Reporting group description:

Participants received a single 0.5 mL intramuscular (IM) injection of Prevnar 13™ on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Reporting group title	Group 4: Prevnar 13™–V114–V114–V114
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Reporting group description:

Participants received a single 0.5 mL IM injection of Prevnar 13™ on Day 1 (Vaccination 1) and a single 0.5 mL IM injection of V114 on Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Reporting group title	Group 5: V114–V114–V114–V114
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Reporting group description:

Participants received a single 0.5 mL IM injection of V114 on Day 1 (Vaccination 1), Month 2 (Vaccination 2), Month 4 (Vaccination 3) and Months 10-13 (Vaccination 4). Participants concomitantly received other licensed background paediatric vaccines as follows: RotaTeq™, Pentacel™, RECOMBIVAX HB™ on Day 1, Month 2, and on Month 4; HIBERIX™, M-M-R™ II, VARIVAX™ on Months 10-13.

Serious adverse events	Group 2: Prevna 13™–Prevna 13™–Prevna 13™–V114	Group 3: Prevna 13™–Prevna 13™–V114–V114	Group 1: Prevna 13™–Prevna 13™–Prevna 13™–Prevna 13™
Total subjects affected by serious adverse events			
subjects affected / exposed	24 / 181 (13.26%)	15 / 178 (8.43%)	21 / 179 (11.73%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hair follicle tumour benign			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foreign body ingestion			
subjects affected / exposed	1 / 181 (0.55%)	0 / 178 (0.00%)	0 / 179 (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
Humerus fracture			
subjects affected / exposed	0 / 181 (0.00%)	1 / 178 (0.56%)	0 / 179 (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
Subdural haemorrhage			
subjects affected / exposed	0 / 181 (0.00%)	1 / 178 (0.56%)	0 / 179 (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
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 181 (0.00%)	1 / 178 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			

subjects affected / exposed	1 / 181 (0.55%)	1 / 178 (0.56%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	2 / 181 (1.10%)	1 / 178 (0.56%)	0 / 179 (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
Syncope			
subjects affected / exposed	0 / 181 (0.00%)	1 / 178 (0.56%)	0 / 179 (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
General disorders and administration site conditions			
Complication associated with device			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 181 (0.55%)	0 / 178 (0.00%)	0 / 179 (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
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 181 (0.55%)	0 / 178 (0.00%)	0 / 179 (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
Gastrointestinal disorders			
Enteritis			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asphyxia			

subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	1 / 181 (0.55%)	0 / 178 (0.00%)	0 / 179 (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
Interstitial lung disease			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper airway obstruction			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Synovitis			
subjects affected / exposed	0 / 181 (0.00%)	1 / 178 (0.56%)	0 / 179 (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
Infections and infestations			
Adenoviral upper respiratory infection			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adenovirus infection			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Arthritis bacterial			
subjects affected / exposed	0 / 181 (0.00%)	1 / 178 (0.56%)	0 / 179 (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
Bacteraemia			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	6 / 181 (3.31%)	3 / 178 (1.69%)	6 / 179 (3.35%)
occurrences causally related to treatment / all	0 / 6	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 181 (0.55%)	0 / 178 (0.00%)	0 / 179 (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
Conjunctivitis			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Croup infectious			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exanthema subitum			
subjects affected / exposed	1 / 181 (0.55%)	0 / 178 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			

subjects affected / exposed	2 / 181 (1.10%)	1 / 178 (0.56%)	4 / 179 (2.23%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	1 / 181 (0.55%)	0 / 178 (0.00%)	0 / 179 (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
Herpangina			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	1 / 181 (0.55%)	0 / 178 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycoplasma infection			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	0 / 181 (0.00%)	1 / 178 (0.56%)	0 / 179 (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
Otitis media acute			
subjects affected / exposed	1 / 181 (0.55%)	0 / 178 (0.00%)	0 / 179 (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
Periorbital cellulitis			
subjects affected / exposed	0 / 181 (0.00%)	1 / 178 (0.56%)	0 / 179 (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
Pharyngitis			

subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 181 (0.00%)	1 / 178 (0.56%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	1 / 181 (0.55%)	0 / 178 (0.00%)	0 / 179 (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
Pneumonia influenzal			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 181 (0.00%)	1 / 178 (0.56%)	0 / 179 (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
Pneumonia viral			
subjects affected / exposed	1 / 181 (0.55%)	1 / 178 (0.56%)	0 / 179 (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
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	2 / 181 (1.10%)	1 / 178 (0.56%)	2 / 179 (1.12%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus infection			

subjects affected / exposed	1 / 181 (0.55%)	0 / 178 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin bacterial infection			
subjects affected / exposed	1 / 181 (0.55%)	0 / 178 (0.00%)	0 / 179 (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
Upper respiratory tract infection			
subjects affected / exposed	1 / 181 (0.55%)	0 / 178 (0.00%)	0 / 179 (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
Urinary tract infection			
subjects affected / exposed	2 / 181 (1.10%)	0 / 178 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	1 / 181 (0.55%)	1 / 178 (0.56%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral pharyngitis			

subjects affected / exposed	1 / 181 (0.55%)	0 / 178 (0.00%)	0 / 179 (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
Viral rash			
subjects affected / exposed	0 / 181 (0.00%)	1 / 178 (0.56%)	0 / 179 (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
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	0 / 179 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 181 (0.00%)	0 / 178 (0.00%)	1 / 179 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Group 4: Prevnar 13™-V114-V114-V114	Group 5: V114-V114-V114-V114	
Total subjects affected by serious adverse events			
subjects affected / exposed	18 / 179 (10.06%)	21 / 179 (11.73%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hair follicle tumour benign			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foreign body ingestion			

subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haemorrhage			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile convulsion			
subjects affected / exposed	0 / 179 (0.00%)	1 / 179 (0.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Complication associated with device			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pyrexia			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Enteritis			
subjects affected / exposed	0 / 179 (0.00%)	1 / 179 (0.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Asphyxia			
subjects affected / exposed	1 / 179 (0.56%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspiration			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	1 / 179 (0.56%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper airway obstruction			

subjects affected / exposed	1 / 179 (0.56%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Synovitis			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Adenoviral upper respiratory infection			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenovirus infection			
subjects affected / exposed	1 / 179 (0.56%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis bacterial			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial infection			
subjects affected / exposed	0 / 179 (0.00%)	1 / 179 (0.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			
subjects affected / exposed	3 / 179 (1.68%)	8 / 179 (4.47%)	
occurrences causally related to treatment / all	0 / 3	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	

Bronchitis			
subjects affected / exposed	2 / 179 (1.12%)	1 / 179 (0.56%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conjunctivitis			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Croup infectious			
subjects affected / exposed	0 / 179 (0.00%)	1 / 179 (0.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exanthema subitum			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 179 (0.00%)	1 / 179 (0.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpangina			
subjects affected / exposed	1 / 179 (0.56%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 179 (0.00%)	3 / 179 (1.68%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mycoplasma infection			

subjects affected / exposed	1 / 179 (0.56%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Otitis media acute			
subjects affected / exposed	1 / 179 (0.56%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periorbital cellulitis			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	1 / 179 (0.56%)	1 / 179 (0.56%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngotonsillitis			
subjects affected / exposed	0 / 179 (0.00%)	1 / 179 (0.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	2 / 179 (1.12%)	2 / 179 (1.12%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia influenzal			

subjects affected / exposed	1 / 179 (0.56%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia viral			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	3 / 179 (1.68%)	3 / 179 (1.68%)	
occurrences causally related to treatment / all	0 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory syncytial virus infection			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	1 / 179 (0.56%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	1 / 179 (0.56%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin bacterial infection			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			

subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	2 / 179 (1.12%)	1 / 179 (0.56%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection bacterial			
subjects affected / exposed	1 / 179 (0.56%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral pharyngitis			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral rash			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 179 (0.00%)	1 / 179 (0.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 179 (0.00%)	0 / 179 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Group 2: Prevnar 13™–Prevnar 13™–Prevnar 13™–V114	Group 3: Prevnar 13™–Prevnar 13™–V114–V114	Group 1: Prevnar 13™–Prevnar 13™–Prevnar 13™–Prevnar 13™
Total subjects affected by non-serious adverse events			
subjects affected / exposed	161 / 181 (88.95%)	160 / 178 (89.89%)	164 / 179 (91.62%)
Nervous system disorders			
Somnolence			
subjects affected / exposed	101 / 181 (55.80%)	101 / 178 (56.74%)	102 / 179 (56.98%)
occurrences (all)	241	207	285
General disorders and administration site conditions			
Injection site erythema			
subjects affected / exposed	68 / 181 (37.57%)	69 / 178 (38.76%)	85 / 179 (47.49%)
occurrences (all)	108	109	137
Injection site induration			
subjects affected / exposed	47 / 181 (25.97%)	50 / 178 (28.09%)	62 / 179 (34.64%)
occurrences (all)	83	84	106
Injection site pain			
subjects affected / exposed	79 / 181 (43.65%)	82 / 178 (46.07%)	79 / 179 (44.13%)
occurrences (all)	140	165	158
Injection site swelling			
subjects affected / exposed	34 / 181 (18.78%)	44 / 178 (24.72%)	41 / 179 (22.91%)
occurrences (all)	55	63	58
Pyrexia			
subjects affected / exposed	66 / 181 (36.46%)	52 / 178 (29.21%)	53 / 179 (29.61%)
occurrences (all)	94	77	83
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	11 / 181 (6.08%)	11 / 178 (6.18%)	15 / 179 (8.38%)
occurrences (all)	12	12	20
Vomiting			
subjects affected / exposed	11 / 181 (6.08%)	4 / 178 (2.25%)	8 / 179 (4.47%)
occurrences (all)	12	4	11
Respiratory, thoracic and mediastinal disorders			

Cough subjects affected / exposed occurrences (all)	12 / 181 (6.63%) 14	10 / 178 (5.62%) 13	17 / 179 (9.50%) 17
Nasal congestion subjects affected / exposed occurrences (all)	15 / 181 (8.29%) 18	12 / 178 (6.74%) 14	24 / 179 (13.41%) 25
Rhinorrhoea subjects affected / exposed occurrences (all)	3 / 181 (1.66%) 3	4 / 178 (2.25%) 4	6 / 179 (3.35%) 6
Skin and subcutaneous tissue disorders Urticaria subjects affected / exposed occurrences (all)	7 / 181 (3.87%) 9	10 / 178 (5.62%) 14	13 / 179 (7.26%) 16
Psychiatric disorders Irritability subjects affected / exposed occurrences (all)	110 / 181 (60.77%) 362	112 / 178 (62.92%) 378	121 / 179 (67.60%) 430
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	11 / 181 (6.08%) 12	13 / 178 (7.30%) 14	10 / 179 (5.59%) 12
Upper respiratory tract infection subjects affected / exposed occurrences (all)	9 / 181 (4.97%) 10	9 / 178 (5.06%) 11	14 / 179 (7.82%) 14
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	58 / 181 (32.04%) 95	48 / 178 (26.97%) 77	64 / 179 (35.75%) 150

Non-serious adverse events	Group 4: Prevnar 13™-V114-V114- V114	Group 5: V114-V114-V114- V114	
Total subjects affected by non-serious adverse events subjects affected / exposed	163 / 179 (91.06%)	160 / 179 (89.39%)	
Nervous system disorders Somnolence subjects affected / exposed occurrences (all)	102 / 179 (56.98%) 248	108 / 179 (60.34%) 237	
General disorders and administration site conditions			

Injection site erythema subjects affected / exposed occurrences (all)	77 / 179 (43.02%) 130	79 / 179 (44.13%) 142	
Injection site induration subjects affected / exposed occurrences (all)	45 / 179 (25.14%) 75	47 / 179 (26.26%) 86	
Injection site pain subjects affected / exposed occurrences (all)	78 / 179 (43.58%) 156	85 / 179 (47.49%) 170	
Injection site swelling subjects affected / exposed occurrences (all)	37 / 179 (20.67%) 59	41 / 179 (22.91%) 71	
Pyrexia subjects affected / exposed occurrences (all)	49 / 179 (27.37%) 78	49 / 179 (27.37%) 68	
Gastrointestinal disorders			
Diarrhoea subjects affected / exposed occurrences (all)	10 / 179 (5.59%) 10	10 / 179 (5.59%) 12	
Vomiting subjects affected / exposed occurrences (all)	11 / 179 (6.15%) 13	11 / 179 (6.15%) 11	
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	18 / 179 (10.06%) 20	17 / 179 (9.50%) 17	
Nasal congestion subjects affected / exposed occurrences (all)	12 / 179 (6.70%) 16	14 / 179 (7.82%) 15	
Rhinorrhoea subjects affected / exposed occurrences (all)	16 / 179 (8.94%) 16	6 / 179 (3.35%) 6	
Skin and subcutaneous tissue disorders			
Urticaria subjects affected / exposed occurrences (all)	16 / 179 (8.94%) 20	12 / 179 (6.70%) 20	

Psychiatric disorders Irritability subjects affected / exposed occurrences (all)	122 / 179 (68.16%) 376	126 / 179 (70.39%) 434	
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	8 / 179 (4.47%) 8	10 / 179 (5.59%) 12	
Upper respiratory tract infection subjects affected / exposed occurrences (all)	12 / 179 (6.70%) 13	14 / 179 (7.82%) 14	
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	63 / 179 (35.20%) 90	62 / 179 (34.64%) 121	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported