



## Clinical trial results:

**Persistence of antibodies after vaccination with a dose of GSK Biologicals' meningococcal vaccine GSK134612 in healthy children and safety and immunogenicity of a booster dose at 68 months post-primary vaccination.**

### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2010-018730-51 |
| Trial protocol           | FR DE          |
| Global end of trial date | 17 May 2014    |

### Results information

|                                |  |
|--------------------------------|--|
| Result version number          | v2   |
| This version publication date  | 21 April 2016  |
| First version publication date | 24 May 2015  |
| Version creation reason        | • New data added to full data set<br>Data for Month 56, 68 and 69 have been added. |

### Trial information

#### Trial identification

|                       |        |
|-----------------------|--------|
| Sponsor protocol code | 113977 |
|-----------------------|--------|

#### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT01266993 |
| WHO universal trial number (UTN)   | -           |

Notes:

### Sponsors

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

Notes:

### Paediatric regulatory details

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

Notes:

## Results analysis stage

|  |               |
|--|---------------|
| Analysis stage                                       | Final         |
| Date of interim/final analysis                       | 27 May 2015   |
| Is this the analysis of the primary completion data? | Yes           |
| Primary completion date                              | 31 March 2014 |
| Global end of trial reached?                         | Yes           |
| Global end of trial date                             | 17 May 2014   |
| Was the trial ended prematurely?                     | No            |

Notes:

## General information about the trial

Main objective of the trial:

Persistence

At 32, 44, 56 and 68 months after primary vaccination with MenACWY-TT or MenC-CRM.

•To evaluate the persistence of meningococcal antibodies in terms of the percentage of subjects with rSBAMenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY titres  $\geq 1:8$ .

Protection of trial subjects:

All subjects were supervised closely for at least 30 minutes following vaccination with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel. Vaccines/products were administered only to eligible subjects that had no contraindications to any components of the vaccines. Subjects were followed-up from the time the subject consents to participate in the study until she/he is discharged.

Background therapy: -

Evidence for comparator: -

|   |                 |
|---|-----------------|
| Actual start date of recruitment                          | 03 January 2011 |
| Long term follow-up planned                               | Yes             |
| Long term follow-up rationale                             | Efficacy        |
| Long term follow-up duration                              | 37 Months       |
| Independent data monitoring committee (IDMC) involvement? | No              |

Notes:

## Population of trial subjects

### Subjects enrolled per country

|                                      |              |
|--------------------------------------|--------------|
| Country: Number of subjects enrolled | France: 97   |
| Country: Number of subjects enrolled | Germany: 185 |
| Worldwide total number of subjects   | 282          |
| EEA total number of subjects         | 282          |

Notes:

### Subjects enrolled per age group

|   |     |
|---|-----|
| In utero                                  | 0   |
| Preterm newborn - gestational age < 37 wk | 0   |
| Newborns (0-27 days)                      | 0   |
| Infants and toddlers (28 days-23 months)  | 0   |
| Children (2-11 years)                     | 282 |

|                           |   |
|---------------------------|---|
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years)      | 0 |
| From 65 to 84 years       | 0 |
| 85 years and over         | 0 |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

During the screening the following steps occurred: check for inclusion/exclusion criteria, contraindications/precautions, medical history of the subjects and signing informed consent forms.

### Pre-assignment period milestones

|                            |     |
|----------------------------|-----|
| Number of subjects started | 282 |
|----------------------------|-----|

|                              |     |
|------------------------------|-----|
| Number of subjects completed | 271 |
|------------------------------|-----|

### Pre-assignment subject non-completion reasons

|                            |                             |
|----------------------------|-----------------------------|
| Reason: Number of subjects | No vaccination received: 11 |
|----------------------------|-----------------------------|

### Period 1

|                |          |
|----------------|----------|
| Period 1 title | Month 32 |
|----------------|----------|

|                              |     |
|------------------------------|-----|
| Is this the baseline period? | Yes |
|------------------------------|-----|

|                   |                         |
|-------------------|-------------------------|
| Allocation method | Randomised - controlled |
|-------------------|-------------------------|

|               |             |
|---------------|-------------|
| Blinding used | Not blinded |
|---------------|-------------|

### Arms

|                              |     |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

|                  |                         |
|------------------|-------------------------|
| <b>Arm title</b> | Nimenrix Month 32 Group |
|------------------|-------------------------|

Arm description:

Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study received a booster dose of the same vaccine in the current study.

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

|  |          |
|--|----------|
| Investigational medicinal product name | Nimerix™ |
|--|----------|

|  |  |
|--|--|
| Investigational medicinal product code |  |
|--|--|

|            |                              |
|------------|------------------------------|
| Other name | GSK134612 vaccine MenACWY-TT |
|------------|------------------------------|

|                      |   |
|----------------------|---|
| Pharmaceutical forms | Powder and solvent for suspension for injection |
|----------------------|---|

|                          |                   |
|--------------------------|-------------------|
| Routes of administration | Intramuscular use |
|--------------------------|-------------------|

Dosage and administration details:

Intramuscular administration, of 1 vaccine dose, in the non-dominant arm, deltoid/thigh region at Day 0.

|                  |                          |
|------------------|--------------------------|
| <b>Arm title</b> | Menjugate Month 32 Group |
|------------------|--------------------------|

Arm description:

Subjects who received Menjugate® in the primary study received a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study.

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

|  |          |
|--|----------|
| Investigational medicinal product name | Nimerix™ |
|--|----------|

|  |  |
|--|--|
| Investigational medicinal product code |  |
|--|--|

|            |                              |
|------------|------------------------------|
| Other name | GSK134612 vaccine MenACWY-TT |
|------------|------------------------------|

|                      |  |
|----------------------|--|
| Pharmaceutical forms | Powder and suspension for suspension for injection |
|----------------------|--|

|                          |                   |
|--------------------------|-------------------|
| Routes of administration | Intramuscular use |
|--------------------------|-------------------|

Dosage and administration details:

Intramuscular administration, of 1 vaccine dose, in the non-dominant arm, deltoid/thigh region at Day 0.

| <b>Number of subjects in period 1</b> <sup>[1]</sup> | Nimenrix Month 32 Group | Menjugate Month 32 Group |
|--|-------------------------|--------------------------|
| Started  | 199                     | 72                       |
| Completed  | 199                     | 72                       |

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Not all subjects who completed a period entered in the next one . The number of subjects who started each period depends on the number of subjects available at the time.

## Period 2

|                              |                         |
|------------------------------|-------------------------|
| Period 2 title               | Month 44                |
| Is this the baseline period? | No                      |
| Allocation method            | Randomised - controlled |
| Blinding used                | Not blinded             |

## Arms

|                              |                         |
|------------------------------|-------------------------|
| Are arms mutually exclusive? | Yes                     |
| <b>Arm title</b>             | Nimenrix Month 44 Group |

Arm description:

Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study received a booster dose of the same vaccine in the current study.

|  |  |
|--|--|
| Arm type                               | Experimental                                       |
| Investigational medicinal product name | Nimerix™   |
| Investigational medicinal product code |  |
| Other name                             | GSK134612 vaccine MenACWY-TT                       |
| Pharmaceutical forms                   | Powder and suspension for suspension for injection |
| Routes of administration               | Intramuscular use                                  |

Dosage and administration details:

Intramuscular administration, of 1 vaccine dose, in the non-dominant arm, deltoid/thigh region at Day 0.

|                  |                          |
|------------------|--------------------------|
| <b>Arm title</b> | Menjugate Month 44 Group |
|------------------|--------------------------|

Arm description:

Subjects who received Menjugate® in the primary study received a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study

|  |   |
|--|---|
| Arm type                               | Experimental                                    |
| Investigational medicinal product name | Nimerix™  |
| Investigational medicinal product code |   |
| Other name                             | GSK134612 vaccine MenACWY-TT                    |
| Pharmaceutical forms                   | Powder and solvent for suspension for injection |
| Routes of administration               | Intramuscular use                               |

Dosage and administration details:

Intramuscular administration, of 1 vaccine dose, in the non-dominant arm, deltoid/thigh region at Day 0.

| <b>Number of subjects in period 2[2]</b> | Nimenrix Month 44 Group | Menjugate Month 44 Group |
|--|-------------------------|--------------------------|
| Started                                  | 193                     | 68                       |
| Completed                                | 193                     | 68                       |

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Not all subjects who completed a period entered in the next one . The number of subjects who started each period depends on the number of subjects available at the time.

### Period 3

|                              |                         |
|------------------------------|-------------------------|
| Period 3 title               | Month 56                |
| Is this the baseline period? | No                      |
| Allocation method            | Randomised - controlled |
| Blinding used                | Not blinded             |

### Arms

|                              |                         |
|------------------------------|-------------------------|
| Are arms mutually exclusive? | Yes                     |
| <b>Arm title</b>             | Nimenrix Month 56 Group |

Arm description:

Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study and a booster dose of the same vaccine in the current study.

|  |   |
|--|---|
| Arm type                               | Experimental                                    |
| Investigational medicinal product name | Nimerix™  |
| Investigational medicinal product code |   |
| Other name                             | GSK134612 vaccine MenACWY-TT                    |
| Pharmaceutical forms                   | Powder and solvent for suspension for injection |
| Routes of administration               | Intramuscular use                               |

Dosage and administration details:

Intramuscular administration, of 1 vaccine dose, in the non-dominant arm, deltoid/thigh region at Day 0.

|                  |                          |
|------------------|--------------------------|
| <b>Arm title</b> | Menjugate Month 56 Group |
|------------------|--------------------------|

Arm description:

Subjects who received Menjugate® in the primary study and a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study

|  |   |
|--|---|
| Arm type                               | Experimental                                    |
| Investigational medicinal product name | Nimerix™  |
| Investigational medicinal product code |   |
| Other name                             | GSK134612 vaccine MenACWY-TT                    |
| Pharmaceutical forms                   | Powder and solvent for suspension for injection |
| Routes of administration               | Intramuscular use                               |

Dosage and administration details:

Intramuscular administration, of 1 vaccine dose, in the non-dominant arm, deltoid/thigh region at Day 0.

| <b>Number of subjects in period 3<sup>[3]</sup></b> | Nimenrix Month 56 Group | Menjugate Month 56 Group |
|---|-------------------------|--------------------------|
| Started   | 193                     | 67                       |
| Completed   | 193                     | 67                       |

Notes:

[3] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Not all subjects who completed a period entered in the next one . The number of subjects who started each period depends on the number of subjects available at the time.

#### **Period 4**

|                              |                         |
|------------------------------|-------------------------|
| Period 4 title               | Month 68                |
| Is this the baseline period? | No                      |
| Allocation method            | Randomised - controlled |
| Blinding used                | Not blinded             |

#### **Arms**

|                              |                         |
|------------------------------|-------------------------|
| Are arms mutually exclusive? | Yes                     |
| <b>Arm title</b>             | Nimenrix Month 68 Group |

Arm description:

Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study received a booster dose of the same vaccine in the current study.

|  |   |
|--|---|
| Arm type                               | Experimental                                    |
| Investigational medicinal product name | Nimerix™  |
| Investigational medicinal product code |   |
| Other name                             | GSK134612 vaccine MenACWY-TT                    |
| Pharmaceutical forms                   | Powder and solvent for suspension for injection |
| Routes of administration               | Intramuscular use                               |

Dosage and administration details:

Intramuscular administration, of 1 vaccine dose, in the non-dominant arm, deltoid/thigh region at Day 0.

|                  |                          |
|------------------|--------------------------|
| <b>Arm title</b> | Menjugate Month 68 Group |
|------------------|--------------------------|

Arm description:

Subjects who received Menjugate® in the primary study received a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study.

|  |  |
|--|--|
| Arm type                               | Experimental                                       |
| Investigational medicinal product name | Nimerix™   |
| Investigational medicinal product code |  |
| Other name                             | GSK134612 vaccine MenACWY-TT                       |
| Pharmaceutical forms                   | Powder and suspension for suspension for injection |
| Routes of administration               | Intramuscular use                                  |

Dosage and administration details:

Intramuscular administration, of 1 vaccine dose, in the non-dominant arm, deltoid/thigh region at Day 0.

| <b>Number of subjects in period 4[4]</b> | <b>Nimenrix Month 68 Group</b> | <b>Menjugate Month 68 Group</b> |
|--|--------------------------------|---------------------------------|
| Started                                  | 179                            | 62                              |
| Completed                                | 179                            | 62                              |

Notes:

[4] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Not all subjects who completed a period entered in the next one . The number of subjects who started each period depends on the number of subjects available at the time.

## Period 5

|                              |                         |
|------------------------------|-------------------------|
| Period 5 title               | Month 69 (Booster)      |
| Is this the baseline period? | No                      |
| Allocation method            | Randomised - controlled |
| Blinding used                | Not blinded             |

## Arms

|                              |                         |
|------------------------------|-------------------------|
| Are arms mutually exclusive? | Yes                     |
| <b>Arm title</b>             | Nimenrix Month 69 Group |

Arm description:

Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study received a booster dose of the same vaccine in the current study.

|  |   |
|--|---|
| Arm type                               | Experimental                                    |
| Investigational medicinal product name | Nimerix™  |
| Investigational medicinal product code |   |
| Other name                             | GSK134612 vaccine MenACWY-TT                    |
| Pharmaceutical forms                   | Powder and solvent for suspension for injection |
| Routes of administration               | Intramuscular use                               |

Dosage and administration details:

Intramuscular administration, of 1 vaccine dose, in the non-dominant arm, deltoid/thigh region at Day 0.

|                  |                          |
|------------------|--------------------------|
| <b>Arm title</b> | Menjugate Month 69 Group |
|------------------|--------------------------|

Arm description:

Subjects who received Menjugate® in the primary study received a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study.

|  |  |
|--|--|
| Arm type                               | Experimental                                       |
| Investigational medicinal product name | Nimerix™   |
| Investigational medicinal product code |  |
| Other name                             | GSK134612 vaccine MenACWY-TT                       |
| Pharmaceutical forms                   | Powder and suspension for suspension for injection |
| Routes of administration               | Intramuscular use                                  |

Dosage and administration details:

Intramuscular administration, of 1 vaccine dose, in the non-dominant arm, deltoid/thigh region at Day 0.



| <b>Number of subjects in period 5</b> | Nimenrix Month 69<br>Group | Menjugate Month 69<br>Group |
|---------------------------------------|----------------------------|-----------------------------|
| Started                               | 179                        | 62                          |
| Completed                             | 174                        | 60                          |
| Not completed                         | 5                          | 2                           |
| Consent withdrawn by subject          | -                          | 1                           |
| Lost to follow-up                     | 5                          | 1                           |

## Baseline characteristics

### Reporting groups

|  |                          |
|--|--------------------------|
| Reporting group title  | Nimenrix Month 32 Group  |
| Reporting group description:<br>Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study received a booster dose of the same vaccine in the current study. |                          |
| Reporting group title  | Menjugate Month 32 Group |
| Reporting group description:<br>Subjects who received Menjugate® in the primary study received a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study.       |                          |

| Reporting group values                             | Nimenrix Month 32 Group | Menjugate Month 32 Group | Total |
|--|-------------------------|--------------------------|-------|
| Number of subjects                                 | 199                     | 72                       | 271   |
| Age categorical<br>Units: Subjects                 |                         |                          |       |
| In utero   |                         |                          | 0     |
| Preterm newborn infants (gestational age < 37 wks) |                         |                          | 0     |
| Newborns (0-27 days)                               |                         |                          | 0     |
| Infants and toddlers (28 days-23 months)           |                         |                          | 0     |
| Children (2-11 years)                              |                         |                          | 0     |
| Adolescents (12-17 years)                          |                         |                          | 0     |
| Adults (18-64 years)                               |                         |                          | 0     |
| From 65-84 years                                   |                         |                          | 0     |
| 85 years and over                                  |                         |                          | 0     |
| Age continuous<br>Units: years                     |                         |                          |       |
| arithmetic mean                                    | 8.4                     | 8.1                      |       |
| standard deviation                                 | ± 2.58                  | ± 2.42                   | -     |
| Gender categorical<br>Units: Subjects              |                         |                          |       |
| Female   | 103                     | 34                       | 137   |
| Male   | 96                      | 38                       | 134   |

## End points

### End points reporting groups

|  |                          |
|--|--------------------------|
| Reporting group title  | Nimenrix Month 32 Group  |
| Reporting group description:<br>Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study received a booster dose of the same vaccine in the current study. |                          |
| Reporting group title  | Menjugate Month 32 Group |
| Reporting group description:<br>Subjects who received Menjugate® in the primary study received a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study.       |                          |
| Reporting group title  | Nimenrix Month 44 Group  |
| Reporting group description:<br>Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study received a booster dose of the same vaccine in the current study. |                          |
| Reporting group title  | Menjugate Month 44 Group |
| Reporting group description:<br>Subjects who received Menjugate® in the primary study received a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study        |                          |
| Reporting group title  | Nimenrix Month 56 Group  |
| Reporting group description:<br>Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study and a booster dose of the same vaccine in the current study.      |                          |
| Reporting group title  | Menjugate Month 56 Group |
| Reporting group description:<br>Subjects who received Menjugate® in the primary study and a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study             |                          |
| Reporting group title  | Nimenrix Month 68 Group  |
| Reporting group description:<br>Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study received a booster dose of the same vaccine in the current study. |                          |
| Reporting group title  | Menjugate Month 68 Group |
| Reporting group description:<br>Subjects who received Menjugate® in the primary study received a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study.       |                          |
| Reporting group title  | Nimenrix Month 69 Group  |
| Reporting group description:<br>Subjects who received Nimenrix™ (GSK134612 vaccine) in the primary study received a booster dose of the same vaccine in the current study. |                          |
| Reporting group title  | Menjugate Month 69 Group |
| Reporting group description:<br>Subjects who received Menjugate® in the primary study received a booster dose of Nimenrix™ (GSK134612 vaccine) in the current study.       |                          |

### Primary: Number of subjects with serum bactericidal assay against *Neisseria meningitidis* serogroup A, C, W-135, Y, using baby rabbit complement (rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY) antibody titres $\geq 1:8$

|  |  |
|--|--|
| End point title  | Number of subjects with serum bactericidal assay against <i>Neisseria meningitidis</i> serogroup A, C, W-135, Y, using baby rabbit complement (rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY) antibody titres $\geq 1:8$ <sup>[1]</sup> |
| End point description:<br>These analyses were performed by the Health Protection Agency (HPA) laboratory |  |

|   |         |
|---|---------|
| End point type  | Primary |
| End point timeframe:  |         |
| At month 32 after primary vaccination   |         |
| Notes:  |         |
| [1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. |         |
| Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed   |         |

| End point values            | Nimenrix<br>Month 32<br>Group | Menjugate<br>Month 32<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 193                           | 69                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| rSBA-MenA [N=193;69]        | 167                           | 15                             |  |  |
| rSBA-MenC [N=192;69]        | 124                           | 53                             |  |  |
| rSBA-MenW-135 [N=193;69]    | 149                           | 5                              |  |  |
| rSBA-MenY [N=193;69]        | 157                           | 10                             |  |  |

## Statistical analyses

No statistical analyses for this end point

## Primary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:8$

|   |  |
|---|--|
| End point title   | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:8$ <sup>[2]</sup> |
| End point description:  |  |
| These analyses were performed by the Health Protection Agency (HPA) laboratory  |  |
| End point type  | Primary  |
| End point timeframe:  |  |
| At month 44 after primary vaccination   |  |
| Notes:  |  |
| [2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. |  |
| Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed   |  |

| End point values            | Nimenrix<br>Month 44<br>Group | Menjugate<br>Month 44<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 189                           | 66                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| rSBA-MenA [N=189;66]        | 162                           | 17                             |  |  |
| rSBA-MenC [N=189;66]        | 70                            | 30                             |  |  |
| rSBA-MenW-135 [N=189;66]    | 129                           | 7                              |  |  |
| rSBA-MenY [N=189;66]        | 118                           | 4                              |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:8$

|                 |  |
|-----------------|--|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:8$ <sup>[3]</sup> |
|-----------------|--|

End point description:

These analyses were performed by the GSK laboratory

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

At 32 months after the primary vaccination

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed

| End point values            | Nimenrix<br>Month 32<br>Group | Menjugate<br>Month 32<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 192                           | 67                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| rSBA-MenA [N=191;57]        | 191                           | 25                             |  |  |
| rSBA-MenC [N=189;67]        | 189                           | 67                             |  |  |
| rSBA-MenW-135 [N=192;65]    | 192                           | 52                             |  |  |
| rSBA-MenY [N=191;65]        | 191                           | 51                             |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:8$

|                 |  |
|-----------------|--|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:8$ <sup>[4]</sup> |
|-----------------|--|

End point description:

These analyses were performed by the GSK laboratory

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

At 44 months after the primary vaccination

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed

| End point values            | Nimenrix<br>Month 44<br>Group | Menjugate<br>Month 44<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 188                           | 64                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| rSBA-MenA [N=187;55]        | 187                           | 24                             |  |  |
| rSBA-MenC [N=186;64]        | 186                           | 64                             |  |  |
| rSBA-MenW-135 [N=188;62]    | 188                           | 49                             |  |  |
| rSBA-MenY [N=187;62]        | 187                           | 49                             |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:8$

|                 |  |
|-----------------|--|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:8$ <sup>[5]</sup> |
|-----------------|--|

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

At 56 months after the primary vaccination

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed

| End point values            | Nimenrix<br>Month 56<br>Group | Menjugate<br>Month 56<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 186                           | 65                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| rSBA-MenA [N=186;65]        | 161                           | 19                             |  |  |
| rSBA-MenC [N=186;65]        | 110                           | 42                             |  |  |
| rSBA-MenW-135 [N=186;65]    | 145                           | 17                             |  |  |
| rSBA-MenY [N=186;64]        | 149                           | 14                             |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:8$

|                 |  |
|-----------------|--|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:8$ <sup>[6]</sup> |
|-----------------|--|

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory

End point type Primary

End point timeframe:

At 68 months after the primary vaccination

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed

| End point values            | Nimenrix<br>Month 68<br>Group | Menjugate<br>Month 68<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 178                           | 61                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| rSBA-MenA [N=178;61]        | 154                           | 18                             |  |  |
| rSBA-MenC [N=178;61]        | 71                            | 38                             |  |  |
| rSBA-MenW-135 [N=178;61]    | 94                            | 9                              |  |  |
| rSBA-MenY [N=178;61]        | 127                           | 8                              |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:8$

End point title Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres  $\geq 1:8$ <sup>[7]</sup>

End point description:

These analyses were performed by the GSK laboratory .

End point type Primary

End point timeframe:

At 56 months after the primary vaccination

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed

| End point values            | Nimenrix<br>Month 56<br>Group | Menjugate<br>Month 56<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 185                           | 63                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| rSBA-MenA [N=184;54]        | 184                           | 24                             |  |  |
| rSBA-MenC [N=182;63]        | 182                           | 63                             |  |  |
| rSBA-MenW-135 [N=185;61]    | 185                           | 48                             |  |  |
| rSBA-MenY [N=184;61]        | 184                           | 49                             |  |  |

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:8$

|                 |  |
|-----------------|--|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:8$ <sup>[8]</sup> |
|-----------------|--|

End point description:

These analyses were performed by the GSK laboratory

|                |         |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

At 68 months after the primary vaccination

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed

| End point values            | Nimenrix<br>Month 68<br>Group | Menjugate<br>Month 68<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 177                           | 59                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| rSBA-MenA [N=176;51]        | 176                           | 24                             |  |  |
| rSBA-MenC [N=174;59]        | 174                           | 59                             |  |  |
| rSBA-MenW-135 [N=177;58]    | 177                           | 46                             |  |  |
| rSBA-MenY [N=176;57]        | 176                           | 47                             |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:128$

|                 |   |
|-----------------|---|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:128$ |
|-----------------|---|

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory

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

End point timeframe:

At 32 months after the primary vaccination



| End point values            | Nimenrix<br>Month 32<br>Group | Menjugate<br>Month 32<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 193                           | 69                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| rSBA-MenA [N=193;69]        | 140                           | 9                              |  |  |
| rSBA-MenC [N=192;69]        | 69                            | 35                             |  |  |
| rSBA-MenW-135 [N=193;69]    | 136                           | 5                              |  |  |
| rSBA-MenY [N=193;69]        | 145                           | 8                              |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:128$

|  |   |
|--|---|
| End point title  | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:128$ |
| End point description:   |   |
| These analyses were performed by the Health Protection Agency (HPA) laboratory |   |
| End point type   | Secondary   |
| End point timeframe:   |   |
| At 44 months after the primary vaccination                                     |   |

| End point values            | Nimenrix<br>Month 44<br>Group | Menjugate<br>Month 44<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 189                           | 66                             |  |  |
| Units: Subject              |                               |                                |  |  |
| rSBA-MenA [N=189;66]        | 151                           | 16                             |  |  |
| rSBA-MenC [N=189;66]        | 38                            | 23                             |  |  |
| rSBA-MenW-135 [N=189;66]    | 120                           | 5                              |  |  |
| rSBA-MenY [N=189;66]        | 107                           | 3                              |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:128$

|   |   |
|---|---|
| End point title   | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:128$ |
| End point description:<br>These analyses were performed by the GSK laboratory |   |
| End point type  | Secondary   |
| End point timeframe:<br>At 32 months after the primary vaccination            |   |

| End point values            | Nimenrix<br>Month 32<br>Group | Menjugate<br>Month 32<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 192                           | 67                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| rSBA-MenA [N=191;57]        | 191                           | 19                             |  |  |
| rSBA-MenC [N=189;67]        | 186                           | 67                             |  |  |
| rSBA-MenW-135 [N=192;65]    | 191                           | 30                             |  |  |
| rSBA-MenY [N=191;65]        | 191                           | 34                             |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:128$

|   |   |
|---|---|
| End point title   | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:128$ |
| End point description:<br>These analyses were performed by the GSK laboratory |   |
| End point type  | Secondary   |
| End point timeframe:<br>At 44 months after the primary vaccination            |   |

| End point values            | Nimenrix<br>Month 44<br>Group | Menjugate<br>Month 44<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 188                           | 64                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| rSBA-MenA [N=187;55]        | 187                           | 18                             |  |  |
| rSBA-MenC [N=186;64]        | 183                           | 64                             |  |  |
| rSBA-MenW-135 [N=188;62]    | 187                           | 29                             |  |  |
| rSBA-MenY [N=187;62]        | 187                           | 32                             |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

|                 |   |
|-----------------|---|
| End point title | Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens |
|-----------------|---|

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory

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

End point timeframe:

At 32 months after the primary vaccination

| End point values                         | Nimenrix<br>Month 32<br>Group | Menjugate<br>Month 32<br>Group |  |  |
|--|-------------------------------|--------------------------------|--|--|
| Subject group type                       | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed              | 193                           | 69                             |  |  |
| Units: Titers                            |                               |                                |  |  |
| geometric mean (confidence interval 95%) |                               |                                |  |  |
| rSBA-MenA [N=193;69]                     | 196.3 (144.1 to 267.2)        | 8 (5.5 to 11.7)                |  |  |
| rSBA-MenC [N=192;69]                     | 34.8 (26 to 46.4)             | 86.5 (47.3 to 158.1)           |  |  |
| rSBA-MenW-135 [193;69]                   | 213.9 (149.3 to 306.6)        | 5.6 (4.2 to 7.6)               |  |  |
| rSBA-MenY [N=193;69]                     | 227.4 (164.8 to 313.7)        | 7.2 (5 to 10.4)                |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

|                 |   |
|-----------------|---|
| End point title | Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens |
|-----------------|---|

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory

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

End point timeframe:

At 44 months after the primary vaccination

| End point values                         | Nimenrix<br>Month 44<br>Group | Menjugate<br>Month 44<br>Group |  |  |
|--|-------------------------------|--------------------------------|--|--|
| Subject group type                       | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed              | 189                           | 66                             |  |  |
| Units: Titers                            |                               |                                |  |  |
| geometric mean (confidence interval 95%) |                               |                                |  |  |
| rSBA-MenA [N=189;66]                     | 307.5 (223.7 to 422.8)        | 13.5 (8 to 23)                 |  |  |
| rSBA-MenC [N=189;66]                     | 14.5 (10.9 to 19.2)           | 31 (16.6 to 58)                |  |  |
| rSBA-MenW-135 [N=189;66]                 | 103.5 (72.5 to 147.6)         | 5.9 (4.3 to 8.1)               |  |  |
| rSBA-MenY [N=189;66]                     | 78.9 (54.6 to 114)            | 4.9 (3.9 to 6.2)               |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

|   |   |
|---|---|
| End point title                                     | Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens |
| End point description:                              |   |
| These analyses were performed by the GSK laboratory |   |
| End point type                                      | Secondary   |
| End point timeframe:                                |   |
| At 32 months after the primary vaccination          |   |

| End point values                         | Nimenrix<br>Month 32<br>Group | Menjugate<br>Month 32<br>Group |  |  |
|--|-------------------------------|--------------------------------|--|--|
| Subject group type                       | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed              | 192                           | 67                             |  |  |
| Units: Titers                            |                               |                                |  |  |
| geometric mean (confidence interval 95%) |                               |                                |  |  |
| rSBA-MenA [N=191;57]                     | 6733.3 (5927 to 7649.3)       | 27.2 (14.4 to 51.1)            |  |  |
| rSBA-MenC [N=189;67]                     | 2588 (2124.5 to 3152.7)       | 5135.3 (3436.5 to 7674.1)      |  |  |

|                          |                            |                      |  |  |
|--------------------------|----------------------------|----------------------|--|--|
| rSBA-MenW-135 [N=192;65] | 8959.1 (7828.9 to 10252.5) | 77.9 (49.4 to 122.9) |  |  |
| rSBA-MenY [N=191;65]     | 8543.9 (7405 to 9858.1)    | 86.5 (54.5 to 137.3) |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

|                 |   |
|-----------------|---|
| End point title | Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens |
|-----------------|---|

End point description:

These analyses were performed by the GSK laboratory

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

End point timeframe:

At 44 months after the primary vaccination

| End point values                         | Nimenrix<br>Month 44<br>Group | Menjugate<br>Month 44<br>Group |  |  |
|--|-------------------------------|--------------------------------|--|--|
| Subject group type                       | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed              | 188                           | 64                             |  |  |
| Units: Titers                            |                               |                                |  |  |
| geometric mean (confidence interval 95%) |                               |                                |  |  |
| rSBA-MenA [N=187;55]                     | 6633.2 (5830.3 to 7546.6)     | 26.9 (14.1 to 51.3)            |  |  |
| rSBA-MenC [N=186;64]                     | 2609 (2134.9 to 3188.3)       | 5120.1 (3432 to 7638.4)        |  |  |
| rSBA-MenW-135 [N=188;62]                 | 9158.4 (7975 to 10517.4)      | 76.9 (47.9 to 123.6)           |  |  |
| rSBA-MenY [N=187;62]                     | 8520.4 (7362.2 to 9860.8)     | 87.2 (54.4 to 139.6)           |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects with serum bactericidal assay against N. meningitidis serogroup A, C, W-135, Y, using human complement (hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY) antibody titres ≥1:4

|                 |   |
|-----------------|---|
| End point title | Number of subjects with serum bactericidal assay against N. |
|-----------------|---|

meningitides serogroup A, C, W-135, Y, using human complement (hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY) antibody titres  $\geq 1:4$

End point description:

This analysis was performed on 50% of the subjects in each group

End point type Secondary

End point timeframe:

At Month 32 after primary vaccination

| End point values            | Nimenrix<br>Month 32<br>Group | Menjugate<br>Month 32<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 91                            | 34                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| hSBA-MenA [N=90;34]         | 24                            | 5                              |  |  |
| hSBA-MenC [N=90;33]         | 86                            | 30                             |  |  |
| hSBA-MenW-135 [N=86;23]     | 73                            | 4                              |  |  |
| hSBA-MenY [N=91;28]         | 74                            | 13                             |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres $\geq 1:4$

End point title Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres  $\geq 1:4$

End point description:

This analysis was performed on 50% of the subjects in each group

End point type Secondary

End point timeframe:

At Month 44 after primary vaccination

| End point values            | Nimenrix<br>Month 44<br>Group | Menjugate<br>Month 44<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 89                            | 31                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| hSBA-MenA [N=89;31]         | 26                            | 5                              |  |  |
| hSBA-MenC [N=82;31]         | 63                            | 20                             |  |  |
| hSBA-MenW-135 [N=87;30]     | 70                            | 8                              |  |  |
| hSBA-MenY [N=76;26]         | 63                            | 12                             |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres $\geq 1:8$

|                 |  |
|-----------------|--|
| End point title | Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres $\geq 1:8$ |
|-----------------|--|

End point description:

This analysis was performed on 50% of the subjects in each group

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

End point timeframe:

At Month 32 after primary vaccination

| End point values            | Nimenrix<br>Month 32<br>Group | Menjugate<br>Month 32<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 91                            | 34                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| hSBA-MenA [N=90;34]         | 23                            | 5                              |  |  |
| hSBA-MenC [N=90;33]         | 86                            | 30                             |  |  |
| hSBA-MenW-135 [N=86;23]     | 73                            | 4                              |  |  |
| hSBA-MenY [N=91;28]         | 74                            | 13                             |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres $\geq 1:8$

|                 |  |
|-----------------|--|
| End point title | Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres $\geq 1:8$ |
|-----------------|--|

End point description:

This analysis was performed on 50% of the subjects in each group

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

End point timeframe:

At Month 44 after primary vaccination

| <b>End point values</b>     | Nimenrix<br>Month 44<br>Group | Menjugate<br>Month 44<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 89                            | 31                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| hSBA-MenA [N=89;31]         | 23                            | 5                              |  |  |
| hSBA-MenC [N=82;31]         | 63                            | 20                             |  |  |
| hSBA-MenW-135 [N=87;30]     | 70                            | 8                              |  |  |
| hSBA-MenY [N=76;26]         | 63                            | 12                             |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY meningococcal antigens

|                        |  |
|------------------------|--|
| End point title        | Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY meningococcal antigens |
| End point description: | This analysis was performed on 50% of the subjects in each group                             |
| End point type         | Secondary  |
| End point timeframe:   | At Month 32 after primary vaccination  |

| <b>End point values</b>                  | Nimenrix<br>Month 32<br>Group | Menjugate<br>Month 32<br>Group |  |  |
|--|-------------------------------|--------------------------------|--|--|
| Subject group type                       | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed              | 91                            | 34                             |  |  |
| Units: Titers                            |                               |                                |  |  |
| geometric mean (confidence interval 95%) |                               |                                |  |  |
| hSBA-MenA [N=90;34]                      | 4.6 (3.3 to 6.3)              | 2.7 (2.1 to 3.4)               |  |  |
| hSBA-MenC [N=90;33]                      | 75.9 (53.4 to 107.9)          | 82.2 (34.6 to 195.8)           |  |  |
| hSBA-MenW-135 [N=86;23]                  | 69.9 (48.2 to 101.5)          | 3.8 (2 to 7.1)                 |  |  |
| hSBA-MenY [N=91;28]                      | 79.2 (52.5 to 119.3)          | 15.1 (6.3 to 36.5)             |  |  |

## Statistical analyses



No statistical analyses for this end point

**Secondary: Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY meningococcal antigens**

|                 |  |
|-----------------|--|
| End point title | Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY meningococcal antigens |
|-----------------|--|

End point description:

This analysis was performed on 50% of the subjects in each group

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

End point timeframe:

At Month 44 after primary vaccination

| End point values                         | Nimenrix<br>Month 44<br>Group | Menjugate<br>Month 44<br>Group |  |  |
|--|-------------------------------|--------------------------------|--|--|
| Subject group type                       | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed              | 89                            | 31                             |  |  |
| Units: Titers                            |                               |                                |  |  |
| geometric mean (confidence interval 95%) |                               |                                |  |  |
| hSBA-MenA [N=89;31]                      | 4.8 (3.4 to 6.7)              | 2.8 (2.1 to 3.7)               |  |  |
| hSBA-MenC [N=82;31]                      | 36.4 (23.1 to 57.2)           | 38.8 (13.3 to 113.2)           |  |  |
| hSBA-MenW-135 [N=87;30]                  | 64.3 (42.7 to 96.8)           | 5.2 (2.8 to 9.5)               |  |  |
| hSBA-MenY [N=76;26]                      | 126.7 (78 to 205.7)           | 16.8 (16.8 to 44.9)            |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Number of subjects with any SAEs**

|                 |                                  |
|-----------------|----------------------------------|
| End point title | Number of subjects with any SAEs |
|-----------------|----------------------------------|

End point description:

SAEs assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization, result in disability/incapacity.

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

End point timeframe:

Up to Month 32, 44, 56 and 68

| End point values            | Nimenrix<br>Month 32<br>Group | Nimenrix<br>Month 44<br>Group | Nimenrix<br>Month 56<br>Group | Menjugate<br>Month 32<br>Group |
|-----------------------------|-------------------------------|-------------------------------|-------------------------------|--------------------------------|
| Subject group type          | Reporting group               | Reporting group               | Reporting group               | Reporting group                |
| Number of subjects analysed | 199                           | 193                           | 193                           | 72                             |
| Units: Subjects             | 0                             | 0                             | 0                             | 0                              |

| End point values            | Menjugate<br>Month 44<br>Group | Menjugate<br>Month 56<br>Group | Nimenrix<br>Month 68<br>Group | Menjugate<br>Month 68<br>Group |
|-----------------------------|--------------------------------|--------------------------------|-------------------------------|--------------------------------|
| Subject group type          | Reporting group                | Reporting group                | Reporting group               | Reporting group                |
| Number of subjects analysed | 68                             | 67                             | 179                           | 62                             |
| Units: Subjects             | 0                              | 0                              | 0                             | 0                              |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:128$

|                 |   |
|-----------------|---|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:128$ |
|-----------------|---|

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory

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

End point timeframe:

At 56 months after the primary vaccination

| End point values            | Nimenrix<br>Month 56<br>Group | Menjugate<br>Month 56<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 186                           | 65                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| rSBA-MenA [N=186;65]        | 107                           | 10                             |  |  |
| rSBA-MenC [N=186;65]        | 65                            | 32                             |  |  |
| rSBA-MenW-135 [N=186;65]    | 123                           | 10                             |  |  |
| rSBA-MenY [N=186;64]        | 139                           | 10                             |  |  |

### Statistical analyses

No statistical analyses for this end point

**Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres  $\geq 1:128$** 

|  |   |
|--|---|
| End point title  | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:128$ |
| End point description:<br>These analyses were performed by the Health Protection Agency (HPA) laboratory |   |
| End point type   | Secondary   |
| End point timeframe:<br>At 68 months after the primary vaccination                                       |   |

| End point values            | Nimenrix<br>Month 68<br>Group | Menjugate<br>Month 68<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 178                           | 61                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| rSBA-MenA                   | 107                           | 12                             |  |  |
| rSBA-MenC                   | 38                            | 25                             |  |  |
| rSBA-MenW-135               | 84                            | 8                              |  |  |
| rSBA-MenY                   | 118                           | 6                              |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres  $\geq 1:128$** 

|   |   |
|---|---|
| End point title   | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:128$ |
| End point description:<br>These analyses were performed by the GSK laboratory |   |
| End point type  | Secondary   |
| End point timeframe:<br>At 56 months after the primary vaccination            |   |

| End point values            | Nimenrix<br>Month 56<br>Group | Menjugate<br>Month 56<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 185                           | 63                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| rSBA-MenA [N=184;54]        | 184                           | 18                             |  |  |
| rSBA-MenC [N=182;63]        | 179                           | 63                             |  |  |
| rSBA-MenW-135 [N=185;61]    | 184                           | 29                             |  |  |
| rSBA-MenY [N=184;61]        | 184                           | 34                             |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:128$

|                 |   |
|-----------------|---|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY antibody titres $\geq 1:128$ |
|-----------------|---|

End point description:

These analyses were performed by the GSK laboratory

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

End point timeframe:

At 68 months after the primary vaccination

| End point values            | Nimenrix<br>Month 68<br>Group | Menjugate<br>Month 68<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 177                           | 59                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| rSBA-MenA [N=176;51]        | 176                           | 19                             |  |  |
| rSBA-MenC [N=174;59]        | 172                           | 59                             |  |  |
| rSBA-MenW-135 [N=177;58]    | 176                           | 27                             |  |  |
| rSBA-MenY [N=176;57]        | 176                           | 32                             |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

|                 |   |
|-----------------|---|
| End point title | Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens |
|-----------------|---|

End point description:

These analyses were performed by the Health Protection Agency (HPA) laboratory

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

End point timeframe:

At 56 months after the primary vaccination

| <b>End point values</b>                  | Nimenrix<br>Month 56<br>Group | Menjugate<br>Month 56<br>Group |  |  |
|--|-------------------------------|--------------------------------|--|--|
| Subject group type                       | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed              | 181                           | 65                             |  |  |
| Units: Titers                            |                               |                                |  |  |
| geometric mean (confidence interval 95%) |                               |                                |  |  |
| rSBA-MenA [N=181;65]                     | 120.1 (87 to 165.9)           | 9.8 (6.4 to 15)                |  |  |
| rSBA-MenC [N=181;65]                     | 30.5 (22.6 to 41.1)           | 69 (36.9 to 128.9)             |  |  |
| rSBA-MenW-135 [N=181;65]                 | 158.3 (112.4 to 222.9)        | 10.3 (6.4 to 16.6)             |  |  |
| rSBA-MenY [N=181;64]                     | 233.2 (166 to 327.6)          | 9 (6 to 13.6)                  |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

|  |   |
|--|---|
| End point title  | Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens |
| End point description:   |   |
| These analyses were performed by the Health Protection Agency (HPA) laboratory |   |
| End point type   | Secondary   |
| End point timeframe:   |   |
| At 68 months after the primary vaccination                                     |   |

| <b>End point values</b>                  | Nimenrix<br>Month 68<br>Group | Menjugate<br>Month 68<br>Group |  |  |
|--|-------------------------------|--------------------------------|--|--|
| Subject group type                       | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed              | 178                           | 61                             |  |  |
| Units: Titers                            |                               |                                |  |  |
| geometric mean (confidence interval 95%) |                               |                                |  |  |
| rSBA-MenA [N=178;61]                     | 129.5 (93.5 to 179.3)         | 11.1 (7 to 17.7)               |  |  |
| rSBA-MenC [N=178;61]                     | 14.2 (10.8 to 18.7)           | 44.5 (23.7 to 83.6)            |  |  |
| rSBA-MenW-135 [N=178;61]                 | 59.2 (39.3 to 89.2)           | 7.8 (5 to 12.1)                |  |  |
| rSBA-MenY [N=178;61]                     | 139.4 (96 to 202.5)           | 6.8 (4.6 to 10.2)              |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

|                 |   |
|-----------------|---|
| End point title | Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens |
|-----------------|---|

End point description:

These analyses were performed by the GSK laboratory

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

End point timeframe:

At 56 months after the primary vaccination

| End point values                         | Nimenrix<br>Month 56<br>Group | Menjugate<br>Month 56<br>Group |  |  |
|--|-------------------------------|--------------------------------|--|--|
| Subject group type                       | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed              | 185                           | 63                             |  |  |
| Units: Titers                            |                               |                                |  |  |
| geometric mean (confidence interval 95%) |                               |                                |  |  |
| rSBA-MenA [N=184;54]                     | 6748.6 (5931.4 to 7678.5)     | 27.9 (14.5 to 53.6)            |  |  |
| rSBA-MenC [N=182;63]                     | 2612.4 (2133.4 to 3199)       | 5327.5 (3508.6 to 8089.4)      |  |  |
| rSBA-MenW-135 [N=185;61]                 | 9350.9 (8134 to 10749.9)      | 78.1 (48.2 to 126.7)           |  |  |
| rSBA-MenY [N=184;61]                     | 8418.8 (7265.3 to 9755.5)     | 94.7 (59.3 to 151.4)           |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens

|                 |   |
|-----------------|---|
| End point title | Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY meningococcal antigens |
|-----------------|---|

End point description:

These analyses were performed by the GSK laboratory

|  |           |
|--|-----------|
| End point type                             | Secondary |
| End point timeframe:                       |           |
| At 68 months after the primary vaccination |           |

| End point values                         | Nimenrix<br>Month 68<br>Group | Menjugate<br>Month 68<br>Group |  |  |
|--|-------------------------------|--------------------------------|--|--|
| Subject group type                       | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed              | 177                           | 59                             |  |  |
| Units: Titers                            |                               |                                |  |  |
| geometric mean (confidence interval 95%) |                               |                                |  |  |
| rSBA-MenA [N=176;51]                     | 6875.3 (6005.7 to 7870.9)     | 31.9 (16.1 to 63.1)            |  |  |
| rSBA-MenC [N=174;59]                     | 2911.5 (2354.6 to 3600.2)     | 5393 (3436.2 to 8464.2)        |  |  |
| rSBA-MenW-135 [N=177;58]                 | 9587.1 (8337.7 to 11023.7)    | 77.4 (47.4 to 126.3)           |  |  |
| rSBA-MenY [N=176;57]                     | 8723 (7530.3 to 10104.7)      | 95.8 (58.9 to 155.6)           |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres $\geq 1:4$

|  |  |
|--|--|
| End point title  | Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres $\geq 1:4$ |
| End point description:   |  |
| This analysis was performed on 50% of the subjects in each group |  |
| End point type   | Secondary  |
| End point timeframe:   |  |
| At Month 56 after primary vaccination                            |  |

| End point values            | Nimenrix<br>Month 56<br>Group | Menjugate<br>Month 56<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 89                            | 31                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| hSBA-MenA [N=89;33]         | 53                            | 19                             |  |  |
| hSBA-MenC [N=86;31]         | 66                            | 21                             |  |  |
| hSBA-MenW-135 [N=83;30]     | 69                            | 13                             |  |  |
| hSBA-MenY [N=89;31]         | 79                            | 22                             |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres $\geq 1:4$

|  |  |
|--|--|
| End point title  | Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres $\geq 1:4$ |
| End point description:<br>This analysis was performed on 50% of the subjects in each group |  |
| End point type   | Secondary  |
| End point timeframe:<br>At Month 68 after primary vaccination                              |  |

| End point values            | Nimenrix<br>Month 68<br>Group | Menjugate<br>Month 68<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 172                           | 59                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| hSBA-MenA [N=170;59]        | 70                            | 23                             |  |  |
| hSBA-MenC [N=172;57]        | 134                           | 43                             |  |  |
| hSBA-MenW-135 [N=159;52]    | 125                           | 19                             |  |  |
| hSBA-MenY [N=159;58]        | 116                           | 24                             |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY meningococcal antigens

|  |  |
|--|--|
| End point title  | Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY meningococcal antigens |
| End point description:<br>This analysis was performed on 50% of the subjects in each group |  |
| End point type   | Secondary  |
| End point timeframe:<br>At Month 56 after primary vaccination                              |  |



| <b>End point values</b>                  | Nimenrix<br>Month 56<br>Group | Menjugate<br>Month 56<br>Group |  |  |
|--|-------------------------------|--------------------------------|--|--|
| Subject group type                       | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed              | 89                            | 31                             |  |  |
| Units: Titers                            |                               |                                |  |  |
| geometric mean (confidence interval 95%) |                               |                                |  |  |
| hSBA-MenA [N=89;33]                      | 10.6 (7.6 to 14.9)            | 7.6 (5 to 11.8)                |  |  |
| hSBA-MenC [N=86;31]                      | 20.6 (13.8 to 30.8)           | 31.2 (11.5 to 85)              |  |  |
| hSBA-MenW-135 [N=83;30]                  | 59.3 (40.2 to 87.6)           | 9.2 (4.7 to 18.2)              |  |  |
| hSBA-MenY [N=89;31]                      | 117.9 (80.8 to 171.9)         | 35.7 (16.8 to 75.9)            |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY meningococcal antigens

|  |  |
|--|--|
| End point title  | Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY meningococcal antigens |
| End point description:   |  |
| This analysis was performed on 50% of the subjects in each group |  |
| End point type   | Secondary  |
| End point timeframe:   |  |
| At Month 68 after primary vaccination                            |  |

| <b>End point values</b>                  | Nimenrix<br>Month 68<br>Group | Menjugate<br>Month 68<br>Group |  |  |
|--|-------------------------------|--------------------------------|--|--|
| Subject group type                       | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed              | 172                           | 59                             |  |  |
| Units: Titers                            |                               |                                |  |  |
| geometric mean (confidence interval 95%) |                               |                                |  |  |
| hSBA-MenA [N=170;59]                     | 6.9 (5.4 to 8.9)              | 4.5 (3.3 to 6)                 |  |  |
| hSBA-MenC [N=172;57]                     | 28.4 (21.2 to 37.9)           | 34.3 (19 to 61.9)              |  |  |
| hSBA-MenW-135 [N=159;52]                 | 56.7 (41.5 to 77.3)           | 8.1 (4.7 to 13.8)              |  |  |
| hSBA-MenY [N=159;58]                     | 56.3 (39.5 to 80.3)           | 13.3 (7 to 25.1)               |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titres $\geq 1:8$

|                 |  |
|-----------------|--|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titres $\geq 1:8$ |
|-----------------|--|

End point description:

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

End point timeframe:

At Month 69 after primary vaccination (one month post-booster vaccination)

| End point values            | Nimenrix<br>Month 69<br>Group | Menjugate<br>Month 69<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 165                           | 55                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| rSBA-MenA                   | 165                           | 55                             |  |  |
| rSBA-MenC                   | 165                           | 55                             |  |  |
| rSBA-MenW-135               | 165                           | 55                             |  |  |
| rSBA-MenY                   | 165                           | 55                             |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titres $\geq 1:128$

|                 |  |
|-----------------|--|
| End point title | Number of subjects with rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibody titres $\geq 1:128$ |
|-----------------|--|

End point description:

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

End point timeframe:

At Month 69 after primary vaccination (one month post-booster vaccination)

| <b>End point values</b>     | Nimenrix<br>Month 69<br>Group | Menjugate<br>Month 69<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 165                           | 55                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| rSBA-MenA                   | 165                           | 55                             |  |  |
| rSBA-MenC                   | 165                           | 55                             |  |  |
| rSBA-MenW-135               | 165                           | 55                             |  |  |
| rSBA-MenY                   | 165                           | 55                             |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY meningococcal antigens

|                 |  |
|-----------------|--|
| End point title | Antibody titers for rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY meningococcal antigens |
|-----------------|--|

End point description:

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

End point timeframe:

At Month 69 after primary vaccination (one month post-booster vaccination)

| <b>End point values</b>                  | Nimenrix<br>Month 69<br>Group | Menjugate<br>Month 69<br>Group |  |  |
|--|-------------------------------|--------------------------------|--|--|
| Subject group type                       | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed              | 165                           | 55                             |  |  |
| Units: Titers                            |                               |                                |  |  |
| geometric mean (confidence interval 95%) |                               |                                |  |  |
| rSBA-MenA                                | 5613 (4946.3 to 6369.4)       | 3521.1 (2912.5 to 4256.9)      |  |  |
| rSBA-MenC                                | 5314.6 (4596.2 to 6145.4)     | 7042.2 (5317.4 to 9326.5)      |  |  |
| rSBA-MenW-135                            | 14750.6 (12779.6 to 17025.6)  | 10540.4 (8455.2 to 13139.8)    |  |  |
| rSBA-MenY                                | 7954.6 (7167.8 to 8827.8)     | 5829.2 (4725.6 to 7190.6)      |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with a vaccine response to rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibodies

|                 |  |
|-----------------|--|
| End point title | Number of subjects with a vaccine response to rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY antibodies |
|-----------------|--|

End point description:

Vaccine response to rSBA-MenA, rSBA-MenC, rSBA-MenW-135 and rSBA-MenY is defined as rSBA antibody titers  $\geq 1:32$ , for initially seronegative subjects (i.e. pre-vaccination rSBA antibody titres  $< 1:8$ ) and at least a 4-fold increase in rSBA antibody titres from pre to post-vaccination for initially seropositive subjects (i.e. pre-vaccination rSBA antibody titres  $\geq 1:8$ ).

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

End point timeframe:

At Month 69 after primary vaccination (one month post-booster vaccination)

| End point values                    | Nimenrix<br>Month 69<br>Group | Menjugate<br>Month 69<br>Group |  |  |
|-------------------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type                  | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed         | 165                           | 55                             |  |  |
| Units: Subjects                     |                               |                                |  |  |
| rSBA-MenA-Post-booster status Total | 147                           | 54                             |  |  |
| rSBA-MenC-Post-booster status Total | 161                           | 48                             |  |  |
| rSBA-MenW-Post-booster status Total | 157                           | 54                             |  |  |
| rSBA-MenY-Post-booster status Total | 156                           | 54                             |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres $\geq 1:4$

|                 |  |
|-----------------|--|
| End point title | Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres $\geq 1:4$ |
|-----------------|--|

End point description:

Vaccine response to hSBA-MenA, hSBA-MenC, rSBA-MenW-135 and hSBA-MenY is defined as hSBA antibody titers  $\geq 1:8$ , for initially seronegative subjects (i.e. pre-vaccination hSBA antibody titres  $< 1:4$ ) and at least a 4-fold increase in hSBA antibody titres from pre to post-vaccination for initially seropositive subjects (i.e. pre-vaccination hSBA antibody titres  $\geq 1:4$ ).

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

End point timeframe:

At Month 69 after primary vaccination

| End point values            | Nimenrix<br>Month 69<br>Group | Menjugate<br>Month 69<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 163                           | 54                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| hSBA-MenA [N=163;53]        | 163                           | 46                             |  |  |
| hSBA-MenC [N=161;54]        | 161                           | 54                             |  |  |
| hSBA-MenW-135 [N=156;52]    | 156                           | 50                             |  |  |
| hSBA-MenY [N=160;54]        | 160                           | 52                             |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres $\geq 1:8$

|                 |  |
|-----------------|--|
| End point title | Number of subjects with hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibody titres $\geq 1:8$ |
|-----------------|--|

End point description:

Vaccine response to hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY is defined as hSBA antibody titres  $\geq 1:8$ , for initially seronegative subjects (i.e. pre-vaccination hSBA antibody titres  $< 1:4$ ) and at least a 4-fold increase in hSBA antibody titres from pre to post-vaccination for initially seropositive subjects (i.e. pre-vaccination hSBA antibody titres  $\geq 1:4$ ).

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

End point timeframe:

At Month 69 after primary vaccination (one month post-booster vaccination)

| End point values            | Nimenrix<br>Month 69<br>Group | Menjugate<br>Month 69<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 163                           | 54                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| hSBA-MenA [N=163;53]        | 163                           | 46                             |  |  |
| hSBA-MenC [N=161;54]        | 161                           | 54                             |  |  |
| hSBA-MenW-135 [N=156;52]    | 156                           | 50                             |  |  |
| hSBA-MenY [N=160;54]        | 160                           | 52                             |  |  |

### Statistical analyses

No statistical analyses for this end point

**Secondary: Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY meningococcal antigens**

|                 |  |
|-----------------|--|
| End point title | Antibody titers for hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY meningococcal antigens |
|-----------------|--|

End point description:

Vaccine response to hSBA-MenA, hSBA-MenC, rSBA-MenW-135 and hSBA-MenY is defined as hSBA antibody titers  $\geq 1:8$ , for initially seronegative subjects (i.e. pre-vaccination hSBA antibody titres  $< 1:4$ ) and at least a 4-fold increase in hSBA antibody titres from pre to post-vaccination for initially seropositive subjects (i.e. pre-vaccination hSBA antibody titres  $\geq 1:4$ ).

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

End point timeframe:

At Month 69 after primary vaccination (one month post-booster vaccination)

| End point values                         | Nimenrix<br>Month 69<br>Group | Menjugate<br>Month 69<br>Group |  |  |
|--|-------------------------------|--------------------------------|--|--|
| Subject group type                       | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed              | 163                           | 54                             |  |  |
| Units: Titers                            |                               |                                |  |  |
| geometric mean (confidence interval 95%) |                               |                                |  |  |
| hSBA-MenA [N=163;53]                     | 1376.5 (1138.2 to 1664.6)     | 101.2 (59.3 to 172.8)          |  |  |
| hSBA-MenC [N=161;54]                     | 11986.8 (10085.2 to 14247)    | 13692.2 (10094.2 to 18572.8)   |  |  |
| hSBA-MenW-135 [N=156;52]                 | 14582.1 (12448.5 to 17081.5)  | 235.7 (152 to 365.5)           |  |  |
| hSBA-MenY [N=160;54]                     | 12835.9 (11074.4 to 14877.5)  | 527.3 (356.5 to 779.9)         |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Number of subjects with a vaccine response to hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibodies**

|                 |  |
|-----------------|--|
| End point title | Number of subjects with a vaccine response to hSBA-MenA, hSBA-MenC, hSBA-MenW-135 and hSBA-MenY antibodies |
|-----------------|--|

End point description:

Vaccine response to hSBA-MenA, hSBA-MenC, rSBA-MenW-135 and hSBA-MenY is defined as hSBA antibody titers  $\geq 1:8$ , for initially seronegative subjects (i.e. pre-vaccination hSBA antibody titres  $< 1:4$ ) and at least a 4-fold increase in hSBA antibody titres from pre to post-vaccination for initially seropositive subjects (i.e. pre-vaccination hSBA antibody titres  $\geq 1:4$ ).

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

End point timeframe:

At Month 69 after primary vaccination (one month post-booster vaccination)

| <b>End point values</b>                         | Nimenrix<br>Month 69<br>Group | Menjugate<br>Month 69<br>Group |  |  |
|---|-------------------------------|--------------------------------|--|--|
| Subject group type                              | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed                     | 159                           | 52                             |  |  |
| Units: Subjects                                 |                               |                                |  |  |
| hSBA-MenA-Post-booster status Total<br>[159;52] | 156                           | 43                             |  |  |
| hSBA-MenC-Post-booster status Total<br>[156;50] | 153                           | 46                             |  |  |
| hSBA-MenW-Post-booster status Total<br>[139;45] | 136                           | 34                             |  |  |
| hSBA-MenY-Post-booster status Total<br>[144;51] | 142                           | 35                             |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with solicited local symptoms

|                 |  |
|-----------------|--|
| End point title | Number of subjects with solicited local symptoms |
|-----------------|--|

End point description:

Solicited local symptoms assessed include pain, redness and swelling. Grade 3 pain was defined as crying when limb was moved/spontaneously painful. Grade 3 swelling/redness was defined as swelling/redness larger than (>) 50 millimeters (mm). "Any" is defined as incidence of the specified symptom regardless of intensity.

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

End point timeframe:

During the 4-day period (Days 0-3) following the booster vaccination.

| <b>End point values</b>     | Nimenrix<br>Month 69<br>Group | Menjugate<br>Month 69<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 171                           | 60                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| Any Pain                    | 113                           | 35                             |  |  |
| Grade 3 Pain                | 7                             | 4                              |  |  |
| Any Redness                 | 62                            | 25                             |  |  |
| Grade 3 Redness             | 8                             | 4                              |  |  |
| Any Swelling                | 52                            | 19                             |  |  |
| Grade 3 Swelling            | 4                             | 3                              |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with solicited general symptoms

|                 |  |
|-----------------|--|
| End point title | Number of subjects with solicited general symptoms |
|-----------------|--|

End point description:

Assessed solicited general symptoms were Fatigue, Gastrointestinal symptoms (Gastro. symptoms), Headache and Temperature (axillary temperature higher than  $\geq$  37.5 degrees Celsius [ $^{\circ}$ C]). Any = Occurrence of the specified solicited general symptom, regardless of intensity or relationship to vaccination. Related = Occurrence of the specified symptom assessed by the investigators as causally related to vaccination. Grade 3 Fatigue = Fatigue that prevented normal activity. Grade 3 Gastro. symptoms = Gastro. symptoms that prevented normal everyday activities. Grade 3 Headache = Headache that prevented normal activity. Grade 3 Fever = Rectal temperature higher than ( $>$ ) 39.5 $^{\circ}$ C.

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

End point timeframe:

During the 4-day period (Days 0-3) following the booster vaccination.

| End point values             | Nimenrix<br>Month 69<br>Group | Menjugate<br>Month 69<br>Group |  |  |
|------------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type           | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed  | 169                           | 58                             |  |  |
| Units: Subjects              |                               |                                |  |  |
| Any Fatigue                  | 38                            | 12                             |  |  |
| Grade 3 Fatigue              | 3                             | 0                              |  |  |
| Related Fatigue              | 28                            | 10                             |  |  |
| Any Gastro. Symptoms         | 19                            | 7                              |  |  |
| Grade 3 Gastro. Symptoms     | 2                             | 1                              |  |  |
| Related Gastro. Symptoms     | 10                            | 3                              |  |  |
| Any Headache                 | 43                            | 10                             |  |  |
| Grade 3 Headache             | 7                             | 0                              |  |  |
| Related Headache             | 27                            | 8                              |  |  |
| Any Temperature/Axillary     | 11                            | 5                              |  |  |
| Grade 3 Temperature/Axillary | 0                             | 0                              |  |  |
| Related Temperature/Axillary | 9                             | 3                              |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with any unsolicited adverse events (AEs)

|                 |  |
|-----------------|--|
| End point title | Number of subjects with any unsolicited adverse events (AEs) |
|-----------------|--|

End point description:

An AE is any untoward medical occurrence in a clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

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

End point timeframe:

During the 31-day period (Days 0-30) following the booster vaccination.



| End point values            | Nimenrix<br>Month 69<br>Group | Menjugate<br>Month 69<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 179                           | 62                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| Any AEs                     | 26                            | 8                              |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with any serious adverse events (SAEs)

|  |   |
|--|---|
| End point title  | Number of subjects with any serious adverse events (SAEs) |
| End point description:<br>SAEs assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization, result in disability/incapacity. |   |
| End point type   | Secondary   |
| End point timeframe:<br>During the 31-day period (Days 0-30) post booster vaccination  |   |

| End point values            | Nimenrix<br>Month 69<br>Group | Menjugate<br>Month 69<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 179                           | 62                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| Any SAEs                    | 0                             | 0                              |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with any new onset of chronic illnesses (NOCIs)

|   |  |
|---|--|
| End point title   | Number of subjects with any new onset of chronic illnesses (NOCIs) |
| End point description:<br>New onset of chronic illnesses (NOCIs) included: autoimmune disorders, asthma, type I diabetes and allergies. |  |
| End point type  | Secondary  |
| End point timeframe:<br>During the 31-day period (Days 0-30) following the booster vaccination.   |  |

| <b>End point values</b>     | Nimenrix<br>Month 69<br>Group | Menjugate<br>Month 69<br>Group |  |  |
|-----------------------------|-------------------------------|--------------------------------|--|--|
| Subject group type          | Reporting group               | Reporting group                |  |  |
| Number of subjects analysed | 179                           | 62                             |  |  |
| Units: Subjects             |                               |                                |  |  |
| Any NOCIs                   | 0                             | 0                              |  |  |

### Statistical analyses

---

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms during the 4-day post-vaccination period, Unsolicited AEs during the 31-day post-vaccination period, SAEs during the entire study period.

|                 |                |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 18.0 |
|--------------------|------|

### Reporting groups

|                       |                         |
|-----------------------|-------------------------|
| Reporting group title | Nimenrix Month 32 Group |
|-----------------------|-------------------------|

|                                |  |
|--------------------------------|--|
| Reporting group description: - |  |
|--------------------------------|--|

|                       |                         |
|-----------------------|-------------------------|
| Reporting group title | Nimenrix Month 44 Group |
|-----------------------|-------------------------|

|                                |  |
|--------------------------------|--|
| Reporting group description: - |  |
|--------------------------------|--|

|                       |                          |
|-----------------------|--------------------------|
| Reporting group title | Menjugate Month 32 Group |
|-----------------------|--------------------------|

|                                |  |
|--------------------------------|--|
| Reporting group description: - |  |
|--------------------------------|--|

|                       |                          |
|-----------------------|--------------------------|
| Reporting group title | Menjugate Month 44 Group |
|-----------------------|--------------------------|

|                                |  |
|--------------------------------|--|
| Reporting group description: - |  |
|--------------------------------|--|

|                       |                         |
|-----------------------|-------------------------|
| Reporting group title | Nimenrix Month 56 Group |
|-----------------------|-------------------------|

|                                |  |
|--------------------------------|--|
| Reporting group description: - |  |
|--------------------------------|--|

|                       |                          |
|-----------------------|--------------------------|
| Reporting group title | Menjugate Month 56 Group |
|-----------------------|--------------------------|

|                                |  |
|--------------------------------|--|
| Reporting group description: - |  |
|--------------------------------|--|

|                       |                         |
|-----------------------|-------------------------|
| Reporting group title | Nimenrix Month 68 Group |
|-----------------------|-------------------------|

|                                |  |
|--------------------------------|--|
| Reporting group description: - |  |
|--------------------------------|--|

|                       |                          |
|-----------------------|--------------------------|
| Reporting group title | Menjugate Month 68 Group |
|-----------------------|--------------------------|

|                                |  |
|--------------------------------|--|
| Reporting group description: - |  |
|--------------------------------|--|

|                       |                         |
|-----------------------|-------------------------|
| Reporting group title | Nimenrix Month 69 Group |
|-----------------------|-------------------------|

|                                |  |
|--------------------------------|--|
| Reporting group description: - |  |
|--------------------------------|--|

|                       |                          |
|-----------------------|--------------------------|
| Reporting group title | Menjugate Month 68 Group |
|-----------------------|--------------------------|

|                                |  |
|--------------------------------|--|
| Reporting group description: - |  |
|--------------------------------|--|

| Serious adverse events                            | Nimenrix Month 32 Group | Nimenrix Month 44 Group | Menjugate Month 32 Group |
|---|-------------------------|-------------------------|--------------------------|
| Total subjects affected by serious adverse events |                         |                         |                          |
| subjects affected / exposed                       | 0 / 192 (0.00%)         | 0 / 193 (0.00%)         | 0 / 72 (0.00%)           |
| number of deaths (all causes)                     | 0                       | 0                       | 0                        |
| number of deaths resulting from adverse events    | 0                       | 0                       | 0                        |

| Serious adverse events                            | Menjugate Month 44 Group | Nimenrix Month 56 Group | Menjugate Month 56 Group |
|---|--------------------------|-------------------------|--------------------------|
| Total subjects affected by serious adverse events |                          |                         |                          |
| subjects affected / exposed                       | 0 / 68 (0.00%)           | 0 / 193 (0.00%)         | 0 / 67 (0.00%)           |
| number of deaths (all causes)                     | 0                        | 0                       | 0                        |
| number of deaths resulting from adverse events    | 0                        |                         |                          |

| <b>Serious adverse events</b>                     | Nimenrix Month 68<br>Group | Menjugate Month 68<br>Group | Nimenrix Month 69<br>Group |
|---|----------------------------|-----------------------------|----------------------------|
| Total subjects affected by serious adverse events |                            |                             |                            |
| subjects affected / exposed                       | 0 / 193 (0.00%)            | 0 / 67 (0.00%)              | 0 / 179 (0.00%)            |
| number of deaths (all causes)                     | 0                          | 0                           | 0                          |
| number of deaths resulting from adverse events    |                            |                             |                            |

| <b>Serious adverse events</b>                     | Menjugate Month 68<br>Group |  |  |
|---|-----------------------------|--|--|
| Total subjects affected by serious adverse events |                             |  |  |
| subjects affected / exposed                       | 0 / 62 (0.00%)              |  |  |
| number of deaths (all causes)                     | 0                           |  |  |
| number of deaths resulting from adverse events    |                             |  |  |

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

| <b>Non-serious adverse events</b>                     | Nimenrix Month 32<br>Group | Nimenrix Month 44<br>Group | Menjugate Month 32<br>Group |
|---|----------------------------|----------------------------|-----------------------------|
| Total subjects affected by non-serious adverse events |                            |                            |                             |
| subjects affected / exposed                           | 0 / 192 (0.00%)            | 0 / 193 (0.00%)            | 0 / 72 (0.00%)              |
| General disorders and administration site conditions  |                            |                            |                             |
| Pain  |                            |                            |                             |
| alternative assessment type: Systematic               |                            |                            |                             |
| subjects affected / exposed <sup>[1]</sup>            | 0 / 192 (0.00%)            | 0 / 193 (0.00%)            | 0 / 72 (0.00%)              |
| occurrences (all)                                     | 0                          | 0                          | 0                           |
| Redness   |                            |                            |                             |
| alternative assessment type: Systematic               |                            |                            |                             |
| subjects affected / exposed <sup>[2]</sup>            | 0 / 192 (0.00%)            | 0 / 193 (0.00%)            | 0 / 72 (0.00%)              |
| occurrences (all)                                     | 0                          | 0                          | 0                           |
| Swelling  |                            |                            |                             |
| alternative assessment type: Systematic               |                            |                            |                             |
| subjects affected / exposed <sup>[3]</sup>            | 0 / 192 (0.00%)            | 0 / 193 (0.00%)            | 0 / 72 (0.00%)              |
| occurrences (all)                                     | 0                          | 0                          | 0                           |
| Fatigue   |                            |                            |                             |
| alternative assessment type: Systematic               |                            |                            |                             |

|  |                 |                 |                |
|--|-----------------|-----------------|----------------|
| subjects affected / exposed <sup>[4]</sup> | 0 / 192 (0.00%) | 0 / 193 (0.00%) | 0 / 72 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0              |
| Gastrointestinal symptoms                  |                 |                 |                |
| alternative assessment type:<br>Systematic |                 |                 |                |
| subjects affected / exposed <sup>[5]</sup> | 0 / 192 (0.00%) | 0 / 193 (0.00%) | 0 / 72 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0              |
| Headache                                   |                 |                 |                |
| alternative assessment type:<br>Systematic |                 |                 |                |
| subjects affected / exposed <sup>[6]</sup> | 0 / 192 (0.00%) | 0 / 193 (0.00%) | 0 / 72 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0              |
| Temperature/(Axillary)                     |                 |                 |                |
| alternative assessment type:<br>Systematic |                 |                 |                |
| subjects affected / exposed <sup>[7]</sup> | 0 / 192 (0.00%) | 0 / 193 (0.00%) | 0 / 72 (0.00%) |
| occurrences (all)                          | 0               | 0               | 0              |

| <b>Non-serious adverse events</b>                     | Menjugate Month 44<br>Group | Nimenrix Month 56<br>Group | Menjugate Month 56<br>Group |
|---|-----------------------------|----------------------------|-----------------------------|
| Total subjects affected by non-serious adverse events |                             |                            |                             |
| subjects affected / exposed                           | 0 / 68 (0.00%)              | 0 / 193 (0.00%)            | 0 / 67 (0.00%)              |
| General disorders and administration site conditions  |                             |                            |                             |
| Pain  |                             |                            |                             |
| alternative assessment type:<br>Systematic            |                             |                            |                             |
| subjects affected / exposed <sup>[1]</sup>            | 0 / 68 (0.00%)              | 0 / 193 (0.00%)            | 0 / 67 (0.00%)              |
| occurrences (all)                                     | 0                           | 0                          | 0                           |
| Redness   |                             |                            |                             |
| alternative assessment type:<br>Systematic            |                             |                            |                             |
| subjects affected / exposed <sup>[2]</sup>            | 0 / 68 (0.00%)              | 0 / 193 (0.00%)            | 0 / 67 (0.00%)              |
| occurrences (all)                                     | 0                           | 0                          | 0                           |
| Swelling  |                             |                            |                             |
| alternative assessment type:<br>Systematic            |                             |                            |                             |
| subjects affected / exposed <sup>[3]</sup>            | 0 / 68 (0.00%)              | 0 / 193 (0.00%)            | 0 / 67 (0.00%)              |
| occurrences (all)                                     | 0                           | 0                          | 0                           |
| Fatigue   |                             |                            |                             |
| alternative assessment type:<br>Systematic            |                             |                            |                             |

|  |                |                 |                |
|--|----------------|-----------------|----------------|
| subjects affected / exposed <sup>[4]</sup> | 0 / 68 (0.00%) | 0 / 193 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all)                          | 0              | 0               | 0              |
| Gastrointestinal symptoms                  |                |                 |                |
| alternative assessment type:<br>Systematic |                |                 |                |
| subjects affected / exposed <sup>[5]</sup> | 0 / 68 (0.00%) | 0 / 193 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all)                          | 0              | 0               | 0              |
| Headache                                   |                |                 |                |
| alternative assessment type:<br>Systematic |                |                 |                |
| subjects affected / exposed <sup>[6]</sup> | 0 / 68 (0.00%) | 0 / 193 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all)                          | 0              | 0               | 0              |
| Temperature/(Axillary)                     |                |                 |                |
| alternative assessment type:<br>Systematic |                |                 |                |
| subjects affected / exposed <sup>[7]</sup> | 0 / 68 (0.00%) | 0 / 193 (0.00%) | 0 / 67 (0.00%) |
| occurrences (all)                          | 0              | 0               | 0              |

| <b>Non-serious adverse events</b>                     | Nimenrix Month 68<br>Group | Menjugate Month 68<br>Group | Nimenrix Month 69<br>Group |
|---|----------------------------|-----------------------------|----------------------------|
| Total subjects affected by non-serious adverse events |                            |                             |                            |
| subjects affected / exposed                           | 0 / 193 (0.00%)            | 0 / 67 (0.00%)              | 113 / 179 (63.13%)         |
| General disorders and administration site conditions  |                            |                             |                            |
| Pain  |                            |                             |                            |
| alternative assessment type:<br>Systematic            |                            |                             |                            |
| subjects affected / exposed <sup>[1]</sup>            | 0 / 193 (0.00%)            | 0 / 67 (0.00%)              | 113 / 171 (66.08%)         |
| occurrences (all)                                     | 0                          | 0                           | 113                        |
| Redness   |                            |                             |                            |
| alternative assessment type:<br>Systematic            |                            |                             |                            |
| subjects affected / exposed <sup>[2]</sup>            | 0 / 193 (0.00%)            | 0 / 67 (0.00%)              | 62 / 171 (36.26%)          |
| occurrences (all)                                     | 0                          | 0                           | 62                         |
| Swelling  |                            |                             |                            |
| alternative assessment type:<br>Systematic            |                            |                             |                            |
| subjects affected / exposed <sup>[3]</sup>            | 0 / 193 (0.00%)            | 0 / 67 (0.00%)              | 52 / 171 (30.41%)          |
| occurrences (all)                                     | 0                          | 0                           | 52                         |
| Fatigue   |                            |                             |                            |
| alternative assessment type:<br>Systematic            |                            |                             |                            |

|  |                 |                |                   |
|--|-----------------|----------------|-------------------|
| subjects affected / exposed <sup>[4]</sup> | 0 / 193 (0.00%) | 0 / 67 (0.00%) | 38 / 169 (22.49%) |
| occurrences (all)                          | 0               | 0              | 38                |
| Gastrointestinal symptoms                  |                 |                |                   |
| alternative assessment type:<br>Systematic |                 |                |                   |
| subjects affected / exposed <sup>[5]</sup> | 0 / 193 (0.00%) | 0 / 67 (0.00%) | 19 / 169 (11.24%) |
| occurrences (all)                          | 0               | 0              | 19                |
| Headache                                   |                 |                |                   |
| alternative assessment type:<br>Systematic |                 |                |                   |
| subjects affected / exposed <sup>[6]</sup> | 0 / 193 (0.00%) | 0 / 67 (0.00%) | 43 / 169 (25.44%) |
| occurrences (all)                          | 0               | 0              | 43                |
| Temperature/(Axillary)                     |                 |                |                   |
| alternative assessment type:<br>Systematic |                 |                |                   |
| subjects affected / exposed <sup>[7]</sup> | 0 / 193 (0.00%) | 0 / 67 (0.00%) | 11 / 169 (6.51%)  |
| occurrences (all)                          | 0               | 0              | 11                |

|  |                             |  |  |
|--|-----------------------------|--|--|
| <b>Non-serious adverse events</b>                        | Menjugate Month 68<br>Group |  |  |
| Total subjects affected by non-serious<br>adverse events |                             |  |  |
| subjects affected / exposed                              | 35 / 62 (56.45%)            |  |  |
| General disorders and administration<br>site conditions  |                             |  |  |
| Pain   |                             |  |  |
| alternative assessment type:<br>Systematic               |                             |  |  |
| subjects affected / exposed <sup>[1]</sup>               | 35 / 60 (58.33%)            |  |  |
| occurrences (all)  | 35                          |  |  |
| Redness  |                             |  |  |
| alternative assessment type:<br>Systematic               |                             |  |  |
| subjects affected / exposed <sup>[2]</sup>               | 25 / 60 (41.67%)            |  |  |
| occurrences (all)  | 25                          |  |  |
| Swelling   |                             |  |  |
| alternative assessment type:<br>Systematic               |                             |  |  |
| subjects affected / exposed <sup>[3]</sup>               | 19 / 60 (31.67%)            |  |  |
| occurrences (all)  | 19                          |  |  |
| Fatigue  |                             |  |  |
| alternative assessment type:<br>Systematic               |                             |  |  |

|  |                  |  |  |
|--|------------------|--|--|
| subjects affected / exposed <sup>[4]</sup> | 12 / 58 (20.69%) |  |  |
| occurrences (all)                          | 12               |  |  |
| Gastrointestinal symptoms                  |                  |  |  |
| alternative assessment type:<br>Systematic |                  |  |  |
| subjects affected / exposed <sup>[5]</sup> | 7 / 58 (12.07%)  |  |  |
| occurrences (all)                          | 7                |  |  |
| Headache                                   |                  |  |  |
| alternative assessment type:<br>Systematic |                  |  |  |
| subjects affected / exposed <sup>[6]</sup> | 10 / 58 (17.24%) |  |  |
| occurrences (all)                          | 10               |  |  |
| Temperature/(Axillary)                     |                  |  |  |
| alternative assessment type:<br>Systematic |                  |  |  |
| subjects affected / exposed <sup>[7]</sup> | 5 / 58 (8.62%)   |  |  |
| occurrences (all)                          | 5                |  |  |

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: The analysis was performed on the Total vaccinated cohort, only on subjects with their symptom sheets completed.



## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date             | Amendment   |
|------------------|---|
| 27 August 2010   | This amendment has been done to answer the requests of the French and German ethics committees to not use Menjugate as a booster vaccination since Menjugate has no booster indication in France and also to not use Menveo as a booster vaccination since Menveo is currently not licensed for the age group in this study and has no booster indication.  |
| 15 December 2011 | <p>The primary objective of the study was to evaluate the persistence of meningococcal antibodies in terms of the percentage of subjects with rabbit serum bactericidal assay (rSBA)-MenA, rSBA-MenC, rSBA-MenW-135, rSBA-MenY titres <math>\geq 1:8</math> at 32, 44, 56 and 68 months after primary vaccination with MenACWY-TT or Menjugate.</p> <p>In addition, to support the data obtained by rSBA testing, antibody titres and concentrations against meningococcal polysaccharides were planned to be assessed by human (h)SBA testing and ELISA (anti-polysaccharides [PS] testing) at 32, 44, 56 and 68 months after primary vaccination with MenACWY-TT or Menjugate and at Month 69, one month after the MenACWY-TT booster vaccination. The sponsor decided not to perform the ELISA testing at all time points for the following reasons:</p> <ul style="list-style-type: none"><li>• the World Health Organisation (WHO) considers SBA the primary means of assessing immune response to meningococcal conjugate vaccines [WHO, 2006; WHO, 1999].</li><li>• circulating bactericidal antibodies are more critical for persistent protection against meningococcal disease than non-functional antibodies against meningococcal polysaccharides [CDC, 2011; WHO, 2006].</li></ul> <p>Although antibody concentrations will not be determined by ELISA at 32, 44, 56 and 68 months after primary vaccination with MenACWY-TT or Menjugate and at Month 69, one month after the MenACWY-TT booster vaccination, all subjects will be informed of their rSBA and hSBA antibody titres at each immunogenicity time point when statistical analyses at that time point have been completed.</p> <p>In addition:</p> <ul style="list-style-type: none"><li>• The protocol amendment clarifies in which laboratory the different assays will be performed.</li><li>• The introduction has been updated with the current licensing status of competitor meningococcal vaccines.</li><li>• The list of abbreviations and reference list have been updated according to changes made throughout the protocol.</li></ul> <p>The authors list has been updated according to changes in the clinical study team.</p> |

Notes:

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported