Clinical trial results:
A Phase 2b Trial To Assess the Safety, Tolerability, And Immunogenicity of MenABCWY in Healthy Infants 2 and 6 Months of Age

Summary

EudraCT number	2020-000948-60
Trial protocol	DE GR
Global end of trial date	15 September 2022

Results information

Result version number	v1 (current)
This version publication date	30 March 2023
First version publication date	30 March 2023

Trial information

Trial identification

Sponsor protocol code	C3511002

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	10 November 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 September 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To describe the immune response for Neisseria meningitidis group A (MenA), MenC, MenW, and MenY induced by Neisseria meningitidis group A, B, C, W, and Y vaccine (MenABCWY) compared to the immune response induced by Nimenrix after 2 primary vaccinations and after a booster dose.

To describe the immune response for MenB induced by MenABCWY compared to the immune response induced by Bexsero after 2 primary vaccinations and after a booster dose.

To describe the immune response for MenB induced by 60 micrograms (mcg) and 120 mcg of bivalent rLP2086 after 2 primary vaccinations and after a booster dose.

To describe the safety profile of MenABCWY after primary vaccinations, by protocol-assigned paracetamol regimen, and after a booster dose.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trials subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 November 2020
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	Germany: 3
Country: Number of subjects enrolled	Greece: 24
Country: Number of subjects enrolled	Spain: 298
Worldwide total number of subjects	325
EEA total number of subjects	325

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)	325
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:

326 subjects signed the informed consent form. Out of which 1 subject was not vaccinated as parent withdrew consent. 325 subjects received vaccination.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1 (MenABCWY +PLP)

Arm description:

Infant subjects aged 6 months were administered a single intramuscular injection of 0.5 millilitre (mL) MenABCWY into the left thigh. Prophylactic liquid paracetamol regimen (PLP) was administered orally with 3 required doses, the first dose starting 30 minutes before vaccination (Day 1 [primary vaccination {vacc}1] and Month 2 [primary vaccination 2]). Subjects received a single intramuscular injection of MenABCWY approximately 6 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at Day 1.

Arm type	Experimental
Investigational medicinal product name	MenABCWY
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Vaxelis
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Prevenar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Paracetamol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

5-mL dose administered orally

Arm title	Group 2 (MenABCWY)

Arm description:

Infant subjects aged 6 months were administered a single intramuscular injection of 0.5 mL MenABCWY into the left thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). Subjects received a single intramuscular injection of MenABCWY approximately 6 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at Day 1.

Arm type	Experimental
Investigational medicinal product name	MenABCWY
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Vaxelis
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Prevenar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Arm title	Group 3 (60 µg rLP2086 +Nimenrix +PLP/SLP)

Arm description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.25 mL bivalent rLP2086 (60 microgram [µg]) into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). PLP or SLP was administered orally. Subjects received a single intramuscular injection of 0.25 mL bivalent rLP2086 (60 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Arm type	Experimental
Investigational medicinal product name	rLP2086
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.25-mL dose administered intramuscularly

Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Vaxelis
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Prevenar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Paracetamol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

2.5-mL dose administered orally

Arm title	Group 4 (60 µg rLP2086 +Nimenrix)

Arm description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.25 mL of bivalent rLP2086 (60 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). Subjects received a single intramuscular injection of 0.25 mL of bivalent rLP2086 (60 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Arm type	Experimental
Investigational medicinal product name	rLP2086
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.25-mL dose administered intramuscularly

Investigational medicinal product name	Vaxelis
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Prevenar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly.

Arm title	Group 5 (120 µg rLP2086 +Nimenrix +PLP)

Arm description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL of bivalent rLP2086 (120 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). PLP was administered orally with 3 required doses, the first dose starting 30 minutes before vaccination at Day 1 and Month 2. Subjects received a single intramuscular injection of 0.5 mL of bivalent rLP2086 (120 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Arm type	Experimental
Investigational medicinal product name	rLP2086
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Paracetamol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

2.5-mL dose administered orally

Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Arm title	Group 7 (MenABCWY +SLP)

Arm description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL MenABCWY into the left thigh. Scheduled liquid paracetamol (SLP) was administered orally at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). Subjects received a single intramuscular injection of 0.5 mL MenABCWY approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Arm type	Experimental
Investigational medicinal product name	MenABCWY
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Vaxelis
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Prevenar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Paracetamol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

2.5-mL dose administered orally

Arm title	Group 8 (Bexsero +Nimenrix +PLP)

Arm description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL of Bexsero into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). PLP was administered orally with 3 required doses, the first dose starting 30 minutes before vaccination at Day 1 and Month 2. Subjects received a single intramuscular injection of 0.5 mL of Bexsero into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Arm type	Active comparator
Investigational medicinal product name	Bexsero
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL dose administered intramuscularly

Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered inteamuscularly

Investigational medicinal product name	Vaxelis
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Prevenar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Paracetamol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

2.5-mL dose administered orally

Arm title	Group 10 (Bexsero +Nimenrix)

Arm description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL of Bexsero into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1), Month 2 (primary vaccination 2) and at approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Arm type	Active comparator
Investigational medicinal product name	Bexsero
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL dose administered intramuscularly

Investigational medicinal product name	Vaxelis
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Prevenar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Arm title	Group 11 (MenABCWY +TLP)

Arm description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL MenABCWY into the left thigh at Day 1 (primary vaccination 1). Therapeutic Liquid Paracetamol regimen (TLP) was administered orally. No subjects received Vaccination 2 and booster dose due to study termination. All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 months of age.

Arm type	Experimental
Investigational medicinal product name	MenABCWY
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Vaxelis
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Prevenar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Paracetamol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

2.5-mL dose administered orally

Number of subjects in period 1	Group 1 (MenABCWY +PLP)	Group 2 (MenABCWY)	Group 3 (60 µg rLP2086 +Nimenrix +PLP/SLP)
Started	23	25	36
Completed	22	25	20
Not completed	1	0	16
Adverse event, serious fatal	-	-	-
Adverse event, non-fatal	1	-	-
No longer meets eligibility criteria	-	-	-
Study terminated by sponsor	-	-	14
Unspecified	-	-	-
Lost to follow-up	-	-	-
Withdrawal by parent/guardian	-	-	2
Protocol deviation	-	-	-

Number of subjects in period 1	Group 4 (60 µg rLP2086 +Nimenrix)	Group 5 (120 µg rLP2086 +Nimenrix +PLP)	Group 7 (MenABCWY +SLP)
Started	16	53	50
Completed	0	2	0
Not completed	16	51	50
Adverse event, serious fatal	-	-	1
Adverse event, non-fatal	-	-	-
No longer meets eligibility criteria	-	-	-
Study terminated by sponsor	15	47	43
Unspecified	-	-	2
Lost to follow-up	-	-	-
Withdrawal by parent/guardian	1	3	4
Protocol deviation	-	1	-

Number of subjects in period 1	Group 8 (Bexsero +Nimenrix +PLP)	Group 10 (Bexsero +Nimenrix)	Group 11 (MenABCWY +TLP)
Started	55	55	12
Completed	25	22	0
Not completed	30	33	12
Adverse event, serious fatal	-	-	-
Adverse event, non-fatal	1	-	-
No longer meets eligibility criteria	-	1	-
Study terminated by sponsor	29	29	12
Unspecified	-	-	-
Lost to follow-up	-	1	-
Withdrawal by parent/guardian	-	2	-
Protocol deviation	-	-	-

Period 2

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1 (MenABCWY +PLP)

Arm description:

Infant subjects aged 6 months were administered a single intramuscular injection of 0.5 millilitre (mL) MenABCWY into the left thigh. Prophylactic liquid paracetamol regimen (PLP) was administered orally with 3 required doses, the first dose starting 30 minutes before vaccination (Day 1 [primary vaccination {vacc}1] and Month 2 [primary vaccination 2]). Subjects received a single intramuscular injection of MenABCWY approximately 6 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at Day 1.

Arm type	Experimental
Investigational medicinal product name	MenABCWY
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Vaxelis
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Prevenar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Paracetamol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

2.5-mL dose administered orally

Arm title	Group 2 (MenABCWY)

Arm description:

Infant subjects aged 6 months were administered a single intramuscular injection of 0.5 mL MenABCWY into the left thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). Subjects

received a single intramuscular injection of MenABCWY approximately 6 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at Day 1.

Arm type	Experimental
Investigational medicinal product name	MenABCWY
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Vaxelis
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Prevenar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Arm title	Group 3 (60 µg rLP2086 +Nimenrix +PLP/SLP)

Arm description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.25 mL bivalent rLP2086 (60 microgram [µg]) into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). PLP or SLP was administered orally. Subjects received a single intramuscular injection of 0.25 mL bivalent rLP2086 (60 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Arm type	Experimental
Investigational medicinal product name	rLP2086
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.25-mL dose administered intramuscularly

Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Vaxelis
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details: 0.5-mL dose administered intramuscularly	
Investigational medicinal product name	Prevenar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: 0.5-mL dose administered intramuscularly	
Investigational medicinal product name	Paracetamol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use
Dosage and administration details: 2.5-mL dose administered orally	
Arm title	Group 5 (120 µg rLP2086 +Nimenrix +PLP)

Arm description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL of bivalent rLP2086 (120 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). PLP was administered orally with 3 required doses, the first dose starting 30 minutes before vaccination at Day 1 and Month 2. Subjects received a single intramuscular injection of 0.5 mL of bivalent rLP2086 (120 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Arm type	Experimental
Investigational medicinal product name	rLP2086
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: 0.5-mL dose administered intramuscularly	
Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: 0.5-mL dose administered intramuscularly	
Investigational medicinal product name	Paracetamol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use
Dosage and administration details: 2.5-mL dose administered orally	
Arm title	Group 8 (Bexsero +Nimenrix +PLP)

Arm description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL of Bexsero into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). PLP was administered orally with 3 required doses, the first dose starting 30 minutes before vaccination at Day 1 and Month 2. Subjects received a single intramuscular

injection of 0.5 mL of Bexsero into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Arm type	Active comparator
Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Bexsero
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL dose administered intramuscularly

Investigational medicinal product name	Vaxelis
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Prevenar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5-mL dose administered intramuscularly

Investigational medicinal product name	Paracetamol
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

2.5-mL dose administered orally

Arm title	Group 10 (Bexsero +Nimenrix)

Arm description:

Infant subjects aged 2 months were administered single intramuscular injection of Bexsero and Nimenrix into the left thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). Subjects received a single intramuscular injection of Bexsero and Nimenrix approximately 6 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months for age.

Arm type	Active comparator
Investigational medicinal product name	Bexsero
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details: 0.5 mL dose administered intramuscularly	
Investigational medicinal product name	Vaxelis
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: 0.5-mL dose administered intramuscularly	
Investigational medicinal product name	Prevenar 13
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: 0.5-mL dose administered intramuscularly	
Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: 0.5-mL dose administered intramuscularly	

Number of subjects in period 2	Group 1 (MenABCWY +PLP)	Group 2 (MenABCWY)	Group 3 (60 µg rLP2086 +Nimenrix +PLP/SLP)
Started	22	25	20
Completed	22	25	20
Not completed	0	0	0
Lost to follow-up	-	-	-

Number of subjects in period 2	Group 5 (120 µg rLP2086 +Nimenrix +PLP)	Group 8 (Bexsero +Nimenrix +PLP)	Group 10 (Bexsero +Nimenrix)
Started	2	25	22
Completed	2	25	21
Not completed	0	0	1
Lost to follow-up	-	-	1

Reporting groups

Reporting group title	Group 1 (MenABCWY +PLP)

Reporting group description:

Infant subjects aged 6 months were administered a single intramuscular injection of 0.5 millilitre (mL) MenABCWY into the left thigh. Prophylactic liquid paracetamol regimen (PLP) was administered orally with 3 required doses, the first dose starting 30 minutes before vaccination (Day 1 [primary vaccination {vacc}1] and Month 2 [primary vaccination 2]). Subjects received a single intramuscular injection of MenABCWY approximately 6 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at Day 1.

Reporting group title	Group 2 (MenABCWY)

Reporting group description:

Infant subjects aged 6 months were administered a single intramuscular injection of 0.5 mL MenABCWY into the left thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). Subjects received a single intramuscular injection of MenABCWY approximately 6 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at Day 1.

Reporting group title	Group 3 (60 µg rLP2086 +Nimenrix +PLP/SLP)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.25 mL bivalent rLP2086 (60 microgram [µg]) into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). PLP or SLP was administered orally. Subjects received a single intramuscular injection of 0.25 mL bivalent rLP2086 (60 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Reporting group title	Group 4 (60 µg rLP2086 +Nimenrix)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.25 mL of bivalent rLP2086 (60 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). Subjects received a single intramuscular injection of 0.25 mL of bivalent rLP2086 (60 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Reporting group title	Group 5 (120 µg rLP2086 +Nimenrix +PLP)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL of bivalent rLP2086 (120 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). PLP was administered orally with 3 required doses, the first dose starting 30 minutes before vaccination at Day 1 and Month 2. Subjects received a single intramuscular injection of 0.5 mL of bivalent rLP2086 (120 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Reporting group title	Group 7 (MenABCWY +SLP)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL MenABCWY into the left thigh. Scheduled liquid paracetamol (SLP) was administered orally at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). Subjects received a single intramuscular injection of 0.5 mL MenABCWY approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Reporting group title	Group 8 (Bexsero +Nimenrix +PLP)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL of Bexsero into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). PLP was administered orally with 3 required doses, the first dose starting 30 minutes before vaccination at Day 1 and Month 2. Subjects received a single intramuscular injection of 0.5 mL of Bexsero into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single

intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Reporting group title	Group 10 (Bexsero +Nimenrix)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL of Bexsero into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1), Month 2 (primary vaccination 2) and at approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Reporting group title	Group 11 (MenABCWY +TLP)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL MenABCWY into the left thigh at Day 1 (primary vaccination 1). Therapeutic Liquid Paracetamol regimen (TLP) was administered orally. No subjects received Vaccination 2 and booster dose due to study termination. All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 months of age.

Reporting group values	Group 1 (MenABCWY +PLP)	Group 2 (MenABCWY)	Group 3 (60 µg rLP2086 +Nimenrix +PLP/SLP)
Number of subjects	23	25	36
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)	23	25	36
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	158.5	161.6	71.1
standard deviation	± 6.87	± 14.45	± 7.00
Gender Categorical Units: Subjects			
Female	12	10	21
Male	11	15	15
Race Units: Subjects			
White	20	24	35
Black or African American	1	1	1
Asian	0	0	0
Unknown	0	0	0
Multiracial	0	0	0
Not reported	2	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	13	9	21
Non-Hispanic/non-Latino	10	16	15

Reporting group values	Group 4 (60 µg rLP2086 +Nimenrix)	Group 5 (120 µg rLP2086 +Nimenrix +PLP)	Group 7 (MenABCWY +SLP)
Number of subjects	16	53	50
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)	16	53	50
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	67.6	68.9	68.0
standard deviation	± 5.81	± 6.39	± 5.99
Gender Categorical			
Units: Subjects			
Female	7	24	27
Male	9	29	23
Race			
Units: Subjects			
White	16	52	50
Black or African American	0	0	0
Asian	0	0	0
Unknown	0	0	0
Multiracial	0	0	0
Not reported	0	1	0
Ethnicity			
Units: Subjects			
Hispanic or Latino	8	10	25
Non-Hispanic/non-Latino	8	43	25

Reporting group values	Group 8 (Bexsero +Nimenrix +PLP)	Group 10 (Bexsero +Nimenrix)	Group 11 (MenABCWY +TLP)
Number of subjects	55	55	12
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)	55	55	12
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	67.4	67.5	69.4
standard deviation	± 7.89	± 7.30	± 7.69
Gender Categorical Units: Subjects			
Female	32	20	7
Male	23	35	5
Race Units: Subjects			
White	55	55	12
Black or African American	0	0	0
Asian	0	0	0
Unknown	0	0	0
Multiracial	0	0	0
Not reported	0	0	0
Ethnicity Units: Subjects			
Hispanic or Latino	18	22	6
Non-Hispanic/non-Latino	37	33	6

Reporting group values	Total		
Number of subjects	325		
Age Categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	325		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		
Age Continuous Units: days			
arithmetic mean			
standard deviation	-		
Gender Categorical Units: Subjects			
Female	160		
Male	165		
Race Units: Subjects			
White	319		
Black or African American	3		
Asian	0		
Unknown	0		
Multiracial	0		
Not reported	3		

Ethnicity Units: Subjects			
Hispanic or Latino	132		
Non-Hispanic/non-Latino	193		

End points reporting groups

Reporting group title	Group 1 (MenABCWY +PLP)

Reporting group description:

Infant subjects aged 6 months were administered a single intramuscular injection of 0.5 millilitre (mL) MenABCWY into the left thigh. Prophylactic liquid paracetamol regimen (PLP) was administered orally with 3 required doses, the first dose starting 30 minutes before vaccination (Day 1 [primary vaccination {vacc}1] and Month 2 [primary vaccination 2]). Subjects received a single intramuscular injection of MenABCWY approximately 6 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at Day 1.

Reporting group title	Group 2 (MenABCWY)

Reporting group description:

Infant subjects aged 6 months were administered a single intramuscular injection of 0.5 mL MenABCWY into the left thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). Subjects received a single intramuscular injection of MenABCWY approximately 6 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at Day 1.

Reporting group title	Group 3 (60 µg rLP2086 +Nimenrix +PLP/SLP)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.25 mL bivalent rLP2086 (60 microgram [µg]) into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). PLP or SLP was administered orally. Subjects received a single intramuscular injection of 0.25 mL bivalent rLP2086 (60 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Reporting group title	Group 4 (60 µg rLP2086 +Nimenrix)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.25 mL of bivalent rLP2086 (60 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). Subjects received a single intramuscular injection of 0.25 mL of bivalent rLP2086 (60 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Reporting group title	Group 5 (120 µg rLP2086 +Nimenrix +PLP)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL of bivalent rLP2086 (120 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). PLP was administered orally with 3 required doses, the first dose starting 30 minutes before vaccination at Day 1 and Month 2. Subjects received a single intramuscular injection of 0.5 mL of bivalent rLP2086 (120 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Reporting group title	Group 7 (MenABCWY +SLP)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL MenABCWY into the left thigh. Scheduled liquid paracetamol (SLP) was administered orally at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). Subjects received a single intramuscular injection of 0.5 mL MenABCWY approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Reporting group title	Group 8 (Bexsero +Nimenrix +PLP)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL of Bexsero into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). PLP was administered orally with 3 required doses, the first dose starting 30 minutes before vaccination at Day 1 and Month 2. Subjects received a single intramuscular injection of 0.5 mL of Bexsero into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single

intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Reporting group title	Group 10 (Bexsero +Nimenrix)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL of Bexsero into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1), Month 2 (primary vaccination 2) and at approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Reporting group title	Group 11 (MenABCWY +TLP)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL MenABCWY into the left thigh at Day 1 (primary vaccination 1). Therapeutic Liquid Paracetamol regimen (TLP) was administered orally. No subjects received Vaccination 2 and booster dose due to study termination. All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 months of age.

Reporting group title	Group 1 (MenABCWY +PLP)

Reporting group description:

Infant subjects aged 6 months were administered a single intramuscular injection of 0.5 millilitre (mL) MenABCWY into the left thigh. Prophylactic liquid paracetamol regimen (PLP) was administered orally with 3 required doses, the first dose starting 30 minutes before vaccination (Day 1 [primary vaccination {vacc}1] and Month 2 [primary vaccination 2]). Subjects received a single intramuscular injection of MenABCWY approximately 6 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at Day 1.

Reporting group title	Group 2 (MenABCWY)

Reporting group description:

Infant subjects aged 6 months were administered a single intramuscular injection of 0.5 mL MenABCWY into the left thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). Subjects received a single intramuscular injection of MenABCWY approximately 6 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at Day 1.

Reporting group title	Group 3 (60 µg rLP2086 +Nimenrix +PLP/SLP)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.25 mL bivalent rLP2086 (60 microgram [µg]) into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). PLP or SLP was administered orally. Subjects received a single intramuscular injection of 0.25 mL bivalent rLP2086 (60 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Reporting group title	Group 5 (120 µg rLP2086 +Nimenrix +PLP)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL of bivalent rLP2086 (120 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). PLP was administered orally with 3 required doses, the first dose starting 30 minutes before vaccination at Day 1 and Month 2. Subjects received a single intramuscular injection of 0.5 mL of bivalent rLP2086 (120 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Reporting group title	Group 8 (Bexsero +Nimenrix +PLP)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL of Bexsero into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). PLP was administered orally with 3 required doses, the first dose starting 30 minutes before vaccination at Day 1 and Month 2. Subjects received a single intramuscular injection of 0.5 mL of Bexsero into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Reporting group title	Group 10 (Bexsero +Nimenrix)

Reporting group description:

Infant subjects aged 2 months were administered single intramuscular injection of Bexsero and Nimenrix into the left thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2).

Subjects received a single intramuscular injection of Bexsero and Nimenrix approximately 6 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months for age.

Subject analysis set title	Group 7 and 11 Combined
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Group7: Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL MenABCWY into the left thigh. Scheduled liquid paracetamol (SLP) was administered orally at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). Subjects received a single intramuscular injection of 0.5 mL MenABCWY approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age. Group11: Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL MenABCWY into the left thigh at Day 1 (primary vaccination 1). Therapeutic Liquid Paracetamol regimen (TLP) was administered orally. No subjects received Vaccination 2 and booster dose due to study termination. All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 months of age.

Subject analysis set title	Group 8 and 10 Combined
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Group8:Infant subjects aged 2 months were administered single IM injection of 0.5mL of Bexsero into left thigh, 0.5mL of Nimenrix into right thigh at Day 1(primary vaccination 1) and Month 2(primary vaccination 2).PLP was administered orally with 3 required doses,first dose starting 30 minutes before vaccination at Day1 and Month2.Subjects received single IM injection of 0.5mL of Bexsero into left thigh and 0.5mL of Nimenrix into right thigh approximately 10 months after vaccination 1 (booster vaccination).Subjects received single IM injection of Prevenar 13 and Vaxelis into right thigh at 2,4 months of age.Group10:Infant subjects aged 2 months were administered single IM injection of 0.5mL of Bexsero into left thigh,0.5mL of Nimenrix into right thigh at Day 1(primary vaccination 1), Month 2(primary vaccination 2) and approximately 10 months after vaccination1 (booster vaccination).Subjects received single IM injection of Prevenar 13 and Vaxelis into right thigh at 2,4 months of age.

Subject analysis set title	Group 3 and 4 Combined
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Group3:Infant subjects aged 2 months were administered single IM injection of 0.25mL bivalent rLP2086(60µg) into left thigh,0.5mL Nimenrix into right thigh at Day 1(primary vacc 1),Month 2(primary vacc 2).PLP or SLP administered orally.Subjects received single IM injection of 0.25mL bivalent rLP2086(60 µg) into left thigh and 0.5mL Nimenrix into right thigh approx. 10 months after vacc1(booster vacc).Subjects received single IM injection of Prevenar 13,Vaxelis into right thigh at 2 and 4 months of age.Group4: Infant subjects aged 2 months were administered single IM injection of 0.25 mL bivalent rLP2086(60 µg) into left thigh,0.5 mL Nimenrix into right thigh at Day 1(primary vacc 1) and Month 2(primary vacc 2).Subjects received single IM injection of 0.25mL of bivalent rLP2086(60 µg) into left thigh and 0.5 mL of Nimenrix into right thigh approx.10 months after vacc 1(booster vacc).Subjects received single IM injection of Prevenar 13,Vaxelis into right thigh at 2 and 4 months of

Primary: Percentage of Subjects Achieving hSBA Titer >=LLOQ for Each MenA, MenC, MenW and MenY Test Strains 1 Month After Primary Vaccination 2: Group 7 and 11 Combined Versus Group 8 and 10 Combined

End point title	Percentage of Subjects Achieving hSBA Titer >=LLOQ for Each MenA, MenC, MenW and MenY Test Strains 1 Month After Primary Vaccination 2: Group 7 and 11 Combined Versus Group 8 and 10 Combined[1][2]

End point description:

Percentage of subjects achieving serum human complement (hSBA) titer greater than or equal to (>=) lowe limit of quantitation (LLOQ) (1:8) for each MenA, MenC, MenW and MenY test strains were reported in this endpoint. Exact 2-sided confidence interval (CI) using the Clopper and Pearson method was presented. Post-primary vaccination 2 evaluable immunogenicity population: subjects randomized to study group of interest; eligible through Visit (V)4;received vaccine at V1 and V3;blood drawn for assay testing within required timeframes at V4; had at least 1 valid, determinate MenA, MenC, MenW, MenY, or MenB assay result at V4; received no prohibited vaccines/treatment and had no protocol deviations through V4. Here, ''Number of Subjects Analysed'' signifies subjects evaluable for this end point; and 'n'=subjects evaluable for specified rows. No serum samples were collected for subjects in Group 11 due to study termination.

End point type	Primary

End point timeframe:

1 month after primary Vaccination 2

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 7 (MenABCWY +SLP)	Group 8 and 10 Combined		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	16	92		
Units: Percentage of subjects				
number (confidence interval 95%)				
MenA (n=16,90)	100.0 (79.4 to 100.0)	100.0 (96.0 to 100.0)		
MenC (n=16,91)	100.0 (79.4 to 100.0)	100.0 (96.0 to 100.0)		
MenW (n=16,91)	100.0 (79.4 to 100.0)	100.0 (96.0 to 100.0)		
MenY (n=16,92)	100.0 (79.4 to 100.0)	100.0 (96.1 to 100.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Achieving hSBA Titer >= LLOQ for Each MenACWY MenA, MenC, MenW and MenY Test Strains 1 Month After Booster Vaccination: Group 7 and 11 Combined Versus Group 8 and 10 Combined

End point title	Percentage of Subjects Achieving hSBA Titer >= LLOQ for Each MenACWY MenA, MenC, MenW and MenY Test Strains 1 Month After Booster Vaccination: Group 7 and 11 Combined Versus Group 8 and 10 Combined[3]

End point description:

Percentage of subjects achieving hSBA titer >= LLOQ (1:8) for each MenA, MenC, MenW and MenY test strains were reported in this endpoint. Exact 2-sided CI using the Clopper and Pearson method was presented. Post–booster vaccination evaluable immunogenicity population: subjects randomized to study group of interest; eligible through V6;received vaccine at V1, V3 and 5;blood drawn for assay testing within required timeframes at V6; had at least 1 valid, determinate MenA, MenC, MenW, MenY, or MenB assay result at V6; received no prohibited vaccines/treatment and had no protocol deviations through V6. Here, ''Number of Subjects Analysed'' signifies subjects evaluable for this end point; and 'n'=subjects evaluable for specified rows. No serum samples were collected post-booster for subjects in Group 7 and Group 11 due to study termination.

End point type	Primary

End point timeframe:

1 Month after booster vaccination

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 8 and 10 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	42			
Units: Percentage of subjects				
number (confidence interval 95%)				
MenA (n=41,0)	100.0 (91.4 to 100.0)			
MenC (n=41,0)	100.0 (91.4 to 100.0)			
MenW (n=42,0)	100.0 (91.6 to 100.0)			
MenY (n=41,0)	100.0 (91.4 to 100.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Achieving hSBA Titer >= LLOQ for Each Neisseria Meningitidis Group B (MenB) Test Strain 1 Month After Primary Vaccination 2: Group 7 and 11 Combined Versus Group 8 and 10 Combined

End point title	Percentage of Subjects Achieving hSBA Titer >= LLOQ for Each Neisseria Meningitidis Group B (MenB) Test Strain 1 Month After Primary Vaccination 2: Group 7 and 11 Combined Versus Group 8 and 10 Combined[4][5]

End point description:

Percentage of subjects achieving hSBA titer>= LLOQ for each MenB test strain(1:16 for strainA22 and1:8 for strain B44)reported.Exact 2-sided CI using Clopper and Pearson method.Post-primary vaccination 2 evaluable immunogenicity population=subjects randomised to study group of interest,eligible through Visit 4:fulfilling all inclusion criteria and none of exclusion criteria at each visit where eligibility criteria collected and confirmed,received investigational products at Visits1, 3 as randomised,blood drawn for assay testing within required time frames at Visit 4(1month after primary vaccination 2 [window 28-42 days]),at least 1 valid,determinate MenA,MenC,MenW,MenY, or MenB assay result at Visit 4,received no prohibited vaccines or treatment through Visit 4,no important protocol deviations through Visit 4.Here, ''Number of Subjects Analysed'' signifies subjects evaluable for this end point; and 'n'=subjects evaluable for specified rows.

End point type	Primary

End point timeframe:

1 Month After primary Vaccination 2

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 7 (MenABCWY +SLP)	Group 8 and 10 Combined		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	18	95		
Units: Percentage of subjects				
number (confidence interval 95%)				

PMB80 (A22) n=18, 94	44.4 (21.5 to 69.2)	9.6 (4.5 to 17.4)		
PMB2707 (B44) n=18,95	88.9 (65.3 to 98.6)	29.5 (20.6 to 39.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Achieving hSBA Titer >= LLOQ for Each Neisseria Meningitidis Group B (MenB) Test Strain 1 Month After Primary Vaccination 2: Group 3 and 4 Combined Versus Group 5

End point title	Percentage of Subjects Achieving hSBA Titer >= LLOQ for Each Neisseria Meningitidis Group B (MenB) Test Strain 1 Month After Primary Vaccination 2: Group 3 and 4 Combined Versus Group 5[6][7]

End point description:

Percentage of subjects achieving hSBA titer>= LLOQ for each MenB test strain(1:16 for strainA22 and1:8 for strain B44)reported.Exact 2-sided CI using Clopper and Pearson method.Post-primary vaccination 2 evaluable immunogenicity population=subjects randomised to study group of interest,eligible through Visit 4:fulfilling all inclusion criteria and none of exclusion criteria at each visit where eligibility criteria collected and confirmed,received investigational products at Visits1, 3 as randomised,blood drawn for assay testing within required time frames at Visit 4(1month after primary vaccination 2 [window 28-42 days]),at least 1 valid,determinate MenA,MenC,MenW,MenY, or MenB assay result at Visit 4,received no prohibited vaccines or treatment through Visit 4,no important protocol deviations through Visit 4. Here, ''Number of Subjects Analysed'' signifies subjects evaluable for this end point; and 'n'=subjects evaluable for specified rows.

End point type	Primary

End point timeframe:

1 Month after primary vaccination 2

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 5 (120 µg rLP2086 +Nimenrix +PLP)	Group 3 and 4 Combined		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	44	30		
Units: Percentage of subjects				
number (confidence interval 95%)				
PMB80 (A22) n=44,30	47.7 (32.5 to 63.3)	46.7 (28.3 to 65.7)		
PMB2707 (B44) n=45, 35	97.8 (88.2 to 99.9)	82.9 (66.4 to 93.4)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Achieving hSBA Titer >= LLOQ for Each MenB Test Strain 1 Month After Booster Vaccination: Group 7 and 11 Combined Versus Group 8 and 10 Combined

End point title	Percentage of Subjects Achieving hSBA Titer >= LLOQ for Each MenB Test Strain 1 Month After Booster Vaccination: Group 7 and 11 Combined Versus Group 8 and 10 Combined[8]

End point description:

Percentage of subjects achieving hSBA titer>= LLOQ for each MenB test strain(1:16 for strain A22 and1:8 for strain B44)reported.Exact 2-sided CI using Clopper and Pearson method.Post–booster vaccination evaluable immunogenicity population=randomised to study group of interest,eligible through Visit 6, ie, fulfilling inclusion criteria,none of exclusion criteria at each visit where eligibility criteria were collected and confirmed.Received investigational products at Visits1,3,5 as randomised,blood drawn for assay testing within required time frames at Visit 6(1 month after booster vaccination[window 28-42 days]).At least 1 valid and determinate MenA,MenC, MenW,MenY,orMenB assay result at Visit 6, received no prohibited vaccines or treatment through Visit 6,no important protocol deviations through Visit 6.Number of subjects analysed=subjects evaluable for end point;n=subjects evaluable for specific rows.No serum sample collected for subjects in Group 7 and 11 due to study termination.

End point type	Primary

End point timeframe:

1 Month after booster vaccination

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 8 and 10 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	41			
Units: Percentage of subjects				
number (confidence interval 95%)				
PMB80 (A22) n=40,0	25.0 (12.7 to 41.2)			
PMB2707 (B44) n=41,0	34.1 (20.1 to 50.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects Achieving hSBA Titer >= LLOQ for Each MenB Test Strain 1 Month After Booster Vaccination: Groups 3, 4 and 5

End point title	Percentage of Subjects Achieving hSBA Titer >= LLOQ for Each MenB Test Strain 1 Month After Booster Vaccination: Groups 3, 4 and 5[9][10]

End point description:

Percentage of subjects achieving hSBA titer >= LLOQ for each MenB test strain(1:16 for strain A22 and 1:8 for strain B44)reported.Exact 2-sided CI using Clopper and Pearson method.Post–booster vaccination evaluable immunogenicity population= randomised to study group of interest,eligible through Visit 6, ie, fulfilling inclusion criteria,none of exclusion criteria at each visit where eligibility criteria were collected and confirmed.Received investigational products at Visits 1, 3, 5 as randomised,blood drawn for assay testing within required time frames at Visit 6(1 month after booster vaccination[window 28-42 days]).At least 1 valid and determinate MenA,MenC, MenW,MenY,orMenB assay result at Visit 6, received no prohibited vaccines or treatment through Visit 6,no important

through Visit 6.Number of subjects analysed=subjects evaluable for end point.

End point type	Primary

End point timeframe:

1 Month after booster vaccination

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 3 (60 µg rLP2086 +Nimenrix +PLP/SLP)	Group 4 (60 µg rLP2086 +Nimenrix)	Group 5 (120 µg rLP2086 +Nimenrix +PLP)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	18	0[11]	0[12]	
Units: Percentage of subjects				
number (confidence interval 95%)				
PMB80 (A22)	38.9 (17.3 to 64.3)	(to)	(to)	
PMB2707 (B44)	83.3 (58.6 to 96.4)	(to)	(to)	

Notes:

[11] - No serum samples were collected for subjects in this group due to study termination.

[12] - No serum samples were collected for subjects in this group due to study termination.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Local Reactions Within 7 Days After Primary Vaccination 1: Group 7 and 11 Combined Versus Group 8 and 10 Combined

End point title	Percentage of Subjects With Local Reactions Within 7 Days After Primary Vaccination 1: Group 7 and 11 Combined Versus Group 8 and 10 Combined[13]

End point description:

Local reactions included tenderness at injection site, redness and swelling and were recorded by subject's parents/legal guardians in an electronic diary (e-diary). Redness and swelling were measured and recorded in caliper units. 1 caliper unit =0.5 centimeter (cm) and graded as mild: 0.5 to 2.0 cm, moderate: >2.0 to 7.0 cm and severe: >7.0 cm. Tenderness at injection site was graded as mild: hurt if gently touched, moderate: hurt if gently touched with crying and severe: caused limitation of limb movement. Exact 2-sided CI was based on the Clopper and Pearson method. Primary vaccination 1 safety population included all randomised subjects who received the first dose of investigational product at Visit 1 and had safety follow-up between Visit 1 and prior to Visit 3. Here, 'Number of Subjects Analysed' (N)=subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Within 7 Days after primary Vaccination 1

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 7 and 11 Combined	Group 8 and 10 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	62	108		
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Mild	22.6 (12.9 to 35.0)	23.1 (15.6 to 32.2)		
Redness: Moderate	11.3 (4.7 to 21.9)	6.5 (2.6 to 12.9)		
Redness: Severe	0 (0.0 to 5.8)	0 (0.0 to 3.4)		
Swelling: Mild	21.0 (11.7 to 33.2)	22.2 (14.8 to 31.2)		
Swelling: Moderate	17.7 (9.2 to 29.5)	12.0 (6.6 to 19.7)		
Swelling: Severe	0 (0.0 to 5.8)	0 (0.0 to 3.4)		
Tenderness at injection site: Mild	22.6 (12.9 to 35.0)	25.9 (18.0 to 35.2)		
Tenderness at injection site: Moderate	48.4 (35.5 to 61.4)	24.1 (16.4 to 33.3)		
Tenderness at injection site: Severe	0 (0.0 to 5.8)	0.9 (0.0 to 5.1)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Local Reactions Within 7 Days After Primary Vaccination 2: Group 7 and 11 Combined Versus Group 8 and 10 Combined

End point title	Percentage of Subjects With Local Reactions Within 7 Days After Primary Vaccination 2: Group 7 and 11 Combined Versus Group 8 and 10 Combined[14]

End point description:

Local reactions included tenderness at injection site, redness and swelling and were recorded by subject's parents/legal guardians in an electronic diary (e-diary). Redness and swelling were measured and recorded in caliper units. 1 caliper unit =0.5 centimeter (cm) and graded as mild: 0.5 to 2.0 cm, moderate: >2.0 to 7.0 cm and severe: >7.0 cm. Tenderness at injection site was graded as mild: hurt if gently touched, moderate: hurt if gently touched with crying and severe: caused limitation of limb movement. Exact 2-sided CI was based on the Clopper and Pearson method. Primary vaccination 2 safety population included all subjects who received the second dose of investigational product at Visit 3 and who had safety follow-up between Visit 3 and prior to Visit 4. Here, 'Number of Subjects Analysed' (N)=subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Within 7 Days after primary Vaccination 2

Notes:

[14] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 7 and 11 Combined	Group 8 and 10 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	41	107		
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Mild	26.8 (14.2 to 42.9)	27.1 (19.0 to 36.6)		
Redness: Moderate	12.2 (4.1 to 26.2)	11.2 (5.9 to 18.8)		
Redness: Severe	0 (0.0 to 8.6)	0 (0.0 to 3.4)		
Swelling: Mild	19.5 (8.8 to 34.9)	25.2 (17.3 to 34.6)		
Swelling: Moderate	14.6 (5.6 to 29.2)	12.1 (6.6 to 19.9)		
Swelling: Severe	0 (0.0 to 8.6)	0 (0.0 to 3.4)		
Tenderness at injection site: Mild	22.0 (10.6 to 37.6)	27.1 (19.0 to 36.6)		
Tenderness at injection site: Moderate	34.1 (20.1 to 50.6)	23.4 (15.7 to 32.5)		
Tenderness at injection site: Severe	4.9 (0.6 to 16.5)	2.8 (0.6 to 8.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Systemic Events and Antipyretic use Within 7 Days After Primary Vaccination 1: Group 7 and 11 Combined Versus Group 8 and 10 Combined

End point title	Percentage of Subjects With Systemic Events and Antipyretic use Within 7 Days After Primary Vaccination 1: Group 7 and 11 Combined Versus Group 8 and 10 Combined[15]

End point description:

Systemic events were recorded by subject's parents/legal guardians in e-diary. Fever was defined as temperature >=38.0 degrees (deg) Celsius(C) and was categorised as 38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C. Exact 2-sided CI was based on the Clopper and Pearson method. Decreased appetite was categorized as Mild:decreased interest in eating, Moderate:decreased oral intake,Severe: refusal to feed. Drowsiness: Mild: Increased or prolonged sleeping bouts,Moderate: Slightly subdued interfering with daily activity, Severe; Disabling, not interested in usual daily activity. Irritability; Mild: Easily consolable, Moderate: requiring increased attention,Severe: Inconsolable; crying could not be comforted. Primary vaccination 1 safety population included all randomised subjects who received the first dose of investigational product at Visit 1 and had safety follow-up between Visit 1 and prior to Visit 3. Here, 'N'=subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Within 7 Days after primary Vaccination 1

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 7 and 11 Combined	Group 8 and 10 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	62	108		
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: ≥38.0°C	62.9 (49.7 to 74.8)	21.3 (14.0 to 30.2)		
Fever: 38.0°C to 38.4°C	29.0 (18.2 to 41.9)	15.7 (9.4 to 24.0)		
Fever: >38.4°C to 38.9°C	24.2 (14.2 to 36.7)	5.6 (2.1 to 11.7)		
Fever: >38.9°C to 40.0°C	9.7 (3.6 to 19.9)	0 (0.0 to 3.4)		
Fever: >40.0°C	0 (0.0 to 5.8)	0 (0.0 to 3.4)		
Decreased appetite: Mild	17.7 (9.2 to 29.5)	17.6 (10.9 to 26.1)		
Decreased appetite: Moderate	43.5 (31.0 to 56.7)	21.3 (14.0 to 30.2)		
Decreased appetite: Severe	4.8 (1.0 to 13.5)	0.9 (0.0 to 5.1)		
Irritability: Mild	21.0 (11.7 to 33.2)	19.4 (12.5 to 28.2)		
Irritability: Moderate	59.7 (46.4 to 71.9)	45.4 (35.8 to 55.2)		
Irritability: Severe	14.5 (6.9 to 25.8)	6.5 (2.6 to 12.9)		
Drowsiness: Mild	37.1 (25.2 to 50.3)	39.8 (30.5 to 49.7)		
Drowsiness: Moderate	32.3 (20.9 to 45.3)	18.5 (11.7 to 27.1)		
Drowsiness: Severe	4.8 (1.0 to 13.5)	0.9 (0.000 to 5.1)		
Use of antipyretic medication	46.8 (34.0 to 59.9)	50.0 (40.2 to 59.8)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Systemic Events and Antipyretic use Within 7 Days After Primary Vaccination 2: Group 7 and 11 Combined Versus Group 8 and 10 Combined

End point title	Percentage of Subjects With Systemic Events and Antipyretic use Within 7 Days After Primary Vaccination 2: Group 7 and 11 Combined Versus Group 8 and 10 Combined[16]

End point description:

Systemic events were recorded by subject's parents/legal guardians in e-diary. Fever was defined as temperature >=38.0 degrees (deg) Celsius(C) and was categorised as 38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C. Exact 2-sided CI was based on the Clopper and Pearson method. Decreased appetite was categorized as Mild:decreased interest in eating, Moderate:decreased oral intake,Severe: refusal to feed. Drowsiness: Mild: Increased or prolonged sleeping bouts,Moderate: Slightly subdued interfering with daily activity, Severe; Disabling, not interested in usual daily activity. Irritability; Mild: Easily consolable, Moderate: requiring increased attention,Severe: Inconsolable; crying could not be comforted. Primary vaccination 2 safety population included all subjects who received the second dose of investigational product at Visit 3 and who had safety follow-up between Visit 3 and prior to Visit 4. Here, 'N'=subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Within 7 Days after primary Vaccination 2

Notes:

[16] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 7 and 11 Combined	Group 8 and 10 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	41	107		
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: ≥38.0°C	65.9 (49.4 to 79.9)	48.6 (38.8 to 58.5)		
Fever: 38.0°C to 38.4°C	26.8 (14.2 to 42.9)	31.8 (23.1 to 41.5)		
Fever: >38.4°C to 38.9°C	26.8 (14.2 to 42.9)	14.0 (8.1 to 22.1)		
Fever: >38.9°C to 40.0°C	12.2 (4.1 to 26.2)	2.8 (0.6 to 8.0)		
Fever: >40.0°C	0 (0.0 to 8.6)	0 (0.0 to 3.4)		
Decreased appetite: Mild	22.0 (10.6 to 37.6)	20.6 (13.4 to 29.5)		
Decreased appetite: Moderate	31.7 (18.1 to 48.1)	25.2 (17.3 to 34.6)		
Decreased appetite: Severe	4.9 (0.6 to 16.5)	3.7 (1.0 to 9.3)		
Irritability: Mild	12.2 (4.1 to 26.2)	21.5 (14.1 to 30.5)		
Irritability: Moderate	53.7 (37.4 to 69.3)	48.6 (38.8 to 58.5)		
Irritability: Severe	22.0 (10.6 to 37.6)	6.5 (2.7 to 13.0)		
Drowsiness: Mild	29.3 (16.1 to 45.5)	45.8 (36.1 to 55.7)		
Drowsiness: Moderate	34.1 (20.1 to 50.6)	14.0 (8.1 to 22.1)		
Drowsiness: Severe	4.9 (0.6 to 16.5)	0.9 (0.0 to 5.1)		
Use of antipyretic medication	41.5 (26.3 to 57.9)	72.9 (63.4 to 81.0)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With AEs, SAEs, MAEs and NDCMC Within 30 Days After Primary Vaccination 1: Group 7 and 11 Combined Versus Group 8 and 10 Combined

End point title	Percentage of Subjects With AEs, SAEs, MAEs and NDCMC Within 30 Days After Primary Vaccination 1: Group 7 and 11 Combined Versus Group 8 and 10 Combined[17]

End point description:

An Adverse Event (AE) was any untoward medical occurrence in a subject, temporally associated with the use of investigational product, whether or not considered related to the investigational product.

Serious Adverse Events (SAE) was any untoward medical occurrence that, at any dose: resulted in death; required inpatient hospitalisation or prolongation of existing hospitalisation; was life-threatening; resulted in persistent disability/incapacity; congenital anomaly/birth defect and other important medical events. Medically Attended Adverse Events (MAE) was defined as a nonserious AE that resulted in an evaluation at a medical facility.Newly Diagnosed Chronic Medical Condition (NDCMC) was defined as a disease or medical condition, not previously identified, that is expected to be persistent or otherwise long-lasting in its effects. Safety population included all randomised subjects who received at least 1 dose of investigational product and had safety data reported after vaccination.

End point type	Primary

End point timeframe:

Within 30 Days after primary Vaccination 1

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 7 and 11 Combined	Group 8 and 10 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	62	110		
Units: Percentage of subjects				
number (not applicable)				
AEs	24.2	16.4		
SAEs	4.8	0		
MAEs	14.5	10.0		
NDCMCs	0	0.9		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With AEs, SAEs, MAEs and NDCMC Within 30 Days After any Primary Vaccination: Group 7 and 11 Combined Versus Group 8 and 10 Combined

End point title	Percentage of Subjects With AEs, SAEs, MAEs and NDCMC Within 30 Days After any Primary Vaccination: Group 7 and 11 Combined Versus Group 8 and 10 Combined[18]

End point description:

An AE was any untoward medical occurrence in a subject, temporally associated with the use of investigational product, whether or not considered related to the investigational product. SAE was any untoward medical occurrence that, at any dose: resulted in death; required inpatient hospitalisation or prolongation of existing hospitalisation; was life-threatening; resulted in persistent disability/incapacity; congenital anomaly/birth defect and other important medical events. MAE was defined as a nonserious AE that resulted in an evaluation at a medical facility. NDCMC was defined as a disease or medical condition, not previously identified, that is expected to be persistent or otherwise long-lasting in its effects. Safety population included all randomised subjects who received at least 1 dose of investigational product and had safety data reported after vaccination.

End point type	Primary

End point timeframe:

Within 30 Days after any primary Vaccination

Notes:

[18] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 7 and 11 Combined	Group 8 and 10 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	62	110		
Units: Percentage of subjects				
number (not applicable)				
AEs	40.3	24.5		
SAEs	6.5	0		
MAEs	29.0	16.4		
NDCMC	0	0.9		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With AEs, SAEs,MAEs and NDCMC Within 30 Days After Primary Vaccination 2: Group 7 and 11 Combined Versus Group 8 and 10 Combined

End point title	Percentage of Subjects With AEs, SAEs,MAEs and NDCMC Within 30 Days After Primary Vaccination 2: Group 7 and 11 Combined Versus Group 8 and 10 Combined[19]

End point description:

An AE was any untoward medical occurrence in a subject, temporally associated with the use of investigational product, whether or not considered related to the investigational product. SAE was any untoward medical occurrence that, at any dose: resulted in death; required inpatient hospitalisation or prolongation of existing hospitalisation; was life-threatening; resulted in persistent disability/incapacity; congenital anomaly/birth defect and other important medical events. MAE was defined as a nonserious AE that resulted in an evaluation at a medical facility. NDCMC was defined as a disease or medical condition, not previously identified, that is expected to be persistent or otherwise long-lasting in its effects. Safety population included all randomised subjects who received at least 1 dose of investigational product and had safety data reported after vaccination. Here, 'N'=subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Within 30 Days after primary Vaccination 2

Notes:

[19] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 7 and 11 Combined	Group 8 and 10 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	109		
Units: Percentage of subjects				
number (not applicable)				
AEs	33.3	12.8		
SAEs	2.4	0		
MAEs	23.8	11.0		
NDCMC	0	0.9		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With AEs, SAEs, MAEs and NDCMC During Primary Series Vaccination Phase: Group 7 and 11 Combined Versus Group 8 and 10 Combined

End point title	Percentage of Subjects With AEs, SAEs, MAEs and NDCMC During Primary Series Vaccination Phase: Group 7 and 11 Combined Versus Group 8 and 10 Combined[20]

End point description:

An AE was any untoward medical occurrence in a subject, temporally associated with the use of investigational product, whether or not considered related to the investigational product. SAE was any untoward medical occurrence that, at any dose: resulted in death; required inpatient hospitalisation or prolongation of existing hospitalisation; was life-threatening; resulted in persistent disability/incapacity; congenital anomaly/birth defect and other important medical events. MAE was defined as a nonserious AE that resulted in an evaluation at a medical facility. NDCMC was defined as a disease or medical condition, not previously identified, that is expected to be persistent or otherwise long-lasting in its effects. Safety population included all randomised subjects who received at least 1 dose of investigational product and had safety data reported after vaccination.

End point type	Primary

End point timeframe:

From day of primary vaccination 1 at Day 1 up to 1 month after primary vaccination 2

Notes:

[20] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 7 and 11 Combined	Group 8 and 10 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	62	110		
Units: Percentage of subjects				
number (not applicable)				
AEs	56.5	33.6		
SAEs	6.5	1.8		
MAEs	43.5	24.5		
NDCMC	1.6	0.9		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With SAEs, MAEs and NDCMC Throughout Primary Series Stage: Group 7 and 11 Combined Versus Group 8 and 10 Combined

End point title	Percentage of Subjects With SAEs, MAEs and NDCMC Throughout Primary Series Stage: Group 7 and 11 Combined Versus Group 8 and 10 Combined[21]

End point description:

An AE was any untoward medical occurrence in a subject, temporally associated with the use of investigational product, whether or not considered related to the investigational product. SAE was any untoward medical occurrence that, at any dose: resulted in death; required inpatient hospitalisation or prolongation of existing hospitalisation; was life-threatening; resulted in persistent disability/incapacity; congenital anomaly/birth defect and other important medical events. MAE was defined as a nonserious AE that resulted in an evaluation at a medical facility. NDCMC was defined as a disease or medical condition, not previously identified, that is expected to be persistent or otherwise long-lasting in its

effects. Safety population included all randomised subjects who received at least 1 dose of investigational product and had safety data reported after vaccination.

End point type	Primary

End point timeframe:

From the date of primary vaccination 1 up to 8 months after primary vaccination 2

Notes:

[21] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 7 and 11 Combined	Group 8 and 10 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	62	110		
Units: Percentage of subjects				
number (not applicable)				
AEs	59.7	40.0		
SAEs	9.7	4.5		
MAEs	45.2	30.0		
NDCMC	1.6	1.8		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With SAEs, MAEs and NDCMC During Primary Series Follow-up Phase: Group 7 and 11 Combined Versus Group 8 and 10 Combined

End point title	Percentage of Subjects With SAEs, MAEs and NDCMC During Primary Series Follow-up Phase: Group 7 and 11 Combined Versus Group 8 and 10 Combined[22]

End point description:

An AE was any untoward medical occurrence in a subject, temporally associated with the use of investigational product, whether or not considered related to the investigational product. SAE was any untoward medical occurrence that, at any dose: resulted in death; required inpatient hospitalisation or prolongation of existing hospitalisation; was life-threatening; resulted in persistent disability/incapacity; congenital anomaly/birth defect and other important medical events. MAE was defined as a nonserious AE that resulted in an evaluation at a medical facility. NDCMC was defined as a disease or medical condition, not previously identified, that is expected to be persistent or otherwise long-lasting in its effects. Safety population included all randomised subjects who received at least 1 dose of investigational product and had safety data reported after vaccination. Here, 'N'=subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

From 1 month after primary vaccination 2 up to booster vaccination

Notes:

[22] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 7 and 11 Combined	Group 8 and 10 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	41	109		
Units: Percentage of subjects				
number (not applicable)				
AEs	17.1	18.3		
SAEs	4.9	2.8		
MAEs	12.2	15.6		
NDCMC	0	0.9		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Immediate AE Within 30 Minutes After Primary Vaccination 2: Groups 7 and 11 Combined Versus Groups 8 and 10 Combined

End point title	Percentage of Subjects With Immediate AE Within 30 Minutes After Primary Vaccination 2: Groups 7 and 11 Combined Versus Groups 8 and 10 Combined[23]

End point description:

Immediate AEs were defined as AEs occurring within the first 30 minutes after investigational product administration. Safety population included all randomised subjects who received at least 1 dose of investigational product and had safety data reported after vaccination.

End point type	Primary

End point timeframe:

Within 30 Minutes After Primary Vaccination 2

Notes:

[23] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 7 and 11 Combined	Group 8 and 10 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	109		
Units: Percentage of subjects				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Immediate AE Within 30 Minutes After Primary Vaccination 1: Groups 7 and 11 Combined Versus Groups 8 and 10 Combined

End point title	Percentage of Subjects With Immediate AE Within 30 Minutes After Primary Vaccination 1: Groups 7 and 11 Combined Versus Groups 8 and 10 Combined[24]

End point description:

Immediate AEs were defined as AEs occurring within the first 30 minutes after investigational product administration. Safety population included all randomised subjects who received at least 1 dose of investigational product and had safety data reported after vaccination.

End point type	Primary

End point timeframe:

Within 30 Minutes After Primary Vaccination 1

Notes:

[24] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 7 and 11 Combined	Group 8 and 10 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	62	110		
Units: Percentage of subjects				
number (not applicable)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Local Reactions Within 7 Days After Booster Vaccination: Group 7 and 11 Combined Versus Group 8 and 10 Combined

End point title	Number of Subjects With Local Reactions Within 7 Days After Booster Vaccination: Group 7 and 11 Combined Versus Group 8 and 10 Combined[25]

End point description:

Local reactions included tenderness at injection site, redness and swelling and were recorded by subject’s parents/legal guardians in an electronic diary (e-diary). Redness and swelling were measured and recorded in caliper units. 1 caliper unit =0.5 centimeter (cm) and graded as mild: 0.5 to 2.0 cm, moderate: >2.0 to 7.0 cm and severe: >7.0 cm. Tenderness at injection site was graded as mild: hurt if gently touched, moderate: hurt if gently touched with crying and severe: caused limitation of limb movement. Exact 2-sided CI was based on the Clopper and Pearson method. Primary vaccination 2 safety population included all subjects who received the second dose of investigational product at Visit 3 and who had safety follow-up between Visit 3 and prior to Visit 4. Here, ‘N'=subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Within 7 Days after booster vaccination

Notes:

[25] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 7 and 11 Combined	Group 8 and 10 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[26]	92		
Units: Subjects				
Redness		38		
Swelling		35		
Tenderness at injection site		63		

Notes:

[26] - Subjects did not receive booster vaccination due to study termination.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Systemic Events and Antipyretic Use Within 7 Days After Booster Vaccination: Group 7 and 11 Combined Versus Group 8 and 10 Combined

End point title	Percentage of Subjects With Systemic Events and Antipyretic Use Within 7 Days After Booster Vaccination: Group 7 and 11 Combined Versus Group 8 and 10 Combined[27]

End point description:

Systemic events were recorded by subject's parents/legal guardians in e-diary.Fever was defined as temperature >=38.0deg C, categorised as 38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C. Exact 2-sided CI based on Clopper and Pearson method.Decreased appetite categorised as Mild:decreased interest in eating, Moderate:decreased oral intake,Severe: refusal to feed. Drowsiness: Mild: Increased or prolonged sleeping bouts,Moderate: Slightly subdued interfering with daily activity,Severe; Disabling, not interested in usual daily activity.Irritability;Mild: Easily consolable, Moderate: requiring increased attention,Severe: Inconsolable; crying could not be comforted.Booster vaccination safety population included subjects who received booster dose of investigational product, had safety follow-up between Visit 5 and prior to Visit 6. Here,'N'=subjects evaluable for this endpoint. No subjects received booster vaccination in Group 7 and 11 due to study termination.

End point type	Primary

End point timeframe:

Within 7 Days after booster vaccination

Notes:

[27] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 8 and 10 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	91			
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: >=38.0°C	35.2 (25.4 to 45.9)			
Fever: 38.0°C to 38.4°C	19.8 (12.2 to 29.4)			
Fever: >38.4°C to 38.9°C	11.0 (5.4 to 19.3)			
Fever: >38.9°C to 40.0°C	4.4 (1.2 to 10.9)			
Fever: >40.0°C	0 (0.0 to 4.0)			
Decreased appetite: Mild	17.6 (10.4 to 27.0)			
Decreased appetite: Moderate	27.5 (18.6 to 37.8)			
Decreased appetite: Severe	2.2 (0.3 to 7.7)			
Irritability: Mild	22.0 (14.0 to 31.9)			

Irritability: Moderate	42.9 (32.5 to 53.7)			
Irritability: Severe	7.7 (3.1 to 15.2)			
Drowsiness: Mild	26.4 (17.7 to 36.7)			
Drowsiness: Moderate	18.7 (11.3 to 28.2)			
Drowsiness: Severe	1.1 (0.0 to 6.0)			
Use of antipyretic medication	63.7 (53.0 to 73.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With Immediate AE After Booster Vaccination: Group 7 and 11 Combined Versus Group 8 and 10 Combined

End point title	Percentage of Subjects With Immediate AE After Booster Vaccination: Group 7 and 11 Combined Versus Group 8 and 10 Combined[28]

End point description:

Immediate AEs were defined as AEs occurring within the first 30 minutes after investigational product administration. Safety population included all randomised subjects who received at least 1 dose of investigational product and had safety data reported after vaccination.

End point type	Primary

End point timeframe:

Within 30 minutes after booster vaccination

Notes:

[28] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 7 and 11 Combined	Group 8 and 10 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[29]	92		
Units: Percentage of subjects				
number (not applicable)		0		

Notes:

[29] - No subject received booster vaccination due to study termination.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With AEs, SAEs, MAEs and NDCMC During Booster Vaccination Phase: Group 7 and 11 Combined Versus Group 8 and 10 Combined

End point title	Percentage of Subjects With AEs, SAEs, MAEs and NDCMC During Booster Vaccination Phase: Group 7 and 11 Combined Versus Group 8 and 10 Combined[30]

End point description:

An AE was any untoward medical occurrence in a subject, temporally associated with the use of

investigational product, whether or not considered related to the investigational product. SAE was any untoward medical occurrence that, at any dose: resulted in death; required inpatient hospitalisation or prolongation of existing hospitalisation; was life-threatening; resulted in persistent disability/incapacity; congenital anomaly/birth defect and other important medical events. MAE was defined as a nonserious AE that resulted in an evaluation at a medical facility. NDCMC was defined as a disease or medical condition, not previously identified, that is expected to be persistent or otherwise long-lasting in its effects. Safety population included all randomised subjects who received at least 1 dose of investigational product and had safety data reported after vaccination. Here,'N' signifies subjects evaluable for this end point

End point type	Primary

End point timeframe:

From date of booster vaccination through 1 month after the booster vaccination

Notes:

[30] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 7 and 11 Combined	Group 8 and 10 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[31]	92		
Units: Percentage of subjects				
number (not applicable)				
AEs		27.2		
SAEs		0		
MAEs		92		
NDCMC		0		

Notes:

[31] - No subject received a booster vaccination in these groups due to study termination.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With AEs, SAEs, MAEs and NDCMC Throughout Booster Stage: Group 7 and 11 Combined Versus Group 8 and 10 Combined

End point title	Percentage of Subjects With AEs, SAEs, MAEs and NDCMC Throughout Booster Stage: Group 7 and 11 Combined Versus Group 8 and 10 Combined[32]

End point description:

An AE was any untoward medical occurrence in a subject, temporally associated with the use of investigational product, whether or not considered related to the investigational product. SAE was any untoward medical occurrence that, at any dose: resulted in death; required inpatient hospitalisation or prolongation of existing hospitalisation; was life-threatening; resulted in persistent disability/incapacity; congenital anomaly/birth defect and other important medical events. MAE was defined as a nonserious AE that resulted in an evaluation at a medical facility. NDCMC was defined as a disease or medical condition, not previously identified, that is expected to be persistent or otherwise long-lasting in its effects. Safety population included all randomised subjects who received at least 1 dose of investigational product and had safety data reported after vaccination. Here,'N' signifies subjects evaluable for this end point; and 'n'=subjects evaluable for specified rows.

End point type	Primary

End point timeframe:

From date of booster vaccination up to 6 months after the booster vaccination

Notes:

[32] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 7 and 11 Combined	Group 8 and 10 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[33]	92		
Units: Percentage of subjects				
number (not applicable)				
AEs (n=37)		40.2		
SAEs (n=2)		2.2		
MAEs (n=23)		25.0		
NDCMC (n=0)		0		

Notes:

[33] - No subject received a booster vaccination in these groups due to study termination.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With AEs, SAEs, MAEs and NDCMC During Booster Follow-up Phase: Group 7 and 11 Combined Versus Group 8 and 10 Combined

End point title	Percentage of Subjects With AEs, SAEs, MAEs and NDCMC During Booster Follow-up Phase: Group 7 and 11 Combined Versus Group 8 and 10 Combined[34]

End point description:

An AE was any untoward medical occurrence in a subject, temporally associated with the use of investigational product, whether or not considered related to the investigational product. SAE was any untoward medical occurrence that, at any dose: resulted in death; required inpatient hospitalisation or prolongation of existing hospitalisation; was life-threatening; resulted in persistent disability/incapacity; congenital anomaly/birth defect and other important medical events. MAE was defined as a nonserious AE that resulted in an evaluation at a medical facility. NDCMC was defined as a disease or medical condition, not previously identified, that is expected to be persistent or otherwise long-lasting in its effects. Safety population included all randomised subjects who received at least 1 dose of investigational product and had safety data reported after vaccination. Here,'N' signifies subjects evaluable for this end point; and 'n'=subjects evaluable for specified rows.

End point type	Primary

End point timeframe:

From 1 month after booster vaccination up to 6 months after booster vaccination

Notes:

[34] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 7 and 11 Combined	Group 8 and 10 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[35]	92		
Units: Percentage of Subjects				
number (not applicable)				
AEs (n=16)		17.4		
SAEs (n=2)		2.2		
MAEs (n=14)		15.2		
NDCMC (n=0)		0		

Notes:

[35] - No subject received a booster vaccination in these groups due to study termination.

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA Geometric Mean Titers (GMTs) for Each of the MenB Test Strains: 1 Month After Primary Vaccination 2 in Group 3 and 4 Combined Versus Group 5

End point title	hSBA Geometric Mean Titers (GMTs) for Each of the MenB Test Strains: 1 Month After Primary Vaccination 2 in Group 3 and 4 Combined Versus Group 5[36]

End point description:

GMTs were calculated by exponentiating mean logarithm of titers and CIs were calculated by exponentiating confidence limits based on the Student t distribution for the mean logarithm of the titers. Post-primary vaccination 2 evaluable immunogenicity population: subjects randomized to study group of interest; eligible through Visit (V)4;received vaccine at V1 and V3;blood drawn for assay testing within required timeframes at V4; had at least 1 valid, determinate MenA, MenC, MenW, MenY, or MenB assay result at V4; received no prohibited vaccines/treatment and had no protocol deviations through V4. Here,'N' signifies subjects evaluable for this end point; and 'n'=subjects evaluable for specified rows.

End point type	Secondary

End point timeframe:

1 Month after primary Vaccination 2

Notes:

[36] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 5 (120 µg rLP2086 +Nimenrix +PLP)	Group 3 and 4 Combined		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	35	45		
Units: Titers				
geometric mean (confidence interval 95%)				
PMB80 (A22) n=30, 40	13.9 (10.8 to 18.0)	15.3 (12.1 to 19.3)		
PMB2707 (B44) n=35, 45	13.4 (9.8 to 18.3)	25.0 (19.9 to 31.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Local Reactions Within 7 Days After Each Primary Vaccination: Group 3, 4 and 5

End point title	Percentage of Subjects With Local Reactions Within 7 Days After Each Primary Vaccination: Group 3, 4 and 5[37]

End point description:

Local reactions included pain at injection site, redness and swelling and were recorded by subjects in an electronic diary (e-diary). Redness and swelling were measured and recorded in caliper units. 1 caliper unit =0.5 centimeter (cm) and graded as mild: >2.0 to 5.0 cm, moderate: >5.0 to 10.0 cm and severe: >10.0 cm. Pain at injection site was graded as mild: did not interfere with daily activity, moderate: interfered with daily activity and severe: prevented daily activity. Percentage of subjects with local reactions at injection site on left arm were reported in this endpoint. Safety population included all randomised subjects who received at least 1 dose of investigational product and had safety data reported after vaccination.

End point type	Secondary

End point timeframe:

Within 7 Days after primary Vaccination(Vac) 1 and 2

Notes:

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

Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 3 (60 µg rLP2086 +Nimenrix +PLP/SLP)	Group 4 (60 µg rLP2086 +Nimenrix)	Group 5 (120 µg rLP2086 +Nimenrix +PLP)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	16	53	
Units: Percentage of subjects				
number (confidence interval 95%)				
Vaccination 1:Redness:Mild(n=36,16,53)	27.8 (14.2 to 45.2)	18.8 (4.0 to 45.6)	13.2 (5.5 to 25.3)	
Vacc1Redness:Moderate9n=36,16,53)	8.3 (1.8 to 22.5)	0 (0.0 to 20.6)	3.8 (0.5 to 13.0)	
Vacc1Redness: Severe(n=36,16,53)	0 (0.0 to 9.7)	0 (0.0 to 20.6)	0 (0.0 to 6.7)	
Vacc1:Swelling: Mild(n=36,16,53)	16.7 (6.4 to 32.8)	6.3 (0.2 to 30.2)	9.4 (3.1 to 20.7)	
Vacc1:Swelling: Moderate(n=36,16,53)	11.1 (3.1 to 26.1)	12.5 (1.6 to 38.3)	5.7 (1.2 to 15.7)	
Vacc1:Swelling: Severe(n=36,16,53)	0 (0. to 9.7)	0 (0.0 to 20.6)	0 (0.0 to 6.7)	
Vac1Tenderness at inj.site:Mildn=36,16,53)	19.4 (8.2 to 36.0)	12.5 (1.6 to 38.3)	22.6 (12.3 to 36.2)	
Vac1Tenderness at inj.site: Moderate(n=36,16,53)	16.0 (4.5 to 36.1)	41.7 (25.5 to 59.2)	18.8 (4.0 to 45.6)	
Vac1Tenderness at inj.site: Severe(n=36,16,53)	0 (0.0 to 9.7)	0 (0.0 to 20.6)	1.9 (0.0 to 10.1)	
Vac2RednessMild(n=21,16,52)	38.1 (18.1 to 61.6)	18.8 (4.0 to 45.6)	23.1 (12.5 to 36.8)	
Vac2Redness Moderate(n=21,16,52)	4.8 (0.1 to 23.8)	0 (0.0 to 20.6)	3.8 (0.5 to 13.2)	
Vac2Redness Severe(n=21,16,52)	0 (0.0 to 16.1)	0 (0.0 to 20.6)	0 (0.0 to 6.8)	
Vac2Swelling Mild(n=21,16,52)	19.0 (5.4 to 41.9)	12.5 (1.6 to 38.3)	9.6 (3.2 to 21.0)	
Vac2SwellingModerate(n=21,16,52)	0 (0.0 to 16.1)	12.5 (1.6 to 38.3)	1.9 (0.0 to 10.3)	
Vac2SwellingSevere(n=21,16,52)	0 (0.0 to 16.1)	0 (0.0 to 20.6)	0 (0.0 to 6.8)	
Vac2Tenderness at inj.siteMild(n=21,16,52)	28.6 (11.3 to 52.2)	12.5 (1.6 to 38.3)	32.7 (20.3 to 47.1)	
Vac2Tenderness at inj.siteModerate(n=21,16,52)	9.5 (1.2 to 30.4)	18.8 (4.0 to 45.6)	17.3 (8.2 to 30.3)	
Vac2Tenderness at inj.siteSevere(n=21,16,52)	0 (0.0 to 16.1)	6.3 (0.2 to 30.2)	1.9 (0.0 to 10.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA GMTs for Each of the MenB Test Strains: 1 Month After Booster

Vaccination in Groups 3, 4 and 5

End point title	hSBA GMTs for Each of the MenB Test Strains: 1 Month After Booster Vaccination in Groups 3, 4 and 5[38]

End point description:

GMTs were calculated by exponentiating the mean logarithm of the titers and CIs were calculated by exponentiating the confidence limits based on the Student t distribution for the mean logarithm of the titers. Post-primary vaccination 2 evaluable immunogenicity population=subjects randomised to study group of interest, eligible through Visit 4, ie, fulfilling all inclusion criteria and none of exclusion criteria at each visit where eligibility criteria are collected and confirmed,received investigational products at Visits 1 and 3 as randomized, blood drawn for assay testing within required time frames at Visit 4(1 month after primary vaccination 2 [window 28-42 days]),at least 1 valid,determinate MenA, MenC, MenW, MenY, or MenB assay result at Visit 4,received no prohibited vaccines or treatment through Visit 4 and no important protocol deviations through Visit 4. Here, 'Number of Subjects Analysed'= subjects evaluable for this end point.

End point type	Secondary

End point timeframe:

1 month after booster vaccination

Notes:

[38] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 3 (60 µg rLP2086 +Nimenrix +PLP/SLP)	Group 4 (60 µg rLP2086 +Nimenrix)	Group 5 (120 µg rLP2086 +Nimenrix +PLP)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	18	0[39]	0[40]	
Units: Titers				
geometric mean (confidence interval 95%)				
PMB80 (A22)	21.8 (11.1 to 42.6)	(to)	(to)	
PMB2707 (B44)	25.4 (12.6 to 51.1)	(to)	(to)	

Notes:

[39] - Group 4 had no serum samples collected after Booster vaccination due to study termination

[40] - Group 5 had no serum samples collected after Booster vaccination due to study termination

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Systemic Events and Antipyretic use Within 7 Days After Each Primary Vaccination: Group 3,4 and 5

End point title	Percentage of Subjects With Systemic Events and Antipyretic use Within 7 Days After Each Primary Vaccination: Group 3,4 and 5[41]

End point description:

Systemic events were recorded by subject's parents/legal guardians in e-diary. Fever was defined as temperature >=38.0 degrees (deg) Celsius(C) and was categorised as 38.0 to 38.4 deg C, >38.4 to 38.9 deg C, >38.9 to 40.0 deg C and >40.0 deg C. Exact 2-sided CI was based on the Clopper and Pearson method. Decreased appetite was categorized as Grade 1:decreased interest in eating, Grade 2:decreased oral intake, Grade3: refusal to feed. Drowsiness: Grade 1 Increased or prolonged sleeping bouts,Grade2: Slightly subdued interfering with daily activity, Grade3; Disabling, not interested in usual daily activity. Irritability; Grade1: Easily consolable, Grade2: requiring increased attention,Grade 3: Inconsolable; crying could not be comforted. Primary vaccination 1 safety population included all randomised subjects who received the first dose of investigational product at Visit 1 and had safety follow-up between Visit 1 and prior to Visit 3.

End point type	Secondary

End point timeframe:

Within 7 Days after primary Vaccination 1 and 2

Notes:

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

Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 3 (60 µg rLP2086 +Nimenrix +PLP/SLP)	Group 4 (60 µg rLP2086 +Nimenrix)	Group 5 (120 µg rLP2086 +Nimenrix +PLP)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	16	53	
Units: Percentage of subjects				
number (confidence interval 95%)				
Vac1 Fever≥38.0°C(n=36,16,53)	58.3 (40.8 to 74.5)	25.0 (7.3 to 52.4)	64.2 (49.8 to 76.9)	
Vac1Fever38.0°C to 38.4°C(n=36,16,53)	30.6 (16.3 to 48.1)	18.8 (4.0 to 45.6)	35.8 (23.1 to 50.2)	
Vac1Fever>38.4°C to 38.9°C(n=36,16,53)	27.8 (14.2 to 45.2)	6.3 (0.2 to 30.2)	17.0 (8.1 to 29.8)	
Vac1Fever>38.9°C to 40.0°C(n=36,16,53)	0 (0.0 to 9.7)	0 (0.0 to 20.6)	11.3 (4.3 to 23.0)	
Vac1Fever >40.0°C(n=36,16,53)	0 (0.0 to 9.7)	0 (0.0 to 20.6)	0 (0.0 to 6.7)	
Vac1Decreased appetiteMild(n=36,16,53)	25.0 (12.1 to 42.2)	6.3 (0.2 to 30.2)	28.3 (16.8 to 42.3)	
Vac1Decreased appetiteModerate(n=36,16,53)	22.2 (10.1 to 39.2)	43.8 (19.8 to 70.1)	34.0 (21.5 to 48.3)	
Vac1DecreasedappetiteSevere(n=36,16,53)	2.8 (0.1 to 14.5)	0 (0.0 to 20.6)	3.8 (0.5 to 13.0)	
Vac1IrritabilityMild(n=36,16,53)	16.7 (6.4 to 32.8)	6.3 (0.2 to 30.2)	5.7 (1.2 to 15.7)	
Vac1IrritabilityModerate(n=36,16,53)	58.3 (40.8 to 74.5)	75.0 (47.6 to 92.7)	58.5 (44.1 to 71.9)	
Vac1IrritabilitySevere(n=36,16,53)	8.3 (1.8 to 22.5)	6.3 (0.22 to 30.2)	13.2 (5.5 to 25.3)	
Vac1DrowsinessMild(n=36,16,53)	36.1 (20.8 to 53.8)	37.5 (15.2 to 64.6)	49.1 (35.1 to 63.2)	
Vac1DrowsinessModerate(n=36,16,53)	33.3 (18.6 to 51.0)	31.3 (11.0 to 58.7)	39.6 (26.5 to 54.0)	
Vac1DrowsinessSever(n=36,16,53)	2.8 (0.1 to 14.5)	0 (0.0 to 20.6)	3.8 (0.5 to 13.0)	
Use of antipyretic medication(n=36,16,53)	58.3 (40.8 to 74.5)	56.3 (29.9 to 80.2)	83.0 (70.2 to 91.9)	
Vac2≥38.0°C(n=21,16,52)	52.4 (29.8 to 74.3)	50.0 (24.7 to 75.3)	67.3 (52.9 to 79.7)	
Vac2 >38.0°C to 38.4°C(n=21,16,52)	23.8 (8.2 to 47.2)	25.0 (7.3 to 52.4)	28.8 (17.1 to 43.1)	
Vac2 >>38.4°C to 38.9°C(n=21,16,52)	23.8 (8.2 to 47.2)	25.0 (7.3 to 52.4)	25.0 (14.0 to 38.9)	
Vac2>>38.9°C to 40.0°C(n=21,16,52)	4.8 (0.1 to 23.8)	0 (0.0 to 20.6)	13.5 (5.6 to 25.8)	
Vac2>40.0°C(n=21,16,52)	0 (0.0 to 16.1)	0 (0.0 to 20.6)	0 (0.0 to 6.8)	
Vac2Decreased appetiteMild(n=21,16,52)	4.8 (0.1 to 23.8)	6.3 (0.2 to 30.2)	28.8 (17.1 to 43.1)	
Vac2Decreased appetiteModerate(n=21,16,52)	28.6 (11.3 to 52.2)	50.0 (24.7 to 75.3)	38.5 (25.3 to 53.0)	

Vac2Decreased appetiteSevere(n=21,16,52)	4.8 (0.1 to 23.8)	6.3 (0.2 to 30.2)	5.8 (1.2 to 15.9)	
Vac2IrritabilityMild(n=21,16,52)	47.6 (25.7 to 70.2)	43.8 (19.8 to 70.1)	40.4 (27.0 to 54.9)	
Vac2IrritabilityModerate(n=21,16,52)	23.8 (8.2 to 47.2)	12.5 (1.6 to 38.3)	28.8 (17.1 to 43.1)	
Vac2IrritabilitySevere(n=21,16,52)	0 (0.0 to 16.1)	0 (0.0 to 20.6)	3.8 (0.5 to 13.2)	
Vac2DrowsinessMild(n=21,16,52)	47.6 (25.7 to 70.2)	43.8 (19.8 to 70.1)	40.4 (27.0 to 54.9)	
Vac2DrowsinessModertae(n=21,16,52)	23.8 (8.2 to 47.2)	12.5 (1.6 to 38.3)	28.8 (17.1 to 43.1)	
Vac2DrowsinessSevere(n=21,16,52)	0 (0.0 to 16.1)	0 (0.0 to 20.6)	3.8 (0.5 to 13.2)	
Vac2Use of antipyretic medication(n=21,16,52)	81.0 (58.1 to 94.6)	87.5 (61.7 to 98.4)	86.5 (74.2 to 94.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With AEs, SAEs, MAEs and NDCMC: Groups 3, 4 and 5

End point title	Percentage of Subjects With AEs, SAEs, MAEs and NDCMC: Groups 3, 4 and 5[42]

End point description:

An AE was any untoward medical occurrence in a subject, temporally associated with the use of investigational product, whether or not considered related to the investigational product. SAE was any untoward medical occurrence that, at any dose: resulted in death; required inpatient hospitalisation or prolongation of existing hospitalisation; was life-threatening; resulted in persistent disability/incapacity; congenital anomaly/birth defect and other important medical events. MAE was defined as a nonserious AE that resulted in an evaluation at a medical facility. NDCMC was defined as a disease or medical condition, not previously identified, that is expected to be persistent or otherwise long-lasting in its effects. Safety population included all randomised subjects who received at least 1 dose of investigational product and had safety data reported after vaccination.

End point type	Secondary

End point timeframe:

Within 30 Days after Each Vaccination

Notes:

[42] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was analyzed only for specified reporting arms.

End point values	Group 3 (60 µg rLP2086 +Nimenrix +PLP/SLP)	Group 4 (60 µg rLP2086 +Nimenrix)	Group 5 (120 µg rLP2086 +Nimenrix +PLP)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	36	16	53	
Units: Percentage of subjects				
number (not applicable)				
AEs	52.8	68.8	60.4	
SAEs	2.8	6.3	20.8	
MAEs	47.2	62.5	47.2	
NDCMC	6.3	0	0	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Systematic assessment(SA): local reactions/systemic events within 7 days after vaccination 1, 2 and booster vaccination; Non-systematic assessment: SAEs and other AEs from Day 1 up to 196 days after last study vaccination

Adverse event reporting additional description:

Same event may appear as both AE and SAE but are distinct events. An event may be categorized as serious in 1 subject and non-serious in another, or a subject may have experienced both AE and non-SAE.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	v25.1

Reporting groups

Reporting group title	Group 2 (MenABCWY)

Reporting group description:

Infant subjects aged 6 months were administered a single intramuscular injection of 0.5 mL MenABCWY into the left thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). Subjects received a single intramuscular injection of MenABCWY approximately 6 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at Day 1.

Reporting group title	Group 1 (MenABCWY +PLP)

Reporting group description:

Infant subjects aged 6 months were administered a single intramuscular injection of 0.5 millilitre (mL) MenABCWY into the left thigh. Prophylactic liquid paracetamol regimen (PLP) was administered orally with 3 required doses, the first dose starting 30 minutes before vaccination (Day 1 [primary vaccination {vacc}1] and Month 2 [primary vaccination 2]). Subjects received a single intramuscular injection of MenABCWY approximately 6 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at Day 1.

Reporting group title	Group 11 (MenABCWY +TLP)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL MenABCWY into the left thigh at Day 1 (primary vaccination 1). Therapeutic Liquid Paracetamol regimen (TLP) was administered orally. No subjects received Vaccination 2 and booster dose due to study termination. All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 months of age.

Reporting group title	Group 7 (MenABCWY +SLP)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL MenABCWY into the left thigh. Scheduled liquid paracetamol (SLP) was administered orally at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). Subjects received a single intramuscular injection of 0.5 mL MenABCWY approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Reporting group title	Group 8 (Bexsero +Nimenrix +PLP)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL of Bexsero into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). PLP was administered orally with 3 required doses, the first dose starting 30 minutes before vaccination at Day 1 and Month 2. Subjects received a single intramuscular injection of 0.5 mL of Bexsero into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Reporting group title	Group 10 (Bexsero +Nimenrix)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL of Bexsero

into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1), Month 2 (primary vaccination 2) and at approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Reporting group title	Group 4 (60 µg rLP2086 +Nimenrix)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.25 mL of bivalent rLP2086 (60 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). Subjects received a single intramuscular injection of 0.25 mL of bivalent rLP2086 (60 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Reporting group title	Group 3 (60 µg rLP2086 +Nimenrix +PLP/SLP)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.25 mL bivalent rLP2086 (60 microgram [µg]) into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). PLP or SLP was administered orally. Subjects received a single intramuscular injection of 0.25 mL bivalent rLP2086 (60 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Reporting group title	Group 5 (120 µg rLP2086 +Nimenrix +PLP)

Reporting group description:

Infant subjects aged 2 months were administered a single intramuscular injection of 0.5 mL of bivalent rLP2086 (120 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh at Day 1 (primary vaccination 1) and Month 2 (primary vaccination 2). PLP was administered orally with 3 required doses, the first dose starting 30 minutes before vaccination at Day 1 and Month 2. Subjects received a single intramuscular injection of 0.5 mL of bivalent rLP2086 (120 µg) into the left thigh and 0.5 mL of Nimenrix into the right thigh approximately 10 months after vaccination 1 (booster vaccination). All subjects received a single intramuscular injection of Prevenar 13 and Vaxelis into the right thigh at 2 and 4 months of age.

Serious adverse events	Group 2 (MenABCWY)	Group 1 (MenABCWY +PLP)	Group 11 (MenABCWY +TLP)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	1 / 12 (8.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Myoclonus			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (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
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (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
General disorders and administration site conditions			

Sudden infant death syndrome			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (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
Eye disorders			
Papilloedema			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 12 (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			
Diarrhoea			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (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			
Bronchospasm			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (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
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (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
COVID-19			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (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
Gastroenteritis bacillus			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (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
Escherichia urinary tract infection			

subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (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
Human herpesvirus 7 infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (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
Otitis media acute			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (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
Meningitis bacterial			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (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 bacterial			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (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 syncytial virus bronchiolitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (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 syncytial virus bronchitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (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
Urinary tract infection bacterial			

subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (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

Serious adverse events	Group 7 (MenABCWY +SLP)	Group 8 (Bexsero +Nimenrix +PLP)	Group 10 (Bexsero +Nimenrix)
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 50 (10.00%)	1 / 55 (1.82%)	6 / 55 (10.91%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	1	0	0
Nervous system disorders			
Myoclonus			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (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
Blood and lymphatic system disorders			
Lymphadenitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (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
General disorders and administration site conditions			
Sudden infant death syndrome			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Eye disorders			
Papilloedema			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (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
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (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			

Bronchospasm			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	2 / 50 (4.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	1 / 55 (1.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis bacillus			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (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
Escherichia urinary tract infection			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (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
Human herpesvirus 7 infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (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
Otitis media acute			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	1 / 55 (1.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis bacterial			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (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
Periorbital cellulitis			

subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	1 / 55 (1.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	1 / 55 (1.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	2 / 55 (3.64%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	1 / 55 (1.82%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (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

Serious adverse events	Group 4 (60 µg rLP2086 +Nimenrix)	Group 3 (60 µg rLP2086 +Nimenrix +PLP/SLP)	Group 5 (120 µg rLP2086 +Nimenrix +PLP)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 16 (6.25%)	1 / 36 (2.78%)	11 / 53 (20.75%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Myoclonus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Lymphadenitis			

subjects affected / exposed	0 / 16 (0.00%)	1 / 36 (2.78%)	0 / 53 (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			
Sudden infant death syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (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
Eye disorders			
Papilloedema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (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
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	2 / 53 (3.77%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 36 (0.00%)	2 / 53 (3.77%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis bacillus			

subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (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
Human herpesvirus 7 infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (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
Meningitis bacterial			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (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
Periorbital cellulitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (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 bacterial			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (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 syncytial virus bronchiolitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (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 syncytial virus bronchitis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection bacterial			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Group 2 (MenABCWY)	Group 1 (MenABCWY +PLP)	Group 11 (MenABCWY +TLP)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 25 (100.00%)	23 / 23 (100.00%)	12 / 12 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign breast neoplasm			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site mass			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Injection site swelling			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pyrexia (FEVER)			
alternative assessment type:			

Systematic			
subjects affected / exposed	19 / 25 (76.00%)	15 / 23 (65.22%)	7 / 12 (58.33%)
occurrences (all)	40	27	7
Pyrexia			
subjects affected / exposed	2 / 25 (8.00%)	6 / 23 (26.09%)	0 / 12 (0.00%)
occurrences (all)	2	7	0
Pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Mass			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tenderness (TENDERNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	20 / 25 (80.00%)	20 / 23 (86.96%)	8 / 12 (66.67%)
occurrences (all)	38	40	8
Swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	14 / 25 (56.00%)	10 / 23 (43.48%)	2 / 12 (16.67%)
occurrences (all)	28	13	2
Immune system disorders			
Food allergy			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Seasonal allergy			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Milk allergy			

subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchial hyperreactivity			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Catarrh			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory symptom			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Bronchospasm			
subjects affected / exposed	3 / 25 (12.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	3	0	0
Stridor			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 25 (0.00%)	2 / 23 (8.70%)	1 / 12 (8.33%)
occurrences (all)	0	3	2
Irritability (IRRITABILITY)			
alternative assessment type: Systematic			
subjects affected / exposed	20 / 25 (80.00%)	22 / 23 (95.65%)	12 / 12 (100.00%)
occurrences (all)	60	59	14
Investigations			
Blood creatine phosphokinase increased			

subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Craniocerebral injury			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Arthropod bite			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Foreign body			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tibia fracture			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Sunburn			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Wound			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Congenital, familial and genetic disorders			

Atrial septal defect			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Congenital skin disorder			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Odontogenic cyst			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Patent ductus arteriosus			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Plagiocephaly			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Partial seizures			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Motor developmental delay			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hypersomnia (INCREASED SLEEP)			
alternative assessment type: Systematic			
subjects affected / exposed	18 / 25 (72.00%)	18 / 23 (78.26%)	10 / 12 (83.33%)
occurrences (all)	43	41	11
External hydrocephalus			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Iron deficiency anaemia subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 23 (0.00%) 0	0 / 12 (0.00%) 0
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 23 (0.00%) 0	0 / 12 (0.00%) 0
Eye disorders Lacrimation increased subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 23 (0.00%) 0	0 / 12 (0.00%) 0
Gastrointestinal disorders Constipation subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 23 (0.00%) 0	0 / 12 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 23 (0.00%) 0	0 / 12 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	2 / 25 (8.00%) 2	0 / 23 (0.00%) 0	0 / 12 (0.00%) 0
Infantile colic subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 23 (0.00%) 0	0 / 12 (0.00%) 0
Gingival cyst subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 23 (0.00%) 0	0 / 12 (0.00%) 0
Gastrooesophageal reflux disease subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	1 / 23 (4.35%) 1	0 / 12 (0.00%) 0
Faeces soft subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 23 (0.00%) 0	0 / 12 (0.00%) 0
Stomatitis subjects affected / exposed occurrences (all)	0 / 25 (0.00%) 0	0 / 23 (0.00%) 0	0 / 12 (0.00%) 0
Teething			

subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 25 (4.00%)	4 / 23 (17.39%)	0 / 12 (0.00%)
occurrences (all)	1	4	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Dermatitis atopic			
subjects affected / exposed	1 / 25 (4.00%)	2 / 23 (8.70%)	1 / 12 (8.33%)
occurrences (all)	1	2	1
Papule			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Miliaria			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	13 / 25 (52.00%)	8 / 23 (34.78%)	4 / 12 (33.33%)
occurrences (all)	23	10	4
Erythema			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Urticaria			

subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	1 / 25 (4.00%)	1 / 23 (4.35%)	1 / 12 (8.33%)
occurrences (all)	1	1	1
Endocrine disorders			
Precocious puberty			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	2 / 12 (16.67%)
occurrences (all)	0	0	2
Acquired plagiocephaly			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Torticollis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	2 / 25 (8.00%)	2 / 23 (8.70%)	0 / 12 (0.00%)
occurrences (all)	2	3	0
Bronchiolitis			
subjects affected / exposed	4 / 25 (16.00%)	2 / 23 (8.70%)	1 / 12 (8.33%)
occurrences (all)	4	2	1
Bronchitis viral			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	3 / 25 (12.00%)	2 / 23 (8.70%)	1 / 12 (8.33%)
occurrences (all)	3	2	1
Candida nappy rash			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Cellulitis			

subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	7 / 25 (28.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	7	0	0
Gastroenteritis			
subjects affected / exposed	8 / 25 (32.00%)	6 / 23 (26.09%)	0 / 12 (0.00%)
occurrences (all)	9	7	0
Ear infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	3 / 25 (12.00%)	4 / 23 (17.39%)	1 / 12 (8.33%)
occurrences (all)	3	5	1
Herpangina			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	3 / 25 (12.00%)	1 / 23 (4.35%)	0 / 12 (0.00%)
occurrences (all)	3	1	0
Influenza			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Mumps			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 25 (8.00%)	5 / 23 (21.74%)	0 / 12 (0.00%)
occurrences (all)	2	8	0
Oral candidiasis			

subjects affected / exposed	1 / 25 (4.00%)	1 / 23 (4.35%)	1 / 12 (8.33%)
occurrences (all)	1	1	2
Otitis externa			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	4 / 25 (16.00%)	1 / 23 (4.35%)	1 / 12 (8.33%)
occurrences (all)	8	1	1
Otitis media acute			
subjects affected / exposed	6 / 25 (24.00%)	4 / 23 (17.39%)	0 / 12 (0.00%)
occurrences (all)	8	5	0
Parvovirus B19 infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	3 / 25 (12.00%)	1 / 23 (4.35%)	0 / 12 (0.00%)
occurrences (all)	3	1	0
Pharyngotonsillitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	3 / 25 (12.00%)	2 / 23 (8.70%)	0 / 12 (0.00%)
occurrences (all)	3	2	0
Respiratory tract infection viral			
subjects affected / exposed	5 / 25 (20.00%)	4 / 23 (17.39%)	1 / 12 (8.33%)
occurrences (all)	9	7	1
Rhinitis			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Skin candida			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Superinfection bacterial			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tracheobronchitis			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Suspected COVID-19			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	5 / 25 (20.00%)	4 / 23 (17.39%)	3 / 12 (25.00%)
occurrences (all)	9	12	5
Viral upper respiratory tract infection			
subjects affected / exposed	3 / 25 (12.00%)	1 / 23 (4.35%)	1 / 12 (8.33%)
occurrences (all)	3	2	1
Vaccination site infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Viraemia			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	2 / 25 (8.00%)	4 / 23 (17.39%)	1 / 12 (8.33%)
occurrences (all)	6	5	1
Urinary tract infection			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Vulvovaginitis			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Viral rash			
subjects affected / exposed	3 / 25 (12.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	3	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 25 (0.00%)	1 / 23 (4.35%)	2 / 12 (16.67%)
occurrences (all)	0	1	2
Decreased appetite (DECREASED APPETITE)			
alternative assessment type: Systematic			
subjects affected / exposed	17 / 25 (68.00%)	18 / 23 (78.26%)	9 / 12 (75.00%)
occurrences (all)	39	35	10
Weight gain poor			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Lactose intolerance			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	1 / 25 (4.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Failure to thrive			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 25 (0.00%)	0 / 23 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Group 7 (MenABCWY +SLP)	Group 8 (Bexsero +Nimenrix +PLP)	Group 10 (Bexsero +Nimenrix)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	50 / 50 (100.00%)	54 / 55 (98.18%)	55 / 55 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Benign breast neoplasm			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Injection site mass			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	1 / 55 (1.82%)
occurrences (all)	0	1	1
Injection site erythema			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Injection site swelling			
subjects affected / exposed	1 / 50 (2.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	1	1	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	38 / 50 (76.00%)	32 / 55 (58.18%)	39 / 55 (70.91%)
occurrences (all)	60	44	66
Pyrexia			
subjects affected / exposed	4 / 50 (8.00%)	3 / 55 (5.45%)	5 / 55 (9.09%)
occurrences (all)	4	3	5
Pain			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Mass			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Swelling			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Vaccination site pain			

subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Tenderness (TENDERNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	41 / 50 (82.00%)	41 / 55 (74.55%)	45 / 55 (81.82%)
occurrences (all)	62	86	104
Swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	26 / 50 (52.00%)	30 / 55 (54.55%)	31 / 55 (56.36%)
occurrences (all)	39	72	71
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Milk allergy			
subjects affected / exposed	1 / 50 (2.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	1	1	0
Respiratory, thoracic and mediastinal disorders			
Bronchial hyperreactivity			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	1 / 55 (1.82%)
occurrences (all)	0	1	1
Rhinorrhoea			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Catarrh			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Respiratory symptom			

subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Stridor			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	4 / 50 (8.00%)	3 / 55 (5.45%)	1 / 55 (1.82%)
occurrences (all)	4	4	2
Irritability (IRRITABILITY)			
alternative assessment type: Systematic			
subjects affected / exposed	49 / 50 (98.00%)	44 / 55 (80.00%)	49 / 55 (89.09%)
occurrences (all)	104	119	149
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Cardiac murmur			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
SARS-CoV-2 test positive			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Craniocerebral injury			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Arthropod bite			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	1 / 55 (1.82%)
occurrences (all)	0	1	1
Foreign body			

subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Tibia fracture			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Limb injury			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	2 / 55 (3.64%)
occurrences (all)	0	0	2
Wound			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
Atrial septal defect			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Congenital skin disorder			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Odontogenic cyst			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Patent ductus arteriosus			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Plagiocephaly			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

Partial seizures			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Motor developmental delay			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Hypersomnia (INCREASED SLEEP)			
alternative assessment type: Systematic			
subjects affected / exposed	39 / 50 (78.00%)	44 / 55 (80.00%)	43 / 55 (78.18%)
occurrences (all)	72	88	94
External hydrocephalus			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Lacrimation increased			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	1 / 50 (2.00%)	2 / 55 (3.64%)	3 / 55 (5.45%)
occurrences (all)	1	2	3
Abdominal pain			

subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 50 (2.00%)	3 / 55 (5.45%)	1 / 55 (1.82%)
occurrences (all)	1	3	1
Infantile colic			
subjects affected / exposed	1 / 50 (2.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	1	1	0
Gingival cyst			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Faeces soft			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Teething			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	3 / 55 (5.45%)
occurrences (all)	0	1	3
Vomiting			
subjects affected / exposed	1 / 50 (2.00%)	2 / 55 (3.64%)	1 / 55 (1.82%)
occurrences (all)	1	2	1
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Dermatitis atopic			
subjects affected / exposed	1 / 50 (2.00%)	2 / 55 (3.64%)	2 / 55 (3.64%)
occurrences (all)	1	2	2
Papule			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	0	1	0

Miliaria			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	22 / 50 (44.00%)	31 / 55 (56.36%)	35 / 55 (63.64%)
occurrences (all)	34	61	68
Erythema			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	1 / 55 (1.82%)
occurrences (all)	0	1	1
Urticaria			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	3 / 55 (5.45%)
occurrences (all)	1	0	3
Endocrine disorders			
Precocious puberty			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Acquired plagiocephaly			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1

Torticollis			
subjects affected / exposed	1 / 50 (2.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	1	1	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	1 / 55 (1.82%)
occurrences (all)	0	2	1
Bronchiolitis			
subjects affected / exposed	3 / 50 (6.00%)	1 / 55 (1.82%)	3 / 55 (5.45%)
occurrences (all)	3	1	3
Bronchitis viral			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	8 / 50 (16.00%)	5 / 55 (9.09%)	6 / 55 (10.91%)
occurrences (all)	8	5	6
Candida nappy rash			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 50 (0.00%)	3 / 55 (5.45%)	0 / 55 (0.00%)
occurrences (all)	0	3	0
Gastroenteritis			
subjects affected / exposed	1 / 50 (2.00%)	4 / 55 (7.27%)	4 / 55 (7.27%)
occurrences (all)	1	5	6
Ear infection			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	1 / 50 (2.00%)	4 / 55 (7.27%)	4 / 55 (7.27%)
occurrences (all)	1	4	6
Herpangina			

subjects affected / exposed	0 / 50 (0.00%)	2 / 55 (3.64%)	1 / 55 (1.82%)
occurrences (all)	0	2	1
Lower respiratory tract infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	2 / 55 (3.64%)
occurrences (all)	0	0	2
Laryngitis			
subjects affected / exposed	2 / 50 (4.00%)	1 / 55 (1.82%)	2 / 55 (3.64%)
occurrences (all)	2	1	2
Influenza			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Impetigo			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Mumps			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	3 / 50 (6.00%)	3 / 55 (5.45%)	5 / 55 (9.09%)
occurrences (all)	3	4	5
Oral candidiasis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Otitis media			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	2 / 55 (3.64%)
occurrences (all)	0	0	2
Otitis media acute			
subjects affected / exposed	1 / 50 (2.00%)	1 / 55 (1.82%)	2 / 55 (3.64%)
occurrences (all)	2	1	2
Parvovirus B19 infection			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			

subjects affected / exposed	1 / 50 (2.00%)	1 / 55 (1.82%)	1 / 55 (1.82%)
occurrences (all)	1	1	1
Pharyngotonsillitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 50 (0.00%)	3 / 55 (5.45%)	1 / 55 (1.82%)
occurrences (all)	0	3	1
Respiratory tract infection viral			
subjects affected / exposed	0 / 50 (0.00%)	2 / 55 (3.64%)	0 / 55 (0.00%)
occurrences (all)	0	2	0
Rhinitis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	1 / 55 (1.82%)
occurrences (all)	1	0	1
Skin candida			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Skin infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Superinfection bacterial			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Tracheobronchitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Suspected COVID-19			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	0 / 55 (0.00%)
occurrences (all)	0	1	0

Tonsillitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	7 / 50 (14.00%)	11 / 55 (20.00%)	11 / 55 (20.00%)
occurrences (all)	7	18	21
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 50 (0.00%)	2 / 55 (3.64%)	3 / 55 (5.45%)
occurrences (all)	0	4	4
Vaccination site infection			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Viraemia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1
Viral infection			
subjects affected / exposed	0 / 50 (0.00%)	1 / 55 (1.82%)	4 / 55 (7.27%)
occurrences (all)	0	2	4
Urinary tract infection			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Vulvovaginitis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	2	0	0
Decreased appetite (DECREASED APPETITE)			
alternative assessment type: Systematic			
subjects affected / exposed	38 / 50 (76.00%)	37 / 55 (67.27%)	41 / 55 (74.55%)
occurrences (all)	67	79	88
Weight gain poor			

subjects affected / exposed	1 / 50 (2.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	1	0	0
Lactose intolerance			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	0 / 55 (0.00%)
occurrences (all)	0	0	0
Failure to thrive			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	2 / 55 (3.64%)
occurrences (all)	0	0	2
Obesity			
subjects affected / exposed	0 / 50 (0.00%)	0 / 55 (0.00%)	1 / 55 (1.82%)
occurrences (all)	0	0	1

Non-serious adverse events	Group 4 (60 µg rLP2086 +Nimenrix)	Group 3 (60 µg rLP2086 +Nimenrix +PLP/SLP)	Group 5 (120 µg rLP2086 +Nimenrix +PLP)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 16 (100.00%)	36 / 36 (100.00%)	53 / 53 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign breast neoplasm			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Injection site mass			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0

Injection site swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	10 / 16 (62.50%)	25 / 36 (69.44%)	42 / 53 (79.25%)
occurrences (all)	13	39	75
Pyrexia			
subjects affected / exposed	0 / 16 (0.00%)	2 / 36 (5.56%)	4 / 53 (7.55%)
occurrences (all)	0	2	5
Pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Mass			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Swelling			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Tenderness (TENDERNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 16 (50.00%)	23 / 36 (63.89%)	35 / 53 (66.04%)
occurrences (all)	14	39	58
Swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 16 (31.25%)	13 / 36 (36.11%)	10 / 53 (18.87%)
occurrences (all)	7	20	15
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			

subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Milk allergy			
subjects affected / exposed	1 / 16 (6.25%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences (all)	1	0	1
Respiratory, thoracic and mediastinal disorders			
Bronchial hyperreactivity			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Catarrh			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 16 (6.25%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Respiratory symptom			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Bronchospasm			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Stridor			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Irritability (IRRITABILITY)			
alternative assessment type: Systematic			
subjects affected / exposed	14 / 16 (87.50%)	32 / 36 (88.89%)	50 / 53 (94.34%)
occurrences (all)	35	69	110
Investigations			

Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Cardiac murmur			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Craniocerebral injury			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Arthropod bite			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Foreign body			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Tibia fracture			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Head injury			
subjects affected / exposed	1 / 16 (6.25%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Wound			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			

Atrial septal defect			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Congenital skin disorder			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Odontogenic cyst			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Patent ductus arteriosus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Plagiocephaly			
subjects affected / exposed	0 / 16 (0.00%)	2 / 36 (5.56%)	0 / 53 (0.00%)
occurrences (all)	0	2	0
Nervous system disorders			
Partial seizures			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Motor developmental delay			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Hypersomnia (INCREASED SLEEP)			
alternative assessment type: Systematic			
subjects affected / exposed	12 / 16 (75.00%)	32 / 36 (88.89%)	50 / 53 (94.34%)
occurrences (all)	25	57	102
External hydrocephalus			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0

Iron deficiency anaemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Lacrimation increased			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	1 / 16 (6.25%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences (all)	1	0	1
Abdominal pain			
subjects affected / exposed	0 / 16 (0.00%)	1 / 36 (2.78%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Infantile colic			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Gingival cyst			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 16 (6.25%)	1 / 36 (2.78%)	3 / 53 (5.66%)
occurrences (all)	1	1	3
Faeces soft			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Teething			

subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 16 (0.00%)	3 / 36 (8.33%)	0 / 53 (0.00%)
occurrences (all)	0	3	0
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 36 (2.78%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Dermatitis atopic			
subjects affected / exposed	1 / 16 (6.25%)	1 / 36 (2.78%)	1 / 53 (1.89%)
occurrences (all)	1	1	1
Papule			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Miliaria			
subjects affected / exposed	0 / 16 (0.00%)	1 / 36 (2.78%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	6 / 16 (37.50%)	18 / 36 (50.00%)	19 / 53 (35.85%)
occurrences (all)	7	27	23
Erythema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 16 (6.25%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences (all)	1	0	1
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Urticaria			

subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Dermatitis diaper			
subjects affected / exposed	0 / 16 (0.00%)	1 / 36 (2.78%)	1 / 53 (1.89%)
occurrences (all)	0	1	1
Endocrine disorders			
Precocious puberty			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Acquired plagiocephaly			
subjects affected / exposed	1 / 16 (6.25%)	0 / 36 (0.00%)	2 / 53 (3.77%)
occurrences (all)	1	0	2
Torticollis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 36 (2.78%)	1 / 53 (1.89%)
occurrences (all)	0	1	1
Bronchiolitis			
subjects affected / exposed	2 / 16 (12.50%)	3 / 36 (8.33%)	2 / 53 (3.77%)
occurrences (all)	2	3	2
Bronchitis viral			
subjects affected / exposed	1 / 16 (6.25%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
COVID-19			
subjects affected / exposed	1 / 16 (6.25%)	0 / 36 (0.00%)	4 / 53 (7.55%)
occurrences (all)	1	0	4
Candida nappy rash			
subjects affected / exposed	1 / 16 (6.25%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Cellulitis			

subjects affected / exposed	1 / 16 (6.25%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 16 (0.00%)	2 / 36 (5.56%)	1 / 53 (1.89%)
occurrences (all)	0	2	1
Ear infection			
subjects affected / exposed	0 / 16 (0.00%)	2 / 36 (5.56%)	0 / 53 (0.00%)
occurrences (all)	0	2	0
Conjunctivitis			
subjects affected / exposed	3 / 16 (18.75%)	0 / 36 (0.00%)	3 / 53 (5.66%)
occurrences (all)	3	0	3
Herpangina			
subjects affected / exposed	1 / 16 (6.25%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 16 (0.00%)	2 / 36 (5.56%)	3 / 53 (5.66%)
occurrences (all)	0	2	3
Influenza			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Mumps			
subjects affected / exposed	0 / 16 (0.00%)	1 / 36 (2.78%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 16 (6.25%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences (all)	1	0	1
Oral candidiasis			

subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	2 / 16 (12.50%)	1 / 36 (2.78%)	0 / 53 (0.00%)
occurrences (all)	4	1	0
Otitis media acute			
subjects affected / exposed	1 / 16 (6.25%)	2 / 36 (5.56%)	2 / 53 (3.77%)
occurrences (all)	1	4	2
Parvovirus B19 infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Pharyngotonsillitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 36 (2.78%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0

Skin candida			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Superinfection bacterial			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Tracheobronchitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Suspected COVID-19			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 16 (0.00%)	1 / 36 (2.78%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 16 (12.50%)	6 / 36 (16.67%)	7 / 53 (13.21%)
occurrences (all)	2	18	10
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 16 (6.25%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences (all)	4	0	1
Vaccination site infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Viraemia			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	0 / 16 (0.00%)	1 / 36 (2.78%)	0 / 53 (0.00%)
occurrences (all)	0	1	0

Vulvovaginitis			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	2 / 16 (12.50%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	2	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	2 / 53 (3.77%)
occurrences (all)	0	0	3
Decreased appetite (DECREASED APPETITE)			
alternative assessment type: Systematic			
subjects affected / exposed	11 / 16 (68.75%)	25 / 36 (69.44%)	46 / 53 (86.79%)
occurrences (all)	24	44	90
Weight gain poor			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Lactose intolerance			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Iron deficiency			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Failure to thrive			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Obesity			
subjects affected / exposed	0 / 16 (0.00%)	0 / 36 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 January 2021	Addition of observer-blind expanded enrollment stage to allow further safety evaluation while minimizing potential bias. Addition of corresponding safety/immunogenicity objectives and analysis triggering enrollment into this stage. Addition of a planned analysis 1 month after the booster vaccination in the open-label expanded-enrollment stage in lieu of the prior final analysis. Separated Bexsero randomization groups (Groups 8 and 10) from sentinel-cohort stepdown structure to allow enrollment into these groups at any time during the sentinel stage as vaccine assigned in these groups represents standard of care. Removed enrollment restrictions from these groups and applied fewer stopping rules.
13 September 2021	Implemented EDMC recommendations that resulted from an analysis of available fever and safety data and a review of paracetamol regimens following completion of enrollment to sentinel Group 5 (Trumenba 120 µg + Nimenrix + PLP).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The study was not completed as initially designed due to study termination by the sponsor.

Notes: