



Clinical trial results:

Immunogenicity and Safety Study of an Investigational Quadrivalent Meningococcal Conjugate Vaccine when Administered Concomitantly with Routine Pediatric Vaccines in Healthy Infants and Toddlers in Europe

Summary

| | |
|--------------------------|----------------------|
| EudraCT number | 2017-004731-36 |
| Trial protocol | CZ SE FI IT ES PL RO |
| Global end of trial date | 24 May 2023 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 |
| This version publication date | 12 January 2025 |
| First version publication date | 12 January 2025 |

Trial information

Trial identification

| | |
|-----------------------|-------|
| Sponsor protocol code | MET58 |
|-----------------------|-------|

Additional study identifiers

| | |
|------------------------------------|-----------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03547271 |
| WHO universal trial number (UTN) | U1111-1183-6653 |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Sanofi Pasteur Inc. |
| Sponsor organisation address | Discovery Drive, Swiftwater, PA, United States, 18370-0187 |
| Public contact | Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.com |
| Scientific contact | Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.com |

Notes:

Paediatric regulatory details

| | |
|--|---------------------|
| Is trial part of an agreed paediatric investigation plan (PIP) | Yes |
| EMA paediatric investigation plan number(s) | EMA-001930-PIP01-16 |
| 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 | 08 July 2024 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 24 May 2023 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the non-inferiority of the antibody response against meningococcal serogroups A, C, W, and Y following the administration of a 3-dose series of MenACYW conjugate vaccine compared to a 3-dose series of Nimenrix® when each vaccine is administered concomitantly with routine pediatric vaccines [pneumococcal conjugate vaccine, 10-valent absorbed (PCV10), and hexavalent vaccine] to infants and toddlers from 6 weeks to 18 months old (Group 1 versus Group 2).

Protection of trial subjects:

Vaccinations were performed by qualified and trained study personnel. Participants with allergy to any of the vaccine components were not vaccinated. After vaccination, participants were also kept under clinical observation for 30 minutes to ensure their safety. Appropriate medical equipment were also available on site in case of any immediate allergic reactions.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 14 December 2018 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------|
| Country: Number of subjects enrolled | Czechia: 140 |
| Country: Number of subjects enrolled | Finland: 907 |
| Country: Number of subjects enrolled | Italy: 60 |
| Country: Number of subjects enrolled | Poland: 241 |
| Country: Number of subjects enrolled | Romania: 132 |
| Country: Number of subjects enrolled | Spain: 160 |
| Country: Number of subjects enrolled | Sweden: 20 |
| Worldwide total number of subjects | 1660 |
| EEA total number of subjects | 1660 |

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) | 1660 |
| 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:

This study was conducted at 33 investigational sites in 7 countries between 14 December 2018 to 24 May 2023.

Pre-assignment

Screening details:

A total of 1660 participants were enrolled in this study.

Period 1

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

Arms

| | |
|------------------------------|------------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Group 1: MenACYW |

Arm description:

Participants received 3 doses of meningococcal polysaccharide (serogroups A, C, Y and W) tetanus toxoid [MenACYW conjugate vaccine] 0.5 milliliter (mL) as an intramuscular (IM) injection at dose 1: 2 months of age (MoA), dose 2: 4 MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (combined diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated poliovirus and haemophilus influenzae type b conjugate vaccine [DTaP-IPV-HB-Hib], the pneumococcal vaccine (PCV10) were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the measles, mumps, rubella (MMR) vaccine was administered at 12 to 18 MoA.

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | MenACYW conjugate vaccine |
| Investigational medicinal product code | |
| Other name | Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate Vaccine |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received MenACYW conjugate vaccine 0.5 mL IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 12 to 18 MoA.

| | |
|--|-------------------------------------|
| Investigational medicinal product name | Hexavalent vaccine |
| Investigational medicinal product code | |
| Other name | DTaP-IPV-HB-Hib; Hexyon®; Hexacima® |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received hexavalent vaccine 0.5 mL IM injection in a 2+1 regimen (2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA])

| | |
|--|--------------------------|
| Investigational medicinal product name | PCV10 |
| Investigational medicinal product code | |
| Other name | Synflorix® |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received PCV10 0.5 mL IM injection in a 2+1 regimen (2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA])

| | |
|--|---|
| Investigational medicinal product name | MMR vaccine |
| Investigational medicinal product code | |
| Other name | M-M-RVAXPRO® |
| Pharmaceutical forms | Powder and solvent for suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received MMR vaccine 0.5 mL IM injection at 12 to 18 MoA.

| | |
|------------------|-------------------|
| Arm title | Group 2: Nimenrix |
|------------------|-------------------|

Arm description:

Participants received 3 doses of Nimenrix® 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the PCV10 were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA.

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | Nimenrix® |
| Investigational medicinal product code | |
| Other name | Meningococcal group A, C, W-135, and Y conjugate vaccine |
| Pharmaceutical forms | Powder and solvent for solution for injection in pre-filled syringe |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received Nimenrix® 0.5 mL IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 12 to 18 MoA.

| | |
|--|---|
| Investigational medicinal product name | MMR vaccine |
| Investigational medicinal product code | |
| Other name | M-M-RVAXPRO® |
| Pharmaceutical forms | Powder and solvent for suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received MMR vaccine 0.5 mL IM injection at 12 to 18 MoA.

| | |
|--|--------------------------|
| Investigational medicinal product name | PCV10 |
| Investigational medicinal product code | |
| Other name | Synflorix® |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received PCV10 0.5 mL IM injection in a 2+1 regimen (2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA])

| | |
|--|-------------------------------------|
| Investigational medicinal product name | Hexavalent vaccine |
| Investigational medicinal product code | |
| Other name | DTaP-IPV-HB-Hib; Hexyon®; Hexacima® |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received hexavalent vaccine 0.5 mL IM injection in a 2+1 regimen (2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA])

| | |
|------------------|------------------|
| Arm title | Group 3: MenACYW |
|------------------|------------------|

Arm description:

Participants received 3 doses of MenACYW conjugate vaccine 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the pneumococcal conjugate vaccine (13-valent, adsorbed) [PCV13] were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA.

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | MenACYW conjugate vaccine |
| Investigational medicinal product code | |
| Other name | Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate Vaccine |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received MenACYW conjugate vaccine 0.5 mL IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 12 to 18 MoA.

| | |
|--|--------------------------|
| Investigational medicinal product name | PCV13 |
| Investigational medicinal product code | |
| Other name | Prevenar 13® |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received PCV13 0.5 mL IM injection in a 2+1 regimen (2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA])

| | |
|--|-------------------------------------|
| Investigational medicinal product name | Hexavalent vaccine |
| Investigational medicinal product code | |
| Other name | DTaP-IPV-HB-Hib; Hexyon®; Hexacima® |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received hexavalent vaccine 0.5 mL IM injection in a 2+1 regimen (2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA])

| | |
|--|---|
| Investigational medicinal product name | MMR vaccine |
| Investigational medicinal product code | |
| Other name | M-M-RVAXPRO® |
| Pharmaceutical forms | Powder and solvent for suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received MMR vaccine 0.5 mL IM injection at 12 to 18 MoA.

| | |
|------------------|------------------|
| Arm title | Group 4: MenACYW |
|------------------|------------------|

Arm description:

Participants received 4 doses of MenACYW conjugate vaccine 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 6 MoA and dose 4: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the PCV13 were administered in a 2+1 regimen (concomitantly with the first and second doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and the toddler dose of MenACYW conjugate vaccine [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA. The third dose of MenACYW conjugate vaccine was administered alone, without any other routine pediatric vaccines.

| | |
|----------|--------------|
| Arm type | Experimental |
|----------|--------------|

| | |
|--|---|
| Investigational medicinal product name | MenACYW conjugate vaccine |
| Investigational medicinal product code | |
| Other name | Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate Vaccine |
| Pharmaceutical forms | Solution for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received MenACYW conjugate vaccine 0.5 mL IM injection at dose 1: 2 MoA, dose 2: 4MoA, and dose 3: 6 MoA and dose 4: 12 to 18 MoA.

| | |
|--|-------------------------------------|
| Investigational medicinal product name | Hexavalent vaccine |
| Investigational medicinal product code | |
| Other name | DTaP-IPV-HB-Hib; Hexyon®; Hexacima® |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received hexavalent vaccine 0.5 mL IM injection in a 2+1 regimen (first between 6 and 12 weeks of age and second between 4 to 5 MoA in infancy and the toddler dose at 12 to 18 MoA).

| | |
|--|--------------------------|
| Investigational medicinal product name | PCV13 |
| Investigational medicinal product code | |
| Other name | Prevenar 13® |
| Pharmaceutical forms | Suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received PCV13 0.5 mL IM injection in a 2+1 regimen (first between 6 and 12 weeks of age and second between 4 to 5 MoA in infancy and the toddler dose at 12 to 18 MoA).

| | |
|--|---|
| Investigational medicinal product name | MMR vaccine |
| Investigational medicinal product code | |
| Other name | M-M-RVAXPRO® |
| Pharmaceutical forms | Powder and solvent for suspension for injection |
| Routes of administration | Intramuscular use |

Dosage and administration details:

Participants received MMR vaccine 0.5 mL IM injection at 12 to 18 MoA.

| Number of subjects in period 1 | Group 1: MenACYW | Group 2: Nimenrix | Group 3: MenACYW |
|---------------------------------------|------------------|-------------------|------------------|
| Started | 714 | 726 | 112 |
| Safety analysis set (SafAS) | 696 | 706 | 112 |
| Completed | 681 | 691 | 106 |
| Not completed | 33 | 35 | 6 |
| Adverse event, non-fatal | 1 | 1 | - |
| Protocol deviation | 5 | 7 | 3 |
| Withdrawal by Parent/Guardian | 24 | 24 | 2 |
| Lost to follow-up | 3 | 3 | 1 |

| Number of subjects in period 1 | Group 4: MenACYW |
|---------------------------------------|------------------|
| Started | 108 |
| Safety analysis set (SafAS) | 108 |

| | |
|-------------------------------|-----|
| Completed | 104 |
| Not completed | 4 |
| Adverse event, non-fatal | - |
| Protocol deviation | - |
| Withdrawal by Parent/Guardian | 4 |
| Lost to follow-up | - |

Baseline characteristics

Reporting groups

| | |
|--|-------------------|
| Reporting group title | Group 1: MenACYW |
| Reporting group description: | |
| Participants received 3 doses of meningococcal polysaccharide (serogroups A, C, Y and W) tetanus toxoid [MenACYW conjugate vaccine] 0.5 milliliter (mL) as an intramuscular (IM) injection at dose 1: 2 months of age (MoA), dose 2: 4 MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (combined diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated poliovirus and haemophilus influenzae type b conjugate vaccine [DTaP-IPV-HB-Hib], the pneumococcal vaccine (PCV10) were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the measles, mumps, rubella (MMR) vaccine was administered at 12 to 18 MoA. | |
| Reporting group title | Group 2: Nimenrix |
| Reporting group description: | |
| Participants received 3 doses of Nimenrix® 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the PCV10 were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA. | |
| Reporting group title | Group 3: MenACYW |
| Reporting group description: | |
| Participants received 3 doses of MenACYW conjugate vaccine 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the pneumococcal conjugate vaccine (13-valent, adsorbed) [PCV13] were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA. | |
| Reporting group title | Group 4: MenACYW |
| Reporting group description: | |
| Participants received 4 doses of MenACYW conjugate vaccine 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 6 MoA and dose 4: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the PCV13 were administered in a 2+1 regimen (concomitantly with the first and second doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and the toddler dose of MenACYW conjugate vaccine [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA. The third dose of MenACYW conjugate vaccine was administered alone, without any other routine pediatric vaccines. | |

| Reporting group values | Group 1: MenACYW | Group 2: Nimenrix | Group 3: MenACYW |
|--|------------------|-------------------|------------------|
| Number of subjects | 714 | 726 | 112 |
| Age categorical | | | |
| Units: Subjects | | | |
| Infants and toddlers (28 days-23 months) | 714 | 726 | 112 |
| Age Continuous | | | |
| Units: Days | | | |
| arithmetic mean | 72.6 | 72.4 | 62.5 |
| standard deviation | ± 12.2 | ± 12.1 | ± 7.12 |
| Sex: Female, Male | | | |
| Units: Participants | | | |
| Female | 355 | 378 | 45 |
| Male | 359 | 348 | 67 |

| | | | |
|---|-----|-----|-----|
| Race/Ethnicity, Customized Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | 1 |
| Asian | 2 | 1 | 4 |
| Black or African American | 0 | 0 | 1 |
| Native Hawaiian or Other Pacific Islander | 0 | 1 | 0 |
| White | 693 | 699 | 106 |
| Not Reported | 13 | 16 | 0 |
| Unknown | 2 | 3 | 0 |
| Multiple origin | 4 | 6 | 0 |

| | | | |
|--|------------------|-------|--|
| Reporting group values | Group 4: MenACYW | Total | |
| Number of subjects | 108 | 1660 | |
| Age categorical Units: Subjects | | | |
| Infants and toddlers (28 days-23 months) | 108 | 1660 | |
| Age Continuous Units: Days arithmetic mean standard deviation | 63.3 ± 7.93 | - | |
| Sex: Female, Male Units: Participants | | | |
| Female | 58 | 836 | |
| Male | 50 | 824 | |
| Race/Ethnicity, Customized Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 1 | |
| Asian | 2 | 9 | |
| Black or African American | 3 | 4 | |
| Native Hawaiian or Other Pacific Islander | 0 | 1 | |
| White | 101 | 1599 | |
| Not Reported | 1 | 30 | |
| Unknown | 0 | 5 | |
| Multiple origin | 1 | 11 | |

End points

End points reporting groups

| | |
|--|-------------------|
| Reporting group title | Group 1: MenACYW |
| Reporting group description: Participants received 3 doses of meningococcal polysaccharide (serogroups A, C, Y and W) tetanus toxoid [MenACYW conjugate vaccine] 0.5 milliliter (mL) as an intramuscular (IM) injection at dose 1: 2 months of age (MoA), dose 2: 4 MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (combined diphtheria, tetanus, acellular pertussis, hepatitis B, inactivated poliovirus and haemophilus influenzae type b conjugate vaccine [DTaP-IPV-HB-Hib], the pneumococcal vaccine (PCV10) were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the measles, mumps, rubella (MMR) vaccine was administered at 12 to 18 MoA. | |
| Reporting group title | Group 2: Nimenrix |
| Reporting group description: Participants received 3 doses of Nimenrix® 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the PCV10 were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA. | |
| Reporting group title | Group 3: MenACYW |
| Reporting group description: Participants received 3 doses of MenACYW conjugate vaccine 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the pneumococcal conjugate vaccine (13-valent, adsorbed) [PCV13] were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA. | |
| Reporting group title | Group 4: MenACYW |
| Reporting group description: Participants received 4 doses of MenACYW conjugate vaccine 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 6 MoA and dose 4: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the PCV13 were administered in a 2+1 regimen (concomitantly with the first and second doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and the toddler dose of MenACYW conjugate vaccine [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA. The third dose of MenACYW conjugate vaccine was administered alone, without any other routine pediatric vaccines. | |

Primary: Groups 1 and 2: Geometric Mean Titers (GMTs) Against Meningococcal Serogroups A, C, W, and Y

| | |
|---|---|
| End point title | Groups 1 and 2: Geometric Mean Titers (GMTs) Against Meningococcal Serogroups A, C, W, and Y ^[1] |
| End point description: Functional meningococcal antibody activity against serogroups A, C, W, and Y were measured in a serum bactericidal assay utilizing the serum bactericidal assay using human complement (hSBA). Per-Protocol Analysis Set 2 (PPAS2) was a subset of Full Analysis Set 2 (FAS2). The FAS2 included the subset of randomized participants who received at least 1 dose of the study vaccine at booster vaccination and had a valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup. | |
| End point type | Primary |
| End point timeframe: At 30 days post Dose 3 [12 to 18 months of age (MoA)] | |

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only participants randomized in Groups 1 and 2 were analyzed in this endpoint.

| End point values | Group 1: MenACYW | Group 2: Nimenrix | | |
|--|---------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 554 | 579 | | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Serogroup A (n=543, 567) | 131 (113 to 151) | 189 (165 to 218) | | |
| Serogroup C (n=550, 578) | 565 (505 to 632) | 120 (106 to 135) | | |
| Serogroup W (n=547, 575) | 423 (382 to 468) | 275 (247 to 305) | | |
| Serogroup Y (n=554, 579) | 285 (260 to 313) | 160 (145 to 177) | | |

Statistical analyses

| Statistical analysis title | Statistical analysis for Serogroup C |
|---|--------------------------------------|
| Statistical analysis description: | |
| The non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI was $>1/1.5$ for all 4 serogroups. 95% CI of the GMT ratio was calculated using a normal approximation of log-transformed titers. | |
| Comparison groups | Group 1: MenACYW v Group 2: Nimenrix |
| Number of subjects included in analysis | 1133 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority |
| Parameter estimate | GMT ratio |
| Point estimate | 4.73 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 4 |
| upper limit | 5.58 |

| Statistical analysis title | Statistical analysis for Serogroup Y |
|---|--------------------------------------|
| Statistical analysis description: | |
| The non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI was $>1/1.5$ for all 4 serogroups. 95% CI of the GMT ratio was calculated using a normal approximation of log-transformed titers. | |
| Comparison groups | Group 1: MenACYW v Group 2: Nimenrix |
| Number of subjects included in analysis | 1133 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority |
| Parameter estimate | GMT ratio |
| Point estimate | 1.78 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.55 |
| upper limit | 2.04 |

| | |
|-----------------------------------|--------------------------------------|
| Statistical analysis title | Statistical analysis for Serogroup W |
|-----------------------------------|--------------------------------------|

Statistical analysis description:

The non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI was $>1/1.5$ for all 4 serogroups. 95% CI of the GMT ratio was calculated using a normal approximation of log-transformed titers.

| | |
|---|--------------------------------------|
| Comparison groups | Group 1: MenACYW v Group 2: Nimenrix |
| Number of subjects included in analysis | 1133 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority |
| Parameter estimate | Slope |
| Point estimate | 1.54 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 1.33 |
| upper limit | 1.78 |

| | |
|-----------------------------------|--------------------------------------|
| Statistical analysis title | Statistical analysis for Serogroup A |
|-----------------------------------|--------------------------------------|

Statistical analysis description:

The non-inferiority was demonstrated if the lower limit of the 2-sided 95% confidence interval (CI) was $>1/1.5$ for all 4 serogroups. 95% CI of the GMT ratio was calculated using a normal approximation of log-transformed titers.

| | |
|---|--------------------------------------|
| Comparison groups | Group 2: Nimenrix v Group 1: MenACYW |
| Number of subjects included in analysis | 1133 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority |
| Parameter estimate | GMT ratio |
| Point estimate | 0.69 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.565 |
| upper limit | 0.842 |

Secondary: Groups 1 and 2: Percentage of Participants who Achieved Antibody Titers $\geq 1:8$ Against Meningococcal Serogroups A, C, W, and Y

| | |
|-----------------|---|
| End point title | Groups 1 and 2: Percentage of Participants who Achieved Antibody Titers $\geq 1:8$ Against Meningococcal Serogroups A, C, W, and Y ^[2] |
|-----------------|---|

End point description:

Functional meningococcal antibody activity against serogroups A, C, W, and Y were measured in a serum bactericidal assay utilizing the hSBA. Percentages are rounded off to the tenth decimal place. PPAS1 was a subset of FAS1. The FAS1 included the subset of randomized participants who received at least 1 dose of the study vaccine in the primary series and had a valid post-primary series vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At 30 days post Dose 2 (4 MoA)

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only participants randomized in Groups 1 and 2 were analyzed in this endpoint.

| End point values | Group 1: MenACYW | Group 2: Nimenrix | | |
|-----------------------------------|---------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 518 | 523 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Serogroup A (n=508, 508) | 63.6 (59.2 to 67.8) | 75.8 (71.8 to 79.5) | | |
| Serogroup C (n=513, 521) | 98.8 (97.5 to 99.6) | 91.9 (89.3 to 94.1) | | |
| Serogroup W (n=518, 523) | 96.5 (94.6 to 97.9) | 94.5 (92.1 to 96.3) | | |
| Serogroup Y (n=516, 523) | 96.5 (94.5 to 97.9) | 93.5 (91.0 to 95.5) | | |

Statistical analyses

| | |
|-----------------------------------|--------------------------------------|
| Statistical analysis title | Statistical analysis for Serogroup A |
|-----------------------------------|--------------------------------------|

Statistical analysis description:

The non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI was $>-10\%$ for all 4 serogroups. 95% CI of the difference was calculated from the Wilson score method without continuity correction.

| | |
|---|--|
| Comparison groups | Group 1: MenACYW v Group 2: Nimenrix |
| Number of subjects included in analysis | 1041 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority |
| Parameter estimate | Difference in percentage of participants |
| Point estimate | -12.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -17.74 |
| upper limit | -6.56 |

| | |
|-----------------------------------|--------------------------------------|
| Statistical analysis title | Statistical analysis for Serogroup Y |
|-----------------------------------|--------------------------------------|

Statistical analysis description:

The non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI was $>-10\%$ for all 4 serogroups. 95% CI of the difference was calculated from the Wilson score method without continuity correction.

| | |
|---|--|
| Comparison groups | Group 1: MenACYW v Group 2: Nimenrix |
| Number of subjects included in analysis | 1041 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority |
| Parameter estimate | Difference in percentage of participants |
| Point estimate | 3.01 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.34 |
| upper limit | 5.77 |

Statistical analysis title

Statistical analysis for Serogroup W

Statistical analysis description:

The non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI was $>-10\%$ for all 4 serogroups. 95% CI of the difference was calculated from the Wilson score method without continuity correction.

| | |
|---|--|
| Comparison groups | Group 1: MenACYW v Group 2: Nimenrix |
| Number of subjects included in analysis | 1041 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority |
| Parameter estimate | Difference in percentage of participants |
| Point estimate | 2.07 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.49 |
| upper limit | 4.7 |

Statistical analysis title

Statistical analysis for Serogroup C

Statistical analysis description:

The non-inferiority was demonstrated if the lower limit of the 2-sided 95% CI was $>-10\%$ for all 4 serogroups. 95% CI of the difference was calculated from the Wilson score method without continuity correction.

| | |
|---|--|
| Comparison groups | Group 1: MenACYW v Group 2: Nimenrix |
| Number of subjects included in analysis | 1041 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority |
| Parameter estimate | Difference in percentage of participants |
| Point estimate | 6.89 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 4.44 |
| upper limit | 9.62 |

Secondary: Groups 3 and 4: Geometric Mean Titers Against Meningococcal Serogroups A, C, W, and Y

| | |
|-----------------|--|
| End point title | Groups 3 and 4: Geometric Mean Titers Against Meningococcal Serogroups A, C, W, and Y ^[3] |
|-----------------|--|

End point description:

Functional meningococcal antibody activity against serogroups A, C, W, and Y were measured in a serum bactericidal assay utilizing the hSBA. PPAS1 was a subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and had valid post-primary series vaccination blood sample result. PPAS2 was a subset of FAS2. FAS2: subset of randomized participants who received at least 1 dose of study vaccine at booster vaccination and had valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup. '9999' denotes that there were no participants analyzed.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Group 3: Day 0 before Dose 1 (2 MoA) and Dose 3 (12 to 18 MoA) and Day 30 Post Dose 2 (4 MoA) and Dose 3 (12 to 18 MoA); Group 4: Day 0 before Dose 1 (2 MoA) and Dose 4 (12 to 18 MoA) and Day 30 Post Dose 3 (6 MoA) and Dose 4 (12 to 18 MoA)

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only participants randomized in Groups 3 and 4 were analyzed in this endpoint.

| End point values | Group 3: MenACYW | Group 4: MenACYW | | |
|--|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 96 | 90 | | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| PPAS1: Serogroup A: Day 0 before dose 1 (n=94, 89) | 3.00 (2.58 to 3.49) | 2.86 (2.49 to 3.28) | | |
| PPAS1: Serogroup A: Day 30 post dose 2 (n=91, 0) | 14.8 (10.6 to 20.8) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup A: Day 30 post dose 3 (n=0, 88) | 9999 (9999 to 9999) | 23.0 (17.1 to 30.9) | | |
| PPAS1: Serogroup C: Day 0 before dose 1 (n=94, 90) | 3.91 (3.16 to 4.84) | 3.88 (3.25 to 4.62) | | |
| PPAS1: Serogroup C: Day 30 post dose 2 (n=95, 0) | 309 (235 to 407) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup C: Day 30 post dose 3 (n=0, 90) | 9999 (9999 to 9999) | 481 (376 to 616) | | |
| PPAS1: Serogroup W: Day 0 before dose 1 (n=94, 90) | 2.67 (2.40 to 2.96) | 3.08 (2.63 to 3.60) | | |
| PPAS1: Serogroup W: Day 30 post dose 2 (n=96, 0) | 102 (79.7 to 131) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup W: Day 30 post dose 3 (n=0, 90) | 9999 (9999 to 9999) | 196 (156 to 245) | | |
| PPAS1: Serogroup Y: Day 0 before dose 1 (n=94, 90) | 2.85 (2.45 to 3.32) | 2.76 (2.36 to 3.23) | | |

| | | | | |
|---|---------------------|---------------------|--|--|
| PPAS1: Serogroup Y: Day 30 post dose 2 (n=96, 0) | 73.4 (57.7 to 93.5) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup Y: Day 30 post dose 3 (n=0, 90) | 9999 (9999 to 9999) | 150 (116 to 195) | | |
| PPAS2: Serogroup A: Day 0 before dose 3 (n=91, 0) | 5.18 (4.22 to 6.37) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup A: Day 30 post dose 3 (n=92, 0) | 104 (67.9 to 161) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup A: Day 0 before dose 4 (n=0, 89) | 9999 (9999 to 9999) | 8.13 (6.33 to 10.4) | | |
| PPAS2: Serogroup A: Day 30 post dose 4 (n=0, 89) | 9999 (9999 to 9999) | 62.0 (39.9 to 96.4) | | |
| PPAS2: Serogroup C: Day 0 before dose 3 (n=94, 0) | 26.2 (18.7 to 36.8) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup C: Day 30 post dose 3 (n=93, 0) | 819 (622 to 1078) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup C: Day 0 before dose 4 (n=0, 89) | 9999 (9999 to 9999) | 56.9 (42.4 to 76.4) | | |
| PPAS2: Serogroup C: Day 30 post dose 4 (n=0, 86) | 9999 (9999 to 9999) | 791 (608 to 1029) | | |
| PPAS2: Serogroup W: Day 0 before dose 3 (n=93, 0) | 39.1 (29.6 to 51.8) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup W: Day 30 post dose 3 (n=87, 0) | 1049 (782 to 1406) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup W: Day 0 before dose 4 (n=0, 90) | 9999 (9999 to 9999) | 92.6 (74.3 to 115) | | |
| PPAS2: Serogroup W: Day 30 post dose 4 (n=0, 86) | 9999 (9999 to 9999) | 1024 (806 to 1301) | | |
| PPAS2: Serogroup Y: Day 0 before dose 3 (n=94, 0) | 33.0 (25.0 to 43.5) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup Y: Day 30 post dose 3 (n=94, 0) | 589 (470 to 737) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup Y: Day 0 before dose 4 (n=0, 90) | 9999 (9999 to 9999) | 85.8 (68.2 to 108) | | |
| PPAS2: Serogroup Y: Day 30 post dose 4 (n=0, 89) | 9999 (9999 to 9999) | 632 (512 to 780) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 1 and 2: Percentage of Participants With Serum Bactericidal Assay Using Human Complement Antibody Titers $\geq 1:4$ and $\geq 1:8$

| | |
|-----------------|--|
| End point title | Groups 1 and 2: Percentage of Participants With Serum Bactericidal Assay Using Human Complement Antibody Titers $\geq 1:4$ and $\geq 1:8$ ^[4] |
|-----------------|--|

End point description:

Functional meningococcal antibody activity against serogroups A, C, W, and Y were measured in a serum bactericidal assay utilizing the hSBA. Percentages are rounded off to the tenth decimal place. PPAS1 was a subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and had valid post-primary series vaccination blood sample result. PPAS2 was a subset of FAS2. FAS2: subset of randomized participants who received at least 1 dose of study vaccine at booster vaccination and had valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup. Dose=D.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Day 0 Before Dose 1 (2 MoA) and Day 30 Post Dose 2 (4 MoA); Day 0 Before Dose 3 (12 to 18 MoA) and Day 30 Post Dose 3 (12 to 18 MoA)

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only participants randomized in Groups 1 and 2 were analyzed in this endpoint.

| End point values | Group 1: MenACYW | Group 2: Nimenrix | | |
|---|---------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 554 | 579 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| PPAS1:Serogroup A: >=1:4:Day0 before D1(n=521,519) | 31.1 (27.1 to 35.3) | 28.3 (24.5 to 32.4) | | |
| PPAS1:Serogroup A: >=1:8: Day0 before D1(n=521,519) | 5.6 (3.8 to 7.9) | 6.4 (4.4 to 8.8) | | |
| PPAS1:Serogroup A: >=1:4:Day30 post D2(n=508,508) | 77.2 (73.3 to 80.7) | 88.0 (84.8 to 90.7) | | |
| PPAS1:Serogroup A: >=1:8:Day30 post D2(n=508,508) | 63.6 (59.2 to 67.8) | 75.8 (71.8 to 79.5) | | |
| PPAS1:Serogroup C: >=1:4:Day0 before D1(n=517,517) | 14.3 (11.4 to 17.6) | 14.9 (11.9 to 18.3) | | |
| PPAS1:Serogroup C: >=1:8:Day0 before D1(n=517,517) | 5.2 (3.5 to 7.5) | 5.2 (3.5 to 7.5) | | |
| PPAS1:Serogroup C: >=1:4:Day30 post D2(n=513,521) | 99.0 (97.7 to 99.7) | 96.4 (94.4 to 97.8) | | |
| PPAS1:Serogroup C: >=1:8:Day30 post D2(n=513,521) | 98.8 (97.5 to 99.6) | 91.9 (89.3 to 94.1) | | |
| PPAS1:Serogroup W: >=1:4:Day0 before D1(n=520,520) | 11.7 (9.1 to 14.8) | 11.0 (8.4 to 14.0) | | |
| PPAS1:Serogroup W: >=1:8:Day0 before D1(n=520,520) | 3.7 (2.2 to 5.6) | 3.5 (2.1 to 5.4) | | |
| PPAS1:Serogroup W: >=1:4:Day30 post D2(n=518,523) | 98.6 (97.2 to 99.5) | 98.3 (96.8 to 99.2) | | |
| PPAS1:Serogroup W: >=1:8:Day30 post D2(n=518,523) | 96.5 (94.6 to 97.9) | 94.5 (92.1 to 96.3) | | |
| PPAS1:Serogroup Y: >=1:4:Day0 before D1(n=519,518) | 10.0 (7.6 to 12.9) | 9.8 (7.4 to 12.7) | | |
| PPAS1:Serogroup Y: >=1:8:Day0 before D1(n=519,518) | 6.4 (4.4 to 8.8) | 5.6 (3.8 to 7.9) | | |
| PPAS1:Serogroup Y: >=1:4:Day30 post D2(n=516,523) | 98.3 (96.7 to 99.2) | 97.3 (95.5 to 98.5) | | |
| PPAS1:Serogroup Y: >=1:8:Day30 post D2(n=516,523) | 96.5 (94.5 to 97.9) | 93.5 (91.0 to 95.5) | | |
| PPAS2:Serogroup A: >=1:4:Day0 before D3(n=540,567) | 69.1 (65.0 to 73.0) | 73.7 (69.9 to 77.3) | | |
| PPAS2:Serogroup A: >=1:8:Day0 before D3(n=540,567) | 33.7 (29.7 to 37.9) | 46.2 (42.0 to 50.4) | | |
| PPAS2:Serogroup A: >=1:4:Day30 post D3(n=543,567) | 98.2 (96.6 to 99.1) | 98.1 (96.6 to 99.0) | | |
| PPAS2:Serogroup A: >=1:8:Day30 post D3(n=543,567) | 94.7 (92.4 to 96.4) | 96.5 (94.6 to 97.8) | | |
| PPAS2:Serogroup C: >=1:4:Day0 before D3(n=545,572) | 92.5 (89.9 to 94.5) | 62.1 (57.9 to 66.1) | | |
| PPAS2:Serogroup C: >=1:8:Day0 before D3(n=545,572) | 88.1 (85.1 to 90.7) | 41.6 (37.5 to 45.8) | | |
| PPAS2:Serogroup C: >=1:4:Day30 post D3(n=550,578) | 99.8 (99.0 to 100) | 98.1 (96.6 to 99.0) | | |
| PPAS2:Serogroup C: >=1:8:Day30 post D3(n=550,578) | 99.6 (98.7 to 100) | 95.5 (93.5 to 97.0) | | |
| PPAS2:Serogroup W: >=1:4:Day0 before D3(n=541,567) | 96.7 (94.8 to 98.0) | 91.2 (88.5 to 93.4) | | |

| | | | | |
|--|---------------------|---------------------|--|--|
| PPAS2:Serogroup W: >=1:8:Day0 before D3(n=541,567) | 89.1 (86.2 to 91.6) | 77.6 (73.9 to 81.0) | | |
| PPAS2:Serogroup W: >=1:4:Day30 post D3(n=547,575) | 100 (99.3 to 100) | 100 (99.4 to 100) | | |
| PPAS2:Serogroup W: >=1:8:Day30 post D3(n=547,575) | 99.8 (99.0 to 100) | 99.5 (98.5 to 99.9) | | |
| PPAS2:Serogroup Y: >=1:4:Day0 before D3(n=545,572) | 95.8 (93.7 to 97.3) | 85.7 (82.5 to 88.4) | | |
| PPAS2:Serogroup Y: >=1:8:Day0 before D3(n=545,572) | 87.9 (84.9 to 90.5) | 69.6 (65.6 to 73.3) | | |
| PPAS2:Serogroup Y: >=1:4:Day30 post D3(n=554,579) | 100 (99.3 to 100) | 100 (99.4 to 100) | | |
| PPAS2:Serogroup Y: >=1:8:Day30 post D3(n=554,579) | 100 (99.3 to 100) | 99.8 (99.0 to 100) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 3 and 4: Percentage of Participants With Serum Bactericidal Assay Using Human Complement Antibody Titers >=1:4 and >=1:8

| | |
|-----------------|--|
| End point title | Groups 3 and 4: Percentage of Participants With Serum Bactericidal Assay Using Human Complement Antibody Titers >=1:4 and >=1:8 ^[5] |
|-----------------|--|

End point description:

Functional meningococcal antibody activity against serogroups A, C, W, and Y were measured in a serum bactericidal assay utilizing the hSBA. Percentages are rounded off to the tenth decimal place. PPAS1 was a subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and had valid post-primary series vaccination blood sample result. PPAS2 was a subset of FAS2. FAS2: subset of randomized participants who received at least 1 dose of study vaccine at booster vaccination and had valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup. '9999' denotes that there were no participants analyzed. Dose=D.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Group 3: Day 0 before Dose 1 (2 MoA) and Dose 3 (12 to 18 MoA) and Day 30 Post Dose 2 (4 MoA) and Dose 3 (12 to 18 MoA); Group 4: Day 0 before Dose 1 (2 MoA) and Dose 4 (12 to 18 MoA) and Day 30 Post Dose 3 (6 MoA) and Dose 4 (12 to 18 MoA)

Notes:

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

Justification: Only participants randomized in Groups 3 and 4 were analyzed in this endpoint.

| End point values | Group 3: MenACYW | Group 4: MenACYW | | |
|--|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 96 | 90 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| PPAS1:Serogroup A: >=1:4:Day0 before D1(n=94,89) | 33.0 (23.6 to 43.4) | 32.6 (23.0 to 43.3) | | |
| PPAS1:Serogroup A: >=1:8:Day0 before D1(n=94,89) | 14.9 (8.4 to 23.7) | 11.2 (5.5 to 19.7) | | |
| PPAS1:Serogroup A: >=1:4:Day30 post D2(n=91,0) | 79.1 (69.3 to 86.9) | 9999 (9999 to 9999) | | |
| PPAS1:Serogroup A: >=1:8:Day30 post D2(n=91,0) | 63.7 (53.0 to 73.6) | 9999 (9999 to 9999) | | |

| | | | | |
|---|---------------------|---------------------|--|--|
| PPAS1:Serogroup A:>=1:4:Day30 post D3(n=0,88) | 9999 (9999 to 9999) | 92.0 (84.3 to 96.7) | | |
| PPAS1:Serogroup A:>=1:8:Day30 post D3(n=0,88) | 9999 (9999 to 9999) | 81.8 (72.2 to 89.2) | | |
| PPAS1:Serogroup C:>=1:4:Day0 before D1(n=94,90) | 43.6 (33.4 to 54.2) | 48.9 (38.2 to 59.7) | | |
| PPAS1:Serogroup C:>=1:8:Day0 before D1(n=94,90) | 26.6 (18.0 to 36.7) | 32.2 (22.8 to 42.9) | | |
| PPAS1:Serogroup C:>=1:4:Day30 post D2(n=95,0) | 98.9 (94.3 to 100) | 9999 (9999 to 9999) | | |
| PPAS1:Serogroup C:>=1:8:Day30 post D2(n=95,0) | 98.9 (94.3 to 100) | 9999 (9999 to 9999) | | |
| PPAS1:Serogroup C:>=1:4:Day30 post D3(n=0,90) | 9999 (9999 to 9999) | 98.9 (94.0 to 100) | | |
| PPAS1:Serogroup C:>=1:8:Day30 post D3(n=0,90) | 9999 (9999 to 9999) | 98.9 (94.0 to 100) | | |
| PPAS1:Serogroup W:>=1:4:Day0 before D1(n=94,90) | 28.7 (19.9 to 39.0) | 35.6 (25.7 to 46.3) | | |
| PPAS1:Serogroup W:>=1:8:Day0 before D1(n=94,90) | 10.6 (5.2 to 18.7) | 16.7 (9.6 to 26.0) | | |
| PPAS1:Serogroup W:>=1:4:Day30 post D2(n=96,0) | 99.0 (94.3 to 100) | 9999 (9999 to 9999) | | |
| PPAS1:Serogroup W:>=1:8:Day30 post D2(n=96,0) | 96.9 (91.1 to 99.4) | 9999 (9999 to 9999) | | |
| PPAS1:Serogroup W:>=1:4:Day30 post D3(n=0,90) | 9999 (9999 to 9999) | 98.9 (94.0 to 100) | | |
| PPAS1:Serogroup W:>=1:8:Day30 post D3(n=0,90) | 9999 (9999 to 9999) | 98.9 (94.0 to 100) | | |
| PPAS1:Serogroup Y:>=1:4:Day0 before D1(n=94,90) | 26.6 (18.0 to 36.7) | 22.2 (14.1 to 32.2) | | |
| PPAS1:Serogroup Y:>=1:8:Day0 before D1(n=94,90) | 12.8 (6.8 to 21.2) | 12.2 (6.3 to 20.8) | | |
| PPAS1:Serogroup Y:>=1:4:Day30 post D2(n=96,0) | 99.0 (94.3 to 100) | 9999 (9999 to 9999) | | |
| PPAS1:Serogroup Y:>=1:8:Day30 post D2(n=96,0) | 95.8 (89.7 to 98.9) | 9999 (9999 to 9999) | | |
| PPAS1:Serogroup Y:>=1:4:Day30 post D3(n=0,90) | 9999 (9999 to 9999) | 98.9 (94.0 to 100) | | |
| PPAS1:Serogroup Y:>=1:8:Day30 post D3(n=0,90) | 9999 (9999 to 9999) | 98.9 (94.0 to 100) | | |
| PPAS2:Serogroup A:>=1:4:Day0 before D3(n=91,0) | 65.9 (55.3 to 75.5) | 9999 (9999 to 9999) | | |
| PPAS2:Serogroup A:>=1:8:Day0 before D3(n=91,0) | 37.4 (27.4 to 48.1) | 9999 (9999 to 9999) | | |
| PPAS2:Serogroup A:>=1:4:Day30 post D3(n=92,0) | 92.4 (84.9 to 96.9) | 9999 (9999 to 9999) | | |
| PPAS2:Serogroup A:>=1:8:Day30 post D3(n=92,0) | 89.1 (80.9 to 94.7) | 9999 (9999 to 9999) | | |
| PPAS2:Serogroup A:>=1:4:Day0 before D4(n=0,89) | 9999 (9999 to 9999) | 80.9 (71.2 to 88.5) | | |
| PPAS2:Serogroup A:>=1:8:Day0 before D4(n=0,89) | 9999 (9999 to 9999) | 52.8 (41.9 to 63.5) | | |
| PPAS2:Serogroup A:>=1:4:Day30 post D4(n=0,89) | 9999 (9999 to 9999) | 82.0 (72.5 to 89.4) | | |
| PPAS2: Serogroup A: >=1:8: Day 30 post D4(n=0,89) | 9999 (9999 to 9999) | 82.0 (72.5 to 89.4) | | |
| PPAS2:Serogroup C:>=1:4:Day0 before D3(n=94,0) | 87.2 (78.8 to 93.2) | 9999 (9999 to 9999) | | |
| PPAS2:Serogroup C:>=1:8:Day0 before D3(n=94,0) | 79.8 (70.2 to 87.4) | 9999 (9999 to 9999) | | |
| PPAS2:Serogroup C:>=1:4:Day30 post D3(n=93,0) | 100 (96.1 to 100) | 9999 (9999 to 9999) | | |

| | | | | |
|--|---------------------|---------------------|--|--|
| PPAS2:Serogroup C:>=1:8:Day30 post D3(n=93,0) | 100 (96.1 to 100) | 9999 (9999 to 9999) | | |
| PPAS2:Serogroup C:>=1:4:Day0 before D4(n=0,89) | 9999 (9999 to 9999) | 97.8 (92.1 to 99.7) | | |
| PPAS2:Serogroup C:>=1:8:Day0 before D4(n=0,89) | 9999 (9999 to 9999) | 92.1 (84.5 to 96.8) | | |
| PPAS2:Serogroup C:>=1:4:Day30 post D4(n=0,86) | 9999 (9999 to 9999) | 100 (95.8 to 100) | | |
| PPAS2:Serogroup C:>=1:8:Day30 post D4(n=0,86) | 9999 (9999 to 9999) | 100 (95.8 to 100) | | |
| PPAS2:Serogroup W:>=1:4:Day0 before D3(n=93,0) | 96.8 (90.9 to 99.3) | 9999 (9999 to 9999) | | |
| PPAS2:Serogroup W:>=1:8:Day0 before D3(n=93,0) | 92.5 (85.1 to 96.9) | 9999 (9999 to 9999) | | |
| PPAS2:Serogroup W:>=1:4:Day30 post D3(n=87,0) | 100 (95.8 to 100) | 9999 (9999 to 9999) | | |
| PPAS2:Serogroup W:>=1:8:Day30 post D3(n=87,0) | 100 (95.8 to 100) | 9999 (9999 to 9999) | | |
| PPAS2:Serogroup W:>=1:4:Day0 before D4(n=0,90) | 9999 (9999 to 9999) | 100 (96.0 to 100) | | |
| PPAS2:Serogroup W:>=1:8:Day0 before D4(n=0,90) | 9999 (9999 to 9999) | 100 (96.0 to 100) | | |
| PPAS2:Serogroup W:>=1:4:Day30 post D4(n=0,86) | 9999 (9999 to 9999) | 100 (95.8 to 100) | | |
| PPAS2:Serogroup W:>=1:8:Day30 post D4(n=0,86) | 9999 (9999 to 9999) | 100 (95.8 to 100) | | |
| PPAS2:Serogroup Y:>=1:4:Day0 before D3(n=94,0) | 94.7 (88.0 to 98.3) | 9999 (9999 to 9999) | | |
| PPAS2:Serogroup Y:>=1:8:Day0 before D3(n=94,0) | 89.4 (81.3 to 94.8) | 9999 (9999 to 9999) | | |
| PPAS2:Serogroup Y:>=1:4:Day30 post D3(n=94,0) | 100 (96.2 to 100) | 9999 (9999 to 9999) | | |
| PPAS2:Serogroup Y:>=1:8:Day30 post D3(n=94,0) | 100 (96.2 to 100) | 9999 (9999 to 9999) | | |
| PPAS2:Serogroup Y:>=1:4:Day0 before D4(n=0,90) | 9999 (9999 to 9999) | 100 (96.0 to 100) | | |
| PPAS2:Serogroup Y:>=1:8:Day0 before D4(n=0,90) | 9999 (9999 to 9999) | 100 (96.0 to 100) | | |
| PPAS2:Serogroup Y:>=1:4:Day30 post D4(n=0,89) | 9999 (9999 to 9999) | 100 (95.9 to 100) | | |
| PPAS2:Serogroup Y:>=1:8:Day30 post D4(n=0,89) | 9999 (9999 to 9999) | 100 (95.9 to 100) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 1 and 2: Percentage of Participants With Vaccine Seroresponse

| | |
|-----------------|---|
| End point title | Groups 1 and 2: Percentage of Participants With Vaccine Seroresponse ^[6] |
|-----------------|---|

End point description:

Functional meningococcal antibody activity against serogroups A, C, W, and Y were measured in a serum bactericidal assay utilizing the hSBA. hSBA vaccine seroresponse was defined for a participant with a pre vaccination titer <1:8, post-vaccination titer must be >=1:16 and for a participant with a pre vaccination titer >=1:8, post-vaccination titer must be at least 4-fold greater than the pre vaccination titer. Percentages are rounded off to tenth decimal place. PPAS1 was subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and had valid post-primary series vaccination blood sample result. PPAS2 was subset of FAS2. FAS2: subset of

randomized participants who received at least 1 dose of study vaccine at booster vaccination and had valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Day 30 Post Doses 2 and 3 (4 MoA and 12 to 18 MoA) | |

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only participants randomized in Groups 1 and 2 were analyzed in this endpoint.

| End point values | Group 1: MenACYW | Group 2: Nimenrix | | |
|--|---------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 539 | 568 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| PPAS1: Serogroup A: Day 30 post dose 2 (n=507,504) | 46.7 (42.3 to 51.2) | 60.9 (56.5 to 65.2) | | |
| PPAS1: Serogroup C: Day 30 post dose 2 (n=508,514) | 97.4 (95.7 to 98.6) | 86.8 (83.5 to 89.6) | | |
| PPAS1: Serogroup W: Day 30 post dose 2 (n=516,519) | 92.6 (90.0 to 94.7) | 88.4 (85.4 to 91.1) | | |
| PPAS1: Serogroup Y: Day 30 post dose 2 (n=513,517) | 87.1 (83.9 to 89.9) | 81.4 (77.8 to 84.7) | | |
| PPAS2: Serogroup A: Day 30 post dose 3 (n=525,553) | 88.6 (85.5 to 91.2) | 87.7 (84.7 to 90.3) | | |
| PPAS2: Serogroup C: Day 30 post dose 3 (n=536,567) | 93.7 (91.2 to 95.6) | 88.9 (86.0 to 91.4) | | |
| PPAS2: Serogroup W: Day 30 post dose 3 (n=531,560) | 92.3 (89.7 to 94.4) | 94.6 (92.4 to 96.4) | | |
| PPAS2: Serogroup Y: Day 30 post dose 3 (n=539,568) | 89.4 (86.5 to 91.9) | 90.1 (87.4 to 92.5) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 3 and 4: Percentage of Participants With Vaccine Seroresponse

| | |
|-----------------|---|
| End point title | Groups 3 and 4: Percentage of Participants With Vaccine Seroresponse ^[7] |
|-----------------|---|

End point description:

Functional meningococcal antibody activity against serogroups A, C, W, and Y were measured in a serum bactericidal assay utilizing hSBA. hSBA vaccine seroresponse was defined for a participant with a pre vaccination titer <1:8, post-vaccination titer must be ≥1:16 and for a participant with a pre vaccination titer ≥1:8, post-vaccination titer must be at least 4-fold greater than pre vaccination titer. Percentages are rounded off to tenth decimal place. PPAS1 was a subset of FAS1. PPAS2 was a subset of FAS2. Here, n=number of participants with data collected for each specific serogroup. '9999' denotes that there were no participants analyzed.

| | |
|---|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Group 3: Day 30 Post Dose 2 (4 MoA), Day 30 Post Dose 3 (12 to 18 MoA); Group 4: D30 Post Dose 3 (6 MoA), Day 30 Post Dose 4 (12 to 18 MoA) | |

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only participants randomized in Groups 3 and 4 were analyzed in this endpoint.

| End point values | Group 3: MenACYW | Group 4: MenACYW | | |
|---|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 94 | 90 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| PPAS1: Serogroup A: Day 30 post dose 2 (n=89,0) | 51.7 (40.8 to 62.4) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup A: Day 30 post dose 3 (n=0,87) | 9999 (9999 to 9999) | 65.5 (54.6 to 75.4) | | |
| PPAS1: Serogroup C: Day 30 post dose 2 (n=93,0) | 92.5 (85.1 to 96.9) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup C: Day 30 post dose 3 (n=0,90) | 9999 (9999 to 9999) | 96.7 (90.6 to 99.3) | | |
| PPAS1: Serogroup W: Day 30 post dose 2 (n=94,0) | 94.7 (88.0 to 98.3) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup W: Day 30 post dose 3 (n=0,90) | 9999 (9999 to 9999) | 95.6 (89.0 to 98.8) | | |
| PPAS1: Serogroup Y: Day 30 post dose 2 (n=94,0) | 89.4 (81.3 to 94.8) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup Y: Day 30 post dose 3 (n=0,90) | 9999 (9999 to 9999) | 94.4 (87.5 to 98.2) | | |
| PPAS2: Serogroup A: Day 30 post dose 3 (n=90,0) | 77.8 (67.8 to 85.9) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup A: Day 30 post dose 4 (n=0,88) | 9999 (9999 to 9999) | 63.6 (52.7 to 73.6) | | |
| PPAS2: Serogroup C: Day 30 post dose 3 (n=93,0) | 97.8 (92.4 to 99.7) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup C: Day 30 post dose 4 (n=0,86) | 9999 (9999 to 9999) | 95.3 (88.5 to 98.7) | | |
| PPAS2: Serogroup W: Day 30 post dose 3 (n=86,0) | 97.7 (91.9 to 99.7) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup W: Day 30 post dose 4 (n=0,86) | 9999 (9999 to 9999) | 89.5 (81.1 to 95.1) | | |
| PPAS2: Serogroup Y: Day 30 post dose 3 (n=94,0) | 91.5 (83.9 to 96.3) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup Y: Day 30 post dose 4 (n=0,89) | 9999 (9999 to 9999) | 80.9 (71.2 to 88.5) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentrations (GMCs) of Anti-Pertussis Antibodies

| | |
|-----------------|---|
| End point title | Geometric Mean Concentrations (GMCs) of Anti-Pertussis Antibodies |
|-----------------|---|

End point description:

GMCs of anti-pertussis antibodies (pertussis toxin [PT], filamentous hemagglutinin [FHA]) were measured by electrochemiluminescent (ECL) assay. PPAS1 was a subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and had valid post-primary series vaccination blood sample result. PPAS2 was a subset of FAS2. FAS2: subset of randomized participants who received at least 1 dose of study vaccine at booster vaccination and had

valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup. '9999' denotes that there were no participants analyzed. Dose=D.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Groups 1, 2 and 3: Day 0 before Dose 1 (2 MoA); Group 4: Day 0 before Dose 4 (12 to 18 MoA)

| End point values | Group 1: MenACYW | Group 2: Nimenrix | Group 3: MenACYW | Group 4: MenACYW |
|---|---------------------|----------------------|---------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 520 | 521 | 95 | 90 |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| PPAS1: Anti-PT: Day 0 before D1 (n=520,521,95,0) | 2.97 (2.68 to 3.29) | 2.61 (2.38 to 2.87) | 11.0 (8.74 to 14.0) | 9999 (9999 to 9999) |
| PPAS1: Anti-FHA: Day 0 before D1 (n=520,521,95,0) | 10.8 (9.73 to 12.1) | 10.1 (9.10 to 11.2) | 55.6 (42.4 to 73.0) | 9999 (9999 to 9999) |
| PPAS2: Anti-PT: Day 0 before D4 (n=0,0,0,90) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 10.7 (8.82 to 13.1) |
| PPAS2: Anti-FHA: Day 0 before D4 (n=0,0,0,90) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 30.3 (25.0 to 36.7) |

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentrations of Hexavalent Vaccines

| | |
|-----------------|--|
| End point title | Geometric Mean Concentrations of Hexavalent Vaccines |
|-----------------|--|

End point description:

GMCs of hexavalent vaccines were measured as:anti-diphtheria (AD),anti-tetanus (AT), anti-pertussis antibodies (PT, FHA) by ECL assay,anti-hepatitis antibodies (anti-Hepatitis B surface antigen [HBsAg]) by the commercially available VITROS ECi/ECiQ, anti-poliovirus(AP) types 1, 2, and 3 by neutralization assay and anti-Haemophilus influenzae type b (anti-polyribosylribitol phosphate [PRP]) by Farr-type radioimmunoassay (RIA). PPAS1: subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and had valid post-primary series vaccination blood sample result. PPAS2: subset of FAS2. FAS2: subset of randomized participants who received at least 1 dose of study vaccine at booster vaccination and had valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup. '9999':no participants analyzed. Dose=D.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Groups 1, 2 and 3: Day 30 Post Doses 2 and 3 (4 MoA and 12 to 18 MoA); Day 0 Before Dose 3 (12 to 18 MoA); Group 4: Day 30 Post Dose 4 (12 to 18 MoA)

| End point values | Group 1: MenACYW | Group 2: Nimenrix | Group 3: MenACYW | Group 4: MenACYW |
|--|------------------------|------------------------|------------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 555 | 583 | 96 | 90 |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| PPAS1: AD: Day 30 after D2 (n=514,520,93,0) | 0.523 (0.474 to 0.578) | 0.489 (0.443 to 0.541) | 0.563 (0.458 to 0.691) | 9999 (9999 to 9999) |
| PPAS1: AT: Day 30 after D2 (n=514,520,93,0) | 1.10 (1.02 to 1.18) | 1.13 (1.05 to 1.22) | 0.931 (0.788 to 1.10) | 9999 (9999 to 9999) |
| PPAS1: Anti-PT: Day 30 after D2 (n=514,520,93,0) | 64.9 (61.4 to 68.7) | 68.1 (64.5 to 72.0) | 50.0 (43.2 to 58.0) | 9999 (9999 to 9999) |
| PPAS1: Anti-FHA: Day 30 after D2 (n=514,520,93,0) | 92.4 (87.3 to 97.8) | 96.6 (90.8 to 103) | 125 (109 to 144) | 9999 (9999 to 9999) |
| PPAS1: Anti-HBsAg:Day30 after D2 (n=505,510,92,0) | 369 (323 to 421) | 345 (303 to 393) | 218 (147 to 322) | 9999 (9999 to 9999) |
| PPAS1: AP 1: Day 30 after D2 (n=486,489,83,0) | 47.1 (40.1 to 55.3) | 43.5 (37.0 to 51.2) | 362 (260 to 504) | 9999 (9999 to 9999) |
| PPAS1: AP 2: Day 30 after D2 (n=482,485,79,0) | 139 (117 to 167) | 143 (120 to 171) | 618 (429 to 890) | 9999 (9999 to 9999) |
| PPAS1: AP 3: Day 30 after D2 (n=488,492,82,0) | 133 (112 to 157) | 145 (123 to 172) | 584 (419 to 814) | 9999 (9999 to 9999) |
| PPAS1: Anti-PRP: Day 30 after D2 (n=517,521,96,0) | 0.376 (0.326 to 0.435) | 0.435 (0.379 to 0.499) | 0.725 (0.492 to 1.07) | 9999 (9999 to 9999) |
| PPAS2: AD: Day 0 before D3 (n=542,569,91,0) | 0.086 (0.079 to 0.095) | 0.080 (0.073 to 0.087) | 0.094 (0.076 to 0.116) | 9999 (9999 to 9999) |
| PPAS2: AD: Day 30 after D3 (n=551,577,92,0) | 1.82 (1.69 to 1.96) | 1.69 (1.57 to 1.81) | 2.71 (2.36 to 3.11) | 9999 (9999 to 9999) |
| PPAS2: AD: Day 30 after D4 (n=0,0,0,89) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 3.26 (2.88 to 3.69) |
| PPAS2: AT: Day 0 before D3 (n=542,571,92,0) | 0.362 (0.336 to 0.391) | 0.424 (0.397 to 0.453) | 0.218 (0.180 to 0.264) | 9999 (9999 to 9999) |
| PPAS2: AT: Day 30 after D3 (n=551,577,92,0) | 6.71 (6.33 to 7.12) | 8.59 (8.13 to 9.08) | 6.02 (5.06 to 7.16) | 9999 (9999 to 9999) |
| PPAS2: AT: Day 30 after D4 (n=0,0,0,89) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 7.00 (5.99 to 8.18) |
| PPAS2: Anti-PT: Day 0 before D3 (n=542,571,92,0) | 14.8 (13.8 to 15.8) | 14.6 (13.7 to 15.6) | 10.4 (8.99 to 12.0) | 9999 (9999 to 9999) |
| PPAS2: Anti-PT: Day 30 after D3 (n=551,577,92,0) | 111 (105 to 118) | 109 (104 to 115) | 79.2 (66.2 to 94.6) | 9999 (9999 to 9999) |
| PPAS2: Anti-PT: Day 30 after D4 (n=0,0,0,89) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 80.9 (68.2 to 95.9) |
| PPAS2: Anti-FHA: Day 0 before D3 (n=542,571,92,0) | 38.4 (35.8 to 41.2) | 38.1 (35.5 to 40.8) | 30.6 (26.0 to 36.0) | 9999 (9999 to 9999) |
| PPAS2: Anti-FHA: Day 30 after D3 (n=551,577,92,0) | 177 (167 to 187) | 184 (173 to 195) | 168 (142 to 200) | 9999 (9999 to 9999) |
| PPAS2: Anti-FHA: Day 30 after D4 (n=0,0,0,89) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 181 (151 to 217) |
| PPAS2: Anti-HBsAg:Day0 before D3 (n=535,565,91,0) | 53.0 (45.5 to 61.8) | 48.8 (42.1 to 56.5) | 26.0 (17.6 to 38.2) | 9999 (9999 to 9999) |
| PPAS2:Anti-HBsAg:Day30 after D3 (n=546,571,90,0) | 2273 (1927 to 2681) | 2158 (1852 to 2515) | 1117 (666 to 1872) | 9999 (9999 to 9999) |
| PPAS2:Anti-HBsAg:Day30 after D4 (n=0,0,0,86) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 1144 (648 to 2020) |
| PPAS2: AP 1: Day 0 before D3 (n=526,559,89,0) | 14.5 (12.7 to 16.5) | 13.6 (12.0 to 15.4) | 55.2 (40.8 to 74.6) | 9999 (9999 to 9999) |
| PPAS2: AP 1: Day 30 after D3 (n=533,553,86,0) | 1099 (980 to 1233) | 994 (883 to 1119) | 1538 (1212 to 1952) | 9999 (9999 to 9999) |
| PPAS2: AP 1: Day 30 after D4 (n=0,0,0,87) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 1625 (1291 to 2047) |

| | | | | |
|--|------------------------|------------------------|------------------------|---------------------|
| PPAS2: AP 2: Day 0 before D3 (n=528,560,88,0) | 33.2 (28.7 to 38.4) | 33.1 (28.8 to 37.9) | 85.3 (63.9 to 114) | 9999 (9999 to 9999) |
| PPAS2: AP 2: Day 30 after D3 (n=530,554,87,0) | 2214 (1982 to 2472) | 2146 (1937 to 2379) | 3549 (2846 to 4425) | 9999 (9999 to 9999) |
| PPAS2: AP 2: Day 30 after D4 (n=0,0,0,87) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 3858 (3001 to 4960) |
| PPAS2: AP 3: Day 0 before D3 (n=529,560,89,0) | 19.7 (17.1 to 22.6) | 18.4 (16.0 to 21.1) | 37.7 (27.6 to 51.5) | 9999 (9999 to 9999) |
| PPAS2: AP 3: Day 30 after D3 (n=531,557,87,0) | 1595 (1393 to 1827) | 1533 (1361 to 1728) | 2431 (1897 to 3115) | 9999 (9999 to 9999) |
| PPAS2: AP 3: Day 30 after D4 (n=0,0,0,87) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 3397 (2567 to 4495) |
| PPAS2: Anti-PRP: Day 0 before D3 (n=545,571,93,0) | 0.201 (0.176 to 0.230) | 0.224 (0.197 to 0.255) | 0.244 (0.174 to 0.343) | 9999 (9999 to 9999) |
| PPAS2: Anti-PRP: Day 30 after D3 (n=555,583,91,0) | 9.42 (8.31 to 10.7) | 11.5 (10.3 to 12.9) | 16.1 (11.9 to 21.6) | 9999 (9999 to 9999) |
| PPAS2: Anti-PRP: Day 30 after D4 (n=0,0,0,90) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 16.1 (12.1 to 21.6) |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Response Rate for Anti-Diphtheria, Anti-Tetanus, Anti-Poliovirus Types 1, 2, and 3, Anti-Haemophilus Influenzae Type b (Anti-PRP)

| | |
|-----------------|---|
| End point title | Percentage of Participants With Response Rate for Anti-Diphtheria, Anti-Tetanus, Anti-Poliovirus Types 1, 2, and 3, Anti-Haemophilus Influenzae Type b (Anti-PRP) |
|-----------------|---|

End point description:

GMCs of AD, AT, AP types 1, 2, and 3, anti-haemophilus influenzae type b (anti-PRP) vaccines were measured as AD, AT by ECL assay, AP types 1, 2, and 3 by neutralization assay and anti-Haemophilus influenzae type b (anti-PRP) by Farr-type RIA. Response rate was defined as percentage of participants who achieved: AD and AT antibody concentrations ≥ 0.01 international units (IU)/milliliter (mL), ≥ 0.1 IU/mL and ≥ 1.0 IU/mL; AP types 1, 2, and 3 antibody titers $\geq 1:8$; anti-PRP antibody concentrations ≥ 0.15 microgram(mcg)/mL and ≥ 1 mcg/mL. Percentages are rounded off to the tenth decimal place. PPAS1 was a subset of FAS1. PPAS2 was a subset of FAS2. Here, n=number of participants with data collected for each specific serogroup. '9999' denotes that there were no participants analyzed. Dose=D.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Groups 1, 2 and 3: Day 30 Post Doses 2 and 3 (4 MoA and 12 to 18 MoA); Day 0 Before Dose 3 (12 to 18 MoA); Group 4: Day 30 Post Dose 4 (12 to 18 MoA)

| End point values | Group 1: MenACYW | Group 2: Nimenrix | Group 3: MenACYW | Group 4: MenACYW |
|---|---------------------|----------------------|---------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 555 | 583 | 96 | 90 |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| PPAS1:AD: ≥ 0.01 IU/mL:Day30 post D2(n=514,520,93,0) | 100 (99.3 to 100) | 99.8 (98.9 to 100) | 100 (96.1 to 100) | 9999 (9999 to 9999) |
| PPAS1:AD: ≥ 0.1 IU/mL:Day30 post D2(n=514,520,93,0) | 90.5 (87.6 to 92.9) | 89.6 (86.7 to 92.1) | 94.6 (87.9 to 98.2) | 9999 (9999 to 9999) |

| | | | | |
|--|---------------------|---------------------|---------------------|---------------------|
| PPAS1:AD:>=1.0IU/mL:Day30 post D2(n=514,520,93,0) | 32.7 (28.6 to 36.9) | 32.5 (28.5 to 36.7) | 33.3 (23.9 to 43.9) | 9999 (9999 to 9999) |
| PPAS1:AT:>=0.01IU/mL:Day30 post D2(n=514,520,93,0) | 100 (99.3 to 100) | 100 (99.3 to 100) | 100 (96.1 to 100) | 9999 (9999 to 9999) |
| PPAS1:AT:>=0.1IU/mL:Day30 post D2(n=514,520,93,0) | 100 (99.3 to 100) | 99.8 (98.9 to 100) | 100 (96.1 to 100) | 9999 (9999 to 9999) |
| PPAS1:AT:>=1.0IU/mL:Day30 post D2(n=514,520,93,0) | 53.3 (48.9 to 57.7) | 56.3 (52.0 to 60.7) | 44.1 (33.8 to 54.8) | 9999 (9999 to 9999) |
| PPAS1:AP 1:>=1:8:Day30 post D2(n=486,489,83,0) | 87.0 (83.7 to 89.9) | 83.2 (79.6 to 86.4) | 98.8 (93.5 to 100) | 9999 (9999 to 9999) |
| PPAS1:AP 2:>=1:8:Day30 post D2(n=482,485,79,0) | 97.5 (95.7 to 98.7) | 98.6 (97.0 to 99.4) | 100 (95.4 to 100) | 9999 (9999 to 9999) |
| PPAS1:AP 3:>=1:8:Day30 post D2(n=488,492,82,0) | 95.9 (93.7 to 97.5) | 96.1 (94.0 to 97.7) | 98.8 (93.4 to 100) | 9999 (9999 to 9999) |
| PPAS1:Anti-PRP:>=0.15:Day30 postD2(n=517,521,96,0) | 71.8 (67.7 to 75.6) | 74.9 (70.9 to 78.5) | 78.1 (68.5 to 85.9) | 9999 (9999 to 9999) |
| PPAS1:Anti-PRP:>=1:Day30 postD2(n=517,521,96,0) | 24.2 (20.5 to 28.1) | 27.3 (23.5 to 31.3) | 39.6 (29.7 to 50.1) | 9999 (9999 to 9999) |
| PPAS2:AD:>=0.01IU/mL:Day0 beforeD3(n=542,569,91,0) | 98.2 (96.6 to 99.1) | 98.6 (97.2 to 99.4) | 97.8 (92.3 to 99.7) | 9999 (9999 to 9999) |
| PPAS2:AD:>=0.01IU/mL:Day30 afterD3(n=551,577,92,0) | 100 (99.3 to 100) | 100 (99.4 to 100) | 100 (96.1 to 100) | 9999 (9999 to 9999) |
| PPAS2:AD:>=0.01IU/mL:Day30 afterD4(n=0,0,0,89) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 100 (95.9 to 100) |
| PPAS2:AD:>=0.1IU/mL:Day0 beforeD3(n=542,569,91,0) | 48.2 (43.9 to 52.5) | 41.3 (37.2 to 45.5) | 47.3 (36.7 to 58.0) | 9999 (9999 to 9999) |
| PPAS2:AD:>=0.1IU/mL:Day30 afterD3(n=551,577,92,0) | 99.6 (98.7 to 100) | 99.8 (99.0 to 100) | 100 (96.1 to 100) | 9999 (9999 to 9999) |
| PPAS2:AD:>=0.1IU/mL:Day30 afterD4(n=0,0,0,89) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 100 (95.9 to 100) |
| PPAS2:AD:>=1.0IU/mL:Day0 beforeD3(n=542,569,91,0) | 1.1 (0.4 to 2.4) | 0.7 (0.2 to 1.8) | 0 (0 to 4.0) | 9999 (9999 to 9999) |
| PPAS2:AD:>=1.0IU/mL:Day30 afterD3(n=551,577,92,0) | 75.5 (71.7 to 79.0) | 72.4 (68.6 to 76.1) | 92.4 (84.9 to 96.9) | 9999 (9999 to 9999) |
| PPAS2:AD:>=1.0IU/mL:Day30 afterD4(n=0,0,0,89) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 100 (95.9 to 100) |
| PPAS2:AT:>=0.01IU/mL:Day0 beforeD3(n=542,571,92,0) | 100 (99.3 to 100) | 100 (99.4 to 100) | 100 (96.1 to 100) | 9999 (9999 to 9999) |
| PPAS2:AT:>=0.01IU/mL:Day30 afterD3(n=551,577,92,0) | 100 (99.3 to 100) | 100 (99.4 to 100) | 100 (96.1 to 100) | 9999 (9999 to 9999) |
| PPAS2:AT:>=0.01IU/mL:Day30 afterD4(n=0,0,0,89) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 100 (95.9 to 100) |
| PPAS2:AT:>=0.1IU/mL:Day0 beforeD3(n=542,571,92,0) | 94.1 (91.8 to 95.9) | 97.4 (95.7 to 98.5) | 83.7 (74.5 to 90.6) | 9999 (9999 to 9999) |
| PPAS2:AT:>=0.1IU/mL:Day30 afterD3(n=551,577,92,0) | 100 (99.3 to 100) | 100 (99.4 to 100) | 100 (96.1 to 100) | 9999 (9999 to 9999) |
| PPAS2:AT:>=0.1IU/mL:Day30 afterD4(n=0,0,0,89) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 100 (95.9 to 100) |
| PPAS2:AT:>=1.0IU/mL:Day0 beforeD3(n=542,571,92,0) | 10.7 (8.2 to 13.6) | 14.7 (11.9 to 17.9) | 6.5 (2.4 to 13.7) | 9999 (9999 to 9999) |
| PPAS2:AT:>=1.0IU/mL:Day30 afterD3(n=551,577,92,0) | 99.6 (98.7 to 100) | 99.7 (98.8 to 100) | 96.7 (90.8 to 99.3) | 9999 (9999 to 9999) |
| PPAS2:AT:>=1.0IU/mL:Day30 afterD4(n=0,0,0,89) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 98.9 (93.9 to 100) |
| PPAS2:AP 1:>=1:8:Day0 before D3(n=526,559,89,0) | 64.4 (60.2 to 68.5) | 63.7 (59.5 to 67.7) | 93.3 (85.9 to 97.5) | 9999 (9999 to 9999) |
| PPAS2:AP 1:>=1:8:Day30 after D3(n=533,553,86,0) | 99.8 (99.0 to 100) | 98.9 (97.7 to 99.6) | 100 (95.8 to 100) | 9999 (9999 to 9999) |
| PPAS2:AP 1:>=1:8:Day30 after D4(n=0,0,0,87) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 100 (95.8 to 100) |
| PPAS2:AP 2:>=1:8:Day0 before D3(n=528,560,88,0) | 79.5 (75.8 to 82.9) | 80.9 (77.4 to 84.1) | 95.5 (88.8 to 98.7) | 9999 (9999 to 9999) |

| | | | | |
|---|---------------------|---------------------|---------------------|---------------------|
| PPAS2:AP 2:>=1:8:Day30 after D3(n=530,554,87,0) | 100 (99.3 to 100) | 100 (99.3 to 100) | 100 (95.8 to 100) | 9999 (9999 to 9999) |
| PPAS2:AP 2:>=1:8:Day30 after D4(n=0,0,0,87) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 100 (95.8 to 100) |
| PPAS2:AP 3:>=1:8:Day0 before D3(n=529,560,89,0) | 68.6 (64.5 to 72.6) | 65.7 (61.6 to 69.6) | 84.3 (75.0 to 91.1) | 9999 (9999 to 9999) |
| PPAS2:AP 3:>=1:8:Day30 after D3(n=531,557,87,0) | 99.2 (98.1 to 99.8) | 99.8 (99.0 to 100) | 100 (95.8 to 100) | 9999 (9999 to 9999) |
| PPAS2:AP 3:>=1:8:Day30 after D4(n=0,0,0,87) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 100 (95.8 to 100) |
| PPAS2:Anti-PRP:>=0.15:Day0beforeD3(n=545,571, | 56.5 (52.2 to 60.7) | 60.4 (56.3 to 64.5) | 60.2 (49.5 to 70.2) | 9999 (9999 to 9999) |
| PPAS2:Anti-PRP:>=0.15:Day30afterD3(n=555,583, | 98.2 (96.7 to 99.1) | 98.8 (97.5 to 99.5) | 100 (96.0 to 100) | 9999 (9999 to 9999) |
| PPAS2:Anti-PRP:>=0.15:Day30afterD4(n=0,0,0,90) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 100 (96.0 to 100) |
| PPAS2:Anti-PRP:>=1:Day0beforeD3(n=545,571,93, | 13.9 (11.1 to 17.1) | 14.9 (12.1 to 18.1) | 15.1 (8.5 to 24.0) | 9999 (9999 to 9999) |
| PPAS2:Anti-PRP:>=1:Day30afterD3(n=555,583,91, | 91.5 (88.9 to 93.7) | 94.9 (92.7 to 96.5) | 97.8 (92.3 to 99.7) | 9999 (9999 to 9999) |
| PPAS2:Anti-PRP:>=1:Day30afterD4(n=0,0,0,90) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 96.7 (90.6 to 99.3) |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved Vaccine Seroresponse for Anti-Pertussis Antibodies

| | |
|-----------------|--|
| End point title | Percentage of Participants who Achieved Vaccine Seroresponse for Anti-Pertussis Antibodies |
|-----------------|--|

End point description:

GMCs of anti-pertussis antibodies (PT, FHA) were measured by ECL assay. Pertussis vaccine seroresponse was defined as: For groups 1, 2, and 3, 30 days after dose 2 in infancy as if pre-primary vaccination concentration is $<4 \times$ lower limit of quantification (LLOQ), post-primary vaccination concentration $\geq 4 \times$ LLOQ, if pre-primary vaccination concentration is $\geq 4 \times$ LLOQ, post-primary vaccination concentration \geq pre-primary vaccination concentration; for Groups 1, 2, and 3, before and 30 days after dose 3 and for group 4, before and 30 days after dose 4 as if pre-booster vaccination concentration is $<4 \times$ LLOQ, post-booster vaccination concentration $\geq 4 \times$ pre-booster concentration, if pre-booster vaccination concentration is $\geq 4 \times$ LLOQ, post-booster vaccination concentration $\geq 2 \times$ pre-booster concentration. Percentages are rounded off to tenth decimal place. PPAS1 and PPAS2. n=number of participants with data collected for each specific serogroup. '9999': no participants analyzed. Dose=D.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Groups 1, 2 and 3: Day 30 Post Doses 2 and 3 (4 MoA and 12 to 18 MoA); Group 4: Day 30 Post Dose 4 (12 to 18 MoA)

| End point values | Group 1: MenACYW | Group 2: Nimenrix | Group 3: MenACYW | Group 4: MenACYW |
|---|---------------------|----------------------|---------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 533 | 565 | 92 | 89 |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| PPAS1: Anti-PT: Day 30 post D2 (n=512,518,92,0) | 94.5 (92.2 to 96.3) | 97.9 (96.2 to 98.9) | 82.6 (73.3 to 89.7) | 9999 (9999 to 9999) |
| PPAS1: Anti-FHA: Day 30 post D2 (n=512,518,92,0) | 89.6 (86.7 to 92.1) | 91.5 (88.8 to 93.8) | 62.0 (51.2 to 71.9) | 9999 (9999 to 9999) |
| PPAS2: Anti-PT: Day 30 post D3 (n=533,565,90,0) | 97.0 (95.2 to 98.3) | 97.0 (95.2 to 98.2) | 93.3 (86.1 to 97.5) | 9999 (9999 to 9999) |
| PPAS2: Anti-PT: Day 30 post D4 (n=0,0,0,89) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 88.8 (80.3 to 94.5) |
| PPAS2: Anti-FHA: Day 30 post D3 (n=533,565,90,0) | 89.1 (86.2 to 91.6) | 90.1 (87.3 to 92.4) | 92.2 (84.6 to 96.8) | 9999 (9999 to 9999) |
| PPAS2: Anti-FHA: Day 30 post D4 (n=0,0,0,89) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 91.0 (83.1 to 96.0) |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved Anti-Hepatitis B Antibody Concentrations ≥ 10 and ≥ 100 Milli-International Units (mIU)/mL

| | |
|-----------------|--|
| End point title | Percentage of Participants who Achieved Anti-Hepatitis B Antibody Concentrations ≥ 10 and ≥ 100 Milli-International Units (mIU)/mL |
|-----------------|--|

End point description:

GMCs of anti-hepatitis antibodies (anti-HBsAg) was measured by the commercially available VITROS ECi/ECiQ. Response rate for anti-HBsAg was defined as percentage of participants who achieved anti-HBsAg antibody concentrations ≥ 10 mIU/mL and ≥ 100 mIU/mL. Percentages are rounded off to the tenth decimal place. PPAS1 was a subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and had valid post-primary series vaccination blood sample result. PPAS2 was a subset of FAS2. FAS2: subset of randomized participants who received at least 1 dose of study vaccine at booster vaccination and had valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup. '9999' denotes that there were no participants analyzed. Dose=D.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Groups 1, 2 and 3: Day 30 Post Doses 2 and 3 (4 MoA and 12 to 18 MoA); Day 0 Before Dose 3 (12 to 18 MoA); Group 4: Day 30 Post Dose 4 (12 to 18 MoA)

| End point values | Group 1: MenACYW | Group 2: Nimenrix | Group 3: MenACYW | Group 4: MenACYW |
|---|---------------------|----------------------|---------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 546 | 571 | 92 | 90 |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| PPAS1:Anti-HBsAg: ≥ 10 :Day30postD2(n=505,510, | 96.4 (94.4 to 97.9) | 97.8 (96.2 to 98.9) | 92.4 (84.9 to 96.9) | 9999 (9999 to 9999) |
| PPAS1:Anti-HBsAg: ≥ 100 :Day30postD2(n=505,51 | 85.7 (82.4 to 88.7) | 81.8 (78.1 to 85.0) | 72.8 (62.6 to 81.6) | 9999 (9999 to 9999) |

| | | | | |
|--|---------------------|---------------------|---------------------|---------------------|
| PPAS2:Anti-HBsAg: >=10:Day0beforeD3(n=535,565) | 81.5 (77.9 to 84.7) | 79.5 (75.9 to 82.7) | 65.9 (55.3 to 75.5) | 9999 (9999 to 9999) |
| PPAS2:Anti-HBsAg: >=10:Day30afterD3(n=546,571, | 98.0 (96.4 to 99.0) | 98.6 (97.3 to 99.4) | 94.4 (87.5 to 98.2) | 9999 (9999 to 9999) |
| PPAS2:Anti-HBsAg: >=10:Day0beforeD4(n=0,0,0,90 | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 64.4 (53.7 to 74.3) |
| PPAS2:Anti-HBsAg: >=10:Day30afterD4(n=0,0,0,86 | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 91.9 (83.9 to 96.7) |
| PPAS2:AntiHBsAg: >=100:Day0beforeD3 (n=535,565,91,0) | 38.7 (34.5 to 43.0) | 35.4 (31.5 to 39.5) | 26.4 (17.7 to 36.7) | 9999 (9999 to 9999) |
| PPAS2:AntiHBsAg: >=100:Day30afterD3 (n=546,571.90,1) | 93.4 (91.0 to 95.3) | 93.5 (91.2 to 95.4) | 80.0 (70.2 to 87.7) | 9999 (9999 to 9999) |
| PPAS2:AntiHBsAg: >=100: Day0beforeD4(n=0,0,0,90) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 27.8 (18.9 to 38.2) |
| PPAS2:AntiHBsAg: >=100:Day30afterD4 (n=0,0,0,86) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 83.7 (74.2 to 90.8) |

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 1 and 2: Geometric Mean Concentrations of Pneumococcal Conjugate Vaccine (10-Valent, Adsorbed) Vaccine

| | |
|-----------------|--|
| End point title | Groups 1 and 2: Geometric Mean Concentrations of Pneumococcal Conjugate Vaccine (10-Valent, Adsorbed) Vaccine ^[8] |
|-----------------|--|

End point description:

GMCs of anti-pneumococcal antibodies was assessed by pneumococcal capsular polysaccharide (PnPS) Immunoglobulin G (IgG) ECL assay which was used to quantitate the amount of anti-streptococcus pneumoniae PS (serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, and 23F) antibodies in human serum. PPAS1 was a subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and had valid post-primary series vaccination blood sample result. PPAS2 was a subset of FAS2. FAS2: subset of randomized participants who received at least 1 dose of study vaccine at booster vaccination and had valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At 30 days post Dose 2 (4 MoA) and Dose 3 (12 to 18 MoA)

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only participants randomized in Groups 1 and 2 were analyzed in this endpoint.

| End point values | Group 1: MenACYW | Group 2: Nimenrix | | |
|--|----------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 545 | 569 | | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| PPAS1: Serogroup 1 (n=505, 512) | 1.68 (1.52 to 1.84) | 1.71 (1.56 to 1.87) | | |
| PPAS1: Serogroup 4 (n=505, 512) | 1.97 (1.83 to 2.12) | 2.06 (1.91 to 2.23) | | |
| PPAS1: Serogroup 5 (n=505, 512) | 1.08 (0.991 to 1.17) | 1.10 (1.01 to 1.19) | | |

| | | | | |
|-----------------------------------|------------------------|------------------------|--|--|
| PPAS1: Serogroup 6B (n=505, 511) | 0.600 (0.534 to 0.675) | 0.660 (0.586 to 0.742) | | |
| PPAS1: Serogroup 7F (n=505, 512) | 2.03 (1.89 to 2.17) | 2.20 (2.05 to 2.37) | | |
| PPAS1: Serogroup 9V (n=504, 512) | 1.67 (1.54 to 1.81) | 1.81 (1.67 to 1.96) | | |
| PPAS1: Serogroup 14 (n=505, 512) | 5.92 (5.41 to 6.48) | 5.97 (5.44 to 6.55) | | |
| PPAS1: Serogroup 18C (n=505, 512) | 0.680 (0.618 to 0.748) | 0.796 (0.722 to 0.879) | | |
| PPAS1: Serogroup 19F (n=505, 512) | 1.59 (1.39 to 1.82) | 1.45 (1.26 to 1.66) | | |
| PPAS1: Serogroup 23F (n=505, 512) | 0.830 (0.746 to 0.924) | 0.869 (0.785 to 0.961) | | |
| PPAS2: Serogroup 1 (n=545, 569) | 4.71 (4.32 to 5.13) | 4.54 (4.18 to 4.94) | | |
| PPAS2: Serogroup 4 (n=545, 569) | 3.61 (3.37 to 3.86) | 3.19 (2.99 to 3.41) | | |
| PPAS2: Serogroup 5 (n=544, 569) | 2.21 (2.05 to 2.39) | 2.05 (1.90 to 2.20) | | |
| PPAS2: Serogroup 6B (n=545, 569) | 4.21 (3.89 to 4.55) | 4.36 (4.04 to 4.71) | | |
| PPAS2: Serogroup 7F (n=545, 568) | 2.91 (2.73 to 3.10) | 2.89 (2.70 to 3.10) | | |
| PPAS2: Serogroup 9V (n=545, 569) | 4.08 (3.80 to 4.38) | 4.17 (3.89 to 4.47) | | |
| PPAS2: Serogroup 14 (n=544, 568) | 9.07 (8.44 to 9.75) | 7.89 (7.25 to 8.59) | | |
| PPAS2: Serogroup 18C (n=545, 569) | 2.12 (1.99 to 2.26) | 2.17 (2.03 to 2.33) | | |
| PPAS2: Serogroup 19F (n=545, 569) | 9.03 (8.32 to 9.81) | 8.41 (7.76 to 9.12) | | |
| PPAS2: Serogroup 23F (n=545, 569) | 2.24 (2.10 to 2.40) | 2.04 (1.90 to 2.18) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 3 and 4: Geometric Mean Concentrations of Pneumococcal Conjugate Vaccine (13-Valent, Adsorbed) Vaccine

| | |
|-----------------|--|
| End point title | Groups 3 and 4: Geometric Mean Concentrations of Pneumococcal Conjugate Vaccine (13-Valent, Adsorbed) Vaccine ^[9] |
|-----------------|--|

End point description:

GMCs of anti-pneumococcal antibodies was assessed by PnPS IgG ECL assay which was used to quantitate the amount of anti-streptococcus pneumoniae PS (serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) antibodies in human serum. PPAS1 was a subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and had valid post-primary series vaccination blood sample result. PPAS2 was a subset of FAS2. FAS2: subset of randomized participants who received at least 1 dose of study vaccine at booster vaccination and had valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup. '9999' denotes that there were no participants analyzed.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Group 3: At 30 days post Dose 2 (4 MoA) and Dose 3 (12 to 18 MoA); Group 4: At 30 days post Dose 4 (12 to 18 MoA)

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only participants randomized in Groups 3 and 4 were analyzed in this endpoint.

| End point values | Group 3: MenACYW | Group 4: MenACYW | | |
|---|------------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 91 | 89 | | |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| PPAS1: Serogroup 1: 30 days post dose 2(n=89, 0) | 1.47 (1.16 to 1.87) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 3: 30 days post dose 2(n=89,0) | 0.658 (0.554 to 0.781) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 4: 30 days post dose 2(n=89,0) | 1.73 (1.42 to 2.12) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 5: 30 days post dose 2(n=89,0) | 0.803 (0.617 to 1.04) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 6A: 30 days post dose 2(n=89,0) | 1.65 (1.24 to 2.19) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 6B: 30 days post dose 2(n=89,0) | 0.275 (0.205 to 0.368) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 7F: 30 days post dose 2(n=89,0) | 3.04 (2.59 to 3.57) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 9V: 30 days post dose 2(n=89,0) | 1.25 (0.987 to 1.59) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 14: 30 days post dose 2(n=89,0) | 5.88 (4.31 to 8.01) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 18C: 30 days post dose 2(n=89,0) | 1.65 (1.30 to 2.10) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 19A: 30 days post dose 2(n=89,0) | 2.17 (1.67 to 2.80) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 19F: 30 days post dose 2(n=89,0) | 5.73 (4.64 to 7.08) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 23F: 30 days post dose 2(n=89,0) | 0.722 (0.552 to 0.945) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 1: 30 days post dose 3(n=91,0) | 5.32 (4.41 to 6.42) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 1: 30 days post dose 4(n=0,89) | 9999 (9999 to 9999) | 5.47 (4.66 to 6.42) | | |
| PPAS2: Serogroup 3: 30 days post dose 3(n=91,0) | 1.13 (0.945 to 1.35) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 3: 30 days post dose 4(n=0,89) | 9999 (9999 to 9999) | 1.21 (0.982 to 1.50) | | |
| PPAS2: Serogroup 4: 30 days post dose 3(n=91,0) | 3.99 (3.43 to 4.64) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 4: 30 days post dose 4(n=0,89) | 9999 (9999 to 9999) | 3.97 (3.35 to 4.70) | | |
| PPAS2: Serogroup 5: 30 days post dose 3(n=91,0) | 3.33 (2.75 to 4.03) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 5: 30 days post dose 4(n=0,89) | 9999 (9999 to 9999) | 3.95 (3.36 to 4.65) | | |
| PPAS2: Serogroup 6A: 30 days post dose 3(n=91,0) | 12.9 (10.9 to 15.4) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 6A: 30 days post dose 4(n=0,89) | 9999 (9999 to 9999) | 14.3 (12.2 to 16.8) | | |
| PPAS2: Serogroup 6B: 30 days post dose 3(n=91,0) | 7.01 (5.38 to 9.13) | 9999 (9999 to 9999) | | |

| | | | | |
|---|---------------------|---------------------|--|--|
| PPAS2: Serogroup 6B: 30 days post dose 4(n=0,89) | 9999 (9999 to 9999) | 9.41 (7.86 to 11.3) | | |
| PPAS2: Serogroup 7F: 30 days post dose 3(n=91,0) | 5.36 (4.56 to 6.29) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 7F: 30 days post dose 4(n=0,89) | 9999 (9999 to 9999) | 4.92 (4.20 to 5.76) | | |
| PPAS2: Serogroup 9V: 30 days post dose 3(n=91,0) | 5.12 (4.26 to 6.17) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 9V: 30 days post dose 4(n=0,89) | 9999 (9999 to 9999) | 5.40 (4.65 to 6.26) | | |
| PPAS2: Serogroup 14: 30 days post dose 3(n=91,0) | 14.8 (12.2 to 18.1) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 14: 30 days post dose 4(n=0,89) | 9999 (9999 to 9999) | 14.7 (12.1 to 17.9) | | |
| PPAS2: Serogroup 18C: 30 days post dose 3(n=91,0) | 3.18 (2.70 to 3.76) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 18C: 30 days post dose 4(n=0,89) | 9999 (9999 to 9999) | 3.48 (3.00 to 4.03) | | |
| PPAS2: Serogroup 19A: 30 days post dose 3(n=91,0) | 8.82 (7.25 to 10.7) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 19A: 30 days post dose 4(n=0,89) | 9999 (9999 to 9999) | 10.9 (9.26 to 12.9) | | |
| PPAS2: Serogroup 19F: 30 days post dose 3(n=91,0) | 12.1 (9.91 to 14.7) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 19F: 30 days post dose 4(n=0,89) | 9999 (9999 to 9999) | 12.2 (10.5 to 14.2) | | |
| PPAS2: Serogroup 23F: 30 days post dose 3(n=91,0) | 3.70 (3.01 to 4.55) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 23F: 30 days post dose 4(n=0,89) | 9999 (9999 to 9999) | 4.06 (3.45 to 4.76) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 1 and 2: Percentage of Participants with Response Rate ≥ 0.35 mcg/mL for Pneumococcal Conjugate Vaccine (10-Valent, Adsorbed) Vaccine

| | |
|-----------------|---|
| End point title | Groups 1 and 2: Percentage of Participants with Response Rate ≥ 0.35 mcg/mL for Pneumococcal Conjugate Vaccine (10-Valent, Adsorbed) Vaccine ^[10] |
|-----------------|---|

End point description:

GMCs of anti-pneumococcal antibodies was assessed by PnPS IgG ECL assay which was used to quantitate the amount of anti-streptococcus pneumoniae PS (serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, and 23F) antibodies in human serum. Percentages are rounded off to the tenth decimal place. PPAS1 was a subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and had valid post-primary series vaccination blood sample result. PPAS2 was a subset of FAS2. FAS2: subset of randomized participants who received at least 1 dose of study vaccine at booster vaccination and had valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

At 30 days post Dose 2 (4 MoA) and Dose 3 (12 to 18 MoA)

Notes:

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

Justification: Only participants randomized in Groups 1 and 2 were analyzed in this endpoint.

| End point values | Group 1: MenACYW | Group 2: Nimenrix | | |
|-----------------------------------|---------------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 545 | 569 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| PPAS1: Serogroup 1 (n=505, 512) | 92.7 (90.0 to 94.8) | 93.6 (91.1 to 95.5) | | |
| PPAS1: Serogroup 4 (n=505, 512) | 96.8 (94.9 to 98.2) | 96.7 (94.7 to 98.1) | | |
| PPAS1: Serogroup 5 (n=505, 512) | 88.5 (85.4 to 91.2) | 90.6 (87.8 to 93.0) | | |
| PPAS1: Serogroup 6B (n=505, 511) | 67.1 (62.8 to 71.2) | 69.9 (65.7 to 73.8) | | |
| PPAS1: Serogroup 7F (n=505, 512) | 98.8 (97.4 to 99.6) | 98.2 (96.7 to 99.2) | | |
| PPAS1: Serogroup 9V (n=504, 512) | 94.6 (92.3 to 96.4) | 95.1 (92.9 to 96.8) | | |
| PPAS1: Serogroup 14 (n=505, 512) | 97.8 (96.1 to 98.9) | 98.2 (96.7 to 99.2) | | |
| PPAS1: Serogroup 18C (n=505, 512) | 72.5 (68.4 to 76.3) | 77.3 (73.5 to 80.9) | | |
| PPAS1: Serogroup 19F (n=505, 512) | 82.2 (78.6 to 85.4) | 79.3 (75.5 to 82.7) | | |
| PPAS1: Serogroup 23F (n=505, 512) | 77.8 (73.9 to 81.4) | 80.3 (76.6 to 83.6) | | |
| PPAS2: Serogroup 1 (n=545, 569) | 99.8 (99.0 to 100) | 99.8 (99.0 to 100) | | |
| PPAS2: Serogroup 4 (n=545, 569) | 99.8 (99.0 to 100) | 99.6 (98.7 to 100) | | |
| PPAS2: Serogroup 5 (n=544, 569) | 98.2 (96.6 to 99.1) | 97.7 (96.1 to 98.8) | | |
| PPAS2: Serogroup 6B (n=545, 569) | 98.9 (97.6 to 99.6) | 99.5 (98.5 to 99.9) | | |
| PPAS2: Serogroup 7F (n=545, 568) | 99.6 (98.7 to 100) | 99.3 (98.2 to 99.8) | | |
| PPAS2: Serogroup 9V (n=545, 569) | 99.8 (99.0 to 100) | 99.8 (99.0 to 100) | | |
| PPAS2: Serogroup 14 (n=544, 568) | 100 (99.3 to 100) | 99.3 (98.2 to 99.8) | | |
| PPAS2: Serogroup 18C (n=545, 569) | 99.1 (97.9 to 99.7) | 98.6 (97.2 to 99.4) | | |
| PPAS2: Serogroup 19F (n=545, 569) | 99.3 (98.1 to 99.8) | 99.3 (98.2 to 99.8) | | |
| PPAS2: Serogroup 23F (n=545, 569) | 98.5 (97.1 to 99.4) | 97.2 (95.5 to 98.4) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Groups 3 and 4: Percentage of Participants with Response Rate ≥ 0.35 mcg/mL for Pneumococcal Conjugate Vaccine (13-Valent, Adsorbed) Vaccine

| | |
|-----------------|---|
| End point title | Groups 3 and 4: Percentage of Participants with Response Rate ≥ 0.35 mcg/mL for Pneumococcal Conjugate Vaccine (13-Valent, Adsorbed) Vaccine ^[11] |
|-----------------|---|

End point description:

GMCs of anti-pneumococcal antibodies was assessed by PnPS IgG ECL assay which was used to quantitate the amount of anti-streptococcus pneumoniae PS (serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) antibodies in human serum. Percentages are rounded off to the tenth decimal place. PPAS1 was a subset of FAS1. FAS1: subset of randomized participants who received at least 1 dose of study vaccine in primary series and had valid post-primary series vaccination blood sample result. PPAS2 was a subset of FAS2. FAS2: subset of randomized participants who received at least 1 dose of study vaccine at booster vaccination and had valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup. '9999' denotes that there were no participants analyzed. Dose=D.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Group 3: At 30 days post Dose 2 (4 MoA) and Dose 3 (12 to 18 MoA); Group 4: At 30 days post Dose 4 (12 to 18 MoA)

Notes:

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

Justification: Only participants randomized in Groups 3 and 4 were analyzed in this endpoint.

| End point values | Group 3: MenACYW | Group 4: MenACYW | | |
|--|---------------------|---------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 91 | 89 | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| PPAS1: Serogroup 1: 30 days post D2 (n=89,0) | 89.9 (81.7 to 95.3) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 3: 30 days post D2 (n=89,0) | 82.0 (72.5 to 89.4) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 4: 30 days post D2 (n=89,0) | 96.6 (90.5 to 99.3) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 5: 30 days post D2 (n=89,0) | 76.4 (66.2 to 84.8) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 6A: 30 days post D2 (n=89,0) | 88.8 (80.3 to 94.5) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 6B: 30 days post D2 (n=89,0) | 40.4 (30.2 to 51.4) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 7F: 30 days post D2 (n=89,0) | 97.8 (92.1 to 99.7) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 9V: 30 days post D2 (n=89,0) | 88.8 (80.3 to 94.5) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 14: 30 days post D2 (n=89,0) | 96.6 (90.5 to 99.3) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 18C: 30 days post D2 (n=89,0) | 91.0 (83.1 to 96.0) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 19A: 30 days post D2 (n=89,0) | 93.3 (85.9 to 97.5) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 19F: 30 days post D2 (n=89,0) | 98.9 (93.9 to 100) | 9999 (9999 to 9999) | | |
| PPAS1: Serogroup 23F: 30 days post D2 (n=89,0) | 71.9 (61.4 to 80.9) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 1: 30 days post D3 (n=91,0) | 100 (96.0 to 100) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 1: 30 days post D4 (n=0,89) | 9999 (9999 to 9999) | 100 (95.9 to 100) | | |
| PPAS2: Serogroup 3: 30 days post D3 (n=91,0) | 97.8 (92.3 to 99.7) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 3: 30 days post D4 (n=0,89) | 9999 (9999 to 9999) | 92.1 (84.5 to 96.8) | | |

| | | | | |
|--|---------------------|---------------------|--|--|
| PPAS2: Serogroup 4: 30 days post D3 (n=91,0) | 100 (96.0 to 100) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 4: 30 days post D4 (n=0,89) | 9999 (9999 to 9999) | 100 (95.9 to 100) | | |
| PPAS2: Serogroup 5: 30 days post D3 (n=91,0) | 98.9 (94.0 to 100) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 5: 30 days post D4 (n=0,89) | 9999 (9999 to 9999) | 100 (95.9 to 100) | | |
| PPAS2: Serogroup 6A: 30 days post D3 (n=91,0) | 100 (96.0 to 100) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 6A: 30 days post D4 (n=0,89) | 9999 (9999 to 9999) | 100 (95.9 to 100) | | |
| PPAS2: Serogroup 6B: 30 days post D3 (n=91,0) | 98.9 (94.0 to 100) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 6B: 30 days post D4 (n=0,89) | 9999 (9999 to 9999) | 100 (95.9 to 100) | | |
| PPAS2: Serogroup 7F: 30 days post D3 (n=91,0) | 100 (96.0 to 100) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 7F: 30 days post D4 (n=0,89) | 9999 (9999 to 9999) | 100 (95.9 to 100) | | |
| PPAS2: Serogroup 9V: 30 days post D3 (n=91,0) | 100 (96.0 to 100) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 9V: 30 days post D4 (n=0,89) | 9999 (9999 to 9999) | 100 (95.9 to 100) | | |
| PPAS2: Serogroup 14: 30 days post D3 (n=91,0) | 100 (96.0 to 100) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 14: 30 days post D4 (n=0,89) | 9999 (9999 to 9999) | 100 (95.9 to 100) | | |
| PPAS2: Serogroup 18C: 30 days post D3 (n=91,0) | 100 (96.0 to 100) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 18C: 30 days post D4 (n=0,89) | 9999 (9999 to 9999) | 100 (95.9 to 100) | | |
| PPAS2: Serogroup 19A: 30 days post D3 (n=91,0) | 100 (96.0 to 100) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 19A: 30 days post D4 (n=0,89) | 9999 (9999 to 9999) | 100 (95.9 to 100) | | |
| PPAS2: Serogroup 19F: 30 days post D3 (n=91,0) | 100 (96.0 to 100) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 19F: 30 days post D4 (n=0,89) | 9999 (9999 to 9999) | 100 (95.9 to 100) | | |
| PPAS2: Serogroup 23F: 30 days post D3 (n=91,0) | 100 (96.0 to 100) | 9999 (9999 to 9999) | | |
| PPAS2: Serogroup 23F: 30 days post D4 (n=0,89) | 9999 (9999 to 9999) | 100 (95.9 to 100) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Concentrations of Anti-Measles, Mumps and Rubella Antibodies

| | |
|-----------------|---|
| End point title | Geometric Mean Concentrations of Anti-Measles, Mumps and Rubella Antibodies |
|-----------------|---|

End point description:

GMCs of anti-measles and anti-rubella antibodies were measured by bulk IgG enzyme immunoassay (EIA) and anti-mumps antibodies were assessed by enzyme-linked immunosorbent assay (ELISA). PPAS2 was a subset of FAS2. FAS2 included subset of randomized participants who received at least 1 dose of the study vaccine at booster vaccination and had a valid post-booster vaccination blood sample

result. Here, n=number of participants with data collected for each specific serogroup. '9999' denotes that there were no participants analyzed. Dose=D.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Groups 1, 2 and 3: At 30 days post Dose 3 (12 to 18 MoA); Group 4: At 30 days post Dose 4 (12 to 18 MoA) | |

| End point values | Group 1: MenACYW | Group 2: Nimenrix | Group 3: MenACYW | Group 4: MenACYW |
|--|---------------------|----------------------|---------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 525 | 553 | 94 | 90 |
| Units: Titer | | | | |
| geometric mean (confidence interval 95%) | | | | |
| Anti-measles: 30 days post D3 (n=525,553,94,0) | 2780 (2581 to 2995) | 2919 (2739 to 3110) | 3457 (2972 to 4021) | 9999 (9999 to 9999) |
| Anti-measles: 30 days post D4(n=0,0,0,90) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 3933 (3241 to 4773) |
| Anti-mumps: 30 days post D3(n=525,553,94,0) | 83.3 (77.5 to 89.6) | 86.1 (80.5 to 92.1) | 105 (90.4 to 121) | 9999 (9999 to 9999) |
| Anti-mumps: 30 days post D4(n=0,0,0,90) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 121 (105 to 141) |
| Anti-rubella: 30 days post D3 (n=525,553,94,0) | 56.8 (53.2 to 60.6) | 56.0 (52.5 to 59.8) | 72.8 (62.7 to 84.6) | 9999 (9999 to 9999) |
| Anti-rubella: 30 days post D4 (n=0,0,0,90) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 74.4 (63.7 to 86.7) |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants who Achieved Vaccine Response for Measles, Mumps and Rubella Antibodies

| | |
|-----------------|--|
| End point title | Percentage of Participants who Achieved Vaccine Response for Measles, Mumps and Rubella Antibodies |
|-----------------|--|

End point description:

GMCs of anti-measles and anti-rubella antibodies were measured by bulk IgG EIA and anti-mumps antibodies were assessed by ELISA. Vaccine response against anti-measles, anti-mumps, anti-rubella antibodies were defined as percentage of participants with anti-measles, anti-mumps, anti-rubella antibody concentration that met the respective mentioned criterion: measles: ≥ 255 mIU/mL; mumps: ≥ 10 mumps antibody units/mL and rubella: ≥ 10 IU/mL. Percentages are rounded off to the tenth decimal place. PPAS2 was a subset of FAS2. FAS2 included subset of randomized participants who received at least 1 dose of the study vaccine at booster vaccination and had a valid post-booster vaccination blood sample result. Here, n=number of participants with data collected for each specific serogroup. '9999' denotes that there were no participants analyzed. Dose=D.

| | |
|--|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Groups 1, 2 and 3: At 30 days post Dose 3 (12 to 18 MoA); Group 4: At 30 days post Dose 4 (12 to 18 MoA) | |

| End point values | Group 1: MenACYW | Group 2: Nimenrix | Group 3: MenACYW | Group 4: MenACYW |
|---|---------------------|----------------------|---------------------|---------------------|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 525 | 553 | 94 | 90 |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Anti-measles: 30 days post D3 (n=525,553,94,0) | 98.3 (96.8 to 99.2) | 99.1 (97.9 to 99.7) | 100 (96.2 to 100) | 9999 (9999 to 9999) |
| Anti-measles: 30 days post D4 (n=0,0,0,90) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 97.8 (92.2 to 99.7) |
| Anti-mumps: 30 days post D3 (n=525,553,94,0) | 98.7 (97.3 to 99.5) | 98.7 (97.4 to 99.5) | 100 (96.2 to 100) | 9999 (9999 to 9999) |
| Anti-mumps: 30 days post D4 (n=0,0,0,90) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 100 (96.0 to 100) |
| Anti-rubella: 30 days post D3 (n=525,553,94,0) | 98.7 (97.3 to 99.5) | 97.3 (95.6 to 98.5) | 98.9 (94.2 to 100) | 9999 (9999 to 9999) |
| Anti-rubella: 30 days post D4 (n=0,0,0,90) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 9999 (9999 to 9999) | 100 (96.0 to 100) |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events (AEs), serious adverse events (SAEs) and deaths: From study vaccine administration (Day 0) until 30 days after last vaccination (Visit 5 [13 to 19 MoA] for Groups 1, 2, and 3 and Visit 6 [13 to 19 MoA] for Group 4), up to 14 to 20 MoA.

Adverse event reporting additional description:

Analysis was performed on the safety analysis set (SafAS) which included those participants who had received at least 1 dose of the study vaccine(s) and had any safety data available.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 26.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|------------------|
| Reporting group title | Group 1: MenACYW |
|-----------------------|------------------|

Reporting group description:

Participants received 3 doses of MenACYW conjugate vaccine 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the PCV10 were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA.

| | |
|-----------------------|------------------|
| Reporting group title | Group 4: MenACYW |
|-----------------------|------------------|

Reporting group description:

Participants received 4 doses of MenACYW conjugate vaccine 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4MoA, and dose 3: 6 MoA and dose 4: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the PCV13 were administered in a 2+1 regimen (concomitantly with the first and second doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and the toddler dose of MenACYW conjugate vaccine [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA. The third dose of MenACYW conjugate vaccine was administered alone, without any other routine pediatric vaccines.

| | |
|-----------------------|------------------|
| Reporting group title | Group 3: MenACYW |
|-----------------------|------------------|

Reporting group description:

Participants received 3 doses of MenACYW conjugate vaccine 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the PCV13 were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA.

| | |
|-----------------------|-------------------|
| Reporting group title | Group 2: Nimenrix |
|-----------------------|-------------------|

Reporting group description:

Participants received 3 doses of Nimenrix® 0.5 mL as an IM injection at dose 1: 2 MoA, dose 2: 4 MoA, and dose 3: 12 to 18 MoA along with routine pediatric vaccines. The routine pediatric vaccines: hexavalent vaccine (DTaP-IPV-HB-Hib), the PCV10 were administered in a 2+1 regimen (ie, 2 doses in infancy [first between 6 and 12 weeks of age and second between 4 to 5 MoA] and 1 final dose in the second year of life [12 to 18 MoA]); and the MMR vaccine was administered at 12 to 18 MoA.

| Serious adverse events | Group 1: MenACYW | Group 4: MenACYW | Group 3: MenACYW |
|---|------------------|------------------|------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 51 / 696 (7.33%) | 3 / 108 (2.78%) | 8 / 112 (7.14%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from | 0 | 0 | 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Haemangioma | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Testicular Yolk Sac Tumour Stage Iii | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| General disorders and administration site conditions | | | |
| Systemic Inflammatory Response Syndrome | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Reproductive system and breast disorders | | | |
| Balanoposthitis | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Interstitial Lung Disease | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Apnoea | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Dyspnoea | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Respiration Abnormal | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Psychiatric disorders | | | |
| Insomnia | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Injury, poisoning and procedural complications | | | |
| Burns Second Degree | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Craniocerebral Injury | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 1 / 108 (0.93%) | 0 / 112 (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 |
| Burns Third Degree | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Concussion | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Exposure To Toxic Agent | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Skull Fracture | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Femur Fracture | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Road Traffic Accident | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Congenital, familial and genetic disorders | | | |
| Congenital Hydronephrosis | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Hydrocele | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Laryngomalacia | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Lymphatic Malformation | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 1 / 108 (0.93%) | 0 / 112 (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 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Phimosis | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Nervous system disorders | | | |
| Clinically Isolated Syndrome | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 1 / 112 (0.89%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Febrile Convulsion | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Somnolence | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Seizure | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Petit Mal Epilepsy | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 | | | |
| Immune Thrombocytopenia | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 1 / 112 (0.89%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Neutropenia | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Eye disorders | | | |
| Blepharitis | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 | | | |
| Anal Stenosis | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Dyspepsia | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Diarrhoea | | | |
| subjects affected / exposed | 2 / 696 (0.29%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Aphthous Ulcer | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Enterocolitis | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 Inflammation | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Food Protein-Induced Enterocolitis Syndrome | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 Pain | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Inguinal Hernia | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Intussusception | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Regurgitation | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Melaena | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Vomiting | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis Atopic | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 |

| | | | |
|---|-----------------|-----------------|-----------------|
| Urticaria | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Renal and urinary disorders | | | |
| Tubulointerstitial Nephritis | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Musculoskeletal and connective tissue disorders | | | |
| Musculoskeletal Stiffness | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Infections and infestations | | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 2 / 696 (0.29%) | 0 / 108 (0.00%) | 2 / 112 (1.79%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Bronchitis | | | |
| subjects affected / exposed | 6 / 696 (0.86%) | 0 / 108 (0.00%) | 0 / 112 (0.00%) |
| occurrences causally related to treatment / all | 0 / 7 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ear Infection | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Cytomegalovirus Infection | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Covid-19 | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Bronchitis Viral | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Exanthema Subitum | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Escherichia Urinary Tract Infection | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 1 / 112 (0.89%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal Infection | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Influenza | | | |
| subjects affected / exposed | 3 / 696 (0.43%) | 0 / 108 (0.00%) | 0 / 112 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal Candidiasis | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 Rotavirus | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 Norovirus | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 Adenovirus | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 | | | |
| subjects affected / exposed | 3 / 696 (0.43%) | 0 / 108 (0.00%) | 0 / 112 (0.00%) |
| occurrences causally related to treatment / all | 0 / 3 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pharyngitis | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Pharyngotonsillitis | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 2 / 108 (1.85%) | 2 / 112 (1.79%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 2 | 0 / 2 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Otitis Media | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Orchitis | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Mastoiditis | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Laryngitis | | | |
| subjects affected / exposed | 2 / 696 (0.29%) | 0 / 108 (0.00%) | 0 / 112 (0.00%) |
| occurrences causally related to treatment / all | 0 / 6 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rhinovirus Infection | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Subcutaneous Abscess | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia Pneumococcal | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Pneumonia Respiratory Syncytial Viral | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Pyelonephritis | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory Syncytial Virus Bronchiolitis | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 2 / 108 (1.85%) | 1 / 112 (0.89%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Respiratory Syncytial Virus Infection | | | |

| | | | |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 1 / 112 (0.89%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Urinary Tract Infection | | | |
| subjects affected / exposed | 2 / 696 (0.29%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 2 / 696 (0.29%) | 0 / 108 (0.00%) | 1 / 112 (0.89%) |
| occurrences causally related to treatment / all | 0 / 2 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tracheitis | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (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 |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Viral Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 0 / 108 (0.00%) | 0 / 112 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Weight Gain Poor | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 0 / 108 (0.00%) | 0 / 112 (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 |

| | | | |
|---|-------------------|--|--|
| Serious adverse events | Group 2: Nimenrix | | |
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 57 / 706 (8.07%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |

| | | | |
|---|-----------------|--|--|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Haemangioma | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Testicular Yolk Sac Tumour Stage Iii | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vascular disorders | | | |
| Haematoma | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| Systemic Inflammatory Response Syndrome | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Reproductive system and breast disorders | | | |
| Balanoposthitis | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Interstitial Lung Disease | | | |
| subjects affected / exposed | 3 / 706 (0.42%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Apnoea | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | |
|---|-----------------|--|--|
| Dyspnoea | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiration Abnormal | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Psychiatric disorders | | | |
| Insomnia | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Injury, poisoning and procedural complications | | | |
| Burns Second Degree | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Craniocerebral Injury | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Burns Third Degree | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Concussion | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Exposure To Toxic Agent | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | |
|---|-----------------|--|--|
| Skull Fracture | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Femur Fracture | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Road Traffic Accident | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Congenital, familial and genetic disorders | | | |
| Congenital Hydronephrosis | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hydrocele | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Laryngomalacia | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Lymphatic Malformation | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Phimosi | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | |
|---|-----------------|--|--|
| Nervous system disorders | | | |
| Clinically Isolated Syndrome | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Febrile Convulsion | | | |
| subjects affected / exposed | 2 / 706 (0.28%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Somnolence | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Seizure | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Petit Mal Epilepsy | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Blood and lymphatic system disorders | | | |
| Immune Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Neutropenia | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | |
|---|-----------------|--|--|
| Eye disorders | | | |
| Blepharitis | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal disorders | | | |
| Anal Stenosis | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Dyspepsia | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Diarrhoea | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Aphthous Ulcer | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Enterocolitis | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal Inflammation | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Food Protein-Induced Enterocolitis Syndrome | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | |
|---|-----------------|--|--|
| Gastrointestinal Pain | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Inguinal Hernia | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Intussusception | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Regurgitation | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Melaena | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Vomiting | | | |
| subjects affected / exposed | 2 / 706 (0.28%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis Atopic | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Urticaria | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Renal and urinary disorders | | | |

| | | | |
|---|-----------------|--|--|
| Tubulointerstitial Nephritis | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Musculoskeletal Stiffness | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 2 / 706 (0.28%) | | |
| occurrences causally related to treatment / all | 0 / 2 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bronchitis | | | |
| subjects affected / exposed | 5 / 706 (0.71%) | | |
| occurrences causally related to treatment / all | 0 / 5 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Ear Infection | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Cytomegalovirus Infection | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Covid-19 | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Bronchitis Viral | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | | |
|---|-----------------|--|--|--|
| Exanthema Subitum | | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Escherichia Urinary Tract Infection | | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastrointestinal Infection | | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Influenza | | | | |
| subjects affected / exposed | 4 / 706 (0.57%) | | | |
| occurrences causally related to treatment / all | 0 / 4 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastrointestinal Candidiasis | | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastroenteritis Rotavirus | | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastroenteritis Norovirus | | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastroenteritis Adenovirus | | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Gastroenteritis | | | | |

| | | | | |
|---|-----------------|--|--|--|
| subjects affected / exposed | 5 / 706 (0.71%) | | | |
| occurrences causally related to treatment / all | 0 / 5 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pharyngitis | | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pharyngotonsillitis | | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia | | | | |
| subjects affected / exposed | 5 / 706 (0.71%) | | | |
| occurrences causally related to treatment / all | 0 / 5 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Otitis Media | | | | |
| subjects affected / exposed | 2 / 706 (0.28%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Orchitis | | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Mastoiditis | | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Laryngitis | | | | |
| subjects affected / exposed | 2 / 706 (0.28%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Rhinovirus Infection | | | | |

| | | | | |
|---|-----------------|--|--|--|
| subjects affected / exposed | 0 / 706 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Subcutaneous Abscess | | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia Pneumococcal | | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pneumonia Respiratory Syncytial Viral | | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Pyelonephritis | | | | |
| subjects affected / exposed | 2 / 706 (0.28%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory Syncytial Virus Bronchiolitis | | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Respiratory Syncytial Virus Infection | | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Urinary Tract Infection | | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | | |
| occurrences causally related to treatment / all | 0 / 0 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Upper Respiratory Tract Infection | | | | |

| | | | |
|---|-----------------|--|--|
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Tracheitis | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Viral Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Metabolism and nutrition disorders | | | |
| Weight Gain Poor | | | |
| subjects affected / exposed | 0 / 706 (0.00%) | | |
| occurrences causally related to treatment / all | 0 / 0 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

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

| Non-serious adverse events | Group 1: MenACYW | Group 4: MenACYW | Group 3: MenACYW |
|---|--------------------|--------------------|--------------------|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 678 / 696 (97.41%) | 103 / 108 (95.37%) | 107 / 112 (95.54%) |
| Nervous system disorders | | | |
| Somnolence | | | |
| subjects affected / exposed | 529 / 696 (76.01%) | 75 / 108 (69.44%) | 67 / 112 (59.82%) |
| occurrences (all) | 1094 | 155 | 112 |
| General disorders and administration site conditions | | | |
| Crying | | | |
| subjects affected / exposed | 579 / 696 (83.19%) | 75 / 108 (69.44%) | 74 / 112 (66.07%) |
| occurrences (all) | 1274 | 158 | 138 |

| | | | |
|---|----------------------------|--------------------------|--------------------------|
| Injection Site Bruising subjects affected / exposed occurrences (all) | 110 / 696 (15.80%) 194 | 4 / 108 (3.70%) 7 | 3 / 112 (2.68%) 5 |
| Injection Site Erythema subjects affected / exposed occurrences (all) | 537 / 696 (77.16%) 2207 | 58 / 108 (53.70%) 188 | 61 / 112 (54.46%) 173 |
| Injection Site Haematoma subjects affected / exposed occurrences (all) | 55 / 696 (7.90%) 97 | 16 / 108 (14.81%) 21 | 7 / 112 (6.25%) 10 |
| Injection Site Swelling subjects affected / exposed occurrences (all) | 422 / 696 (60.63%) 1445 | 47 / 108 (43.52%) 164 | 41 / 112 (36.61%) 118 |
| Injection Site Induration subjects affected / exposed occurrences (all) | 68 / 696 (9.77%) 137 | 4 / 108 (3.70%) 6 | 6 / 112 (5.36%) 8 |
| Injection Site Mass subjects affected / exposed occurrences (all) | 64 / 696 (9.20%) 139 | 1 / 108 (0.93%) 1 | 3 / 112 (2.68%) 3 |
| Injection Site Pain subjects affected / exposed occurrences (all) | 562 / 696 (80.75%) 2842 | 76 / 108 (70.37%) 450 | 88 / 112 (78.57%) 430 |
| Pyrexia subjects affected / exposed occurrences (all) | 375 / 696 (53.88%) 570 | 42 / 108 (38.89%) 70 | 46 / 112 (41.07%) 57 |
| Gastrointestinal disorders | | | |
| Diarrhoea subjects affected / exposed occurrences (all) | 55 / 696 (7.90%) 63 | 2 / 108 (1.85%) 2 | 4 / 112 (3.57%) 4 |
| Teething subjects affected / exposed occurrences (all) | 99 / 696 (14.22%) 142 | 15 / 108 (13.89%) 28 | 7 / 112 (6.25%) 10 |
| Toothache subjects affected / exposed occurrences (all) | 13 / 696 (1.87%) 16 | 5 / 108 (4.63%) 5 | 6 / 112 (5.36%) 7 |
| Vomiting | | | |

| | | | |
|--|---------------------------|-------------------------|-------------------------|
| subjects affected / exposed occurrences (all) | 196 / 696 (28.16%) 268 | 27 / 108 (25.00%) 33 | 25 / 112 (22.32%) 32 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 6 / 108 (5.56%) | 2 / 112 (1.79%) |
| occurrences (all) | 1 | 7 | 4 |
| Dermatitis Diaper | | | |
| subjects affected / exposed | 6 / 696 (0.86%) | 3 / 108 (2.78%) | 6 / 112 (5.36%) |
| occurrences (all) | 6 | 3 | 6 |
| Rash | | | |
| subjects affected / exposed | 16 / 696 (2.30%) | 6 / 108 (5.56%) | 1 / 112 (0.89%) |
| occurrences (all) | 18 | 6 | 1 |
| Psychiatric disorders | | | |
| Irritability | | | |
| subjects affected / exposed | 600 / 696 (86.21%) | 86 / 108 (79.63%) | 91 / 112 (81.25%) |
| occurrences (all) | 1413 | 217 | 190 |
| Infections and infestations | | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 65 / 696 (9.34%) | 8 / 108 (7.41%) | 2 / 112 (1.79%) |
| occurrences (all) | 80 | 8 | 2 |
| Gastroenteritis | | | |
| subjects affected / exposed | 10 / 696 (1.44%) | 9 / 108 (8.33%) | 6 / 112 (5.36%) |
| occurrences (all) | 10 | 11 | 6 |
| Conjunctivitis | | | |
| subjects affected / exposed | 16 / 696 (2.30%) | 7 / 108 (6.48%) | 4 / 112 (3.57%) |
| occurrences (all) | 16 | 9 | 4 |
| Bronchiolitis | | | |
| subjects affected / exposed | 1 / 696 (0.14%) | 12 / 108 (11.11%) | 11 / 112 (9.82%) |
| occurrences (all) | 1 | 13 | 12 |
| Respiratory Tract Infection | | | |
| subjects affected / exposed | 7 / 696 (1.01%) | 2 / 108 (1.85%) | 7 / 112 (6.25%) |
| occurrences (all) | 8 | 2 | 7 |
| Respiratory Tract Infection Viral | | | |
| subjects affected / exposed | 0 / 696 (0.00%) | 22 / 108 (20.37%) | 18 / 112 (16.07%) |
| occurrences (all) | 0 | 31 | 21 |
| Rhinitis | | | |

| | | | |
|--|---------------------------|--------------------------|-------------------------|
| subjects affected / exposed occurrences (all) | 47 / 696 (6.75%) 56 | 1 / 108 (0.93%) 1 | 1 / 112 (0.89%) 1 |
| Upper Respiratory Tract Infection subjects affected / exposed occurrences (all) | 54 / 696 (7.76%) 64 | 5 / 108 (4.63%) 6 | 3 / 112 (2.68%) 3 |
| Metabolism and nutrition disorders Decreased Appetite subjects affected / exposed occurrences (all) | 389 / 696 (55.89%) 594 | 58 / 108 (53.70%) 103 | 60 / 112 (53.57%) 90 |

| | | | |
|--|----------------------------|--|--|
| Non-serious adverse events | Group 2: Nimenrix | | |
| Total subjects affected by non-serious adverse events subjects affected / exposed | 680 / 706 (96.32%) | | |
| Nervous system disorders Somnolence subjects affected / exposed occurrences (all) | 545 / 706 (77.20%) 1060 | | |
| General disorders and administration site conditions Crying subjects affected / exposed occurrences (all) | 579 / 706 (82.01%) 1279 | | |
| Injection Site Bruising subjects affected / exposed occurrences (all) | 124 / 706 (17.56%) 188 | | |
| Injection Site Erythema subjects affected / exposed occurrences (all) | 520 / 706 (73.65%) 2169 | | |
| Injection Site Haematoma subjects affected / exposed occurrences (all) | 56 / 706 (7.93%) 92 | | |
| Injection Site Swelling subjects affected / exposed occurrences (all) | 417 / 706 (59.07%) 1458 | | |
| Injection Site Induration subjects affected / exposed occurrences (all) | 52 / 706 (7.37%) 91 | | |
| Injection Site Mass | | | |

| | | | |
|--|--------------------|--|--|
| subjects affected / exposed | 60 / 706 (8.50%) | | |
| occurrences (all) | 134 | | |
| Injection Site Pain | | | |
| subjects affected / exposed | 566 / 706 (80.17%) | | |
| occurrences (all) | 2851 | | |
| Pyrexia | | | |
| subjects affected / exposed | 345 / 706 (48.87%) | | |
| occurrences (all) | 537 | | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 37 / 706 (5.24%) | | |
| occurrences (all) | 44 | | |
| Teething | | | |
| subjects affected / exposed | 93 / 706 (13.17%) | | |
| occurrences (all) | 135 | | |
| Toothache | | | |
| subjects affected / exposed | 8 / 706 (1.13%) | | |
| occurrences (all) | 13 | | |
| Vomiting | | | |
| subjects affected / exposed | 197 / 706 (27.90%) | | |
| occurrences (all) | 271 | | |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis | | | |
| subjects affected / exposed | 3 / 706 (0.42%) | | |
| occurrences (all) | 3 | | |
| Dermatitis Diaper | | | |
| subjects affected / exposed | 3 / 706 (0.42%) | | |
| occurrences (all) | 4 | | |
| Rash | | | |
| subjects affected / exposed | 23 / 706 (3.26%) | | |
| occurrences (all) | 25 | | |
| Psychiatric disorders | | | |
| Irritability | | | |
| subjects affected / exposed | 608 / 706 (86.12%) | | |
| occurrences (all) | 1426 | | |
| Infections and infestations | | | |

| | | | |
|------------------------------------|--------------------|--|--|
| Nasopharyngitis | | | |
| subjects affected / exposed | 64 / 706 (9.07%) | | |
| occurrences (all) | 76 | | |
| Gastroenteritis | | | |
| subjects affected / exposed | 18 / 706 (2.55%) | | |
| occurrences (all) | 18 | | |
| Conjunctivitis | | | |
| subjects affected / exposed | 21 / 706 (2.97%) | | |
| occurrences (all) | 21 | | |
| Bronchiolitis | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences (all) | 1 | | |
| Respiratory Tract Infection | | | |
| subjects affected / exposed | 12 / 706 (1.70%) | | |
| occurrences (all) | 13 | | |
| Respiratory Tract Infection Viral | | | |
| subjects affected / exposed | 1 / 706 (0.14%) | | |
| occurrences (all) | 1 | | |
| Rhinitis | | | |
| subjects affected / exposed | 47 / 706 (6.66%) | | |
| occurrences (all) | 50 | | |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 61 / 706 (8.64%) | | |
| occurrences (all) | 71 | | |
| Metabolism and nutrition disorders | | | |
| Decreased Appetite | | | |
| subjects affected / exposed | 372 / 706 (52.69%) | | |
| occurrences (all) | 566 | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|------------------|---|
| 25 June 2019 | Study calendar was readjusted considering the study starts (FVFS) and the same inclusion period. Study design, schedule of study procedures, and methodology were modified. Inclusion and exclusion criteria were updated. Table of study procedures for Groups 1, 2, 3, 4 and list of abbreviations was updated. Clarification was given on the need to ensure that parents/legally acceptable representative agrees for further contact to follow those specific AEs as per protocol. Definitive contraindications, labeling and packaging concomitant medications and other therapies were modified. Rewording was done in management of samples section. Future use of stored serum samples for research was updated. Immunogenicity assessment methods was modified to clarify that the testing laboratories which would perform the assays described below would be reported in the final clinical study report. Safety definitions, confidentiality of data, data protection and access to subject records and reference list were updated. |
| 22 January 2020 | Cover page was modified for team member update. History of protocol versions, planned study period, study design, schedule of study procedures, and methodology and study plan were modified. Update was made in secondary objectives, secondary endpoints, immunogenicity and observational endpoints. Inclusion and exclusion criteria were modified. Table of study procedures for Groups 1, 2, 3, 4 and investigators and study organization details were updated. Clarified justification of the study design, vaccination and blood sampling schedule in Groups 1, 2, 3 and 4, study plan and study procedures. Planned study calendar, temporary contraindications, dose selection and timing were updated. Labeling and packaging, concomitant medications and other therapies, immunogenicity assessment methods and blood sampling schedule and testing plan in Groups 1, 2, 3 and 4 were modified. Team member updates were made in initial reporting by the investigator and reporting SAEs to health authorities and institutional ethics committee/ institutional review boards. Updated were made in the reference list. |
| 03 February 2022 | Cover page was modified for team member update. Updates were made in the table on "history of protocol versions", planned study period, study design, schedule of study procedures, and methodology. Secondary endpoints were corrected for few inconsistencies. Observational objective and observational endpoints were modified. Updated were made in planned sample size, study plan, investigators and trial organization and planned study calendar. Clarifications were made in temporary contraindications, contraindications for subsequent blood draw, concomitant medications and other therapies, statistical methods for observational objectives and monitoring. Blood sampling schedule and testing plan in Groups 1, 2, 3 and 4 were corrected. Immunogenicity assessment method was updated. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported