Clinical trial results:
A Phase 2b, Randomized, Controlled, Observer-Blind, Multi-Center Study Assessing the Immunogenicity and Safety of GlaxoSmithKline (GSK) Biologicals' Meningococcal ABCWY Vaccine Administered at Different Schedules Compared to GSK Meningococcal group B vaccine, in Healthy Adolescents

Summary

EudraCT number	2013-002451-15
Trial protocol	FI PL
Global end of trial date	03 March 2016

Results information

Result version number	v3 (current)
This version publication date	07 April 2019
First version publication date	18 May 2017
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	205215

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02212457
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, 44 2089904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, 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	10 March 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	21 May 2015
Global end of trial reached?	Yes
Global end of trial date	03 March 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate the non-inferiority of the Meningococcal (groups A, C, W and Y) oligosaccharide diphtheria CRM-197 conjugate combined with meningococcal (group B) multicomponent recombinant (MenABCWY) vaccine to that of the Meningococcal (group B) multicomponent recombinant adsorbed (rMenB +OMV) vaccine administered according to 0, 2 month schedule, as measured by hSBA GMTs against N. meningitidis serogroup B test strains1 at 1 month after the last meningococcal vaccination.

Protection of trial subjects:

Standard immunization practices were observed and care was taken to administer the injection intramuscularly. As with all injectable vaccines, appropriate medical treatment and supervision was readily available in case of rare anaphylactic reactions following administration of the study vaccine. Epinephrine 1:1000 and diphenhydramine was available in case of any anaphylactic reactions. Care was taken to ensure that the vaccine is not injected into a blood vessel. The measures of safety used in this study are routine clinical procedures. They include a close vigilance for, and stringent reporting of, selected local and systemic adverse events routinely monitored in vaccine clinical studies as indicators of reactogenicity. The period of observation for AEs extended from the time a subject signed an informed consent until he or she completed the final study visit (Visit Month 13) or terminated the study early (whichever came first).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 August 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Finland: 495
Country: Number of subjects enrolled	Poland: 433
Country: Number of subjects enrolled	United States: 135
Worldwide total number of subjects	1063
EEA total number of subjects	928

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)	289
Adolescents (12-17 years)	448
Adults (18-64 years)	326
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited from 32 centers from Finland, Poland and United States.

Pre-assignment

Screening details:

All subjects were included in the trial.

Period 1

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

Blinding implementation details:

The trial was designed as an observer-blind study. Observer-blind means that during the course of study, the subject, the parents/guardians of the subjects and the study personnel responsible for the evaluation of any study endpoint (e.g. safety and reactogenicity) were unaware which vaccine was administered.

Arms

Are arms mutually exclusive?	Yes
Arm title	rMenB_0_2 Group

Arm description:

Subjects received two injections of Bexsero vaccine at Visit Month 0 and Visit Month 2, Havrix vaccine at Visit Month 6 and Visit Month 12 and saline placebo at Visit Month 1.

Arm type	Active comparator
Investigational medicinal product name	Havrix Vaccine
Investigational medicinal product code	
Other name	Hepatitis A vaccine
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects between 1 and 15 years of age received one pediatric dose (0.5 mL) of Havrix Junior Monodose Vaccine (Hepatitis A virus antigen, 720 ELISA units/0.5 mL dose), administered in the deltoid muscle. Subjects 16 years of age or older received one adult dose (1.0 mL) of Havrix Monodose Vaccine (Hepatitis A virus antigen, 1440 ELISA units/1 mL dose of hepatitis A virus antigen), administered in the deltoid muscle.

Investigational medicinal product name	Bexsero
Investigational medicinal product code	rMenB+OMV
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 milliliters (mL) dose of injectable suspension administered into the deltoid area of the non-dominant arm

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	Saline Solution
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL dose of injectable saline solution administered into the deltoid area of the non-dominant arm

Arm title	ABCWY_ 0_2 Group

Arm description:

Subjects received MenABCWY vaccine at Visit Month 0 and Visit Month 2, Havrix vaccine at Visit Month 6 and Visit Month 12 and saline placebo at Visit Month 1.

Arm type	Experimental
Investigational medicinal product name	MenABCWY
Investigational medicinal product code	
Other name	GSK Meningococcal ABCWY Vaccine
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL dose of injectable suspension administered into the deltoid area of the non-dominant arm

Investigational medicinal product name	Havrix Vaccine
Investigational medicinal product code	
Other name	Hepatitis A vaccine
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects between 1 and 15 years of age received one pediatric dose (0.5 mL) of Havrix Junior Monodose Vaccine (Hepatitis A virus antigen, 720 ELISA units/0.5 mL dose), administered in the deltoid muscle. Subjects 16 years of age or older received one adult dose (1.0 mL) of Havrix Monodose Vaccine (Hepatitis A virus antigen, 1440 ELISA units/1 mL dose of hepatitis A virus antigen), administered in the deltoid muscle.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	Saline solution
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL dose of injectable saline solution administered into the deltoid area of the non-dominant arm

Arm title	ABCWY_0_1 Group

Arm description:

Subjects received MenABCWY vaccine at Visit Month 0 and Visit Month 1, Havrix vaccine at Visit Month 2 and Visit Month 12 and saline placebo at Visit Month 6.

Arm type	Experimental
Investigational medicinal product name	MenABCWY
Investigational medicinal product code	
Other name	GSK Meningococcal ABCWY Vaccine
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL dose of injectable suspension administered into the deltoid area of the non-dominant arm

Investigational medicinal product name	Havrix Vaccine
Investigational medicinal product code	
Other name	Hepatitis A vaccine
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects between 1 and 15 years of age received one pediatric dose (0.5 mL) of Havrix Junior Monodose Vaccine (Hepatitis A virus antigen, 720 ELISA units/0.5 mL dose), administered in the deltoid muscle. Subjects 16 years of age or older received one adult dose (1.0 mL) of Havrix Monodose Vaccine (Hepatitis A virus antigen, 1440 ELISA units/1 mL dose of hepatitis A virus antigen), administered in the deltoid muscle.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	Saline Solution
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL dose of injectable saline solution administered into the deltoid area of the non-dominant arm

Arm title	ABCWY_0_6 Group

Arm description:

Subjects received MenABCWY vaccine at Visit Month 0 and Visit Month 6, Havrix vaccine at Visit Month 1 and Visit Month 12 and saline placebo at Visit Month 2.

Arm type	Experimental
Investigational medicinal product name	MenABCWY
Investigational medicinal product code	
Other name	GSK Meningococcal ABCWY Vaccine
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL dose of injectable suspension administered into the deltoid area of the non-dominant arm

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	Saline Solution
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

0.5 mL dose of injectable saline solution administered into the deltoid area of the non-dominant arm

Investigational medicinal product name	Havrix Vaccine
Investigational medicinal product code	
Other name	Hepatitis A Vaccine
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects between 1 and 15 years of age received one pediatric dose (0.5 mL) of Havrix Junior Monodose Vaccine (Hepatitis A virus antigen, 720 ELISA units/0.5 mL dose), administered in the deltoid muscle. Subjects 16 years of age or older received one adult dose (1.0 mL) of Havrix Monodose Vaccine (Hepatitis A virus antigen, 1440 ELISA units/1 mL dose of hepatitis A virus antigen), administered in the deltoid muscle.

Arm title	ABCWY_0_11 Group

Arm description:

Subjects received MenABCWY vaccine at Visit Month 1 and Visit Month 12, Havrix vaccine at Visit Month 0 and Visit Month 6 and saline placebo at Visit Month 2.

Arm type	Experimental
Investigational medicinal product name	MenABCWY
Investigational medicinal product code	
Other name	GSK Meningococcal ABCWY Vaccine
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:	
0.5 mL dose of injectable suspension administered into the deltoid area of the non-dominant arm	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	Saline Solution
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
0.5 mL dose of injectable saline solution administered into the deltoid area of the non-dominant arm	
Investigational medicinal product name	Havrix Vaccine
Investigational medicinal product code	
Other name	Hepatitis A Vaccine
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Subjects between 1 and 15 years of age received one pediatric dose (0.5 mL) of Havrix Junior Monodose Vaccine (Hepatitis A virus antigen, 720 ELISA units/0.5 mL dose), administered in the deltoid muscle. Subjects 16 years of age or older received one adult dose (1.0 mL) of Havrix Monodose Vaccine (Hepatitis A virus antigen, 1440 ELISA units/1 mL dose of hepatitis A virus antigen), administered in the deltoid muscle.	
Arm title	ABCWY_0_2_6 Group
Arm description:	
Subjects received MenABCWY vaccine at Visit Month 0, Visit Month 2 and Visit Month 6 and Havrix vaccine at Visit Month 1 and Visit Month 12.	
Arm type	Experimental
Investigational medicinal product name	MenABCWY
Investigational medicinal product code	
Other name	GSK Meningococcal ABCWY Vaccine
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
0.5 mL dose of injectable suspension administered into the deltoid area of the non-dominant arm	
Investigational medicinal product name	Havrix Vaccine
Investigational medicinal product code	
Other name	Hepatitis A Vaccine
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Subjects between 1 and 15 years of age received one pediatric dose (0.5 mL) of Havrix Junior Monodose Vaccine (Hepatitis A virus antigen, 720 ELISA units/0.5 mL dose), administered in the deltoid muscle. Subjects 16 years of age or older received one adult dose (1.0 mL) of Havrix Monodose Vaccine (Hepatitis A virus antigen, 1440 ELISA units/1 mL dose of hepatitis A virus antigen), administered in the deltoid muscle.	

Number of subjects in period 1	rMenB_0_2 Group	ABCWY_ 0_2 Group	ABCWY_0_1 Group
Started	228	232	157
Completed	209	211	141
Not completed	19	21	16
Consent withdrawn by subject	8	10	8

Adverse event, non-fatal	1	2	2
Unspecified	2	1	2
Lost to follow-up	6	7	4
Protocol deviation	2	1	-

Number of subjects in period 1	ABCWY_0_6 Group	ABCWY_0_11 Group	ABCWY_0_2_6 Group
Started	134	152	160
Completed	123	137	147
Not completed	11	15	13
Consent withdrawn by subject	6	5	4
Adverse event, non-fatal	2	-	1
Unspecified	1	-	1
Lost to follow-up	1	8	4
Protocol deviation	1	2	3

Baseline characteristics

Reporting groups	
Reporting group title	rMenB_0_2 Group
Reporting group description:	
Subjects received two injections of Bexsero vaccine at Visit Month 0 and Visit Month 2, Havrix vaccine at Visit Month 6 and Visit Month 12 and saline placebo at Visit Month 1.	
Reporting group title	ABCWY_ 0_2 Group
Reporting group description:	
Subjects received MenABCWY vaccine at Visit Month 0 and Visit Month 2, Havrix vaccine at Visit Month 6 and Visit Month 12 and saline placebo at Visit Month 1.	
Reporting group title	ABCWY_0_1 Group
Reporting group description:	
Subjects received MenABCWY vaccine at Visit Month 0 and Visit Month 1, Havrix vaccine at Visit Month 2 and Visit Month 12 and saline placebo at Visit Month 6.	
Reporting group title	ABCWY_0_6 Group
Reporting group description:	
Subjects received MenABCWY vaccine at Visit Month 0 and Visit Month 6, Havrix vaccine at Visit Month 1 and Visit Month 12 and saline placebo at Visit Month 2.	
Reporting group title	ABCWY_0_11 Group
Reporting group description:	
Subjects received MenABCWY vaccine at Visit Month 1 and Visit Month 12, Havrix vaccine at Visit Month 0 and Visit Month 6 and saline placebo at Visit Month 2.	
Reporting group title	ABCWY_0_2_6 Group
Reporting group description:	
Subjects received MenABCWY vaccine at Visit Month 0, Visit Month 2 and Visit Month 6 and Havrix vaccine at Visit Month 1 and Visit Month 12.	

Reporting group values	rMenB_0_2 Group	ABCWY_ 0_2 Group	ABCWY_0_1 Group
Number of subjects	228	232	157
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	56	73	39
Adolescents (12-17 years)	96	93	72
Adults (18-64 years)	76	66	46
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	14.5	14.2	14.4
standard deviation	± 3.09	± 3.17	± 3.01
Sex: Female, Male Units: Subjects			
Female	130	119	101
Male	98	113	56

Reporting group values	ABCWY_0_6 Group	ABCWY_0_11 Group	ABCWY_0_2_6 Group
Number of subjects	134	152	160
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	35	39	47
Adolescents (12-17 years)	59	64	64
Adults (18-64 years)	40	49	49
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	14.4	14.5	14.3
standard deviation	± 3.06	± 3.1	± 3.16
Sex: Female, Male Units: Subjects			
Female	76	89	96
Male	58	63	64

Reporting group values	Total		
Number of subjects	1063		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	289		
Adolescents (12-17 years)	448		
Adults (18-64 years)	326		
From 65-84 years	0		
85 years and over	0		
Age Continuous Units: Years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male Units: Subjects			
Female	611		
Male	452		

End points

End points reporting groups

Reporting group title	rMenB_0_2 Group
Reporting group description:	
Subjects received two injections of Bexsero vaccine at Visit Month 0 and Visit Month 2, Havrix vaccine at Visit Month 6 and Visit Month 12 and saline placebo at Visit Month 1.	
Reporting group title	ABCWY_ 0_2 Group
Reporting group description:	
Subjects received MenABCWY vaccine at Visit Month 0 and Visit Month 2, Havrix vaccine at Visit Month 6 and Visit Month 12 and saline placebo at Visit Month 1.	
Reporting group title	ABCWY_0_1 Group
Reporting group description:	
Subjects received MenABCWY vaccine at Visit Month 0 and Visit Month 1, Havrix vaccine at Visit Month 2 and Visit Month 12 and saline placebo at Visit Month 6.	
Reporting group title	ABCWY_0_6 Group
Reporting group description:	
Subjects received MenABCWY vaccine at Visit Month 0 and Visit Month 6, Havrix vaccine at Visit Month 1 and Visit Month 12 and saline placebo at Visit Month 2.	
Reporting group title	ABCWY_0_11 Group
Reporting group description:	
Subjects received MenABCWY vaccine at Visit Month 1 and Visit Month 12, Havrix vaccine at Visit Month 0 and Visit Month 6 and saline placebo at Visit Month 2.	
Reporting group title	ABCWY_0_2_6 Group
Reporting group description:	
Subjects received MenABCWY vaccine at Visit Month 0, Visit Month 2 and Visit Month 6 and Havrix vaccine at Visit Month 1 and Visit Month 12.	

Primary: Human Serum Bactericidal Assay (hSBA) Geometric Mean Titers (GMTs) against N. meningitidis serogroup B test strains when administered according to 0_2 month schedule.

End point title	Human Serum Bactericidal Assay (hSBA) Geometric Mean Titers (GMTs) against N. meningitidis serogroup B test strains when administered according to 0_2 month schedule.[1]

End point description:

The non-inferiority of the Meningococcal (groups A, C, W and Y) oligosaccharide diphtheria CRM-197 conjugate combined with meningococcal (group B) multicomponent recombinant (MenABCWY) vaccine to Meningococcal (group B) multicomponent recombinant adsorbed (Bexsero) vaccine, administered according to 0, 2 month schedule, as measured by hSBA GMTs against N.meningitidis serogroup B test strains at 1 month after the last meningococcal vaccination, is reported. The test strains assessed were NZ98/254, M14459, M07-0241084 and 96217. This outcome measure was evaluated in the rMenB_0_2 and ABCWY_ 0_2 Groups. Analysis was done on Per Protocol Set (PPS)–Month 3, which included all screened subjects who received a study vaccination, provided evaluable serum samples at pre- & post-vaccination, with results available for at least 1 serogroup B test strain & who was not excluded due to protocol deviations/other reasons defined before unblinding/analysis

End point type	Primary

End point timeframe:

At baseline (Month 0) and 1 month after the last meningococcal vaccination (Month 3)

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	rMenB_0_2 Group	ABCWY_ 0_2 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	150	158		
Units: Titers				
geometric mean (confidence interval 95%)				
M14459 strain (Month 0) (N-155, 147)	1.31 (1.09 to 1.57)	1.28 (1.07 to 1.53)		
M14459 strain (Month 3)	15.78 (12 to 22)	11.64 (8.61 to 16)		
M07-0241084 strain (Month 0)(N-151,148)	2.16 (1.61 to 2.89)	2.12 (1.60 to 2.82)		
M07-0241084 strain (Month 3)(N-154,150)	11.56 (8.86 to 15)	8.19 (6.31 to 11)		
96217 strain (Month 0)(N-152,143)	2.36 (1.70 to 3.28)	2.93 (2.13 to 4.03)		
96217 strain (Month 3)(N-156,149)	229.29 (179 to 294)	150.82 (118 to 192)		
NZ98/254 strain (Month 0)(N-154,147)	1.15 (0.95 to 1.39)	1.27 (1.06 to 1.53)		
NZ98/254 strain (Month 3)(N-157,150)	24.31 (18 to 32)	11.95 (9.10 to 16)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Non-inferiority response against N. meningitidis serogroup B test strain M14459 of the MenABCWY vaccine to that of the Bexsero vaccine, administered according to 0, 2 month schedule.	
Comparison groups	ABCWY_ 0_2 Group v rMenB_0_2 Group
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	non-inferiority[2]
Method	ANCOVA
Parameter estimate	Geometric Mean Ratio
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.53
upper limit	1.02

Notes:

[2] - Non-inferiority was concluded when, at 1 month after the second meningococcal vaccination (Visit Month 3), the lower limit of the two-sided 95% confidence interval for the between-group ratios of GMTs (ABCWY_0_2 versus rMenB_0_2) was greater than 0.5 for each of the four serogroup B test strains.

Statistical analysis title	Staistical analysis 2
Statistical analysis description:	
Non-inferiority response against N. meningitidis serogroup B test strain M07-0241084 of the MenABCWY vaccine to that of the Bexsero vaccine, administered according to 0, 2 month schedule.	
Comparison groups	ABCWY_ 0_2 Group v rMenB_0_2 Group

Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Method	ANCOVA
Parameter estimate	Geometric Mean Ratio
Point estimate	0.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.54
upper limit	0.94

Notes:

[3] - Non-inferiority was concluded when, at 1 month after the second meningococcal vaccination (Visit Month 3), the lower limit of the two-sided 95% confidence interval for the between-group ratios of GMTs (ABCWY_0_2 versus rMenB_0_2) was greater than 0.5 for each of the four serogroup B test strains.

Statistical analysis title	Statistical analysis 3

Statistical analysis description:

Non-inferiority response against N. meningitidis serogroup B test strain 96217 of the MenABCWY vaccine to that of the Bexsero vaccine, administered according to 0, 2 month schedule.

Comparison groups	ABCWY_ 0_2 Group v rMenB_0_2 Group
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	non-inferiority[4]
Method	ANCOVA
Parameter estimate	Geometric Mean Ratio
Point estimate	0.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.51
upper limit	0.85

Notes:

[4] - Non-inferiority was concluded when, at 1 month after the second meningococcal vaccination (Visit Month 3), the lower limit of the two-sided 95% confidence interval for the between-group ratios of GMTs (ABCWY_0_2 versus rMenB_0_2) was greater than 0.5 for each of the four serogroup B test strains.

Statistical analysis title	Statistical analysis 4

Statistical analysis description:

Non-inferiority response against N. meningitidis serogroup B test strain NZ98/254 of the MenABCWY vaccine to that of the Bexsero vaccine, administered according to 0, 2 month schedule.

Comparison groups	ABCWY_ 0_2 Group v rMenB_0_2 Group
Number of subjects included in analysis	308
Analysis specification	Pre-specified
Analysis type	non-inferiority[5]
Method	ANCOVA
Parameter estimate	Geometric Mean Ratio
Point estimate	0.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.37
upper limit	0.66

Notes:

[5] - Non-inferiority was concluded when, at 1 month after the second meningococcal vaccination (Visit Month 3), the lower limit of the two-sided 95% confidence interval for the between-group ratios of GMTs (ABCWY_0_2 versus rMenB_0_2) was greater than 0.5 for each of the four serogroup B test strains.

Secondary: hSBA GMTs against N. meningitidis serogroups A, C, W and Y and serogroup B test strains when administered according to 0_2_6 month and 0_2 month schedule.

End point title	hSBA GMTs against N. meningitidis serogroups A, C, W and Y and serogroup B test strains when administered according to 0_2_6 month and 0_2 month schedule.[6]

End point description:

The immunogenicity of MenABCWY vaccine, administered according to 0, 2, 6 months schedule was compared with those administered according to 0, 2 months schedule, as measured by hSBA GMTs against N. meningitidis serogroup B test strains and serogroups A,C, W and Y at 1 month after the last meningococcal vaccination. The B test strains assessed were NZ98/254,M14459, M07-0241084 and 96217. This outcome measure was evaluated in the ABCWY_ 0_2 and ABCWY_0_2_6 Groups. 1 month post last meningococcal vaccination corresponds to Month 3 for ABCWY_0_2 Group and Month 7 for ABCWY_0_2_6 Group.Analysis was done on the FAS-1 month after the last meningococcal vaccination.All subjects in All Enrolled Set who received a study meningococcal vaccination & provided evaluable serum samples at pre- & at one month after the last meningococcal vaccination whose result is available for at least one A,C,W,or Y serogroup or serogroup B test strain.

End point type	Secondary

End point timeframe:

At baseline (Month 0) and 1 month after the last meningococcal vaccination (Month 3 for ABCWY_ 0_2 Group and Month 7 for ABCWY_0_2_6 Group)

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	ABCWY_ 0_2 Group	ABCWY_0_2_6 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	213	151		
Units: Titers				
geometric mean (confidence interval 95%)				
M14459 (M-0)(N-207,151)	1.21 (1.07 to 1.37)	1.12 (0.98 to 1.28)		
M14459 (M-3/M-7)(N-211,151)	12.17 (9.60 to 15)	27.09 (21 to 35)		
M07-0241084(M-0)(N-201,145)	2.36 (1.85 to 3.01)	2.05 (1.58 to 2.67)		
M07-0241084(M-3/M-7)(N-206,148)	8.91 (7.10 to 11)	18.03 (14 to 23)		
96217(M-0)(N-205,146)	2.31 (1.75 to 3.06)	2.28 (1.68 to 3.07)		
96217(M-3/M-7)(N-210,150)	174.27 (142 to 215)	298.76 (239 to 374)		
NZ98/254(M-0)(N-208,151)	1.24 (1.09 to 1.41)	1.07 (0.93 to 1.23)		
NZ98/254(M-3/M-7)(N-212,151)	12.57 (9.81 to 16)	17.55 (13 to 23)		
A serogroup(M-0)(N-206,146)	1.19 (1.04 to 1.36)	1.10 (0.95 to 1.27)		
A serogroup(M-3/M-7)(N-211,147)	66.73 (54 to 83)	125.45 (99 to 159)		
C serogroup(M-0)(N-206,145)	3.59 (2.85 to 4.53)	3.19 (2.48 to 4.10)		

C serogroup(M-3/M-7)(N-212,149)	158.8 (127 to 199)	376.44 (295 to 481)		
W serogroup(M-0)(N-198,138)	5.20 (3.56 to 7.59)	4.64 (3.05 to 7.05)		
W serogroup(M-3/M-7)(N-208,140)	206.62 (175 to 244)	295.9 (246 to 356)		
Y serogroup(M-0)(N-202,150)	1.33 (1.10 to 1.60)	1.26 (1.03 to 1.55)		
Y serogroup(M-3/M-7)(N-213,150)	79.84 (62 to 103)	163.69 (124 to 216)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with hSBA titers ≥LLQ against N. meningitidis serogroups A, C, W and y and serogroup B test strains when administered according to 0_2_6 month and 0_2 month schedule.

End point title	Percentages of subjects with hSBA titers ≥LLQ against N. meningitidis serogroups A, C, W and y and serogroup B test strains when administered according to 0_2_6 month and 0_2 month schedule.[7]

End point description:

The immunogenicity of MenABCWY vaccine, administered according to 0, 2, 6 month schedule, was compared with those, administered according to 0, 2 month schedule, as measured by the percentages of subjects with hSBA titers ≥ LLQ against N. meningitidis serogroup B test strains at 1 month after the last meningococcal vaccination.Analysis was done on the FAS-1 month after the last meningococcal vaccination.All subjects in All Enrolled Set who received a study meningococcal vaccination & provided evaluable serum samples at pre- & at one month after the last meningococcal vaccination whose result is available for at least one A,C,W,or Y serogroup or serogroup B test strain.

End point type	Secondary

End point timeframe:

At baseline (Month 0) and 1 month after the last meningococcal vaccination (Month 3 for ABCWY_ 0_2 Group and Month 7 for ABCWY_0_2_6 Group)

Notes:

[7] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	ABCWY_ 0_2 Group	ABCWY_0_2_6 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	213	151		
Units: Percentages of subjects				
number (confidence interval 95%)				
NZ98/254(M-0)(N-208,151)	6 (3.37 to 10.45)	2 (0.41 to 5.70)		
NZ98/254(M-3/7)(N-212,151)	63 (55.85 to 69.26)	74 (65.72 to 80.35)		
M14459(M-0)(N-207,151)	5 (2.68 to 9.31)	2 (0.41 to 5.70)		
M14459(M-3/M-7)(N-211,151)	70 (63.48 to 76.23)	89 (83.36 to 93.82)		
M07-0241084(M-0)(N-201,145)	18 (13.30 to 24.47)	18 (12.06 to 25.16)		

M07-0241084(M-3/7)(N-206,148)	49 (41.54 to 55.59)	72 (64.35 to 79.33)		
96217(M-0)(N-205,144)	28 (22.24 to 34.99)	27 (20.02 to 35.11)		
96217(M-3/7)(N-210,150)	97 (93.25 to 98.65)	99 (96.34 to 99.98)		
Serogroup A(M-0)(N-206,146)	3 (1.08 to 6.23)	1 (0.02 to 3.76)		
Serogroup A(M-3/7)(N-211,147)	88 (83.01 to 92.18)	95 (89.56 to 97.62)		
Serogroup C(M-0)(N-206,145)	44 (37.28 to 51.24)	41 (32.62 to 49.15)		
Serogroup C(M-3/7)(N-212,149)	99 (96.63 to 99.89)	100 (97.55 to 100)		
Serogroup W(M-0)(N-198,138)	27 (21.20 to 34.04)	22 (15.17 to 29.56)		
Serogroup W(M-3/7)(N-208,140)	97 (93.19 to 98.64)	99 (96.08 to 99.98)		
Serogroup Y(M-0)(N-202,150)	9 (5.37 to 13.72)	6 (2.78 to 11.08)		
Serogroup Y(M-3/7)(N-213,150)	92 (86.97 to 94.91)	97 (93.31 to 99.27)		

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA GMTs against each of N. meningitidis serogroups A, C, W and Y and serogroup B test strains when administered according to 0_1 month, 0_2 month, 0_6 month and 0, 11 month schedule.

End point title	hSBA GMTs against each of N. meningitidis serogroups A, C, W and Y and serogroup B test strains when administered according to 0_1 month, 0_2 month, 0_6 month and 0, 11 month schedule.[8]

End point description:

The immunogenicity of MenABCWY vaccine, administered according to 0, 2 months schedule, was compared with those, administered according to 0, 1 month, 0, 6 month and 0, 11 month schedules as measured by hSBA GMTs against N. meningitidis serogroups A, C, W and Y and serogroup B test strains at 1 month after the second meningococcal vaccination.Analysis was done on the FAS-1 month after the last meningococcal vaccination.All subjects in All Enrolled Set who received a study meningococcal vaccination & provided evaluable serum samples at pre- & at one month after the last meningococcal vaccination whose result is available for at least one A,C,W,or Y serogroup or serogroup B test strain.

End point type	Secondary

End point timeframe:

At 1 Month after the last vaccination (Month 2 for ABCWY_0_1 Group, Month 3 for ABCWY_0_2 Group, Month 7 for ABCWY_0_6 Group and Month 13 for ABCWY_0_11 Group)

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	ABCWY_ 0_2 Group	ABCWY_0_1 Group	ABCWY_0_6 Group	ABCWY_0_11 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	213	143	123	133
Units: Titers				
geometric mean (confidence interval 95%)				
NZ98/254(N-212,142,121,131)	12.32 (9.82 to 15)	6.33 (4.86 to 8.23)	13.64 (10 to 18)	15.87 (12 to 21)
M14459(N-211,140,122,133)	12.72 (10 to 16)	9.19 (7.11 to 12)	26.48 (20 to 35)	29.57 (23 to 39)
M07-0241084(N-206,140,123,131)	9.15 (7.52 to 11)	6.59 (5.25 to 8.27)	15.04 (12 to 19)	16.22 (13 to 21)
96217(N-210,143,121,133)	165.47 (133 to 206)	117.28 (91 to 151)	237.89 (182 to 310)	244.97 (189 to 317)
A serogroup(N-211,142,123,133)	69.61 (56 to 87)	79.87 (62 to 103)	140.76 (108 to 184)	162.76 (126 to 211)
C serogroup(N-212,142,123,131)	162.57 (132 to 201)	145.73 (114 to 186)	225.00 (174 to 290)	292.61 (227 to 376)
W serogroup(N-208,143,123,131)	215.72 (182 to 256)	197.69 (162 to 241)	376.03 (306 to 462)	531.79 (434 to 652)
Y serogroup(N-213,142,123,132)	71.66 (55 to 93)	57.45 (42 to 78)	120.76 (88 to 166)	209.53 (153 to 286)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with hSBA titers ≥ Lower Limit of Quantitation (LLQ) against N. meningitidis serogroup B test strains when administered according to 0_2 month schedule.

End point title	Percentages of subjects with hSBA titers ≥ Lower Limit of Quantitation (LLQ) against N. meningitidis serogroup B test strains when administered according to 0_2 month schedule.[9]

End point description:

A sufficient immune response following Bexsero vaccine, administered according to 0, 2 month schedule, as measured by the percentage of subjects with hSBA titers ≥ Lower Limit of Quantitation (LLQ) against N. meningitidis serogroup B test strains at 1 month after the last meningococcal vaccination, was to be demonstrated. Criterion: the immune response was to be considered sufficient if the lower limit of the two-sided 95% CI for the percentage of subjects with hSBA titers ≥ LLQ was greater than 75% for each of the four serogroup B test strains. The test strains assessed were Meningitis B NZ98/254 Ab, Meningitis B M14459 Ab, Meningitis B M07-0241084 Ab and Meningitis B 96217 Ab.

End point type	Secondary

End point timeframe:

At baseline (Month 0) and 1 month after the last meningococcal vaccination (Month 3)

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	rMenB_0_2 Group	ABCWY_ 0_2 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	188	185		
Units: Percentages of subjects				
number (confidence interval 95%)				
NZ98/254(M-0)(LLQ=8.2)(N-188,185)	7 (3.73 to 11.53)	6 (3.40 to 11.06)		
NZ98/254(M-3)(LLQ=8.2)(N-188,185)	88 (82.82 to 92.52)	61 (53.65 to 68.15)		
M14459(M-0)(LLQ=8.0)(N-184,179)	7 (3.41 to 11.11)	5 (2.32 to 9.33)		
M14459(M-3)(LLQ=8.0)(N-184,179)	82 (75.75 to 87.32)	68 (60.21 to 74.39)		
M07-0241084(M-0)(LLQ=8.9)(N-188,176)	21 (15.19 to 27.25)	18 (12.78 to 24.69)		
M07-0241084(M-3)LLQ=8.9)(N-188,176)	66 (59.26 to 73.19)	47 (39.60 to 54.81)		
96217(M-0)(LLQ=8.6)(N-186,178)	23 (17.26 to 29.85)	29 (22.14 to 35.89)		
96217(M-3)(LLQ=8.6)(N-186,178)	99 (97.04 to 99.99)	97 (92.81 to 98.75)		

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA GMTs against N. meningitidis serogroups A, C, W and Y and serogroup B test strains when administered according to 0_2_6 month and 0_6 month schedule.

End point title	hSBA GMTs against N. meningitidis serogroups A, C, W and Y and serogroup B test strains when administered according to 0_2_6 month and 0_6 month schedule.[10]

End point description:

The immunogenicity of MenABCWY vaccine, administered according to 0, 2, 6 months schedule was compared with those administered according to 0, 6 months schedule, as measured by hSBA GMTs against N. meningitidis serogroups A, C, W and Y and serogroup B test strains at 1 month after the last meningococcal vaccination.

End point type	Secondary

End point timeframe:

At 1 month after last vaccination (Month 7)

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	ABCWY_0_6 Group	ABCWY_0_2_6 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	123	151		
Units: Titers				
geometric mean (confidence interval 95%)				

NZ98/254(N-121,151)	13.62 (9.98 to 19)	17.13 (13 to 23)		
M14459(N-122,151)	27.82 (21 to 36)	29.27 (23 to 37)		
M07-0241084(N-123,148)	17.43 (13 to 23)	20.92 (16 to 27)		
96217(N-121,150)	240.13 (186 to 310)	291.63 (232 to 367)		
Serogroup A(N-123,147)	140.14 (107 to 184)	128.75 (101 to 164)		
Serogroup C(N-123,149)	246.48 (191 to 318)	413.60 (328 to 522)		
Serogroup W(N-123,140)	341.90 (283 to 413)	282.74 (237 to 338)		
Serogroup Y(N-123,150)	123.96 (91 to 169)	151.36 (115 to 200)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with hSBA titers ≥ Lower Limit of Quantitation (LLQ) against serogroups A, C, W and Y and serogroup B test strains when administered according to 0_2_6 month and 0_6 month schedule.

End point title	Percentages of subjects with hSBA titers ≥ Lower Limit of Quantitation (LLQ) against serogroups A, C, W and Y and serogroup B test strains when administered according to 0_2_6 month and 0_6 month schedule.[11]

End point description:

The immunogenicity of MenABCWY vaccine, administered according to 0, 2, 6 month schedule, was compared with those, administered according to 0, 6 month schedule, as measured by the percentages of subjects with hSBA titers ≥ LLQ against serogroups A, C, W and Y and serogroup B test strains at 1 month after the last meningococcal vaccination.Analysis was done on the FAS- 1 month after last meningococcal vaccination, which included all screened subjects who provided informed consent, received a study vaccination & provided evaluable serum samples at 1 month after last vaccination whose results were available for atleast 1 serogroup or B strains

End point type	Secondary

End point timeframe:

At baseline (Month 0) and 1 month after the last meningococcal vaccination (Month 7)

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	ABCWY_0_6 Group	ABCWY_0_2_6 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	123	151		
Units: Percentages of subjects				
number (confidence interval 95%)				
NZ98/254(M-0)(LLQ=8.2)(N-120,151)	5 (1.86 to 10.57)	2 (0.41 to 5.70)		
NZ98/254(M-7)(LLQ=8.2)(N-121,151)	64 (55.25 to 72.95)	74 (65.72 to 80.35)		

M14459(M-0)(LLQ=8.0)(N-121,151)	5 (1.84 to 10.48)	2 (0.41 to 5.70)		
M14459(M-7)(LLQ=8.0)(N-122,151)	87 (79.58 to 92.31)	89 (83.36 to 93.82)		
M07-0241084(M-0)(LLQ=8.9)(N-122,145)	14 (8.33 to 21.37)	18 (12.06 to 25.16)		
M07-0241084(M-7)(LLQ=8.9)(N-123,148)	66 (56.76 to 74.16)	72 (64.35 to 79.33)		
96217(M-0)(LLQ=8.6)(N-119,144)	27 (19.18 to 35.79)	27 (20.02 to 35.11)		
996217(M-7)(LLQ=8.6)(N-121,150)	98 (92.93 to 99.49)	99 (96.34 to 99.98)		
A serogroup(M-0)(LLQ=22.7)(N-118,146)	2 (0.21 to 5.99)	1 (0.02 to 3.76)		
A serogroup(M-7)(LLQ=22.7)(N-123,147)	94 (88.63 to 97.68)	95 (89.56 to 97.62)		
C serogroup(M-0)(LLQ=5.2)(N-122,145)	42 (32.94 to 51.07)	41 (32.62 to 49.15)		
C serogroup(M-7)(LLQ=5.2)(N-123,149)	99 (95.55 to 99.98)	100 (97.55 to 100)		
W serogroup(M-0)(LLQ=39.6)(N-119,138)	20 (13.37 to 28.51)	22 (15.17 to 29.56)		
W serogroup(M-7)(LLQ=39.6)(N-123,140)	99 (95.55 to 99.98)	99 (96.08 to 99.98)		
Y serogroup(M-0)(LLQ=14.7)(N-120,150)	7 (2.92 to 12.71)	6 (2.78 to 11.08)		
Y serogroup(M-7)(LLQ=14.7)(N-123,150)	94 (88.63 to 97.68)	97 (93.31 to 99.27)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with hSBA titers ≥ LLQ against N. meningitidis serogroups A, C, W and Y and serogroup B test strains when administered according to 0_1 month, 0_2 month, 0_6 month and 0_11 month schedule.

End point title	Percentages of subjects with hSBA titers ≥ LLQ against N. meningitidis serogroups A, C, W and Y and serogroup B test strains when administered according to 0_1 month, 0_2 month, 0_6 month and 0_11 month schedule.[12]

End point description:

The immunogenicity of MenABCWY vaccine, administered according to 0, 2 month schedule, was compared with those, administered according to 0, 1 month, 0, 6 month and 0, 11 month schedules, as measured by the percentages of subjects with hSBA titers ≥ LLQ against N. meningitidis serogroups A, C, W and Y and serogroup B test strains at 1 month after the second meningococcal vaccination.Analysis was done on the FAS- 1 month after last meningococcal vaccination, which included all screened subjects who provided informed
consent, received a study vaccination & provided evaluable serum samples at 1 month after last vaccination whose results were available for atleast 1 serogroup or B strains

End point type	Secondary

End point timeframe:

At 1 month after second vaccination (Month 2 for ABCWY_0_1 Group, Month 3 for ABCWY_0_2 Group , Month 7 for ABCWY_0_6 Group and Month 13 for ABCWY_0_11 Group)

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each

related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	ABCWY_ 0_2 Group	ABCWY_0_1 Group	ABCWY_0_6 Group	ABCWY_0_11 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	213	143	123	133
Units: Percentages of subjects				
number (confidence interval 95%)				
NZ98/254(LLQ=8.2)(N-212,142,121,131)	63 (55.85 to 69.26)	44 (35.36 to 52.23)	64 (55.25 to 72.95)	73 (64.85 to 80.63)
M14459(LLQ=8.0)(N-211,140,122,133)	70 (63.48 to 76.23)	62 (53.56 to 70.20)	87 (79.58 to 92.31)	89 (82.08 to 93.55)
M07-0241084(LLQ=8.9)(N-206,140,123,131)	49 (41.54 to 55.59)	40 (31.82 to 48.61)	66 (56.76 to 74.16)	69 (60.82 to 77.21)
96217(LLQ=8.6)(N-210,143,121,133)	97 (93.25 to 98.65)	97 (92.99 to 99.23)	98 (92.93 to 99.49)	98 (93.55 to 99.53)
Serogroup A (LLQ=22.7)(N-211,142,123,133)	88 (83.01 to 92.18)	92 (85.70 to 95.56)	94 (88.63 to 97.68)	94 (88.49 to 97.37)
Serogroup C (LLQ=5.2)(N-212,142,123,131)	99 (96.63 to 99.89)	100 (97.44 to 100)	99 (95.55 to 99.99)	100 (97.22 to 100)
Serogroup W (LLQ=39.6)(N-208,143,123,131)	97 (93.19 to 98.64)	96 (91.09 to 98.44)	99 (95.55 to 99.98)	98 (93.45 to 99.53)
Serogroup Y (LLQ=14.7)(N-213,142,123,132)	92 (86.97 to 94.91)	85 (78.29 to 90.61)	94 (88.63 to 97.68)	97 (92.42 to 99.17)

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA GMTs against serogroups A, C, W and Y and serogroup B test strains at all the relevant time points for all schedules.

End point title	hSBA GMTs against serogroups A, C, W and Y and serogroup B test strains at all the relevant time points for all schedules.

End point description:

The kinetic of immune response (at Months 0, 2, 3, 7 and 13) following different vaccination schedules as measured by the adjusted hSBA GMTs against serogroups A,C, W and Y and serogroup B test strains was assessed.

End point type	Secondary

End point timeframe:

At Month 0, Month 2, Month 3, Month 7 and Month 13

End point values	rMenB_0_2 Group	ABCWY_ 0_2 Group	ABCWY_0_1 Group	ABCWY_0_6 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	188	185	122	114
Units: Titers				
geometric mean (confidence interval 95%)				
NZ98/254(M-0)(N-188,185,120,112126,134)	1.22 (1.08 to 1.38)	1.22 (1.08 to 1.38)	1.21 (1.04 to 1.40)	1.13 (0.97 to 1.31)

NZ98/254(M-2)(N-188,185,120,112,126,134)	2.67 (2.14 to 3.34)	2.27 (1.82 to 2.84)	6.50 (4.98 to 8.48)	1.92 (1.46 to 2.51)
NZ98/254(M-3)(N-188,185,120,112,126,134)	27.17 (22 to 34)	11.46 (9.28 to 14)	3.15 (2.44 to 4.05)	1.69 (1.31 to 2.19)
NZ98/254 (M-7)(N-188,185,120,112,126,134)	3.00 (2.44 to 3.67)	2.41 (1.97 to 2.95)	1.88 (1.47 to 2.40)	14.30 (11 to 18)
NZ98/254(M-13)(N-188,185,120,112,126,134)	2.33 (1.92 to 2.83)	1.93 (1.59 to 2.33)	1.81 (1.44 to 2.27)	2.57 (2.04 to 3.25)
M14459(M-0)(N-184,179,112,108,123,134)	1.37 (1.21 to 1.56)	1.22 (1.08 to 1.39)	1.22 (1.04 to 1.42)	1.21 (1.04 to 1.41)
M14459(M-2)(N-184,179,112,108,123,134)	2.83 (2.31 to 3.46)	2.55 (2.08 to 3.13)	9.23 (7.21 to 12)	2.34 (1.82 to 2.99)
M14459(M-3)(N-184,179,112,108,123,134)	18.29 (15 to 23)	12.85 (10 to 16)	5.30 (4.04 to 6.93)	2.15 (1.64 to 2.82)
M14459(M-7)(N-184,179,112,108,123,134)	3.52 (2.91 to 4.26)	3.24 (2.68 to 3.93)	2.19 (1.74 to 2.77)	27.47 (22 to 35)
M14459(M-13)(N-184,179,112,108,123,134)	2.46 (2.03 to 2.97)	2.29 (1.89 to 2.78)	1.95 (1.54 to 2.45)	3.22 (2.55 to 4.06)
M07-0241084 (M-0)(N-188,176,117,113,121,128)	2.26 (1.81 to 2.82)	2.07 (1.65 to 2.59)	2.01 (1.53 to 2.63)	2.06 (1.57 to 2.71)
M07-0241084(M-2)(N-188,176,117,113,121,128)	5.09 (4.26 to 6.07)	4.30 (3.59 to 5.14)	6.73 (5.44 to 8.34)	3.51 (2.83 to 4.35)
M07-0241084 (M-3)(N-188,176,117,113,121,128)	13.91 (12 to 17)	8.82 (7.29 to 11)	4.39 (3.49 to 5.50)	3.30 (2.62 to 4.15)
M07-0241084 (M-7)(N-188,176,117,113,121,128)	5.42 (4.51 to 6.51)	4.68 (3.88 to 5.63)	3.36 (2.69 to 4.20)	15.70 (13 to 20)
M07-0241084(M-13)(N-188,176,117,113,121,128)	4.45 (3.71 to 5.35)	4.01 (3.34 to 4.83)	3.07 (2.46 to 3.83)	5.42 (4.33 to 6.77)
96217(M-0)(N-186,178,120,112,128,121)	2.32 (1.82 to 2.95)	2.84 (2.23 to 3.62)	2.88 (2.16 to 3.83)	2.39 (1.78 to 3.21)
96217 (M-2)(N-186,178,120,112,128,121)	16.48 (13 to 21)	11.62 (8.96 to 15)	124.75 (92 to 169)	11.61 (8.49 to 16)
96217(M-3)(N-186,178,120,112,128,121)	263.56 (211 to 329)	169.65 (136 to 212)	82.23 (63 to 107)	8.61 (6.57 to 11)
96217(M-7)(N-186,178,120,112,128,121)	61.46 (50 to 75)	43.01 (35 to 53)	37.26 (29 to 47)	264.85 (207 to 340)
96217(M-13)(N-186,178,120,112,128,121)	33.07 (27 to 41)	22.48 (18 to 28)	24.00 (18 to 31)	42.27 (32 to 55)
Serogroup A (M-0)(N-172,178,107,105,120,127)	1.37 (1.18 to 1.59)	1.17 (1.02 to 1.36)	1.38 (1.15 to 1.65)	1.08 (0.90 to 1.30)
Serogroup A (M-2)(N-172,178,107,105,120,127)	4.05 (2.97 to 5.54)	8.35 (6.14 to 11)	85.49 (59 to 125)	7.64 (5.22 to 11)
Serogroup A (M-3)(N-172,178,107,105,120,127)	106.70 (82 to 139)	68.85 (53 to 89)	52.42 (38 to 72)	5.31 (3.86 to 7.31)
Serogroup A (M-7)(N-172,178,107,105,120,127)	14.15 (11 to 19)	11.49 (8.71 to 15)	9.88 (7.04 to 14)	165.14 (117 to 233)
Serogroup A (M-13)(N-172,178,107,105,120,127)	5.80 (4.30 to 7.82)	4.64 (3.45 to 6.23)	5.90 (4.11 to 8.46)	15.20 (11 to 22)
Serogroup C (M-0)(N-186,185,122,114,123,130)	3.46 (2.76 to 4.33)	3.38 (2.71 to 4.23)	3.87 (2.96 to 5.04)	3.36 (2.56 to 4.40)
Serogroup C (M-2)(N-186,185,122,114,123,130)	9.47 (7.18 to 13)	31.56 (24 to 42)	163.28 (118 to 227)	37.24 (27 to 52)
Serogroup C(M-3)(N-186,185,122,114,123,130)	41.25 (32 to 52)	184.05 (145 to 234)	119.71 (90 to 159)	31.50 (24 to 42)
Serogroup C(M-7)(N-186,185,122,114,123,130)	11.03 (8.81 to 14)	80.70 (65 to 101)	76.97 (59 to 100)	260.57 (199 to 342)
Serogroup C(M-13)(N-186,185,122,114,123,130)	8.45 (6.79 to 11)	37.45 (30 to 47)	38.42 (30 to 50)	57.48 (44 to 75)
Serogroup W (M-0)(N-162,180,119,108,123,123)	6.43 (4.46 to 9.27)	4.75 (3.35 to 6.73)	4.54 (2.98 to 6.90)	4.29 (2.80 to 6.58)
Serogroup W (M-2)(N-162,180,119,108,123,123)	17.43 (13 to 23)	50.71 (39 to 66)	175.57 (128 to 241)	59.37 (43 to 82)

Serogroup W (M-3)(N-162,180,119,108,123,123)	138.43 (111 to 173)	214.70 (173 to 266)	125.70 (97 to 162)	59.26 (46 to 77)
Serogroup W (M-7)(N-162,180,119,108,123,123)	22.53 (18 to 29)	79.96 (63 to 101)	74.84 (57 to 99)	340.85 (256 to 453)
Serogroup W (M-13)(N-162,180,119,108,123,123)	12.63 (9.86 to 16)	45.63 (36 to 58)	46.83 (35 to 62)	96.43 (72 to 129)
Serogroup Y (M-0)(N-188,180,120,110,127,137)	1.72 (1.41 to 2.10)	1.40 (1.14 to 1.71)	1.68 (1.32 to 2.13)	1.24 (0.97 to 1.59)
Serogroup Y (M-2)(N-188,180,120,110,127,137)	2.36 (1.72 to 3.23)	19.43 (14 to 27)	63.45 (44 to 93)	16.41 (11 to 24)
Serogroup Y (M-3)(N-188,180,120,110,127,137)	3.12 (2.34 to 4.17)	90.61 (68 to 121)	42.97 (30 to 61)	15.95 (11 to 23)
Serogroup Y (M-7)(N-188,180,120,110,127,137)	2.44 (1.87 to 3.17)	34.27 (26 to 45)	27.86 (20 to 38)	152.73 (111 to 211)
Serogroup Y (M-13)(N-188,180,120,110,127,137)	2.28 (1.75 to 2.96)	18.13 (14 to 24)	15.19 (11 to 21)	42.14 (31 to 58)

End point values	ABCWY_0_11 Group	ABCWY_0_2_6 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	128	137		
Units: Titers				
geometric mean (confidence interval 95%)				
NZ98/254(M-0)(N-188,185,120,112126,134)	1.12 (0.97 to 1.29)	1.06 (0.93 to 1.22)		
NZ98/254(M-2)(N-188,185,120,112,126,134)	3.87 (2.98 to 5.01)	2.20 (1.71 to 2.82)		
NZ98/254(M-3)(N-188,185,120,112,126,134)	2.38 (1.86 to 3.05)	12.80 (10 to 16)		
NZ98/254 (M-7)(N-188,185,120,112,126,134)	1.75 (1.38 to 2.22)	18.24 (14 to 23)		
NZ98/254(M-13)(N-188,185,120,112,126,134)	17.08 (14 to 21)	2.82 (2.28 to 3.51)		
M14459(M-0)(N-184,179,112,108,123,134)	1.34 (1.15 to 1.55)	1.17 (1.02 to 1.35)		
M14459(M-2)(N-184,179,112,108,123,134)	3.94 (3.11 to 4.98)	2.40 (1.92 to 3.01)		
M14459(M-3)(N-184,179,112,108,123,134)	3.11 (2.40 to 4.02)	15.24 (12 to 20)		
M14459(M-7)(N-184,179,112,108,123,134)	1.95 (1.56 to 2.43)	28.56 (23 to 35)		
M14459(M-13)(N-184,179,112,108,123,134)	29.01 (23 to 36)	3.17 (2.57 to 3.92)		
M07-0241084 (M-0)(N-188,176,117,113,121,128)	2.59 (1.99 to 3.37)	1.83 (1.42 to 2.36)		
M07-0241084(M-2)(N-188,176,117,113,121,128)	4.90 (3.97 to 6.04)	4.20 (3.43 to 5.15)		
M07-0241084 (M-3)(N-188,176,117,113,121,128)	3.55 (2.84 to 4.43)	9.29 (7.49 to 12)		
M07-0241084 (M-7)(N-188,176,117,113,121,128)	2.96 (2.38 to 3.67)	19.18 (16 to 24)		
M07-0241084(M-13)(N-188,176,117,113,121,128)	15.68 (13 to 19)	5.80 (4.70 to 7.16)		
96217(M-0)(N-186,178,120,112,128,121)	2.78 (2.11 to 3.68)	2.57 (1.94 to 3.40)		
96217 (M-2)(N-186,178,120,112,128,121)	11.94 (8.87 to 16)	8.54 (6.33 to 12)		

96217(M-3)(N-186,178,120,112,128,121)	7.72 (5.97 to 9.99)	162.27 (125 to 210)		
96217(M-7)(N-186,178,120,112,128,121)	5.19 (4.10 to 6.58)	306.14 (242 to 388)		
96217(M-13)(N-186,178,120,112,128,121)	264.32 (205 to 341)	47.22 (37 to 61)		
Serogroup A (M-0)(N-172,178,107,105,120,127)	1.19 (1.00 to 1.41)	1.06 (0.90 to 1.25)		
Serogroup A (M-2)(N-172,178,107,105,120,127)	22.54 (16 to 32)	5.18 (3.65 to 7.34)		
Serogroup A (M-3)(N-172,178,107,105,120,127)	8.77 (6.49 to 12)	78.30 (58 to 105)		
Serogroup A (M-7)(N-172,178,107,105,120,127)	3.25 (2.35 to 4.49)	140.73 (103 to 193)		
Serogroup A (M-13)(N-172,178,107,105,120,127)	168.23 (119 to 238)	13.32 (9.52 to 19)		
Serogroup C (M-0)(N-186,185,122,114,123,130)	3.80 (2.92 to 4.94)	2.99 (2.32 to 3.87)		
Serogroup C (M-2)(N-186,185,122,114,123,130)	54.75 (40 to 76)	40.29 (29 to 55)		
Serogroup C(M-3)(N-186,185,122,114,123,130)	41.15 (31 to 54)	236.97 (180 to 312)		
Serogroup C(M-7)(N-186,185,122,114,123,130)	24.59 (19 to 32)	476.44 (369 to 615)		
Serogroup C(M-13)(N-186,185,122,114,123,130)	303.63 (235 to 392)	113.72 (89 to 146)		
Serogroup W (M-0)(N-162,180,119,108,123,123)	4.95 (3.30 to 7.44)	4.46 (2.97 to 6.69)		
Serogroup W (M-2)(N-162,180,119,108,123,123)	94.34 (69 to 128)	47.54 (35 to 65)		
Serogroup W (M-3)(N-162,180,119,108,123,123)	86.66 (68 to 111)	200.91 (157 to 258)		
Serogroup W (M-7)(N-162,180,119,108,123,123)	58.19 (44 to 76)	270.12 (206 to 354)		
Serogroup W (M-13)(N-162,180,119,108,123,123)	478.73 (363 to 631)	95.90 (73 to 126)		
Serogroup Y (M-0)(N-188,180,120,110,127,137)	1.79 (1.42 to 2.25)	1.34 (1.07 to 1.67)		
Serogroup Y (M-2)(N-188,180,120,110,127,137)	27.00 (19 to 39)	19.82 (14 to 28)		
Serogroup Y (M-3)(N-188,180,120,110,127,137)	18.76 (13 to 26)	97.12 (70 to 134)		
Serogroup Y (M-7)(N-188,180,120,110,127,137)	14.29 (11 to 19)	180.33 (135 to 242)		
Serogroup Y (M-13)(N-188,180,120,110,127,137)	231.39 (171 to 313)	53.78 (40 to 72)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against NZ98/254 B strain for all schedules.

End point title	Percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against NZ98/254 B strain for all schedules.

End point description:

The kinetic of immune response (at Months 0, 2, 3, 7 and 13) following different vaccination schedules as measured by the percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128

against NZ98/254 B strain was assessed.

End point type	Secondary

End point timeframe:

At Month 0, Month 2, Month 3, Month 7 and Month 13.

End point values	rMenB_0_2 Group	ABCWY_ 0_2 Group	ABCWY_0_1 Group	ABCWY_0_6 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	188	185	120	112
Units: Percentages of subjects				
number (confidence interval 95%)				
NZ98/254 strain (At Month 0) ≥LLQ (8.2)	7 (3.73 to 11.53)	6 (3.40 to 11.06)	6 (2.38 to 11.65)	5 (1.99 to 11.30)
NZ98/254 Strain (At Month 0) ≥ 5	9 (4.94 to 13.45)	7 (3.79 to 11.72)	7 (2.92 to 12.71)	5 (1.99 to 11.30)
NZ98/254 Strain (At Month 0) ≥ 8	7 (4.13 to 12.18)	6 (3.40 to 11.06)	6 (2.38 to 11.65)	5 (1.99 to 11.30)
NZ98/254 Strain (At Month 0) ≥ 16	4 (1.85 to 8.21)	5 (2.62 to 9.72)	4 (1.37 to 9.46)	4 (0.98 to 8.89)
NZ98/254 Strain (At Month 0) ≥ 32	2 (0.33 to 4.59)	3 (0.88 to 6.19)	3 (0.52 to 7.13)	1 (0.02 to 4.87)
NZ98/254 Strain (At Month 0) ≥ 64	0 (0 to 1.94)	3 (0.34 to 4.67)	0 (0 to 3.03)	1 (0.02 to 4.87)
NZ98/254 Strain (At Month 0) ≥ 128	0 (0 to 1.94)	0 (0 to 1.97)	0 (0 to 3.03)	0 (0 to 3.24)
NZ98/254 Strain (At Month 2) ≥ LLQ (8.2)	23 (17.55 to 30.12)	20 (14.49 to 26.50)	43 (33.53 to 51.85)	17 (10.53 to 25.22)
NZ98/254 Strain (At Month 2) ≥ 5	29 (22.86 to 36.32)	24 (18.33 to 31.16)	58 (48.98 to 67.26)	18 (11.26 to 26.22)
NZ98/254 Strain (At Month 2) ≥ 8	23 (17.55 to 30.12)	20 (14.49 to 26.50)	43 (33.53 to 51.85)	17 (10.53 to 25.22)
NZ98/254 Strain (At Month 2) ≥ 16	19 (13.79 to 25.51)	15 (10.30 to 21.13)	28 (20.49 to 37.28)	11 (5.66 to 17.97)
NZ98/254 Strain (At Month 2) ≥ 32	15 (10.13 to 20.80)	10 (5.87 to 14.94)	20 (13.25 to 28.28)	9 (4.36 to 15.81)
NZ98/254 Strain (At Month 2) ≥ 64	9 (4.94 to 13.45)	7 (3.79 to 11.72)	12 (6.53 to 18.80)	4 (0.98 to 8.89)
NZ98/254 Strain (At Month 2) ≥ 128	2 (0.33 to 4.59)	5 (2.25 to 9.03)	5 (1.86 to 10.57)	3 (0.56 to 7.63)
NZ98/254 Strain (At Month 3) ≥ LLQ (8.2)	88 (82.82 to 92.52)	61 (53.65 to 68.15)	30 (21.98 to 39.04)	14 (8.39 to 22.16)
NZ98/254 Strain (At Month 3) ≥ 5	94 (89.12 to 96.66)	76 (68.84 to 81.67)	38 (29.61 to 47.65)	17 (10.53 to 25.22)
NZ98/254 Strain (At Month 3) ≥ 8	88 (82.82 to 92.52)	63 (55.30 to 69.69)	30 (21.98 to 39.04)	14 (8.39 to 22.16)
NZ98/254 Strain (At Month 3) ≥ 16	74 (67.05 to 80.05)	44 (37.04 to 51.79)	18 (11.86 to 26.43)	11 (5.66 to 17.97)
NZ98/254 Strain (At Month 3) ≥ 32	50 (42.64 to 57.36)	23 (17.36 to 30.00)	13 (7.17 to 19.78)	5 (1.99 to 11.30)
NZ98/254 Strain (At Month 3) ≥ 64	29 (22.86 to 36.32)	12 (7.60 to 17.45)	6 (2.38 to 11.65)	4 (0.98 to 8.89)
NZ98/254 Strain (At Month 3) ≥ 128	12 (7.48 to 17.18)	6 (3.40 to 11.06)	4 (1.37 to 9.46)	2 (0.22 to 6.30)
NZ98/254 Strain (At Month 7) ≥ LLQ (8.2)	27 (20.43 to 33.52)	19 (14.02 to 25.91)	14 (8.47 to 21.71)	63 (53.76 to 72.29)
NZ98/254 Strain (At Month 7) ≥ 5	33 (26.31 to 40.19)	27 (20.77 to 34.03)	18 (11.86 to 26.43)	80 (71.78 to 87.26)

NZ98/254 Strain (At Month 7) ≥ 8	27 (20.43 to 33.52)	20 (14.49 to 26.50)	14 (8.47 to 21.71)	69 (59.30 to 77.17)
NZ98/254 Strain (At Month 7) ≥ 16	21 (15.19 to 27.25)	14 (9.39 to 19.91)	12 (6.53 to 18.80)	46 (36.10 to 55.22)
NZ98/254 Strain (At Month 7) ≥ 32	12 (7.92 to 17.79)	10 (6.30 to 15.57)	9 (4.67 to 15.81)	26 (18.08 to 35.03)
NZ98/254 Strain (At Month 7) ≥ 64	6 (3.34 to 10.88)	6 (3.40 to 11.06)	6 (2.38 to 11.65)	13 (7.69 to 21.13)
NZ98/254 Strain (At Month 7) ≥ 128	2 (0.33 to 4.59)	4 (1.53 to 7.64)	5 (1.86 to 10.57)	7 (3.13 to 13.59)
NZ98/254 Strain (At Month 13) ≥ LLQ (8.2)	21 (15.19 to 27.25)	16 (11.22 to 22.33)	15 (9.14 to 22.67)	18 (11.26 to 26.22)
NZ98/254 Strain (At Month 13) ≥ 5	27 (20.43 to 33.52)	19 (14.02 to 25.91)	16 (9.81 to 23.62)	28 (19.64 to 36.93)
NZ98/254 Strain (At Month 13) ≥ 8	21 (15.19 to 27.25)	16 (11.22 to 22.33)	15 (9.14 to 22.67)	18 (11.26 to 26.22)
NZ98/254 Strain (At Month 13) ≥ 16	15 (10.13 to 20.80)	12 (8.05 to 18.07)	8 (4.07 to 14.79)	12 (6.33 to 19.03)
NZ98/254 Strain (At Month 13) ≥ 32	7 (4.13 to 12.18)	7 (3.79 to 11.72)	8 (3.49 to 13.76)	8 (3.74 to 14.71)
NZ98/254 Strain (At Month 13) ≥ 64	3 (0.87 to 6.10)	5 (2.25 to 9.03)	5 (1.86 to 10.57)	5 (1.99 to 11.30)
NZ98/254 Strain (At Month 13) ≥ 128	2 (0.33 to 4.59)	3 (0.88 to 6.19)	3 (0.92 to 8.31)	3 (0.56 to 7.63)

End point values	ABCWY_0_11 Group	ABCWY_0_2_6 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	134		
Units: Percentages of subjects				
number (confidence interval 95%)				
NZ98/254 strain (At Month 0) ≥LLQ (8.2)	4 (1.30 to 9.02)	2 (0.46 to 6.40)		
NZ98/254 Strain (At Month 0) ≥ 5	6 (2.26 to 11.11)	3 (0.82 to 7.47)		
NZ98/254 Strain (At Month 0) ≥ 8	4 (1.30 to 9.02)	2 (0.46 to 6.40)		
NZ98/254 Strain (At Month 0) ≥ 16	2 (0.19 to 5.62)	1 (0.02 to 4.09)		
NZ98/254 Strain (At Month 0) ≥ 32	0 (0 to 2.89)	0 (0 to 2.72)		
NZ98/254 Strain (At Month 0) ≥ 64	0 (0 to 2.89)	0 (0 to 2.72)		
NZ98/254 Strain (At Month 0) ≥ 128	0 (0 to 2.89)	0 (0 to 2.72)		
NZ98/254 Strain (At Month 2) ≥ LLQ (8.2)	27 (19.47 to 35.62)	18 (11.83 to 25.47)		
NZ98/254 Strain (At Month 2) ≥ 5	36 (27.38 to 44.74)	20 (13.72 to 27.95)		
NZ98/254 Strain (At Month 2) ≥ 8	28 (20.17 to 36.46)	18 (11.83 to 25.47)		
NZ98/254 Strain (At Month 2) ≥ 16	23 (15.99 to 31.35)	13 (7.57 to 19.53)		
NZ98/254 Strain (At Month 2) ≥ 32	17 (10.62 to 24.34)	7 (3.64 to 13.30)		
NZ98/254 Strain (At Month 2) ≥ 64	13 (7.44 to 19.80)	2 (0.46 to 6.40)		
NZ98/254 Strain (At Month 2) ≥ 128	6 (2.78 to 12.13)	1 (0.18 to 5.29)		

NZ98/254 Strain (At Month 3) ≥ LLQ (8.2)	20 (13.27 to 27.88)	68 (59.30 to 75.71)		
NZ98/254 Strain (At Month 3) ≥ 5	27 (19.47 to 35.62)	78 (70.42 to 85.00)		
NZ98/254 Strain (At Month 3) ≥ 8	21 (13.94 to 28.75)	69 (60.86 to 77.07)		
NZ98/254 Strain (At Month 3) ≥ 16	14 (8.69 to 21.63)	46 (37.62 to 55.08)		
NZ98/254 Strain (At Month 3) ≥ 32	10 (5.02 to 16.05)	19 (12.45 to 26.30)		
NZ98/254 Strain (At Month 3) ≥ 64	6 (2.26 to 11.11)	14 (8.76 to 21.25)		
NZ98/254 Strain (At Month 3) ≥ 128	4 (1.30 to 9.02)	4 (1.66 to 9.49)		
NZ98/254 Strain (At Month 7) ≥ LLQ (8.2)	13 (7.44 to 19.80)	72 (64.00 to 79.76)		
NZ98/254 Strain (At Month 7) ≥ 5	17 (11.28 to 25.23)	82 (74.53 to 88.17)		
NZ98/254 Strain (At Month 7) ≥ 8	13 (7.44 to 19.80)	74 (65.59 to 81.08)		
NZ98/254 Strain (At Month 7) ≥ 16	10 (5.02 to 16.05)	55 (46.40 to 63.82)		
NZ98/254 Strain (At Month 7) ≥ 32	4 (1.30 to 9.02)	34 (25.66 to 42.25)		
NZ98/254 Strain (At Month 7) ≥ 64	2 (0.19 to 5.62)	16 (10.58 to 23.80)		
NZ98/254 Strain (At Month 7) ≥ 128	1 (0.02 to 4.34)	5 (2.13 to 10.47)		
NZ98/254 Strain (At Month 13) ≥ LLQ (8.2)	73 (64.38 to 80.53)	19 (13.08 to 27.12)		
NZ98/254 Strain (At Month 13) ≥ 5	85 (77.46 to 90.67)	25 (17.60 to 32.81)		
NZ98/254 Strain (At Month 13) ≥ 8	74 (65.23 to 81.24)	19 (13.08 to 27.12)		
NZ98/254 Strain (At Month 13) ≥ 16	49 (40.19 to 58.26)	14 (8.76 to 21.25)		
NZ98/254 Strain (At Month 13) ≥ 32	30 (22.31 to 38.97)	4 (1.66 to 9.49)		
NZ98/254 Strain (At Month 13) ≥ 64	13 (8.06 to 20.72)	3 (0.82 to 7.47)		
NZ98/254 Strain (At Month 13) ≥ 128	6 (2.78 to 12.13)	2 (0.46 to 6.40)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against M14459 B strain for all schedules.

End point title	Percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against M14459 B strain for all schedules.

End point description:

The kinetic of immune response (at Months 0, 2, 3, 7 and 13) following different vaccination schedules as measured by the percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against M14459 B strain was assessed.

End point type	Secondary

End point timeframe:
At Month 0, Month 2, Month 3, Month 7 and Month 13.

End point values	rMenB_0_2 Group	ABCWY_ 0_2 Group	ABCWY_0_1 Group	ABCWY_0_6 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	184	179	112	108
Units: Percentages of subjects				
number (confidence interval 95%)				
M14459 Strain (At Month 0) ≥ LLQ (8.0)	7 (3.41 to 11.11)	5 (2.32 to 9.33)	6 (2.55 to 12.45)	4 (1.02 to 9.21)
M14459 Strain (At Month 0) ≥ 5	12 (7.65 to 17.54)	7 (3.92 to 12.10)	6 (2.55 to 12.45)	6 (2.65 to 12.90)
M14459 Strain (At Month 0) ≥ 8	7 (3.41 to 11.11)	5 (2.32 to 9.33)	6 (2.55 to 12.45)	4 (1.02 to 9.21)
M14459 Strain (At Month 0) ≥ 16	3 (0.89 to 6.23)	2 (0.35 to 4.82)	2 (0.22 to 6.30)	3 (0.58 to 7.90)
M14459 Strain (At Month 0) ≥ 32	2 (0.34 to 4.69)	0 (0 to 2.04)	1 (0.02 to 4.87)	1 (0.02 to 5.05)
M14459 Strain (At Month 0) ≥ 64	1 (0.13 to 3.87)	0 (0 to 2.04)	0 (0 to 3.24)	0 (0 to 3.36)
M14459 Strain (At Month 0) ≥ 128	0 (0 to 1.98)	0 (0 to 2.04)	0 (0 to 3.24)	0 (0 to 3.36)
M14459 Strain (At Month 2) ≥ LLQ (8.0)	28 (21.88 to 35.35)	24 (17.96 to 30.96)	61 (51.04 to 69.81)	17 (10.19 to 25.06)
M14459 Strain (At Month 2) ≥ 5	38 (30.49 to 44.92)	30 (23.03 to 36.88)	75 (65.93 to 82.70)	26 (17.97 to 35.25)
M14459 Strain (At Month 2) ≥ 8	28 (21.88 to 35.35)	24 (17.96 to 30.96)	61 (51.04 to 69.81)	17 (10.19 to 25.06)
M14459 Strain (At Month 2) ≥ 16	17 (11.74 to 23.05)	13 (8.32 to 18.65)	34 (25.25 to 43.48)	11 (5.87 to 18.06)
M14459 Strain (At Month 2) ≥ 32	9 (5.05 to 13.74)	6 (3.11 to 10.73)	19 (12.00 to 27.22)	6 (2.07 to 11.70)
M14459 Strain (At Month 2) ≥ 64	4 (1.90 to 8.39)	2 (0.61 to 5.62)	4 (0.98 to 8.89)	2 (0.23 to 6.53)
M14459 Strain (At Month 2) ≥ 128	1 (0.01 to 2.99)	2 (0.35 to 4.82)	2 (0.22 to 6.30)	1 (0.02 to 5.05)
M14459 Strain (At Month 3) ≥ LLQ (8.0)	82 (75.75 to 87.32)	68 (60.21 to 74.39)	44 (34.39 to 53.44)	16 (9.45 to 24.00)
M14459 Strain (At Month 3) ≥ 5	84 (78.16 to 89.18)	74 (66.66 to 80.03)	54 (44.78 to 63.90)	20 (13.23 to 29.20)
M14459 Strain (At Month 3) ≥ 8	82 (75.75 to 87.32)	68 (60.21 to 74.39)	44 (34.39 to 53.44)	16 (9.45 to 24.00)
M14459 Strain (At Month 3) ≥ 16	66 (58.98 to 73.09)	51 (43.83 to 58.92)	24 (16.53 to 33.10)	9 (4.53 to 16.37)
M14459 Strain (At Month 3) ≥ 32	39 (32.03 to 46.58)	30 (23.54 to 37.46)	6 (2.55 to 12.45)	4 (1.02 to 9.21)
M14459 Strain (At Month 3) ≥ 64	18 (12.68 to 24.25)	11 (6.51 to 16.08)	3 (0.56 to 7.63)	1 (0.02 to 5.05)
M14459 Strain (At Month 3) ≥ 128	7 (3.41 to 11.11)	2 (0.61 to 5.62)	2 (0.22 to 6.30)	1 (0.02 to 5.05)
M14459 Strain (At Month 7) ≥ LLQ (8.0)	34 (26.91 to 41.02)	30 (23.03 to 36.88)	17 (10.53 to 25.22)	86 (78.13 to 92.01)
M14459 Strain (At Month 7) ≥ 5	44 (36.73 to 51.51)	35 (28.22 to 42.67)	21 (14.24 to 30.19)	92 (84.77 to 96.12)
M14459 Strain (At Month 7) ≥ 8	34 (26.91 to 41.02)	30 (23.03 to 36.88)	17 (10.53 to 25.22)	86 (78.13 to 92.01)

M14459 Strain (At Month 7) ≥ 16	19 (13.62 to 25.45)	14 (9.25 to 19.92)	10 (5.01 to 16.89)	69 (59.84 to 77.95)
M14459 Strain (At Month 7) ≥ 32	11 (7.21 to 16.92)	7 (3.51 to 11.42)	5 (1.99 to 11.30)	50 (40.22 to 59.78)
M14459 Strain (At Month 7) ≥ 64	3 (1.21 to 6.96)	4 (1.59 to 7.89)	3 (0.56 to 7.63)	23 (15.57 to 32.25)
M14459 Strain (At Month 7) ≥ 128	0 (0 to 1.98)	1 (0.01 to 3.07)	1 (0.02 to 4.87)	10 (5.20 to 17.49)
M14459 Strain (At Month 13) ≥ LLQ (8.0)	23 (17.46 to 30.16)	20 (14.01 to 26.13)	13 (7.01 to 20.08)	23 (15.57 to 32.25)
M14459 Strain (At Month 13) ≥ 5	30 (23.88 to 37.63)	26 (19.47 to 32.75)	20 (12.74 to 28.22)	37 (27.94 to 46.86)
M14459 Strain (At Month 13) ≥ 8	23 (17.46 to 30.16)	20 (14.01 to 26.13)	13 (7.01 to 20.08)	23 (15.57 to 32.25)
M14459 Strain (At Month 13) ≥ 16	15 (9.90 to 20.63)	9 (5.63 to 14.77)	7 (3.13 to 13.59)	13 (7.27 to 20.79)
M14459 Strain (At Month 13) ≥ 32	5 (2.64 to 9.77)	4 (1.95 to 8.62)	4 (0.98 to 8.89)	7 (3.25 to 14.07)
M14459 Strain (At Month 13) ≥ 64	2 (0.34 to 4.69)	2 (0.61 to 5.62)	3 (0.56 to 7.63)	1 (0.02 to 5.05)
M14459 Strain (At Month 13) ≥ 128	0 (0 to 1.98)	1 (0.01 to 3.07)	2 (0.22 to 6.30)	1 (0.02 to 5.05)

End point values	ABCWY_0_11 Group	ABCWY_0_2_6 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	123	134		
Units: Percentages of subjects				
number (confidence interval 95%)				
M14459 Strain (At Month 0) ≥ LLQ (8.0)	7 (2.85 to 12.41)	2 (0.46 to 6.40)		
M14459 Strain (At Month 0) ≥ 5	11 (6.36 to 18.36)	4 (1.22 to 8.49)		
M14459 Strain (At Month 0) ≥ 8	7 (2.85 to 12.41)	2 (0.46 to 6.40)		
M14459 Strain (At Month 0) ≥ 16	2 (0.51 to 6.96)	1 (0.18 to 5.29)		
M14459 Strain (At Month 0) ≥ 32	0 (0 to 2.95)	1 (0.02 to 4.09)		
M14459 Strain (At Month 0) ≥ 64	0 (0 to 2.95)	1 (0.02 to 4.09)		
M14459 Strain (At Month 0) ≥ 128	0 (0 to 2.95)	0 (0 to 2.72)		
M14459 Strain (At Month 2) ≥ LLQ (8.0)	34 (25.84 to 43.24)	17 (11.20 to 24.63)		
M14459 Strain (At Month 2) ≥ 5	42 (33.42 to 51.51)	22 (15.64 to 30.39)		
M14459 Strain (At Month 2) ≥ 8	34 (25.84 to 43.24)	17 (11.20 to 24.63)		
M14459 Strain (At Month 2) ≥ 16	25 (17.81 to 33.83)	12 (6.98 to 18.67)		
M14459 Strain (At Month 2) ≥ 32	13 (7.62 to 20.26)	5 (2.13 to 10.47)		
M14459 Strain (At Month 2) ≥ 64	8 (3.97 to 14.44)	2 (0.46 to 6.40)		
M14459 Strain (At Month 2) ≥ 128	5 (1.81 to 10.32)	1 (0.18 to 5.29)		
M14459 Strain (At Month 3) ≥ LLQ (8.0)	28 (20.69 to 37.29)	73 (64.80 to 80.42)		

M14459 Strain (At Month 3) ≥ 5	35 (26.58 to 44.08)	80 (72.05 to 86.28)		
M14459 Strain (At Month 3) ≥ 8	28 (20.69 to 37.29)	73 (64.80 to 80.42)		
M14459 Strain (At Month 3) ≥ 16	18 (11.56 to 25.82)	51 (41.98 to 59.48)		
M14459 Strain (At Month 3) ≥ 32	9 (4.55 to 15.44)	28 (20.91 to 36.79)		
M14459 Strain (At Month 3) ≥ 64	4 (1.33 to 9.23)	10 (5.83 to 16.91)		
M14459 Strain (At Month 3) ≥ 128	3 (0.89 to 8.12)	3 (0.82 to 7.47)		
M14459 Strain (At Month 7) ≥ LLQ (8.0)	15 (9.56 to 23.07)	89 (82.21 to 93.60)		
M14459 Strain (At Month 7) ≥ 5	20 (12.92 to 27.63)	93 (87.63 to 96.88)		
M14459 Strain (At Month 7) ≥ 8	15 (9.56 to 23.07)	89 (82.21 to 93.60)		
M14459 Strain (At Month 7) ≥ 16	8 (3.97 to 14.44)	72 (63.21 to 79.09)		
M14459 Strain (At Month 7) ≥ 32	6 (2.32 to 11.37)	49 (40.52 to 58.02)		
M14459 Strain (At Month 7) ≥ 64	4 (1.33 to 9.23)	22 (15.64 to 30.39)		
M14459 Strain (At Month 7) ≥ 128	2 (0.20 to 5.75)	7 (3.12 to 12.37)		
M14459 Strain (At Month 13) ≥ LLQ (8.0)	89 (81.64 to 93.64)	27 (19.58 to 35.20)		
M14459 Strain (At Month 13) ≥ 5	93 (86.56 to 96.60)	38 (29.82 to 46.84)		
M14459 Strain (At Month 13) ≥ 8	89 (81.64 to 93.64)	27 (19.58 to 35.20)		
M14459 Strain (At Month 13) ≥ 16	76 (67.05 to 82.90)	13 (7.57 to 19.53)		
M14459 Strain (At Month 13) ≥ 32	54 (45.25 to 63.47)	6 (2.61 to 11.42)		
M14459 Strain (At Month 13) ≥ 64	29 (21.41 to 38.15)	1 (0.18 to 5.29)		
M14459 Strain (At Month 13) ≥ 128	11 (5.75 to 17.40)	1 (0.02 to 4.09)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against M07-0241084 B strain for all schedules.

End point title	Percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against M07-0241084 B strain for all schedules.

End point description:

The kinetic of immune response (at Months 0, 2, 3, 7 and 13) following different vaccination schedules as measured by the percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against M07-0241084 B strain was assessed.

End point type	Secondary

End point timeframe:

At Month 0, Month 2, Month 3, Month 7 and Month 13.

End point values	rMenB_0_2 Group	ABCWY_ 0_2 Group	ABCWY_0_1 Group	ABCWY_0_6 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	188	176	117	113
Units: Percentages of subjects				
number (confidence interval 95%)				
M07-0241084 Strain (At Month 0) ≥ LLQ (8.9)	21 (15.19 to 27.25)	18 (12.78 to 24.69)	17 (10.77 to 25.16)	14 (8.32 to 21.97)
M07-0241084 Strain (At Month 0) ≥ 5	30 (23.35 to 36.87)	28 (21.36 to 35.08)	25 (17.27 to 33.62)	27 (19.46 to 36.63)
M07-0241084 Strain (At Month 0) ≥ 8	22 (16.13 to 28.40)	20 (14.26 to 26.56)	18 (11.47 to 26.12)	19 (12.62 to 27.98)
M07-0241084 Strain (At Month 0) ≥ 16	13 (8.79 to 19.00)	14 (9.41 to 20.25)	12 (6.70 to 19.26)	6 (2.53 to 12.35)
M07-0241084 Strain (At Month 0) ≥ 32	8 (4.53 to 12.82)	6 (3.16 to 10.91)	7 (3.00 to 13.03)	4 (0.97 to 8.82)
M07-0241084 Strain (At Month 0) ≥ 64	3 (1.18 to 6.82)	2 (0.35 to 4.90)	3 (0.53 to 7.31)	2 (0.22 to 6.25)
M07-0241084 Strain (At Month 0) ≥ 128	0 (0 to 1.94)	0 (0 to 2.07)	0 (0 to 3.10)	2 (0.22 to 6.25)
M07-0241084 Strain (At Month 2) ≥ LLQ (8.9)	38 (30.81 to 45.11)	29 (22.40 to 36.28)	37 (28.03 to 46.16)	28 (20.24 to 37.57)
M07-0241084 Strain (At Month 2) ≥ 5	47 (40.03 to 54.74)	43 (35.75 to 50.85)	54 (44.39 to 63.10)	40 (30.73 to 49.46)
M07-0241084 Strain (At Month 2) ≥ 8	42 (34.88 to 49.42)	32 (25.54 to 39.84)	43 (33.63 to 52.21)	31 (22.61 to 40.36)
M07-0241084 Strain (At Month 2) ≥ 16	31 (24.33 to 37.98)	22 (16.26 to 29.02)	29 (21.04 to 38.17)	16 (9.72 to 24.00)
M07-0241084 Strain (At Month 2) ≥ 32	20 (14.72 to 26.67)	15 (10.36 to 21.53)	17 (10.77 to 25.16)	7 (3.11 to 13.47)
M07-0241084 Strain (At Month 2) ≥ 64	10 (5.77 to 14.71)	7 (3.99 to 12.30)	9 (4.17 to 15.16)	2 (0.22 to 6.25)
M07-0241084 Strain (At Month 2) ≥ 128	3 (1.18 to 6.82)	2 (0.35 to 4.90)	3 (0.53 to 7.31)	1 (0.02 to 4.83)
M07-0241084 Strain (At Month 3) ≥ LLQ (8.9)	66 (59.26 to 73.19)	47 (39.60 to 54.81)	28 (20.28 to 37.27)	28 (20.24 to 37.57)
M07-0241084 Strain (At Month 3) ≥ 5	79 (72.75 to 84.81)	69 (61.94 to 76.04)	43 (33.63 to 52.21)	40 (30.73 to 49.46)
M07-0241084 Strain (At Month 3) ≥ 8	69 (62.02 to 75.67)	55 (47.45 to 62.60)	34 (25.67 to 43.53)	31 (22.61 to 40.36)
M07-0241084 Strain (At Month 3) ≥ 16	52 (44.74 to 59.45)	33 (26.07 to 40.43)	21 (14.33 to 29.91)	12 (6.27 to 18.87)
M07-0241084 Strain (At Month 3) ≥ 32	33 (26.31 to 40.19)	18 (12.78 to 24.69)	15 (9.38 to 23.22)	5 (1.97 to 11.20)
M07-0241084 Strain (At Month 3) ≥ 64	18 (12.40 to 23.76)	11 (7.08 to 17.00)	5 (1.90 to 10.83)	1 (0.02 to 4.83)
M07-0241084 Strain (At Month 3) ≥ 128	5 (2.21 to 8.89)	3 (0.93 to 6.50)	3 (0.53 to 7.31)	1 (0.02 to 4.83)
M07-0241084 Strain (At Month 7) ≥ LLQ (8.9)	40 (32.84 to 47.27)	30 (22.92 to 36.88)	26 (18.02 to 34.54)	66 (56.88 to 74.99)
M07-0241084 Strain (At Month 7) ≥ 5	50 (42.64 to 57.36)	44 (36.30 to 51.42)	32 (24.11 to 41.76)	83 (74.99 to 89.56)
M07-0241084 Strain (At Month 7) ≥ 8	42 (34.88 to 49.42)	32 (25.54 to 39.84)	27 (19.52 to 36.36)	70 (60.57 to 78.18)
M07-0241084 Strain (At Month 7) ≥ 16	29 (22.37 to 35.76)	24 (18.28 to 31.47)	19 (12.18 to 27.07)	53 (43.48 to 62.55)

M07-0241084 Strain (At Month 7) ≥ 32	21 (15.19 to 27.25)	14 (8.94 to 19.61)	9 (4.79 to 16.20)	28 (20.24 to 37.57)
M07-0241084 Strain (At Month 7) ≥ 64	6 (2.96 to 10.23)	8 (4.42 to 12.99)	6 (2.44 to 11.94)	10 (4.96 to 16.75)
M07-0241084 Strain (At Month 7) ≥ 128	1 (0.01 to 2.93)	2 (0.35 to 4.90)	1 (0.02 to 4.67)	3 (0.55 to 7.56)
M07-0241084 Strain (At Month 13) ≥ LLQ (8.9)	34 (26.81 to 40.74)	27 (20.84 to 34.48)	23 (15.79 to 31.77)	34 (25.01 to 43.12)
M07-0241084 Strain (At Month 13) ≥ 5	46 (38.48 to 53.15)	39 (31.95 to 46.83)	36 (27.24 to 45.29)	57 (46.99 to 65.93)
M07-0241084 Strain (At Month 13) ≥ 8	37 (29.81 to 44.02)	34 (26.60 to 41.01)	27 (19.52 to 36.36)	39 (29.91 to 48.56)
M07-0241084 Strain (At Month 13) ≥ 16	26 (19.46 to 32.39)	23 (16.76 to 29.64)	17 (10.77 to 25.16)	19 (12.62 to 27.98)
M07-0241084 Strain (At Month 13) ≥ 32	16 (11.03 to 21.99)	13 (8.47 to 18.96)	11 (6.05 to 18.25)	12 (6.27 to 18.87)
M07-0241084 Strain (At Month 13) ≥ 64	6 (3.34 to 10.88)	3 (1.26 to 7.27)	4 (1.40 to 9.69)	5 (1.97 to 11.20)
M07-0241084 Strain (At Month 13) ≥ 128	2 (0.58 to 5.36)	1 (0.01 to 3.12)	2 (0.21 to 6.04)	1 (0.02 to 4.83)

End point values	ABCWY_0_11 Group	ABCWY_0_2_6 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	121	128		
Units: Percentages of subjects				
number (confidence interval 95%)				
M07-0241084 Strain (At Month 0) ≥ LLQ (8.9)	21 (14.54 to 29.88)	19 (12.40 to 26.60)		
M07-0241084 Strain (At Month 0) ≥ 5	30 (21.79 to 38.74)	21 (14.38 to 29.19)		
M07-0241084 Strain (At Month 0) ≥ 8	24 (16.68 to 32.57)	20 (13.72 to 28.33)		
M07-0241084 Strain (At Month 0) ≥ 16	16 (9.73 to 23.43)	15 (9.18 to 22.21)		
M07-0241084 Strain (At Month 0) ≥ 32	9 (4.63 to 15.68)	6 (2.74 to 11.94)		
M07-0241084 Strain (At Month 0) ≥ 64	3 (0.91 to 8.25)	3 (0.86 to 7.81)		
M07-0241084 Strain (At Month 0) ≥ 128	1 (0.02 to 4.52)	1 (0.02 to 4.28)		
M07-0241084 Strain (At Month 2) ≥ LLQ (8.9)	39 (30.12 to 48.13)	30 (22.65 to 39.22)		
M07-0241084 Strain (At Month 2) ≥ 5	54 (44.43 to 62.83)	41 (32.04 to 49.66)		
M07-0241084 Strain (At Month 2) ≥ 8	43 (34.01 to 52.29)	35 (26.93 to 44.09)		
M07-0241084 Strain (At Month 2) ≥ 16	30 (21.79 to 38.74)	19 (12.40 to 26.60)		
M07-0241084 Strain (At Month 2) ≥ 32	19 (12.45 to 27.14)	9 (4.37 to 14.86)		
M07-0241084 Strain (At Month 2) ≥ 64	9 (4.63 to 15.68)	5 (1.74 to 9.92)		
M07-0241084 Strain (At Month 2) ≥ 128	5 (1.84 to 10.48)	0 (0 to 2.84)		
M07-0241084 Strain (At Month 3) ≥ LLQ (8.9)	30 (21.79 to 38.74)	53 (44.11 to 62.00)		

M07-0241084 Strain (At Month 3) ≥ 5	43 (34.01 to 52.29)	62 (52.72 to 70.17)		
M07-0241084 Strain (At Month 3) ≥ 8	34 (25.53 to 43.05)	56 (47.21 to 65.00)		
M07-0241084 Strain (At Month 3) ≥ 16	21 (14.54 to 29.88)	40 (31.30 to 48.87)		
M07-0241084 Strain (At Month 3) ≥ 32	15 (9.06 to 22.49)	23 (15.73 to 30.89)		
M07-0241084 Strain (At Month 3) ≥ 64	4 (1.36 to 9.38)	13 (7.32 to 19.50)		
M07-0241084 Strain (At Month 3) ≥ 128	2 (0.51 to 7.07)	2 (0.49 to 6.70)		
M07-0241084 Strain (At Month 7) ≥ LLQ (8.9)	26 (18.12 to 34.35)	70 (61.60 to 78.06)		
M07-0241084 Strain (At Month 7) ≥ 5	36 (27.81 to 45.60)	80 (72.53 to 86.94)		
M07-0241084 Strain (At Month 7) ≥ 8	28 (20.31 to 36.99)	77 (68.26 to 83.59)		
M07-0241084 Strain (At Month 7) ≥ 16	18 (11.76 to 26.22)	58 (48.77 to 66.49)		
M07-0241084 Strain (At Month 7) ≥ 32	8 (4.03 to 14.67)	34 (25.49 to 42.48)		
M07-0241084 Strain (At Month 7) ≥ 64	4 (1.36 to 9.38)	17 (11.10 to 24.86)		
M07-0241084 Strain (At Month 7) ≥ 128	1 (0.02 to 4.52)	4 (1.28 to 8.88)		
M07-0241084 Strain (At Month 13) ≥ LLQ (8.9)	69 (59.53 to 76.73)	37 (28.38 to 45.69)		
M07-0241084 Strain (At Month 13) ≥ 5	82 (73.78 to 88.24)	51 (41.80 to 59.72)		
M07-0241084 Strain (At Month 13) ≥ 8	74 (64.76 to 81.16)	42 (33.51 to 51.23)		
M07-0241084 Strain (At Month 13) ≥ 16	55 (45.24 to 63.62)	26 (18.46 to 34.26)		
M07-0241084 Strain (At Month 13) ≥ 32	35 (26.29 to 43.90)	12 (6.71 to 18.59)		
M07-0241084 Strain (At Month 13) ≥ 64	20 (13.14 to 28.06)	5 (1.74 to 9.92)		
M07-0241084 Strain (At Month 13) ≥ 128	9 (4.63 to 15.68)	1 (0.02 to 4.28)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against 96217 B strain for all schedules.

End point title	Percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against 96217 B strain for all schedules.

End point description:

The kinetic of immune response (at Months 0, 2, 3, 7 and 13) following different vaccination schedules as measured by the percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against 96217 B strain was assessed.

End point type	Secondary

End point timeframe:

At Month 0, Month 2, Month 3, Month 7 and Month 13.

End point values	rMenB_0_2 Group	ABCWY_ 0_2 Group	ABCWY_0_1 Group	ABCWY_0_6 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	186	178	120	112
Units: Percentages of subjects				
number (confidence interval 95%)				
96217 Strain (At Month 0) ≥ LLQ (8.6)	23 (17.26 to 29.85)	29 (22.14 to 35.89)	29 (21.23 to 38.16)	28 (19.64 to 36.93)
96217 Strain (At Month 0) ≥ 5	26 (19.68 to 32.72)	35 (28.38 to 42.90)	35 (26.52 to 44.24)	29 (21.23 to 38.82)
96217 Strain (At Month 0) ≥ 8	24 (18.23 to 31.00)	30 (23.68 to 37.66)	31 (22.73 to 39.91)	28 (19.64 to 36.93)
96217 Strain (At Month 0) ≥ 16	16 (11.15 to 22.22)	17 (11.67 to 23.18)	22 (14.67 to 30.11)	19 (12.00 to 27.22)
96217 Strain (At Month 0) ≥ 32	6 (3.38 to 11.00)	8 (4.37 to 12.84)	8 (4.07 to 14.79)	4 (1.47 to 10.11)
96217 Strain (At Month 0) ≥ 64	2 (0.33 to 4.64)	2 (0.62 to 5.65)	3 (0.52 to 7.13)	0 (0 to 3.24)
96217 Strain (At Month 0) ≥ 128	1 (0.01 to 2.96)	1 (0.14 to 4.00)	0 (0 to 3.03)	0 (0 to 3.24)
96217 Strain (At Month 2) ≥ LLQ (8.6)	69 (61.63 to 75.39)	64 (56.53 to 71.09)	97 (91.69 to 99.08)	62 (51.94 to 70.64)
96217 Strain (At Month 2) ≥ 5	75 (68.42 to 81.29)	67 (60.00 to 74.24)	97 (91.69 to 99.08)	66 (56.52 to 74.75)
96217 Strain (At Month 2) ≥ 8	70 (63.31 to 76.88)	64 (56.53 to 71.09)	97 (91.69 to 99.08)	63 (53.76 to 72.29)
96217 Strain (At Month 2) ≥ 16	48 (41.01 to 55.81)	48 (40.78 to 55.91)	94 (88.35 to 97.62)	48 (38.67 to 57.85)
96217 Strain (At Month 2) ≥ 32	27 (21.15 to 34.43)	21 (15.57 to 28.10)	84 (76.38 to 90.19)	20 (12.74 to 28.22)
96217 Strain (At Month 2) ≥ 64	11 (6.69 to 16.12)	15 (9.77 to 20.67)	73 (63.60 to 80.25)	9 (4.36 to 15.81)
96217 Strain (At Month 2) ≥ 128	7 (3.77 to 11.66)	4 (1.96 to 8.66)	45 (35.91 to 54.35)	4 (1.47 to 10.11)
96217 Strain (At Month 3) ≥ LLQ (8.6)	99 (97.04 to 99.99)	97 (92.81 to 98.75)	94 (88.35 to 97.62)	58 (48.34 to 67.30)
96217 Strain (At Month 3) ≥ 5	99 (97.04 to 99.99)	97 (93.57 to 99.08)	96 (90.54 to 98.53)	61 (51.04 to 69.81)
96217 Strain (At Month 3) ≥ 8	99 (97.04 to 99.99)	97 (92.81 to 98.75)	95 (89.43 to 98.14)	58 (48.34 to 67.30)
96217 Strain (At Month 3) ≥ 16	99 (97.04 to 99.99)	95 (90.62 to 97.66)	91 (84.19 to 95.33)	40 (31.03 to 49.86)
96217 Strain (At Month 3) ≥ 32	98 (95.36 to 99.67)	89 (83.83 to 93.45)	83 (75.44 to 89.51)	21 (13.49 to 29.20)
96217 Strain (At Month 3) ≥ 64	90 (84.51 to 93.74)	81 (74.34 to 86.39)	62 (52.35 to 70.39)	6 (2.55 to 12.45)
96217 Strain (At Month 3) ≥ 128	74 (67.28 to 80.32)	63 (55.38 to 70.03)	34 (25.76 to 43.38)	4 (1.47 to 10.11)
96217 Strain (At Month 7) ≥ LLQ (8.6)	95 (91.01 to 97.76)	91 (85.81 to 94.77)	88 (80.22 to 92.83)	97 (92.37 to 99.44)
96217 Strain (At Month 7) ≥ 5	96 (92.40 to 98.47)	93 (87.83 to 96.05)	91 (84.19 to 95.33)	97 (92.37 to 99.44)
96217 Strain (At Month 7) ≥ 8	95 (91.01 to 97.76)	91 (85.81 to 94.77)	88 (80.22 to 92.83)	97 (92.37 to 99.44)
96217 Strain (At Month 7) ≥ 16	93 (88.34 to 96.23)	85 (79.33 to 90.23)	76 (67.17 to 83.18)	96 (91.11 to 99.02)

96217 Strain (At Month 7) ≥ 32	75 (67.85 to 80.80)	65 (57.68 to 72.14)	57 (47.31 to 65.68)	96 (89.89 to 98.53)
96217 Strain (At Month 7) ≥ 64	43 (35.79 to 50.46)	34 (26.81 to 41.16)	32 (23.48 to 40.78)	87 (78.87 to 92.31)
96217 Strain (At Month 7) ≥ 128	11 (7.13 to 16.74)	7 (3.53 to 11.48)	12 (6.53 to 18.80)	73 (64.02 to 81.14)
96217 Strain (At Month 13) ≥ LLQ (8.6)	87 (81.41 to 91.55)	83 (76.20 to 87.85)	81 (72.64 to 87.44)	90 (83.11 to 94.99)
96217 Strain (At Month 13) ≥ 5	90 (85.14 to 94.16)	85 (78.70 to 89.76)	83 (75.44 to 89.51)	92 (85.29 to 96.26)
96217 Strain (At Month 13) ≥ 8	88 (82.03 to 92.00)	83 (76.82 to 88.33)	81 (72.64 to 87.44)	90 (83.11 to 94.99)
96217 Strain (At Month 13) ≥ 16	76 (69.00 to 81.77)	69 (61.75 to 75.80)	66 (56.62 to 74.24)	79 (70.80 to 86.51)
96217 Strain (At Month 13) ≥ 32	52 (44.72 to 59.51)	40 (32.64 to 47.48)	41 (31.95 to 50.18)	57 (47.45 to 66.45)
96217 Strain (At Month 13) ≥ 64	23 (17.26 to 29.85)	13 (8.37 to 18.76)	23 (15.38 to 31.02)	30 (22.02 to 39.76)
96217 Strain (At Month 13) ≥ 128	4 (1.87 to 8.30)	3 (0.92 to 6.43)	8 (3.49 to 13.76)	13 (7.69 to 21.13)

End point values	ABCWY_0_11 Group	ABCWY_0_2_6 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	128	121		
Units: Percentages of subjects				
number (confidence interval 95%)				
96217 Strain (At Month 0) ≥ LLQ (8.6)	25 (17.77 to 33.42)	27 (19.57 to 36.12)		
96217 Strain (At Month 0) ≥ 5	35 (26.93 to 44.09)	29 (21.05 to 37.87)		
96217 Strain (At Month 0) ≥ 8	25 (17.77 to 33.42)	27 (19.57 to 36.12)		
96217 Strain (At Month 0) ≥ 16	18 (11.74 to 25.73)	16 (9.73 to 23.43)		
96217 Strain (At Month 0) ≥ 32	8 (3.81 to 13.90)	7 (2.90 to 12.61)		
96217 Strain (At Month 0) ≥ 64	2 (0.49 to 6.70)	5 (1.84 to 10.48)		
96217 Strain (At Month 0) ≥ 128	1 (0.02 to 4.28)	2 (0.20 to 5.84)		
96217 Strain (At Month 2) ≥ LLQ (8.6)	58 (48.77 to 66.49)	50 (40.37 to 58.82)		
96217 Strain (At Month 2) ≥ 5	66 (56.72 to 73.79)	53 (43.61 to 62.03)		
96217 Strain (At Month 2) ≥ 8	59 (50.34 to 67.96)	51 (41.99 to 60.43)		
96217 Strain (At Month 2) ≥ 16	42 (33.51 to 51.23)	39 (30.12 to 48.13)		
96217 Strain (At Month 2) ≥ 32	26 (18.46 to 34.26)	24 (16.68 to 32.57)		
96217 Strain (At Month 2) ≥ 64	14 (8.55 to 21.31)	12 (6.47 to 18.65)		
96217 Strain (At Month 2) ≥ 128	9 (4.94 to 15.80)	7 (3.46 to 13.65)		
96217 Strain (At Month 3) ≥ LLQ (8.6)	47 (38.00 to 55.89)	97 (91.75 to 99.09)		

96217 Strain (At Month 3) ≥ 5	56 (47.21 to 65.00)	98 (92.93 to 99.49)		
96217 Strain (At Month 3) ≥ 8	52 (43.34 to 61.24)	97 (91.75 to 99.09)		
96217 Strain (At Month 3) ≥ 16	36 (27.65 to 44.89)	95 (89.52 to 98.16)		
96217 Strain (At Month 3) ≥ 32	23 (15.73 to 30.89)	92 (85.33 to 95.97)		
96217 Strain (At Month 3) ≥ 64	11 (6.11 to 17.67)	84 (76.57 to 90.27)		
96217 Strain (At Month 3) ≥ 128	4 (1.28 to 8.88)	60 (51.04 to 69.11)		
96217 Strain (At Month 7) ≥ LLQ (8.6)	39 (30.56 to 48.08)	99 (95.48 to 99.98)		
96217 Strain (At Month 7) ≥ 5	44 (35.00 to 52.79)	99 (95.48 to 99.98)		
96217 Strain (At Month 7) ≥ 8	40 (31.30 to 48.87)	99 (95.48 to 99.98)		
96217 Strain (At Month 7) ≥ 16	30 (22.65 to 39.22)	99 (95.48 to 99.98)		
96217 Strain (At Month 7) ≥ 32	18 (11.74 to 25.73)	98 (94.16 to 99.80)		
96217 Strain (At Month 7) ≥ 64	7 (3.27 to 12.93)	98 (92.93 to 99.49)		
96217 Strain (At Month 7) ≥ 128	2 (0.49 to 6.70)	85 (77.51 to 90.94)		
96217 Strain (At Month 13) ≥ LLQ (8.6)	98 (93.30 to 99.51)	93 (87.39 to 97.10)		
96217 Strain (At Month 13) ≥ 5	98 (94.47 to 99.81)	93 (87.39 to 97.10)		
96217 Strain (At Month 13) ≥ 8	98 (94.47 to 99.81)	93 (87.39 to 97.10)		
96217 Strain (At Month 13) ≥ 16	98 (93.30 to 99.51)	88 (80.38 to 92.89)		
96217 Strain (At Month 13) ≥ 32	96 (91.12 to 98.72)	64 (55.25 to 72.95)		
96217 Strain (At Month 13) ≥ 64	85 (77.79 to 90.82)	36 (27.81 to 45.60)		
96217 Strain (At Month 13) ≥ 128	73 (64.08 to 80.16)	12 (7.11 to 19.62)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against A human serogroup for all schedules.

End point title	Percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against A human serogroup for all schedules.

End point description:

The kinetic of immune response (at Months 0, 2, 3, 7 and 13) following different vaccination schedules as measured by the percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against A human serogroup was assessed.

End point type	Secondary

End point timeframe:

At Month 0, Month 2, Month 3, Month 7 and Month 13.

End point values	rMenB_0_2 Group	ABCWY_ 0_2 Group	ABCWY_0_1 Group	ABCWY_0_6 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	172	178	107	105
Units: Percentages of subjects				
number (confidence interval 95%)				
A human Serogroup (At Month 0) ≥ LLQ (22.7)	6 (2.82 to 10.43)	3 (1.25 to 7.19)	5 (1.53 to 10.57)	2 (0.23 to 6.71)
A human Serogroup (At Month 0) ≥ 5	10 (6.32 to 16.03)	6 (3.12 to 10.79)	10 (5.24 to 17.65)	4 (1.05 to 9.47)
A human Serogroup (At Month 0) ≥ 8	10 (5.86 to 15.35)	6 (2.73 to 10.09)	10 (5.24 to 17.65)	3 (0.59 to 8.12)
A human Serogroup (At Month 0) ≥ 16	7 (3.66 to 11.87)	4 (1.96 to 8.66)	7 (3.28 to 14.20)	2 (0.23 to 6.71)
A human Serogroup (At Month 0) ≥ 32	4 (1.65 to 8.21)	2 (0.62 to 5.65)	3 (0.58 to 7.98)	1 (0.02 to 5.19)
A human Serogroup (At Month 0) ≥ 64	1 (0.14 to 4.14)	1 (0.14 to 4.00)	2 (0.23 to 6.59)	1 (0.02 to 5.19)
A human Serogroup (At Month 0) ≥ 128	1 (0.01 to 3.20)	1 (0.01 to 3.09)	1 (0.02 to 5.10)	0 (0 to 3.45)
A human Serogroup (At Month 2) ≥ LLQ (22.7)	22 (16.13 to 29.04)	35 (27.86 to 42.32)	93 (85.80 to 96.72)	33 (24.43 to 43.20)
A human Serogroup (At Month 2) ≥ 5	37 (29.97 to 44.89)	53 (45.76 to 60.87)	95 (89.43 to 98.47)	48 (37.78 to 57.59)
A human Serogroup (At Month 2) ≥ 8	37 (29.43 to 44.30)	51 (42.98 to 58.12)	94 (88.19 to 97.91)	46 (35.96 to 55.72)
A human Serogroup (At Month 2) ≥ 16	28 (21.35 to 35.24)	44 (36.41 to 51.44)	93 (86.98 to 97.33)	41 (31.45 to 50.98)
A human Serogroup (At Month 2) ≥ 32	19 (13.09 to 25.24)	33 (26.28 to 40.58)	88 (80.12 to 93.37)	30 (21.02 to 39.22)
A human Serogroup (At Month 2) ≥ 64	12 (7.72 to 18.06)	19 (13.12 to 25.04)	69 (59.50 to 77.73)	18 (11.26 to 26.81)
A human Serogroup (At Month 2) ≥ 128	4 (1.65 to 8.21)	10 (5.66 to 14.85)	34 (24.80 to 43.42)	9 (3.99 to 15.65)
A human Serogroup (At Month 3) ≥ LLQ (22.7)	94 (89.57 to 97.18)	87 (80.61 to 91.17)	80 (71.58 to 87.42)	30 (21.02 to 39.22)
A human Serogroup (At Month 3) ≥ 5	97 (93.35 to 99.05)	94 (89.21 to 96.88)	92 (84.63 to 96.08)	40 (30.56 to 50.02)
A human Serogroup (At Month 3) ≥ 8	97 (93.35 to 99.05)	93 (87.83 to 96.05)	91 (83.48 to 95.43)	39 (29.67 to 49.06)
A human Serogroup (At Month 3) ≥ 16	95 (90.30 to 97.58)	91 (85.81 to 94.77)	86 (77.93 to 91.94)	33 (24.43 to 43.20)
A human Serogroup (At Month 3) ≥ 32	91 (85.33 to 94.59)	83 (76.20 to 87.85)	74 (64.45 to 81.85)	27 (18.51 to 36.19)
A human Serogroup (At Month 3) ≥ 64	71 (63.53 to 77.59)	57 (49.69 to 64.67)	46 (36.12 to 55.70)	12 (6.76 to 20.24)
A human Serogroup (At Month 3) ≥ 128	45 (37.76 to 53.10)	30 (23.17 to 37.07)	21 (14.14 to 30.49)	6 (2.13 to 12.02)
A human Serogroup (At Month 7) ≥ LLQ (22.7)	53 (45.74 to 61.12)	46 (38.04 to 53.12)	41 (31.70 to 51.05)	95 (89.24 to 98.44)
A human Serogroup (At Month 7) ≥ 5	70 (62.31 to 76.53)	62 (54.80 to 69.50)	60 (49.89 to 69.18)	97 (91.88 to 99.41)
A human Serogroup (At Month 7) ≥ 8	68 (60.50 to 74.92)	58 (50.82 to 65.75)	58 (48.01 to 67.42)	97 (91.88 to 99.41)
A human Serogroup (At Month 7) ≥ 16	61 (53.33 to 68.38)	51 (43.53 to 58.67)	49 (38.82 to 58.46)	97 (91.88 to 99.41)

A human Serogroup (At Month 7) ≥ 32	42 (34.95 to 50.20)	37 (29.44 to 44.05)	35 (25.65 to 44.39)	91 (84.35 to 96.01)
A human Serogroup (At Month 7) ≥ 64	19 (13.59 to 25.88)	19 (13.61 to 25.66)	18 (11.04 to 26.33)	76 (66.89 to 83.96)
A human Serogroup (At Month 7) ≥ 128	5 (2.42 to 9.70)	6 (2.73 to 10.09)	10 (5.24 to 17.65)	63 (52.88 to 72.09)
A human Serogroup (At Month 13) ≥ LLQ (22.7)	33 (26.16 to 40.71)	26 (20.09 to 33.52)	34 (24.80 to 43.42)	51 (41.47 to 61.30)
A human Serogroup (At Month 13) ≥ 5	51 (42.87 to 58.28)	42 (34.25 to 49.18)	48 (37.92 to 57.54)	68 (57.79 to 76.43)
A human Serogroup (At Month 13) ≥ 8	48 (40.59 to 55.99)	39 (31.57 to 46.34)	47 (37.02 to 56.62)	66 (55.81 to 74.70)
A human Serogroup (At Month 13) ≥ 16	38 (30.52 to 45.49)	30 (23.68 to 37.66)	41 (31.70 to 51.05)	59 (49.02 to 68.55)
A human Serogroup (At Month 13) ≥ 32	24 (17.68 to 30.92)	20 (14.09 to 26.27)	27 (18.96 to 36.55)	44 (34.14 to 53.83)
A human Serogroup (At Month 13) ≥ 64	13 (8.67 to 19.39)	8 (4.79 to 13.52)	13 (7.34 to 20.98)	27 (18.51 to 36.19)
A human Serogroup (At Month 13) ≥ 128	4 (1.65 to 8.21)	2 (0.35 to 4.85)	6 (2.09 to 11.81)	8 (3.35 to 14.46)

End point values	ABCWY_0_11 Group	ABCWY_0_2_6 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	120	127		
Units: Percentages of subjects				
number (confidence interval 95%)				
A human Serogroup (At Month 0) ≥ LLQ (22.7)	3 (0.52 to 7.13)	1 (0.02 to 4.31)		
A human Serogroup (At Month 0) ≥ 5	8 (3.49 to 13.76)	3 (0.86 to 7.87)		
A human Serogroup (At Month 0) ≥ 8	5 (1.86 to 10.57)	2 (0.49 to 6.75)		
A human Serogroup (At Month 0) ≥ 16	4 (1.37 to 9.46)	2 (0.19 to 5.57)		
A human Serogroup (At Month 0) ≥ 32	2 (0.20 to 5.89)	1 (0.02 to 4.31)		
A human Serogroup (At Month 0) ≥ 64	0 (0 to 3.03)	1 (0.02 to 4.31)		
A human Serogroup (At Month 0) ≥ 128	0 (0 to 3.03)	1 (0.02 to 4.31)		
A human Serogroup (At Month 2) ≥ LLQ (22.7)	54 (44.83 to 63.29)	28 (20.01 to 36.19)		
A human Serogroup (At Month 2) ≥ 5	75 (66.27 to 82.45)	39 (30.08 to 47.63)		
A human Serogroup (At Month 2) ≥ 8	74 (65.38 to 81.72)	38 (29.35 to 46.83)		
A human Serogroup (At Month 2) ≥ 16	67 (57.48 to 75.01)	31 (22.83 to 39.51)		
A human Serogroup (At Month 2) ≥ 32	42 (32.74 to 51.02)	22 (15.18 to 30.26)		
A human Serogroup (At Month 2) ≥ 64	33 (24.23 to 41.65)	14 (8.62 to 21.47)		
A human Serogroup (At Month 2) ≥ 128	14 (8.47 to 21.71)	6 (2.76 to 12.03)		
A human Serogroup (At Month 3) ≥ LLQ (22.7)	38 (28.83 to 46.80)	92 (86.00 to 96.16)		

A human Serogroup (At Month 3) ≥ 5	55 (45.65 to 64.09)	94 (88.97 to 97.76)		
A human Serogroup (At Month 3) ≥ 8	53 (43.18 to 61.69)	94 (87.97 to 97.24)		
A human Serogroup (At Month 3) ≥ 16	42 (32.74 to 51.02)	92 (86.00 to 96.16)		
A human Serogroup (At Month 3) ≥ 32	31 (22.73 to 39.91)	90 (83.13 to 94.44)		
A human Serogroup (At Month 3) ≥ 64	19 (12.56 to 27.36)	61 (51.57 to 69.18)		
A human Serogroup (At Month 3) ≥ 128	10 (5.27 to 16.82)	29 (21.41 to 37.85)		
A human Serogroup (At Month 7) ≥ LLQ (22.7)	21 (13.96 to 29.20)	94 (87.97 to 97.24)		
A human Serogroup (At Month 7) ≥ 5	29 (21.23 to 38.16)	98 (93.25 to 99.51)		
A human Serogroup (At Month 7) ≥ 8	28 (19.75 to 36.40)	98 (93.25 to 99.51)		
A human Serogroup (At Month 7) ≥ 16	22 (14.67 to 30.11)	97 (92.13 to 99.14)		
A human Serogroup (At Month 7) ≥ 32	14 (8.47 to 21.71)	93 (86.97 to 96.71)		
A human Serogroup (At Month 7) ≥ 64	7 (2.92 to 12.71)	80 (72.33 to 86.84)		
A human Serogroup (At Month 7) ≥ 128	3 (0.52 to 7.13)	54 (44.48 to 62.44)		
A human Serogroup (At Month 13) ≥ LLQ (22.7)	93 (87.29 to 97.08)	54 (45.26 to 63.19)		
A human Serogroup (At Month 13) ≥ 5	98 (92.87 to 99.48)	65 (55.59 to 72.85)		
A human Serogroup (At Month 13) ≥ 8	98 (92.87 to 99.48)	64 (54.78 to 72.12)		
A human Serogroup (At Month 13) ≥ 16	95 (89.43 to 98.14)	60 (50.78 to 68.44)		
A human Serogroup (At Month 13) ≥ 32	88 (81.20 to 93.47)	41 (32.30 to 50.02)		
A human Serogroup (At Month 13) ≥ 64	81 (72.64 to 87.44)	16 (9.89 to 23.27)		
A human Serogroup (At Month 13) ≥ 128	61 (51.50 to 69.61)	6 (2.24 to 11.03)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against C human serogroup for all schedules.

End point title	Percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against C human serogroup for all schedules.

End point description:

The kinetic of immune response (at Months 0, 2, 3, 7 and 13) following different vaccination schedules as measured by the percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against C human serogroup was assessed.

End point type	Secondary

End point timeframe:

At Month 0, Month 2, Month 3, Month 7 and Month 13.

End point values	rMenB_0_2 Group	ABCWY_ 0_2 Group	ABCWY_0_1 Group	ABCWY_0_6 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	186	185	122	114
Units: Percentages of subjects				
number (confidence interval 95%)				
C human Serogroup (At Month 0) ≥ LLQ (5.2)	43 (35.79 to 50.46)	45 (38.09 to 52.87)	48 (38.43 to 56.78)	41 (32.09 to 50.83)
C human Serogroup (At Month 0) ≥ 5	46 (38.91 to 53.68)	45 (38.09 to 52.87)	49 (40.02 to 58.38)	43 (33.75 to 52.59)
C human Serogroup (At Month 0) ≥ 8	34 (27.61 to 41.71)	30 (23.75 to 37.44)	36 (27.57 to 45.25)	30 (21.62 to 39.11)
C human Serogroup (At Month 0) ≥ 16	19 (13.47 to 25.19)	14 (8.94 to 19.30)	20 (13.03 to 27.84)	14 (8.24 to 21.79)
C human Serogroup (At Month 0) ≥ 32	5 (2.61 to 9.66)	6 (3.40 to 11.06)	9 (4.59 to 15.56)	4 (0.96 to 8.74)
C human Serogroup (At Month 0) ≥ 64	2 (0.59 to 5.41)	2 (0.34 to 4.67)	2 (0.20 to 5.80)	3 (0.55 to 7.50)
C human Serogroup (At Month 0) ≥ 128	1 (0.01 to 2.96)	2 (0.34 to 4.67)	0 (0 to 2.98)	1 (0.02 to 4.79)
C human Serogroup (At Month 2) ≥ LLQ (5.2)	61 (53.89 to 68.33)	84 (78.27 to 89.24)	100 (97.02 to 100)	84 (76.20 to 90.37)
C human Serogroup (At Month 2) ≥ 5	62 (54.98 to 69.35)	84 (78.27 to 89.24)	100 (97.02 to 100)	84 (76.20 to 90.37)
C human Serogroup (At Month 2) ≥ 8	53 (45.25 to 60.04)	78 (71.16 to 83.60)	98 (94.20 to 99.80)	80 (71.28 to 86.76)
C human Serogroup (At Month 2) ≥ 16	35 (28.62 to 42.82)	65 (57.52 to 71.73)	95 (89.60 to 98.17)	64 (54.51 to 72.81)
C human Serogroup (At Month 2) ≥ 32	18 (13.00 to 24.60)	40 (32.88 to 47.44)	89 (81.50 to 93.58)	44 (34.58 to 53.46)
C human Serogroup (At Month 2) ≥ 64	8 (4.58 to 12.95)	23 (17.36 to 30.00)	79 (70.35 to 85.58)	29 (20.84 to 38.19)
C human Serogroup (At Month 2) ≥ 128	3 (0.88 to 6.16)	16 (10.76 to 21.73)	53 (44.03 to 62.36)	17 (10.34 to 24.80)
C human Serogroup (At Month 3) ≥ LLQ (5.2)	97 (93.84 to 99.12)	99 (96.15 to 99.87)	98 (94.20 to 99.80)	81 (72.25 to 87.49)
C human Serogroup (At Month 3) ≥ 5	97 (93.84 to 99.12)	99 (96.15 to 99.87)	98 (94.20 to 99.80)	81 (72.25 to 87.49)
C human Serogroup (At Month 3) ≥ 8	94 (89.00 to 96.62)	98 (94.56 to 99.41)	98 (92.98 to 99.49)	77 (68.40 to 84.53)
C human Serogroup (At Month 3) ≥ 16	78 (71.89 to 84.17)	96 (92.36 to 98.47)	95 (89.60 to 98.17)	62 (52.72 to 71.19)
C human Serogroup (At Month 3) ≥ 32	56 (48.46 to 63.17)	90 (84.43 to 93.70)	86 (78.63 to 91.67)	43 (33.75 to 52.59)
C human Serogroup (At Month 3) ≥ 64	26 (19.68 to 32.72)	78 (71.16 to 83.60)	67 (58.13 to 75.44)	25 (17.75 to 34.45)
C human Serogroup (At Month 3) ≥ 128	11 (6.69 to 16.12)	58 (50.92 to 65.57)	40 (31.39 to 49.42)	18 (11.06 to 25.79)
C human Serogroup (At Month 7) ≥ LLQ (5.2)	69 (61.63 to 75.39)	96 (92.36 to 98.47)	97 (91.82 to 99.10)	99 (95.21 to 99.98)
C human Serogroup (At Month 7) ≥ 5	69 (62.19 to 75.89)	96 (92.36 to 98.47)	97 (91.82 to 99.10)	99 (95.21 to 99.98)
C human Serogroup (At Month 7) ≥ 8	58 (50.62 to 65.24)	96 (92.36 to 98.47)	96 (90.69 to 98.66)	99 (95.21 to 99.98)
C human Serogroup (At Month 7) ≥ 16	38 (30.65 to 45.02)	90 (85.06 to 94.13)	91 (84.44 to 95.41)	98 (93.81 to 99.79)

C human Serogroup (At Month 7) ≥ 32	23 (16.79 to 29.27)	74 (66.54 to 79.72)	77 (68.57 to 84.18)	95 (88.90 to 98.04)
C human Serogroup (At Month 7) ≥ 64	9 (5.00 to 13.59)	53 (45.51 to 60.34)	53 (44.03 to 62.36)	86 (78.21 to 91.76)
C human Serogroup (At Month 7) ≥ 128	3 (0.88 to 6.16)	30 (23.75 to 37.44)	25 (17.96 to 34.09)	74 (64.61 to 81.49)
C human Serogroup (At Month 13) ≥ LLQ (5.2)	60 (52.25 to 66.79)	92 (87.63 to 95.80)	94 (88.54 to 97.66)	97 (92.50 to 99.45)
C human Serogroup (At Month 13) ≥ 5	61 (53.34 to 67.82)	92 (87.63 to 95.80)	94 (88.54 to 97.66)	98 (93.81 to 99.79)
C human Serogroup (At Month 13) ≥ 8	48 (41.01 to 55.81)	88 (82.55 to 92.40)	89 (82.47 to 94.20)	91 (84.46 to 95.71)
C human Serogroup (At Month 13) ≥ 16	30 (23.61 to 37.25)	78 (71.26 to 83.60)	79 (70.35 to 85.58)	83 (75.20 to 89.66)
C human Serogroup (At Month 13) ≥ 32	15 (10.24 to 21.02)	51 (43.37 to 58.22)	57 (48.10 to 66.28)	61 (51.83 to 70.37)
C human Serogroup (At Month 13) ≥ 64	9 (5.00 to 13.59)	28 (21.76 to 35.17)	25 (17.25 to 33.21)	38 (28.81 to 47.28)
C human Serogroup (At Month 13) ≥ 128	2 (0.59 to 5.41)	16 (10.76 to 21.73)	16 (10.31 to 24.18)	25 (16.98 to 33.51)

End point values	ABCWY_0_11 Group	ABCWY_0_2_6 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	123	130		
Units: Percentages of subjects				
number (confidence interval 95%)				
C human Serogroup (At Month 0) ≥ LLQ (5.2)	48 (38.88 to 57.16)	41 (32.24 to 49.73)		
C human Serogroup (At Month 0) ≥ 5	49 (39.67 to 57.95)	42 (32.97 to 50.51)		
C human Serogroup (At Month 0) ≥ 8	36 (27.33 to 44.91)	30 (22.28 to 38.66)		
C human Serogroup (At Month 0) ≥ 16	24 (17.10 to 32.95)	8 (3.75 to 13.69)		
C human Serogroup (At Month 0) ≥ 32	7 (3.40 to 13.44)	3 (0.84 to 7.69)		
C human Serogroup (At Month 0) ≥ 64	3 (0.89 to 8.12)	1 (0.02 to 4.21)		
C human Serogroup (At Month 0) ≥ 128	1 (0.02 to 4.45)	0 (0 to 2.80)		
C human Serogroup (At Month 2) ≥ LLQ (5.2)	89 (82.60 to 94.25)	88 (80.78 to 92.80)		
C human Serogroup (At Month 2) ≥ 5	89 (82.60 to 94.25)	88 (80.78 to 92.80)		
C human Serogroup (At Month 2) ≥ 8	86 (78.80 to 91.74)	78 (69.56 to 84.52)		
C human Serogroup (At Month 2) ≥ 16	72 (62.71 to 79.31)	61 (51.82 to 69.21)		
C human Serogroup (At Month 2) ≥ 32	55 (46.06 to 64.25)	44 (35.16 to 52.82)		
C human Serogroup (At Month 2) ≥ 64	39 (30.36 to 48.23)	25 (17.49 to 32.94)		
C human Serogroup (At Month 2) ≥ 128	26 (18.52 to 34.70)	19 (12.85 to 27.07)		
C human Serogroup (At Month 3) ≥ LLQ (5.2)	88 (80.68 to 93.01)	99 (95.79 to 99.98)		

C human Serogroup (At Month 3) ≥ 5	88 (80.68 to 93.01)	100 (97.20 to 100)		
C human Serogroup (At Month 3) ≥ 8	84 (76.01 to 89.78)	99 (95.79 to 99.98)		
C human Serogroup (At Month 3) ≥ 16	63 (54.25 to 71.91)	98 (93.40 to 99.52)		
C human Serogroup (At Month 3) ≥ 32	46 (36.53 to 54.75)	94 (88.23 to 97.31)		
C human Serogroup (At Month 3) ≥ 64	30 (22.14 to 39.00)	85 (77.24 to 90.34)		
C human Serogroup (At Month 3) ≥ 128	21 (14.30 to 29.42)	60 (51.05 to 68.49)		
C human Serogroup (At Month 7) ≥ LLQ (5.2)	82 (74.18 to 88.44)	100 (97.20 to 100)		
C human Serogroup (At Month 7) ≥ 5	82 (74.18 to 88.44)	100 (97.20 to 100)		
C human Serogroup (At Month 7) ≥ 8	73 (64.43 to 80.76)	99 (95.79 to 99.98)		
C human Serogroup (At Month 7) ≥ 16	55 (46.06 to 64.25)	99 (95.79 to 99.98)		
C human Serogroup (At Month 7) ≥ 32	35 (26.58 to 44.08)	98 (94.55 to 99.81)		
C human Serogroup (At Month 7) ≥ 64	26 (18.52 to 34.70)	96 (91.25 to 98.74)		
C human Serogroup (At Month 7) ≥ 128	16 (10.22 to 23.99)	85 (78.12 to 90.97)		
C human Serogroup (At Month 13) ≥ LLQ (5.2)	100 (97.05 to 100)	99 (95.79 to 99.98)		
C human Serogroup (At Month 13) ≥ 5	100 (97.05 to 100)	99 (95.79 to 99.98)		
C human Serogroup (At Month 13) ≥ 8	98 (94.25 to 99.80)	98 (93.40 to 99.52)		
C human Serogroup (At Month 13) ≥ 16	98 (93.04 to 99.49)	94 (88.23 to 97.31)		
C human Serogroup (At Month 13) ≥ 32	97 (91.88 to 99.11)	81 (72.93 to 87.15)		
C human Serogroup (At Month 13) ≥ 64	93 (87.59 to 97.15)	58 (49.49 to 67.03)		
C human Serogroup (At Month 13) ≥ 128	85 (76.93 to 90.44)	40 (31.51 to 48.95)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against W human serogroup for all schedules.

End point title	Percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against W human serogroup for all schedules.

End point description:

The kinetic of immune response (at Months 0, 2, 3, 7 and 13) following different vaccination schedules as measured by the percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against W human serogroup was assessed.

End point type	Secondary

End point timeframe:

At Month 0, Month 2, Month 3, Month 7 and Month 13.

End point values	rMenB_0_2 Group	ABCWY_ 0_2 Group	ABCWY_0_1 Group	ABCWY_0_6 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	162	180	119	108
Units: Percentages of subjects				
number (confidence interval 95%)				
W human Serogroup (At Month 0) ≥ LLQ (39.6)	30 (23.29 to 37.95)	26 (19.86 to 33.17)	29 (21.42 to 38.46)	20 (13.23 to 29.20)
W human Serogroup (At Month 0) ≥ 5	51 (43.27 to 59.15)	43 (35.98 to 50.91)	41 (32.24 to 50.57)	42 (32.25 to 51.55)
W human Serogroup (At Month 0) ≥ 8	49 (41.45 to 57.34)	41 (33.85 to 48.67)	40 (31.45 to 49.72)	41 (31.38 to 50.62)
W human Serogroup (At Month 0) ≥ 16	44 (36.05 to 51.83)	39 (31.73 to 46.42)	39 (30.66 to 48.87)	34 (25.40 to 44.01)
W human Serogroup (At Month 0) ≥ 32	35 (27.86 to 43.07)	31 (24.43 to 38.42)	31 (22.93 to 40.23)	24 (16.37 to 33.25)
W human Serogroup (At Month 0) ≥ 64	21 (14.99 to 28.07)	19 (13.45 to 25.38)	20 (13.37 to 28.51)	13 (7.27 to 20.79)
W human Serogroup (At Month 0) ≥ 128	8 (4.34 to 13.33)	9 (5.17 to 14.03)	10 (5.32 to 16.95)	10 (5.20 to 17.49)
W human Serogroup (At Month 2) ≥ LLQ (39.6)	48 (40.24 to 56.12)	65 (57.55 to 71.95)	96 (90.47 to 98.62)	67 (56.95 to 75.45)
W human Serogroup (At Month 2) ≥ 5	66 (58.21 to 73.29)	90 (84.66 to 93.96)	99 (95.41 to 99.98)	92 (84.77 to 96.12)
W human Serogroup (At Month 2) ≥ 8	64 (56.30 to 71.57)	86 (80.18 to 90.81)	99 (95.41 to 99.98)	92 (84.77 to 96.12)
W human Serogroup (At Month 2) ≥ 16	60 (52.52 to 68.07)	82 (75.84 to 87.51)	99 (95.41 to 99.98)	81 (72.86 to 88.31)
W human Serogroup (At Month 2) ≥ 32	52 (44.49 to 60.36)	69 (62.16 to 76.08)	98 (94.06 to 99.80)	72 (62.78 to 80.41)
W human Serogroup (At Month 2) ≥ 64	44 (36.05 to 51.83)	50 (42.47 to 57.53)	84 (76.19 to 90.10)	52 (42.03 to 61.57)
W human Serogroup (At Month 2) ≥ 128	29 (22.16 to 36.65)	31 (23.92 to 37.84)	62 (52.84 to 70.91)	33 (24.55 to 43.05)
W human Serogroup (At Month 3) ≥ LLQ (39.6)	89 (83.01 to 93.28)	97 (92.89 to 98.77)	85 (77.15 to 90.78)	68 (57.91 to 76.28)
W human Serogroup (At Month 3) ≥ 5	96 (92.11 to 98.63)	99 (96.04 to 99.87)	98 (94.06 to 99.80)	94 (87.10 to 97.35)
W human Serogroup (At Month 3) ≥ 8	96 (92.11 to 98.63)	99 (96.04 to 99.87)	97 (92.81 to 99.48)	90 (82.51 to 94.80)
W human Serogroup (At Month 3) ≥ 16	96 (91.30 to 98.25)	99 (96.04 to 99.87)	96 (90.47 to 98.62)	81 (71.83 to 87.54)
W human Serogroup (At Month 3) ≥ 32	91 (85.19 to 94.72)	98 (94.41 to 99.39)	91 (84.06 to 95.29)	73 (63.76 to 81.22)
W human Serogroup (At Month 3) ≥ 64	80 (73.27 to 86.08)	93 (88.64 to 96.51)	77 (68.73 to 84.48)	50 (40.22 to 59.78)
W human Serogroup (At Month 3) ≥ 128	61 (53.15 to 68.66)	74 (66.83 to 80.14)	50 (41.11 to 59.71)	33 (24.55 to 43.05)
W human Serogroup (At Month 7) ≥ LLQ (39.6)	60 (51.90 to 67.49)	82 (75.23 to 87.03)	79 (70.57 to 85.92)	99 (94.95 to 99.98)
W human Serogroup (At Month 7) ≥ 5	71 (63.35 to 77.84)	97 (92.89 to 98.77)	96 (90.47 to 98.62)	100 (96.64 to 100)
W human Serogroup (At Month 7) ≥ 8	70 (62.70 to 77.28)	95 (90.72 to 97.69)	95 (89.35 to 98.13)	100 (96.64 to 100)
W human Serogroup (At Month 7) ≥ 16	69 (61.41 to 76.15)	92 (87.29 to 95.68)	91 (84.06 to 95.29)	100 (96.64 to 100)

W human Serogroup (At Month 7) ≥ 32	63 (55.03 to 70.41)	84 (78.31 to 89.41)	84 (76.19 to 90.10)	100 (96.64 to 100)
W human Serogroup (At Month 7) ≥ 64	49 (40.85 to 56.73)	68 (60.42 to 74.54)	67 (58.02 to 75.55)	97 (92.10 to 99.42)
W human Serogroup (At Month 7) ≥ 128	31 (23.85 to 38.59)	41 (33.31 to 48.11)	34 (25.98 to 43.72)	87 (79.21 to 92.73)
W human Serogroup (At Month 13) ≥ LLQ (39.6)	47 (39.04 to 54.90)	64 (56.41 to 70.90)	66 (56.28 to 74.02)	82 (73.90 to 89.06)
W human Serogroup (At Month 13) ≥ 5	62 (54.40 to 69.83)	93 (87.97 to 96.10)	90 (83.05 to 94.68)	99 (94.95 to 99.98)
W human Serogroup (At Month 13) ≥ 8	60 (52.52 to 68.07)	90 (84.66 to 93.96)	90 (83.05 to 94.68)	98 (93.47 to 99.77)
W human Serogroup (At Month 13) ≥ 16	57 (48.79 to 64.54)	84 (77.69 to 88.94)	81 (72.42 to 87.34)	94 (87.10 to 97.35)
W human Serogroup (At Month 13) ≥ 32	50 (42.05 to 57.95)	71 (63.90 to 77.61)	72 (63.32 to 80.08)	85 (77.06 to 91.29)
W human Serogroup (At Month 13) ≥ 64	35 (27.28 to 42.43)	44 (36.52 to 51.47)	48 (38.66 to 57.25)	73 (63.76 to 81.22)
W human Serogroup (At Month 13) ≥ 128	21 (14.99 to 28.07)	22 (16.38 to 29.01)	28 (19.92 to 36.68)	43 (33.13 to 52.47)

End point values	ABCWY_0_11 Group	ABCWY_0_2_6 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	123	123		
Units: Percentages of subjects				
number (confidence interval 95%)				
W human Serogroup (At Month 0) ≥ LLQ (39.6)	29 (21.41 to 38.15)	22 (14.99 to 30.31)		
W human Serogroup (At Month 0) ≥ 5	45 (35.75 to 53.94)	45 (35.75 to 53.94)		
W human Serogroup (At Month 0) ≥ 8	45 (35.75 to 53.94)	43 (34.20 to 52.32)		
W human Serogroup (At Month 0) ≥ 16	41 (31.89 to 49.88)	38 (29.60 to 47.41)		
W human Serogroup (At Month 0) ≥ 32	33 (25.09 to 42.40)	26 (18.52 to 34.70)		
W human Serogroup (At Month 0) ≥ 64	21 (14.30 to 29.42)	12 (6.99 to 19.32)		
W human Serogroup (At Month 0) ≥ 128	7 (2.85 to 12.41)	4 (1.33 to 9.23)		
W human Serogroup (At Month 2) ≥ LLQ (39.6)	77 (68.81 to 84.31)	60 (50.95 to 68.88)		
W human Serogroup (At Month 2) ≥ 5	93 (86.56 to 96.60)	93 (86.56 to 96.60)		
W human Serogroup (At Month 2) ≥ 8	93 (86.56 to 96.60)	89 (81.64 to 93.64)		
W human Serogroup (At Month 2) ≥ 16	89 (82.60 to 94.25)	80 (72.37 to 87.08)		
W human Serogroup (At Month 2) ≥ 32	78 (69.69 to 85.01)	65 (55.92 to 73.42)		
W human Serogroup (At Month 2) ≥ 64	67 (58.45 to 75.65)	44 (34.97 to 53.13)		
W human Serogroup (At Month 2) ≥ 128	49 (39.67 to 57.95)	27 (19.24 to 35.57)		
W human Serogroup (At Month 3) ≥ LLQ (39.6)	77 (68.81 to 84.31)	97 (91.88 to 99.11)		

W human Serogroup (At Month 3) ≥ 5	92 (85.56 to 96.03)	100 (97.05 to 100)		
W human Serogroup (At Month 3) ≥ 8	90 (83.58 to 94.86)	100 (97.05 to 100)		
W human Serogroup (At Month 3) ≥ 16	86 (78.80 to 91.74)	99 (95.55 to 99.98)		
W human Serogroup (At Month 3) ≥ 32	78 (69.69 to 85.01)	98 (93.04 to 99.49)		
W human Serogroup (At Month 3) ≥ 64	64 (55.09 to 72.67)	91 (84.56 to 95.45)		
W human Serogroup (At Month 3) ≥ 128	44 (34.97 to 53.13)	70 (61.00 to 77.86)		
W human Serogroup (At Month 7) ≥ LLQ (39.6)	74 (65.30 to 81.48)	99 (95.55 to 99.98)		
W human Serogroup (At Month 7) ≥ 5	93 (86.56 to 96.60)	100 (97.05 to 100)		
W human Serogroup (At Month 7) ≥ 8	91 (84.56 to 95.45)	100 (97.05 to 100)		
W human Serogroup (At Month 7) ≥ 16	87 (79.74 to 92.38)	100 (97.05 to 100)		
W human Serogroup (At Month 7) ≥ 32	76 (67.93 to 83.61)	99 (95.55 to 99.98)		
W human Serogroup (At Month 7) ≥ 64	59 (49.31 to 67.35)	98 (93.04 to 99.49)		
W human Serogroup (At Month 7) ≥ 128	34 (25.84 to 43.24)	82 (74.18 to 88.44)		
W human Serogroup (At Month 13) ≥ LLQ (39.6)	98 (93.04 to 99.49)	84 (76.01 to 89.78)		
W human Serogroup (At Month 13) ≥ 5	99 (95.55 to 99.98)	98 (94.25 to 99.80)		
W human Serogroup (At Month 13) ≥ 8	99 (95.55 to 99.98)	98 (94.25 to 99.80)		
W human Serogroup (At Month 13) ≥ 16	99 (95.55 to 99.98)	96 (90.77 to 98.67)		
W human Serogroup (At Month 13) ≥ 32	98 (94.25 to 99.80)	89 (82.60 to 94.25)		
W human Serogroup (At Month 13) ≥ 64	98 (93.04 to 99.49)	68 (59.29 to 76.39)		
W human Serogroup (At Month 13) ≥ 128	94 (88.63 to 97.68)	45 (35.75 to 53.94)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against Y human serogroup for all schedules.

End point title	Percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against Y human serogroup for all schedules.

End point description:

The kinetic of immune response (at Months 0, 2, 3, 7 and 13) following different vaccination schedules as measured by the percentages of subjects with hSBA titers ≥LLQ, ≥5, ≥8, ≥16, ≥32, ≥64, ≥128 against Y human serogroup was assessed.

End point type	Secondary

End point timeframe:

At Month 0, Month 2, Month 3, Month 7 and Month 13.

End point values	rMenB_0_2 Group	ABCWY_ 0_2 Group	ABCWY_0_1 Group	ABCWY_0_6 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	188	180	120	110
Units: Percentages of subjects				
number (confidence interval 95%)				
Y human Serogroup (At Month 0) ≥ LLQ (14.7)	15 (10.13 to 20.80)	10 (6.04 to 15.34)	13 (7.82 to 20.75)	6 (2.60 to 12.67)
Y human Serogroup (At Month 0) ≥ 5	16 (11.03 to 21.99)	11 (6.92 to 16.64)	15 (9.14 to 22.67)	7 (3.19 to 13.83)
Y human Serogroup (At Month 0) ≥ 8	16 (11.03 to 21.99)	11 (6.92 to 16.64)	14 (8.47 to 21.71)	7 (3.19 to 13.83)
Y human Serogroup (At Month 0) ≥ 16	15 (10.13 to 20.80)	10 (6.04 to 15.34)	13 (7.17 to 19.78)	6 (2.60 to 12.67)
Y human Serogroup (At Month 0) ≥ 32	9 (5.36 to 14.08)	3 (0.91 to 6.36)	8 (4.07 to 14.79)	3 (0.57 to 7.76)
Y human Serogroup (At Month 0) ≥ 64	2 (0.58 to 5.36)	2 (0.35 to 4.79)	4 (1.37 to 9.46)	0 (0 to 3.30)
Y human Serogroup (At Month 0) ≥ 128	0 (0 to 1.94)	1 (0.01 to 3.06)	1 (0.02 to 4.56)	0 (0 to 3.30)
Y human Serogroup (At Month 2) ≥ LLQ (14.7)	21 (15.19 to 27.25)	66 (58.70 to 72.99)	85 (77.33 to 90.86)	60 (50.22 to 69.22)
Y human Serogroup (At Month 2) ≥ 5	27 (20.91 to 34.08)	72 (64.48 to 78.12)	90 (83.18 to 94.73)	65 (55.79 to 74.26)
Y human Serogroup (At Month 2) ≥ 8	26 (19.95 to 32.95)	70 (62.74 to 76.59)	89 (82.19 to 94.10)	62 (52.07 to 70.92)
Y human Serogroup (At Month 2) ≥ 16	20 (14.72 to 26.67)	64 (56.41 to 70.90)	85 (77.33 to 90.86)	58 (48.39 to 67.52)
Y human Serogroup (At Month 2) ≥ 32	13 (8.35 to 18.40)	47 (39.75 to 54.79)	75 (66.27 to 82.45)	47 (37.68 to 57.02)
Y human Serogroup (At Month 2) ≥ 64	5 (2.21 to 8.89)	31 (23.92 to 37.84)	59 (49.82 to 68.05)	30 (21.63 to 39.48)
Y human Serogroup (At Month 2) ≥ 128	1 (0.13 to 3.79)	14 (9.19 to 19.82)	39 (30.39 to 48.50)	12 (6.45 to 19.36)
Y human Serogroup (At Month 3) ≥ LLQ (14.7)	27 (20.43 to 33.52)	92 (87.29 to 95.68)	80 (71.72 to 86.75)	58 (48.39 to 67.52)
Y human Serogroup (At Month 3) ≥ 5	33 (26.31 to 40.19)	94 (89.33 to 96.91)	84 (76.38 to 90.19)	65 (54.85 to 73.43)
Y human Serogroup (At Month 3) ≥ 8	30 (23.84 to 37.43)	93 (88.64 to 96.51)	83 (75.44 to 89.51)	60 (50.22 to 69.22)
Y human Serogroup (At Month 3) ≥ 16	26 (19.95 to 32.95)	92 (86.63 to 95.26)	79 (70.80 to 86.04)	57 (47.48 to 66.66)
Y human Serogroup (At Month 3) ≥ 32	18 (12.86 to 24.34)	84 (77.69 to 88.94)	68 (58.35 to 75.77)	44 (34.20 to 53.42)
Y human Serogroup (At Month 3) ≥ 64	9 (4.94 to 13.45)	68 (61.00 to 75.05)	47 (37.51 to 55.99)	24 (16.06 to 32.68)
Y human Serogroup (At Month 3) ≥ 128	2 (0.58 to 5.36)	39 (32.25 to 46.99)	28 (19.75 to 36.40)	16 (10.00 to 24.62)
Y human Serogroup (At Month 7) ≥ LLQ (14.7)	23 (17.07 to 29.55)	78 (70.99 to 83.62)	72 (62.72 to 79.51)	95 (88.51 to 97.97)
Y human Serogroup (At Month 7) ≥ 5	26 (19.95 to 32.95)	86 (79.56 to 90.34)	80 (71.72 to 86.75)	95 (89.71 to 98.51)
Y human Serogroup (At Month 7) ≥ 8	26 (19.46 to 32.39)	84 (77.69 to 88.94)	77 (68.07 to 83.90)	95 (89.71 to 98.51)
Y human Serogroup (At Month 7) ≥ 16	22 (16.13 to 28.40)	74 (66.83 to 80.14)	69 (60.09 to 77.27)	94 (87.33 to 97.40)

Y human Serogroup (At Month 7) ≥ 32	13 (8.35 to 18.40)	63 (55.27 to 69.85)	54 (44.83 to 63.29)	87 (79.57 to 92.86)
Y human Serogroup (At Month 7) ≥ 64	3 (0.87 to 6.10)	37 (30.15 to 44.73)	35 (26.52 to 44.24)	79 (70.30 to 86.26)
Y human Serogroup (At Month 7) ≥ 128	1 (0.01 to 2.93)	14 (9.66 to 20.44)	22 (14.67 to 30.11)	57 (47.48 to 66.66)
Y human Serogroup (At Month 13) ≥ LLQ (14.7)	19 (13.32 to 24.93)	64 (56.41 to 70.90)	58 (48.15 to 66.47)	78 (69.30 to 85.49)
Y human Serogroup (At Month 13) ≥ 5	25 (18.98 to 31.82)	76 (68.61 to 81.64)	73 (64.49 to 80.99)	91 (83.92 to 95.55)
Y human Serogroup (At Month 13) ≥ 8	24 (18.03 to 30.69)	71 (63.90 to 77.61)	63 (54.05 to 71.94)	84 (75.38 to 90.00)
Y human Serogroup (At Month 13) ≥ 16	18 (12.40 to 23.76)	61 (53.58 to 68.27)	55 (45.65 to 64.09)	76 (67.32 to 83.94)
Y human Serogroup (At Month 13) ≥ 32	10 (5.77 to 14.71)	43 (35.45 to 50.35)	40 (31.17 to 49.34)	60 (50.22 to 69.22)
Y human Serogroup (At Month 13) ≥ 64	3 (1.18 to 6.82)	21 (15.39 to 27.81)	23 (15.38 to 31.02)	41 (31.63 to 50.69)
Y human Serogroup (At Month 13) ≥ 128	1 (0.13 to 3.79)	9 (5.17 to 14.03)	11 (5.90 to 17.81)	21 (13.74 to 29.70)

End point values	ABCWY_0_11 Group	ABCWY_0_2_6 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	127	137		
Units: Percentages of subjects				
number (confidence interval 95%)				
Y human Serogroup (At Month 0) ≥ LLQ (14.7)	13 (7.38 to 19.65)	7 (3.05 to 12.10)		
Y human Serogroup (At Month 0) ≥ 5	17 (10.54 to 24.16)	9 (4.61 to 14.80)		
Y human Serogroup (At Month 0) ≥ 8	16 (9.89 to 23.27)	9 (4.61 to 14.80)		
Y human Serogroup (At Month 0) ≥ 16	12 (6.76 to 18.73)	6 (2.55 to 11.18)		
Y human Serogroup (At Month 0) ≥ 32	8 (3.84 to 14.00)	4 (1.62 to 9.29)		
Y human Serogroup (At Month 0) ≥ 64	5 (1.75 to 10.00)	3 (0.80 to 7.31)		
Y human Serogroup (At Month 0) ≥ 128	1 (0.02 to 4.31)	1 (0.02 to 4.00)		
Y human Serogroup (At Month 2) ≥ LLQ (14.7)	72 (62.98 to 79.29)	61 (52.62 to 69.51)		
Y human Serogroup (At Month 2) ≥ 5	78 (69.74 to 84.82)	65 (56.35 to 72.91)		
Y human Serogroup (At Month 2) ≥ 8	76 (68.03 to 83.46)	64 (54.85 to 71.56)		
Y human Serogroup (At Month 2) ≥ 16	69 (60.49 to 77.17)	60 (51.14 to 68.13)		
Y human Serogroup (At Month 2) ≥ 32	54 (44.48 to 62.44)	50 (41.70 to 59.01)		
Y human Serogroup (At Month 2) ≥ 64	39 (30.08 to 47.63)	39 (31.18 to 48.12)		
Y human Serogroup (At Month 2) ≥ 128	23 (15.86 to 31.12)	23 (16.56 to 31.34)		
Y human Serogroup (At Month 3) ≥ LLQ (14.7)	62 (53.17 to 70.65)	90 (83.45 to 94.30)		

Y human Serogroup (At Month 3) ≥ 5	70 (61.32 to 77.88)	93 (86.99 to 96.44)		
Y human Serogroup (At Month 3) ≥ 8	67 (58.03 to 75.02)	93 (86.99 to 96.44)		
Y human Serogroup (At Month 3) ≥ 16	59 (49.98 to 67.70)	90 (83.45 to 94.30)		
Y human Serogroup (At Month 3) ≥ 32	44 (35.30 to 53.17)	83 (75.88 to 89.05)		
Y human Serogroup (At Month 3) ≥ 64	31 (23.55 to 40.33)	65 (56.35 to 72.91)		
Y human Serogroup (At Month 3) ≥ 128	23 (15.86 to 31.12)	47 (38.15 to 55.43)		
Y human Serogroup (At Month 7) ≥ LLQ (14.7)	54 (44.48 to 62.44)	97 (92.69 to 99.20)		
Y human Serogroup (At Month 7) ≥ 5	69 (59.67 to 76.45)	99 (94.83 to 99.82)		
Y human Serogroup (At Month 7) ≥ 8	64 (54.78 to 72.12)	98 (93.73 to 99.55)		
Y human Serogroup (At Month 7) ≥ 16	52 (42.93 to 60.91)	97 (92.69 to 99.20)		
Y human Serogroup (At Month 7) ≥ 32	40 (31.56 to 49.22)	91 (85.20 to 95.39)		
Y human Serogroup (At Month 7) ≥ 64	27 (19.31 to 35.35)	75 (67.08 to 82.16)		
Y human Serogroup (At Month 7) ≥ 128	13 (8.00 to 20.56)	57 (48.20 to 65.36)		
Y human Serogroup (At Month 13) ≥ LLQ (14.7)	97 (92.13 to 99.14)	82 (75.06 to 88.44)		
Y human Serogroup (At Month 13) ≥ 5	97 (92.13 to 99.14)	91 (85.20 to 95.39)		
Y human Serogroup (At Month 13) ≥ 8	97 (92.13 to 99.14)	87 (80.03 to 92.02)		
Y human Serogroup (At Month 13) ≥ 16	97 (92.13 to 99.14)	81 (73.44 to 87.21)		
Y human Serogroup (At Month 13) ≥ 32	93 (86.97 to 96.71)	69 (60.13 to 76.27)		
Y human Serogroup (At Month 13) ≥ 64	92 (86.00 to 96.16)	46 (37.44 to 54.70)		
Y human Serogroup (At Month 13) ≥ 128	73 (64.65 to 80.69)	28 (21.09 to 36.80)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with two-, three- and four-fold titer rise against serogroups A, C, W and Y and serogroup B test Strains for all schedules.

End point title	Percentages of subjects with two-, three- and four-fold titer rise against serogroups A, C, W and Y and serogroup B test Strains for all schedules.

End point description:

The kinetic of immune response (at Months 2, 3, 7 and 13) following different vaccination schedules as measured by the percentages of subjects with two-, three- and four-fold titer rise against serogroups A, C, W and Y and serogroup B test strains was assessed. The two/three/four fold titer rise is defined as: a) for subjects with prevaccination hSBA titers ≤ LLQ, a postvaccination hSBA ≥ 2/3/4 LLQ; b) for subjects with a prevaccination hSBA titers ≥ LLQ, an increase of at least 2/3/4 times of the prevaccination hSBA titer.

End point type	Secondary

End point timeframe:
At Month 2, Month 3, Month 7 and Month 13

End point values	rMenB_0_2 Group	ABCWY_ 0_2 Group	ABCWY_0_1 Group	ABCWY_0_6 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	188	185	122	114
Units: Percentages of subjects				
number (confidence interval 95%)				
NZ98/254≥2-fold(M-2) N-188,185,122,114,128,137	18 (12.86 to 24.34)	13 (8.49 to 18.69)	28 (19.75 to 36.40)	9 (4.36 to 15.81)
NZ98/254≥3-fold(M-2)N-188,185,122,114,128,137	14 (9.24 to 19.60)	9 (5.44 to 14.30)	19 (12.56 to 27.36)	9 (4.36 to 15.81)
NZ98/254≥4-fold(M-2)N-188,185,122,114,128,137	11 (7.05 to 16.57)	8 (4.61 to 13.02)	17 (10.49 to 24.56)	7 (3.13 to 13.59)
NZ98/254≥2-fold(M-3)N-188,185,122,114,128,137	73 (66.48 to 79.57)	42 (34.43 to 49.08)	18 (11.17 to 25.50)	9 (4.36 to 15.81)
NZ98/254≥3-fold (M-3)N-188,185,122,114,128,137	61 (53.81 to 68.18)	32 (25.25 to 39.13)	13 (7.17 to 19.78)	5 (1.99 to 11.30)
NZ98/254≥4-fold (M-3)N-188,185,122,114,128,137	47 (39.51 to 54.21)	22 (15.92 to 28.26)	9 (4.67 to 15.81)	4 (0.98 to 8.89)
NZ98/254≥2-fold (M-7)N-188,185,122,114,128,137	19 (13.32 to 24.93)	12 (8.05 to 18.07)	11 (5.90 to 17.81)	45 (35.24 to 54.33)
NZ98/254≥3-fold (M-7)N-188,185,122,114,128,137	11 (7.05 to 16.57)	10 (6.30 to 15.57)	7 (2.92 to 12.71)	33 (24.44 to 42.56)
NZ98/254≥4-fold (M-7)N-188,185,122,114,128,137	9 (5.36 to 14.08)	8 (4.61 to 13.02)	6 (2.38 to 11.65)	24 (16.53 to 33.10)
NZ98/254≥2-fold (M-13)N-188,185,122,114,128,137	11 (6.62 to 15.95)	9 (5.44 to 14.30)	7 (2.92 to 12.71)	10 (5.01 to 16.89)
NZ98/254≥3-fold (M-13)N-188,185,122,114,128,137	5 (2.58 to 9.56)	7 (3.79 to 11.72)	6 (2.38 to 11.65)	9 (4.36 to 15.81)
NZ98/254≥4-fold (M-13)N-188,185,122,114,128,137	4 (1.85 to 8.21)	5 (2.62 to 9.72)	5 (1.86 to 10.57)	6 (2.55 to 12.45)
M14459≥2-fold (M-2)N-184,179,112,108,123,137	14 (9.44 to 20.02)	13 (8.32 to 18.65)	34 (25.25 to 43.48)	8 (3.88 to 15.23)
M14459≥3-fold (M-2)N-184,179,112,108,123,137	10 (5.90 to 15.02)	10 (6.07 to 15.43)	23 (15.76 to 32.14)	6 (2.07 to 11.70)
M14459≥4-fold (M-2)N-184,179,112,108,123,137	7 (3.82 to 11.78)	6 (2.71 to 10.03)	15 (9.10 to 23.19)	4 (1.02 to 9.21)
M14459≥2-fold (M-3)N-184,179,112,108,123,137	65 (57.86 to 72.07)	50 (42.72 to 57.82)	24 (16.53 to 33.10)	6 (2.65 to 12.90)
M14459≥3-fold (M-3)N-184,179,112,108,123,137	49 (41.49 to 56.37)	39 (31.38 to 46.10)	10 (5.01 to 16.89)	3 (0.58 to 7.90)
M14459≥4-fold (M-3)N-184,179,112,108,123,137	38 (30.49 to 44.92)	28 (22.01 to 35.70)	4 (1.47 to 10.11)	3 (0.58 to 7.90)
M14459≥2-fold (M-7)N-184,179,112,108,123,137	16 (11.28 to 22.45)	14 (9.25 to 19.92)	9 (4.36 to 15.81)	69 (58.88 to 77.12)
M14459≥3-fold (M-7)N-184,179,112,108,123,137	12 (7.65 to 17.54)	7 (3.92 to 12.10)	6 (2.55 to 12.45)	55 (44.76 to 64.24)
M14459≥4-fold (M-7)N-184,179,112,108,123,137	8 (4.22 to 12.44)	6 (3.11 to 10.73)	4 (0.98 to 8.89)	48 (38.43 to 57.97)
M14459≥2-fold(M-13)N-184,179,112,108,123,137	11 (7.21 to 16.92)	9 (5.63 to 14.77)	6 (2.55 to 12.45)	10 (5.20 to 17.49)
M14459≥3-fold (M-13)N-184,179,112,108,123,137	8 (4.22 to 12.44)	4 (1.95 to 8.62)	4 (1.47 to 10.11)	7 (3.25 to 14.07)
M14459≥4-fold (M-13)N-184,179,112,108,123,137	3 (1.21 to 6.96)	4 (1.59 to 7.89)	3 (0.56 to 7.63)	6 (2.07 to 11.70)

M07-0241084≥2-fold (M-2)N-188,176,117,113,121,128	16 (11.49 to 22.58)	11 (6.63 to 16.34)	20 (12.89 to 28.02)	5 (1.97 to 11.20)
M07-0241084≥3-fold (M-2)N-188,176,117,113,121,128	12 (7.92 to 17.79)	7 (3.57 to 11.61)	9 (4.79 to 16.20)	2 (0.22 to 6.25)
M07-0241084≥4-fold (M-2)N-188,176,117,113,121,128	8 (4.53 to 12.82)	5 (1.98 to 8.76)	7 (3.00 to 13.03)	2 (0.22 to 6.25)
M07-0241084≥2-fold (M-3)N-188,176,117,113,121,128	37 (29.81 to 44.02)	22 (16.26 to 29.02)	11 (6.05 to 18.25)	2 (0.22 to 6.25)
M07-0241084≥3-fold (M-3)N-188,176,117,113,121,128	28 (21.40 to 34.64)	12 (7.54 to 17.66)	7 (3.00 to 13.03)	1 (0.02 to 4.83)
M07-0241084≥4-fold (M-3)N-188,176,117,113,121,128	19 (13.32 to 24.93)	9 (5.29 to 14.34)	4 (1.40 to 9.69)	0 (0 to 3.21)
M07-0241084≥2-fold (M-7)N-188,176,117,113,121,128	19 (13.32 to 24.93)	13 (8.00 to 18.31)	8 (3.58 to 14.10)	43 (34.07 to 53.01)
M07-0241084≥3-fold (M-7)N-188,176,117,113,121,128	11 (7.05 to 16.57)	7 (3.99 to 12.30)	6 (2.44 to 11.94)	31 (22.61 to 40.36)
M07-0241084≥4-fold (M-7)N-188,176,117,113,121,128	7 (4.13 to 12.18)	6 (2.76 to 10.20)	3 (0.94 to 8.52)	19 (12.62 to 27.98)
M07-0241084≥2-fold (M-13)N-188,176,117,113,121,128	13 (8.35 to 18.40)	11 (7.08 to 17.00)	8 (3.58 to 14.10)	13 (7.62 to 20.95)
M07-0241084≥3-fold (M-13)N-188,176,117,113,121,128	9 (4.94 to 13.45)	7 (3.99 to 12.30)	5 (1.90 to 10.83)	9 (4.33 to 15.67)
M07-0241084≥4-fold (M-13)N-188,176,117,113,121,128	5 (2.58 to 9.56)	6 (2.76 to 10.20)	4 (1.40 to 9.69)	6 (2.53 to 12.35)
96217≥ 2-fold (M-2)(N-186,178,120,112,128,121)	34 (27.61 to 41.71)	29 (22.65 to 36.48)	88 (81.20 to 93.47)	32 (23.63 to 41.63)
96217≥ 3-fold (M-2)(N-186,178,120,112,128,121)	26 (19.68 to 32.72)	20 (14.09 to 26.27)	81 (72.64 to 87.44)	19 (12.00 to 27.22)
96217≥ 4-fold (M-2)(N-186,178,120,112,128,121)	18 (12.54 to 24.00)	13 (8.37 to 18.76)	76 (67.17 to 83.18)	12 (6.33 to 19.03)
96217≥ 2-fold (M-3)(N-186,178,120,112,128,121)	97 (93.84 to 99.12)	92 (87.16 to 95.63)	85 (77.33 to 90.86)	28 (19.64 to 36.93)
96217≥ 3-fold (M-3)(N-186,178,120,112,128,121)	96 (92.40 to 98.47)	89 (83.18 to 93.00)	76 (67.17 to 83.18)	14 (8.39 to 22.16)
96217≥ 4-fold (M-3)(N-186,178,120,112,128,121)	94 (89.66 to 97.01)	83 (76.20 to 87.85)	69 (60.09 to 77.27)	11 (5.66 to 17.97)
96217≥ 2-fold (M-7)(N-186,178,120,112,128,121)	81 (74.81 to 86.53)	74 (66.48 to 79.91)	64 (54.90 to 72.71)	96 (91.11 to 99.02)
96217≥ 3-fold (M-7)(N-186,178,120,112,128,121)	73 (65.57 to 78.85)	63 (55.38 to 70.03)	52 (42.37 to 60.88)	96 (91.11 to 99.02)
96217≥ 4-fold (M-7)(N-186,178,120,112,128,121)	61 (53.89 to 68.33)	50 (42.43 to 57.57)	42 (32.74 to 51.02)	95 (88.70 to 98.01)
96217≥ 2-fold (M-13)(N-186,178,120,112,128,121)	65 (57.73 to 71.88)	54 (46.32 to 61.42)	52 (42.37 to 60.88)	72 (63.07 to 80.36)
96217≥ 3-fold (M-13)(N-186,178,120,112,128,121)	53 (45.78 to 60.56)	39 (32.10 to 46.91)	34 (25.76 to 43.38)	54 (44.78 to 63.90)
96217 ≥ 4-fold (M-13)(N-186,178,120,112,128,121)	35 (28.62 to 42.82)	22 (16.57 to 29.32)	28 (19.75 to 36.40)	45 (35.24 to 54.33)
A Serogroup≥2-fold(M-2)N-172,178,107,105,120,127	12 (7.72 to 18.06)	23 (17.07 to 29.92)	78 (68.49 to 85.07)	21 (13.62 to 29.99)
A Serogroup≥3-fold(M-2)N-172,178,107,105,120,127	9 (5.41 to 14.67)	16 (11.19 to 22.55)	64 (53.69 to 72.64)	14 (8.22 to 22.47)
A Serogroup≥4-fold(M-2)N-172,178,107,105,120,127	6 (2.82 to 10.43)	11 (6.55 to 16.17)	50 (39.72 to 59.37)	11 (6.05 to 19.11)
A Serogroup≥2-fold(M-3)N-172,178,107,105,120,127	80 (72.85 to 85.40)	71 (63.52 to 77.35)	61 (50.84 to 70.05)	20 (12.83 to 28.93)
A Serogroup≥3-fold (M-3)N-172,178,107,105,120,127	66 (58.09 to 72.76)	52 (44.64 to 59.77)	41 (31.70 to 51.05)	12 (6.76 to 20.24)
A Serogroup≥4-fold (M-3)N-172,178,107,105,120,127	56 (48.64 to 63.93)	42 (34.79 to 49.75)	31 (22.27 to 40.50)	7 (2.72 to 13.25)
A Serogroup≥2-fold (M-7)N-172,178,107,105,120,127	27 (20.82 to 34.63)	28 (21.11 to 34.71)	25 (17.33 to 34.55)	87 (78.64 to 92.51)

A Serogroup≥3-fold (M-7)N-172,178,107,105,120,127	17 (11.59 to 23.31)	16 (11.19 to 22.55)	16 (9.54 to 24.21)	76 (66.89 to 83.96)
A Serogroup≥4-fold (M-7)N-172,178,107,105,120,127	11 (6.78 to 16.71)	10 (5.66 to 14.85)	13 (7.34 to 20.98)	70 (60.78 to 78.98)
A Serogroup≥2-fold(M-13)N-172,178,107,105,120,127	16 (10.61 to 22.01)	12 (7.91 to 18.11)	18 (11.04 to 26.33)	31 (22.72 to 41.22)
A Serogroup≥3-fold (M-13)N-172,178,107,105,120,127	9 (5.41 to 14.67)	8 (4.37 to 12.84)	11 (5.93 to 18.77)	25 (16.86 to 34.14)
A Serogroup≥4-fold (M-13)N-172,178,107,105,120,127	5 (2.42 to 9.70)	4 (1.60 to 7.93)	9 (4.57 to 16.52)	15 (8.97 to 23.56)
C Serogroup≥2-fold(M-2)N-186,185,122,114,123,130	24 (18.23 to 31.00)	64 (56.41 to 70.71)	95 (89.60 to 98.17)	55 (45.66 to 64.58)
C Serogroup≥3-fold (M-2)N-186,185,122,114,123,130	15 (10.24 to 21.02)	50 (42.84 to 57.69)	91 (84.44 to 95.41)	48 (38.79 to 57.80)
C Serogroup≥4-fold (M-2)N-186,185,122,114,123,130	9 (5.00 to 13.59)	42 (34.43 to 49.08)	88 (80.53 to 92.95)	44 (34.58 to 53.46)
C Serogroup≥2-fold (M-3)N-186,185,122,114,123,130	80 (73.05 to 85.12)	94 (89.61 to 96.99)	93 (86.46 to 96.57)	58 (48.29 to 67.08)
C Serogroup≥3-fold (M-3)N-186,185,122,114,123,130	64 (56.63 to 70.87)	90 (85.06 to 94.13)	90 (83.45 to 94.81)	47 (37.94 to 56.94)
C Serogroup≥4-fold (M-3)N-186,185,122,114,123,130	49 (41.54 to 56.34)	87 (81.31 to 91.51)	83 (74.90 to 89.02)	41 (32.09 to 50.83)
C Serogroup≥2-fold (M-7)N-186,185,122,114,123,130	29 (22.62 to 36.12)	86 (80.70 to 91.06)	89 (81.50 to 93.58)	97 (92.50 to 99.45)
C Serogroup≥3-fold (M-7)N-186,185,122,114,123,130	16 (10.70 to 21.62)	80 (73.50 to 85.51)	79 (70.35 to 85.58)	94 (87.76 to 97.50)
C Serogroup≥4-fold (M-7)N-186,185,122,114,123,130	10 (6.26 to 15.49)	71 (64.26 to 77.75)	72 (63.29 to 79.87)	92 (85.54 to 96.33)
C Serogroup≥2-fold (M-13)N-186,185,122,114,123,130	19 (13.94 to 25.77)	73 (65.97 to 79.23)	74 (65.04 to 81.32)	82 (73.23 to 88.22)
C Serogroup≥3-fold (M-13)N-186,185,122,114,123,130	13 (8.89 to 19.20)	64 (56.41 to 70.71)	61 (52.24 to 70.14)	70 (60.89 to 78.38)
C Serogroup≥4-fold (M-13)N-186,185,122,114,123,130	10 (5.84 to 14.86)	51 (43.91 to 58.75)	53 (44.03 to 62.36)	56 (46.54 to 65.42)
W Serogroup≥2-fold (M-2)N-162,180,119,108,123,123	24 (17.71 to 31.41)	32 (24.95 to 39.00)	65 (55.42 to 73.24)	35 (26.24 to 44.96)
W Serogroup≥3-fold (M-2)N-162,180,119,108,123,123	17 (11.28 to 23.31)	19 (13.93 to 25.99)	52 (42.75 to 61.34)	25 (17.17 to 34.25)
W Serogroup≥4-fold (M-2)N-162,180,119,108,123,123	11 (6.72 to 16.99)	16 (11.06 to 22.31)	42 (33.03 to 51.41)	18 (10.94 to 26.10)
W Serogroup≥2-fold (M-3)N-162,180,119,108,123,123	67 (59.48 to 74.44)	78 (71.59 to 84.12)	55 (46.07 to 64.57)	34 (25.40 to 44.01)
W Serogroup≥3-fold (M-3)N-162,180,119,108,123,123	54 (46.32 to 62.16)	65 (57.55 to 71.95)	39 (29.87 to 48.02)	23 (15.57 to 32.25)
W Serogroup≥4-fold (M-3)N-162,180,119,108,123,123	43 (34.87 to 50.59)	57 (49.09 to 64.02)	30 (22.17 to 39.35)	19 (12.46 to 28.17)
W Serogroup≥2-fold (M-7)N-162,180,119,108,123,123	31 (24.42 to 39.23)	51 (43.57 to 58.62)	43 (33.83 to 52.25)	90 (82.51 to 94.80)
W Serogroup≥3-fold (M-7)N-162,180,119,108,123,123	22 (15.53 to 28.74)	30 (23.41 to 37.26)	29 (20.67 to 37.57)	81 (71.83 to 87.54)
W Serogroup≥4-fold (M-7)N-162,180,119,108,123,123	13 (8.21 to 19.13)	21 (14.91 to 27.20)	17 (10.58 to 24.76)	73 (63.76 to 81.22)
W Serogroup≥2-fold (M-13)N-162,180,119,108,123,123	20 (13.92 to 26.73)	26 (19.36 to 32.58)	32 (23.69 to 41.10)	56 (46.60 to 66.00)
W Serogroup≥3-fold (M-13)N-162,180,119,108,123,123	9 (4.81 to 14.07)	13 (8.28 to 18.55)	17 (10.58 to 24.76)	38 (28.80 to 47.81)
W Serogroup≥4-fold (M-13)N-162,180,119,108,123,123	7 (3.44 to 11.82)	11 (6.48 to 15.99)	13 (7.88 to 20.91)	27 (18.78 to 36.24)
Y Serogroup≥2-fold (M-2) N-188,180,120,110,127,137	6 (2.96 to 10.23)	49 (41.38 to 56.43)	74 (65.38 to 81.72)	47 (37.68 to 57.02)
Y Serogroup≥3-fold (M-2)N-188,180,120,110,127,137	4 (1.51 to 7.52)	39 (32.25 to 46.99)	64 (54.90 to 72.71)	40 (30.78 to 49.78)

Y Serogroup≥4-fold (M-2)N-188,180,120,110,127,137	2 (0.58 to 5.36)	32 (25.46 to 39.58)	58 (48.15 to 66.47)	33 (24.08 to 42.33)
Y Serogroup≥2-fold (M-3)N-188,180,120,110,127,137	10 (5.77 to 14.71)	84 (78.31 to 89.41)	66 (56.62 to 74.24)	45 (35.93 to 55.23)
Y Serogroup≥3-fold (M-3)N-188,180,120,110,127,137	7 (3.73 to 11.53)	80 (73.40 to 85.58)	55 (45.65 to 64.09)	35 (25.74 to 44.21)
Y Serogroup≥4-fold (M-3)N-188,180,120,110,127,137	4 (1.85 to 8.21)	68 (61.00 to 75.05)	48 (39.12 to 57.63)	29 (20.82 to 38.52)
Y Serogroup≥2-fold (M-7)N-188,180,120,110,127,137	5 (2.21 to 8.89)	60 (52.45 to 67.22)	51 (41.55 to 60.07)	90 (82.81 to 94.90)
Y Serogroup≥3-fold (M-7)N-188,180,120,110,127,137	3 (1.18 to 6.82)	48 (40.29 to 55.34)	44 (35.11 to 53.52)	83 (74.35 to 89.27)
Y Serogroup≥4-fold (M-7)N-188,180,120,110,127,137	3 (0.87 to 6.10)	41 (33.31 to 48.11)	38 (29.61 to 47.65)	79 (70.30 to 86.26)
Y Serogroup≥2-fold (M-13)N-188,180,120,110,127,137	5 (2.21 to 8.89)	43 (35.45 to 50.35)	38 (29.61 to 47.65)	60 (50.22 to 69.22)
Y Serogroup≥3-fold (M-13)N-188,180,120,110,127,137	3 (1.18 to 6.82)	34 (27.01 to 41.30)	28 (20.49 to 37.28)	48 (38.55 to 57.91)
Y Serogroup≥4-fold (M-13)N-188,180,120,110,127,137	2 (0.58 to 5.36)	25 (18.86 to 31.99)	23 (16.10 to 31.93)	45 (35.93 to 55.23)

End point values	ABCWY_0_11 Group	ABCWY_0_2_6 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	128	137		
Units: Percentages of subjects				
number (confidence interval 95%)				
NZ98/254≥2-fold(M-2) N-188,185,122,114,128,137	21 (14.62 to 29.62)	12 (6.98 to 18.67)		
NZ98/254≥3-fold(M-2)N-188,185,122,114,128,137	17 (11.28 to 25.23)	7 (3.64 to 13.30)		
NZ98/254≥4-fold(M-2)N-188,185,122,114,128,137	17 (10.62 to 24.34)	7 (3.12 to 12.37)		
NZ98/254≥2-fold(M-3)N-188,185,122,114,128,137	13 (8.06 to 20.72)	43 (34.76 to 52.11)		
NZ98/254≥3-fold (M-3)N-188,185,122,114,128,137	10 (5.61 to 17.00)	28 (20.91 to 36.79)		
NZ98/254≥4-fold (M-3)N-188,185,122,114,128,137	9 (4.44 to 15.08)	19 (12.45 to 26.30)		
NZ98/254≥2-fold (M-7)N-188,185,122,114,128,137	7 (3.32 to 13.13)	54 (44.92 to 62.38)		
NZ98/254≥3-fold (M-7)N-188,185,122,114,128,137	6 (2.78 to 12.13)	43 (34.76 to 52.11)		
NZ98/254≥4-fold (M-7)N-188,185,122,114,128,137	4 (1.30 to 9.02)	33 (24.97 to 41.47)		
NZ98/254≥2-fold (M-13)N-188,185,122,114,128,137	49 (40.19 to 58.26)	14 (8.76 to 21.25)		
NZ98/254≥3-fold (M-13)N-188,185,122,114,128,137	37 (28.12 to 45.55)	7 (3.64 to 13.30)		
NZ98/254≥4-fold (M-13)N-188,185,122,114,128,137	26 (18.76 to 34.77)	4 (1.66 to 9.49)		
M14459≥2-fold (M-2)N-184,179,112,108,123,137	23 (15.69 to 31.19)	11 (6.40 to 17.79)		
M14459≥3-fold (M-2)N-184,179,112,108,123,137	15 (9.56 to 23.07)	6 (2.61 to 11.42)		
M14459≥4-fold (M-2)N-184,179,112,108,123,137	12 (6.99 to 19.32)	4 (1.22 to 8.49)		

M14459≥2-fold (M-3)N-184,179,112,108,123,137	14 (8.26 to 21.20)	50 (41.25 to 58.75)		
M14459≥3-fold (M-3)N-184,179,112,108,123,137	11 (5.75 to 17.40)	39 (30.52 to 47.60)		
M14459≥4-fold (M-3)N-184,179,112,108,123,137	7 (3.40 to 13.44)	28 (20.24 to 36.00)		
M14459≥2-fold (M-7)N-184,179,112,108,123,137	7 (2.85 to 12.41)	72 (63.21 to 79.09)		
M14459≥3-fold (M-7)N-184,179,112,108,123,137	6 (2.32 to 11.37)	54 (45.65 to 63.10)		
M14459≥4-fold (M-7)N-184,179,112,108,123,137	5 (1.81 to 10.32)	49 (39.79 to 57.29)		
M14459≥2-fold(M-13)N-184,179,112,108,123,137	74 (65.30 to 81.48)	12 (6.98 to 18.67)		
M14459≥3-fold (M-13)N-184,179,112,108,123,137	59 (50.12 to 68.11)	6 (2.61 to 11.42)		
M14459≥4-fold (M-13)N-184,179,112,108,123,137	51 (42.05 to 60.33)	4 (1.66 to 9.49)		
M07-0241084≥2-fold (M-2)N-188,176,117,113,121,128	19 (12.45 to 27.14)	8 (3.81 to 13.90)		
M07-0241084≥3-fold (M-2)N-188,176,117,113,121,128	12 (6.47 to 18.65)	4 (1.28 to 8.88)		
M07-0241084≥4-fold (M-2)N-188,176,117,113,121,128	9 (4.63 to 15.68)	1 (0.02 to 4.28)		
M07-0241084≥2-fold (M-3)N-188,176,117,113,121,128	8 (4.03 to 14.67)	21 (14.38 to 29.19)		
M07-0241084≥3-fold (M-3)N-188,176,117,113,121,128	5 (1.84 to 10.48)	17 (11.10 to 24.86)		
M07-0241084≥4-fold (M-3)N-188,176,117,113,121,128	4 (1.36 to 9.38)	13 (7.93 to 20.41)		
M07-0241084≥2-fold (M-7)N-188,176,117,113,121,128	4 (1.36 to 9.38)	42 (33.51 to 51.23)		
M07-0241084≥3-fold (M-7)N-188,176,117,113,121,128	1 (0.02 to 4.52)	32 (24.06 to 40.85)		
M07-0241084≥4-fold (M-7)N-188,176,117,113,121,128	1 (0.02 to 4.52)	22 (15.05 to 30.04)		
M07-0241084≥2-fold (M-13)N-188,176,117,113,121,128	41 (32.45 to 50.63)	15 (9.18 to 22.21)		
M07-0241084≥3-fold (M-13)N-188,176,117,113,121,128	34 (25.53 to 43.05)	10 (5.52 to 16.74)		
M07-0241084≥4-fold (M-13)N-188,176,117,113,121,128	21 (13.84 to 28.97)	6 (2.74 to 11.94)		
96217≥ 2-fold (M-2)(N-186,178,120,112,128,121)	31 (23.35 to 40.04)	26 (18.84 to 35.24)		
96217≥ 3-fold (M-2)(N-186,178,120,112,128,121)	18 (11.74 to 25.73)	19 (12.45 to 27.14)		
96217≥ 4-fold (M-2)(N-186,178,120,112,128,121)	14 (8.55 to 21.31)	16 (9.73 to 23.43)		
96217≥ 2-fold (M-3)(N-186,178,120,112,128,121)	23 (16.41 to 31.74)	91 (84.32 to 95.37)		
96217≥ 3-fold (M-3)(N-186,178,120,112,128,121)	17 (11.10 to 24.86)	88 (81.35 to 93.53)		
96217≥ 4-fold (M-3)(N-186,178,120,112,128,121)	13 (7.93 to 20.41)	83 (75.63 to 89.60)		
96217≥ 2-fold (M-7)(N-186,178,120,112,128,121)	16 (10.45 to 23.98)	97 (91.75 to 99.09)		
96217≥ 3-fold (M-7)(N-186,178,120,112,128,121)	9 (4.94 to 15.80)	96 (90.62 to 98.64)		
96217≥ 4-fold (M-7)(N-186,178,120,112,128,121)	7 (3.27 to 12.93)	94 (88.44 to 97.64)		
96217≥ 2-fold (M-13)(N-186,178,120,112,128,121)	96 (91.12 to 98.72)	77 (68.32 to 84.04)		

96217≥ 3-fold (M-13)(N-186,178,120,112,128,121)	95 (89.06 to 97.77)	62 (52.71 to 70.65)		
96217 ≥ 4-fold (M-13)(N-186,178,120,112,128,121)	93 (87.07 to 96.73)	51 (41.99 to 60.43)		
A Serogroup≥2-fold(M-2)N-172,178,107,105,120,127	38 (28.83 to 46.80)	17 (10.54 to 24.16)		
A Serogroup≥3-fold(M-2)N-172,178,107,105,120,127	30 (21.98 to 39.04)	13 (7.38 to 19.65)		
A Serogroup≥4-fold(M-2)N-172,178,107,105,120,127	20 (13.25 to 28.28)	7 (3.29 to 13.03)		
A Serogroup≥2-fold(M-3)N-172,178,107,105,120,127	24 (16.82 to 32.83)	74 (65.49 to 81.39)		
A Serogroup≥3-fold (M-3)N-172,178,107,105,120,127	18 (11.86 to 26.43)	56 (46.83 to 64.70)		
A Serogroup≥4-fold (M-3)N-172,178,107,105,120,127	14 (8.47 to 21.71)	40 (31.56 to 49.22)		
A Serogroup≥2-fold (M-7)N-172,178,107,105,120,127	8 (3.49 to 13.76)	88 (81.27 to 93.24)		
A Serogroup≥3-fold (M-7)N-172,178,107,105,120,127	6 (2.38 to 11.65)	77 (68.88 to 84.14)		
A Serogroup≥4-fold (M-7)N-172,178,107,105,120,127	5 (1.86 to 10.57)	70 (61.32 to 77.88)		
A Serogroup≥2-fold(M-13)N-172,178,107,105,120,127	85 (77.33 to 90.86)	28 (20.71 to 37.02)		
A Serogroup≥3-fold (M-13)N-172,178,107,105,120,127	80 (71.72 to 86.75)	15 (9.25 to 22.37)		
A Serogroup≥4-fold (M-13)N-172,178,107,105,120,127	78 (68.98 to 84.62)	7 (3.29 to 13.03)		
C Serogroup≥2-fold(M-2)N-186,185,122,114,123,130	73 (64.43 to 80.76)	62 (52.61 to 69.93)		
C Serogroup≥3-fold (M-2)N-186,185,122,114,123,130	59 (49.31 to 67.35)	54 (44.89 to 62.62)		
C Serogroup≥4-fold (M-2)N-186,185,122,114,123,130	50 (40.46 to 58.75)	42 (32.97 to 50.51)		
C Serogroup≥2-fold (M-3)N-186,185,122,114,123,130	65 (55.92 to 73.42)	98 (93.40 to 99.52)		
C Serogroup≥3-fold (M-3)N-186,185,122,114,123,130	50 (40.46 to 58.75)	96 (91.25 to 98.74)		
C Serogroup≥4-fold (M-3)N-186,185,122,114,123,130	42 (33.42 to 51.51)	92 (85.36 to 95.70)		
C Serogroup≥2-fold (M-7)N-186,185,122,114,123,130	50 (40.46 to 58.75)	98 (94.55 to 99.81)		
C Serogroup≥3-fold (M-7)N-186,185,122,114,123,130	37 (28.09 to 45.75)	98 (94.55 to 99.81)		
C Serogroup≥4-fold (M-7)N-186,185,122,114,123,130	28 (19.96 to 36.43)	98 (93.40 to 99.52)		
C Serogroup≥2-fold (M-13)N-186,185,122,114,123,130	97 (91.88 to 99.11)	92 (86.31 to 96.25)		
C Serogroup≥3-fold (M-13)N-186,185,122,114,123,130	96 (90.77 to 98.67)	89 (82.59 to 93.99)		
C Serogroup≥4-fold (M-13)N-186,185,122,114,123,130	93 (87.59 to 97.15)	85 (77.24 to 90.34)		
W Serogroup≥2-fold (M-2)N-162,180,119,108,123,123	50 (41.25 to 59.54)	33 (25.09 to 42.40)		
W Serogroup≥3-fold (M-2)N-162,180,119,108,123,123	40 (31.12 to 49.05)	22 (14.99 to 30.31)		
W Serogroup≥4-fold (M-2)N-162,180,119,108,123,123	34 (25.84 to 43.24)	18 (11.56 to 25.82)		
W Serogroup≥2-fold (M-3)N-162,180,119,108,123,123	46 (37.31 to 55.56)	76 (67.93 to 83.61)		
W Serogroup≥3-fold (M-3)N-162,180,119,108,123,123	34 (25.84 to 43.24)	67 (58.45 to 75.65)		

W Serogroup≥4-fold (M-3)N-162,180,119,108,123,123	28 (20.69 to 37.29)	56 (46.87 to 65.03)		
W Serogroup≥2-fold (M-7)N-162,180,119,108,123,123	41 (31.89 to 49.88)	89 (81.64 to 93.64)		
W Serogroup≥3-fold (M-7)N-162,180,119,108,123,123	28 (19.96 to 36.43)	80 (72.37 to 87.08)		
W Serogroup≥4-fold (M-7)N-162,180,119,108,123,123	20 (13.61 to 28.52)	73 (64.43 to 80.76)		
W Serogroup≥2-fold (M-13)N-162,180,119,108,123,123	94 (88.63 to 97.68)	61 (51.77 to 69.64)		
W Serogroup≥3-fold (M-13)N-162,180,119,108,123,123	92 (85.56 to 96.03)	46 (36.53 to 54.75)		
W Serogroup≥4-fold (M-13)N-162,180,119,108,123,123	89 (82.60 to 94.25)	29 (21.41 to 38.15)		
Y Serogroup≥2-fold (M-2) N-188,180,120,110,127,137	53 (43.70 to 61.68)	51 (42.42 to 59.73)		
Y Serogroup≥3-fold (M-2)N-188,180,120,110,127,137	41 (32.30 to 50.02)	43 (34.64 to 51.80)		
Y Serogroup≥4-fold (M-2)N-188,180,120,110,127,137	36 (27.88 to 45.22)	37 (29.13 to 45.89)		
Y Serogroup≥2-fold (M-3)N-188,180,120,110,127,137	46 (36.81 to 54.74)	83 (75.88 to 89.05)		
Y Serogroup≥3-fold (M-3)N-188,180,120,110,127,137	35 (26.43 to 43.60)	75 (67.08 to 82.16)		
Y Serogroup≥4-fold (M-3)N-188,180,120,110,127,137	31 (23.55 to 40.33)	66 (57.86 to 74.26)		
Y Serogroup≥2-fold (M-7)N-188,180,120,110,127,137	39 (30.08 to 47.63)	92 (86.09 to 95.92)		
Y Serogroup≥3-fold (M-7)N-188,180,120,110,127,137	28 (20.71 to 37.02)	87 (80.03 to 92.02)		
Y Serogroup≥4-fold (M-7)N-188,180,120,110,127,137	23 (15.86 to 31.12)	76 (67.87 to 82.80)		
Y Serogroup≥2-fold (M-13)N-188,180,120,110,127,137	94 (88.97 to 97.76)	72 (63.20 to 78.91)		
Y Serogroup≥3-fold (M-13)N-188,180,120,110,127,137	91 (84.08 to 95.02)	54 (45.30 to 62.56)		
Y Serogroup≥4-fold (M-13)N-188,180,120,110,127,137	89 (82.20 to 93.84)	47 (38.15 to 55.43)		

Statistical analyses

No statistical analyses for this end point

Secondary: The area under the curve (AUC) for percentage of subjects with hSBA titers ≥LLQ for all serogroups and strains.

End point title	The area under the curve (AUC) for percentage of subjects with hSBA titers ≥LLQ for all serogroups and strains.

End point description:

The area under the curve for percentage of subjects with hSBA titers ≥ LLQ for all serogroups (A, C, W and Y) and for all serogroup B test strains (M14459, 96217, NZ98/254 and M07-0241084) was summarized overall (from Month 0 to Month 13) and by period (from Month 0 to Month 2, Month 2 to Month 3, Month 3 to Month 7 and Month 7 to Month 13) by vaccine groups. It was computed as the sum of the trapezoidal areas and the time unit used was the month. AUC 0_13 = (r0+r2)(2-0)/2 + (r2+r3)(3-2)/2 + (r3+r7)(7-3)/2 + (r7+r13)(13-7)/2 with ri = percentages of subjects with both hSBA titers >= LLQ against N. meningitis for all serogroups A, C, W and Y and for all serogroup B test strains at Month 1. The LLQ for serogroups A,C,W and Y were 22.7,5.2,39.6 and 14.7 respectively. The LLQ for strains M14459,96217,NZ98/254 and M07-0241084 were 8.0,8.6,8.2 and 8.9 respectively.

End point type	Secondary

End point timeframe:
From Month 0 to Month 13

End point values	rMenB_0_2 Group	ABCWY_ 0_2 Group	ABCWY_0_1 Group	ABCWY_0_6 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	200	196	131	118
Units: Area Under Curve				
number (not applicable)				
Serogroup A(M- 0-2)N-191,189,129,113,126,140	26.52	38.01	98.62	38.05
Serogroup A(M-2-3)N-197,193,125,118,130,135	57.69	60.98	86.91	33.40
Serogroup A(M-3-7)N-191,194,124,118,127,136	292.53	264.81	243.86	252.54
Serogroup A(M-7-13)N-194,191,127,113,132,136	256.04	214.62	217.88	446.58
M14459(M-0-2)N-196,194,127,113,130,140	35.10	27.81	67.02	21.09
M14459(M-2-3)N-198,193,127,117,129,139	55.45	46.06	52.36	16.53
M14459(M-3-7)N-197,192,129,117,132,140	228.61	196.15	117.62	206.84
M14459(M-7-13)N-197,188,125,115,132,135	162.94	141.79	82.51	329.36
96217(M-0-2)N-197,190,130,117,130,134	93.52	91.00	124.70	88.27
96217(M2-3)N-197,192,130,117,132,134	85.03	80.02	95.77	58.55
96217(M-3-7)N-199,193,131,116,132,139	388.93	373.02	361.75	307.65
96217(M-7-13)N-200,191,127,117,132,139	545.92	515.49	495.00	561.47
NZ98/254(M-0-2)N-198,194,129,116,131,139	30.27	25.84	48.92	22.37
NZ98/254(M-2-3)N-198,194,129,117,131,137	55.56	40.77	37.21	15.89
NZ98/254(M-3-7)N-196,194,130,116,132,140	227.81	162.89	92.78	156.65
NZ98/254(M-7-13)N-200,193,129,117,130,138	142.59	105.40	90.34	242.66
M07-0241084(M-0-2)N-196,191,127,117,130,140	57.74	43.20	53.67	42.74
M07-0241084(M-2-3)N-198,189,129,116,128,137	52.46	37.16	34.01	28.33
M07-0241084(M-3-7)N-197,193,129,118,132,137	213.53	151.20	111.63	190.79
M07-0241084(M-7-13)N-198,190,130,116,130,136	217.26	159.73	145.97	301.71
Serogroup C(M-0-2)N-198,193,129,118,131,140	102.82	129.30	148.03	126.63
Serogroup C(M-2-3)N-197,194,129,117,132,136	78.78	91.97	99.22	82.97
Serogroup C(M-3-7)N-199,196,131,118,131,138	331.60	390.80	390.79	360.70
Serogroup C(M-7-13)N-196,192,130,116,130,139	382.55	567.41	574.69	589.70

Serogroup W(M-0-2)N-199,195,130,116,131,138	75.66	93.12	124.89	85.71
Serogroup W(M-2-3)N-186,190,129,114,131,137	68.51	81.75	90.33	65.66
Serogroup W(M-3-7)N-195,195,131,118,131,129	293.42	359.84	327.79	331.64
Serogroup W(M-7-13)N-194,192,130,117,130,139	305.31	444.54	434.34	543.61
Serogroup Y(M-0-2)N-199,193,129,115,131,139	36.25	76.31	99.44	67.83
Serogroup Y(M-2-3)N-197,195,128,116,132,138	24.51	79.32	83.26	58.88
Serogroup Y(M-3-7)N-199,194,131,118,132,139	100.05	339.26	339.26	303.62
Serogroup Y(M-7-13)N-199,191,129,117,131,139	125.13	425.13	389.69	520.64

End point values	ABCWY_0_11 Group	ABCWY_0_2_6 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	132	140		
Units: Area Under Curve				
number (not applicable)				
Serogroup A(M- 0-2)N-191,189,129,113,126,140	57.12	27.86		
Serogroup A(M-2-3)N-197,193,125,118,130,135	47.00	59.13		
Serogroup A(M-3-7)N-191,194,124,118,127,136	119.41	370.46		
Serogroup A(M-7-13)N-194,191,127,113,132,136	343.24	436.76		
M14459(M-0-2)N-196,194,127,113,130,140	40.10	18.57		
M14459(M-2-3)N-198,193,127,117,129,139	30.88	44.90		
M14459(M-3-7)N-197,192,129,117,132,140	84.60	325.33		
M14459(M-7-13)N-197,188,125,115,132,135	309.09	347.86		
96217(M-0-2)N-197,190,130,117,130,134	83.08	79.10		
96217(M2-3)N-197,192,130,117,132,134	52.33	74.25		
96217(M-3-7)N-199,193,131,116,132,139	172.73	392.59		
96217(M-7-13)N-200,191,127,117,132,139	411.36	578.42		
NZ98/254(M-0-2)N-198,194,129,116,131,139	31.33	20.13		
NZ98/254(M-2-3)N-198,194,129,117,131,137	24.05	42.93		
NZ98/254(M-3-7)N-196,194,130,116,132,140	65.46	282.91		
NZ98/254(M-7-13)N-200,193,129,117,130,138	257.90	277.24		
M07-0241084(M-0-2)N-196,191,127,117,130,140	58.93	47.53		

M07-0241084(M-2-3)N-198,189,129,116,128,137	34.47	41.65		
M07-0241084(M-3-7)N-197,193,129,118,132,137	110.94	251.09		
M07-0241084(M-7-13)N-198,190,130,116,130,136	282.69	320.48		
Serogroup C(M-0-2)N-198,193,129,118,131,140	135.79	128.34		
Serogroup C(M-2-3)N-197,194,129,117,132,136	88.21	92.85		
Serogroup C(M-3-7)N-199,196,131,118,131,138	339.12	398.53		
Serogroup C(M-7-13)N-196,192,130,116,130,139	545.04	595.68		
Serogroup W(M-0-2)N-199,195,130,116,131,138	103.94	84.23		
Serogroup W(M-2-3)N-186,190,129,114,131,137	75.19	78.97		
Serogroup W(M-3-7)N-195,195,131,118,131,129	297.71	392.61		
Serogroup W(M-7-13)N-194,192,130,117,130,139	512.92	550.19		
Serogroup Y(M-0-2)N-199,193,129,115,131,139	84.92	67.58		
Serogroup Y(M-2-3)N-197,195,128,116,132,138	67.70	75.50		
Serogroup Y(M-3-7)N-199,194,131,118,132,139	234.85	373.95		
Serogroup Y(M-7-13)N-199,191,129,117,131,139	454.48	537.41		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants reporting any solicited local or systemic AEs and other indicators of reactogenicity within 30 minutes after vaccination.

End point title	Number of participants reporting any solicited local or systemic AEs and other indicators of reactogenicity within 30 minutes after vaccination.

End point description:

Number of participants reporting any solicited local or systemic AEs and other indicators of reactogenicity within 30 minutes after each vaccination. Assessed solicited symptoms were Pain, erythema and induration. Assessed solicited systemic symptoms were Fatigue, headache, myalgia, arthralgia, loss of appetite, nausea, chills, and fever (body temperature ≥38.0°C).

End point type	Secondary

End point timeframe:

Within 30 minutes after vaccination

End point values	rMenB_0_2 Group	ABCWY_ 0_2 Group	ABCWY_0_1 Group	ABCWY_0_6 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	228	232	155	134
Units: Participants				
Any Induration(1st vacc)N-217,219,146,128,143,151	0	0	0	0
Grade3Induration(1stvacc)N-217,219,146,128,143,151	0	0	0	0
Any Induration(2nd vacc)N-215,217,150,125,144,151	0	0	0	0
Grade 3 Induration(2nd vaccination)	0	0	0	0
Any Induration(3rd vaccination)	0	0	0	0
Grade 3 Induration(3rd vaccination)	0	0	0	0
Any Induration(4th vaccination)	0	0	0	0
Grade 3 Induration(4th vaccination)	0	0	0	0
Any Induration(5th vaccination)	0	0	0	0
Grade 3 Induration(5th vaccination)	0	0	0	0
Any Erythema(1st vaccination)	1	0	0	0
Grade 3 Erythema(1st vaccination)	0	0	0	0
Any Erythema(2nd vaccination)	2	0	0	1
Grade 3 Erythema(2nd vaccination)	0	0	0	0
Any Erythema(3rd vaccination)	0	1	0	1
Grade 3 Erythema(3rd vaccination)	0	0	0	0
Any Erythema(4th vaccination)	0	1	0	0
Grade 3 Erythema(4th vaccination)	0	0	0	0
Any Erythema(5th vaccination)	0	0	0	0
Grade 3 Erythema(5th vaccination)	0	0	0	0
Any Pain(1st vaccination)	19	4	12	8
Grade 3 Pain(1st vaccination)	0	0	0	0
Any Pain(2nd vaccination)	10	12	11	9
Grade 3 Pain(2nd vaccination)	0	0	0	0
Any Pain(3rd vaccination)	10	11	8	7
Grade 3 Pain(3rd vaccination)	0	0	0	0
Any Pain(4th vaccination)	28	22	7	14
Grade 3 Pain(4th vaccination)	0	0	0	0
Any Pain(5th vaccination)	19	16	12	15
Grade 3 Pain(5th vaccination)	0	0	0	0
Any Nausea(1st vaccination)	0	0	2	1
Grade 3 Nausea(1st vaccination)	0	0	0	0
Any Nausea(2nd vaccination)	2	0	1	1
Grade 3 Nausea(2nd vaccination)	0	0	0	0
Any Nausea(3rd vaccination)	2	0	2	0
Grade 3 Nausea(3rd vaccination)	0	0	0	0
Any Nausea(4th vaccination)	2	0	2	0
Grade 3 Nausea(4th vaccination)	0	0	0	0
Any Nausea(5th vaccination)	1	0	3	1
Grade 3 Nausea(5th vaccination)	0	0	0	0
Any Fatigue (1st vaccination)	4	6	6	1
Grade 3 Fatigue(1st vaccination)	0	0	0	0
Any Fatigue (2nd vaccination)	4	3	1	1
Grade 3 Fatigue(2nd vaccination)	0	0	0	0
Any Fatigue (3rd vaccination)	2	4	0	1

Grade 3 Fatigue(3rd vaccination)	0	0	0	1
Any Fatigue (4th vaccination)	2	1	1	0
Grade 3 Fatigue(4th vaccination)	0	0	0	0
Any Fatigue (5th vaccination)	1	2	1	3
Grade 3 Fatigue(5th vaccination)	0	0	0	0
Any Myalgia(1st vaccination)	0	1	0	0
Grade 3 Myalgia(1st vaccination)	0	0	0	0
Any Myalgia(2nd vaccination)	0	0	1	0
Grade 3 Myalgia(2nd vaccination)	0	0	0	0
Any Myalgia(3rd vaccination)	0	0	0	1
Grade 3 Myalgia(3rd vaccination)	0	0	0	0
Any Myalgia(4th vaccination)	0	0	0	0
Grade 3 Myalgia(4th vaccination)	0	0	0	0
Any Myalgia(5th vaccination)	0	4	1	0
Grade 3 Myalgia(5th vaccination)	0	0	0	0
Any Arthralgia(1st vaccination)	0	0	0	0
Grade 3 Arthralgia(1st vaccination)	0	0	0	0
Any Arthralgia(2nd vaccination)	0	0	0	0
Grade 3 Arthralgia(2nd vaccination)	0	0	0	0
Any Arthralgia(3rd vaccination)	0	0	0	0
Grade 3 Arthralgia(3rd vaccination)	0	0	0	0
Any Arthralgia(4th vaccination)	0	0	0	0
Grade 3 Arthralgia(4th vaccination)	0	0	0	0
Any Arthralgia(5th vaccination)	0	0	0	0
Grade 3 Arthralgia(5th vaccination)	0	0	0	0
Any Headache(1st vaccination)	2	3	1	1
Grade 3 Headache(1st vaccination)	0	0	0	0
Any Headache(2nd vaccination)	3	1	2	1
Grade 3 Headache(2nd vaccination)	0	0	0	0
Any Headache(3rd vaccination)	2	1	2	0
Grade 3 Headache(3rd vaccination)	0	0	0	0
Any Headache(4th vaccination)	3	2	0	0
Grade 3 Headache(4th vaccination)	0	0	0	0
Any Headache(5th vaccination)	2	1	0	0
Grade 3 Headache(5th vaccination)	0	0	0	0
Any Chills(1st vaccination)	0	1	1	0
Grade 3 Chills(1st vaccination)	0	0	0	0
Any Chills(2nd vaccination)	1	1	1	1
Gradec3 Chills(2nd vaccination)	0	0	0	0
Any Chills(3rd vaccination)	1	1	0	0
Grade 3 Chills(3rd vaccination)	0	0	0	0
Any Chills(4th vaccination)	1	1	0	0
Grade 3 Chills(4th vaccination)	0	0	0	0
Any Chills(5th vaccination)	1	1	0	0
Grade 3 Chills(5th vaccination)	0	0	0	0
Any Appetite Loss(1st vaccination)	0	0	0	0
Grade 3 Appetite Loss(1st vaccination)	0	0	0	0
Any Appetite Loss(2nd vaccination)	0	0	0	0
Grade 3 Appetite Loss(2nd vaccination)	0	0	0	0
Any Appetite Loss(3rd vaccination)	0	0	0	0
Grade 3 Appetite Loss(3rd vaccination)	0	0	0	0
Any Appetite Loss(4th vaccination)	0	0	0	0

Grade 3 Appetite Loss(4th vaccination)	0	0	0	0
AnyAppetiteLoss(5th vaccination)	0	0	0	0
Grade 3 Appetite Loss(5th vaccination)	0	0	0	0
Fever(1st vaccination)	0	0	0	0
Fever(2nd vaccination)	0	0	0	0
Fever(3rd vaccination)	0	0	0	0
Fever(4th vaccination)	0	0	0	0
Fever(5th vaccination)	0	0	0	0
Pain/Fever prevention(1st vaccination)	0	0	0	0
Pain/Fever prevention(2nd vaccination)	0	2	0	0
Pain/Fever prevention(3rd vaccination)	1	0	0	0
Pain/Fever prevention(4th vaccination)	0	0	0	0
Pain/Fever prevention(5th vaccination)	0	0	0	0
Pain/Fever treatment(1st vaccination)	0	0	1	0
Pain/Fever treatment(2nd vaccination)	1	0	0	0
Pain/Fever treatment(3rd vaccination)	0	0	0	0
Pain/Fever treatment(4th vaccination)	0	1	0	0
Pain/Fever treatment(5th vaccination)	0	0	0	0

End point values	ABCWY_0_11 Group	ABCWY_0_2_6 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	151	159		
Units: Participants				
Any Induration(1st vacc)N-217,219,146,128,143,151	0	0		
Grade3Induration(1stvacc)N-217,219,146,128,143,151	0	0		
Any Induration(2nd vacc)N-215,217,150,125,144,151	0	0		
Grade 3 Induration(2nd vaccination)	0	0		
Any Induration(3rd vaccination)	0	0		
Grade 3 Induration(3rd vaccination)	0	0		
Any Induration(4th vaccination)	0	0		
Grade 3 Induration(4th vaccination)	0	0		
Any Induration(5th vaccination)	0	0		
Grade 3 Induration(5th vaccination)	0	0		
Any Erythema(1st vaccination)	1	0		
Grade 3 Erythema(1st vaccination)	0	0		
Any Erythema(2nd vaccination)	0	0		
Grade 3 Erythema(2nd vaccination)	0	0		
Any Erythema(3rd vaccination)	0	0		
Grade 3 Erythema(3rd vaccination)	0	0		
Any Erythema(4th vaccination)	0	1		
Grade 3 Erythema(4th vaccination)	0	0		
Any Erythema(5th vaccination)	0	0		
Grade 3 Erythema(5th vaccination)	0	0		
Any Pain(1st vaccination)	17	13		
Grade 3 Pain(1st vaccination)	0	0		
Any Pain(2nd vaccination)	14	9		

Grade 3 Pain(2nd vaccination)	0	0		
Any Pain(3rd vaccination)	5	13		
Grade 3 Pain(3rd vaccination)	0	0		
Any Pain(4th vaccination)	8	17		
Grade 3 Pain(4th vaccination)	0	0		
Any Pain(5th vaccination)	13	12		
Grade 3 Pain(5th vaccination)	0	0		
Any Nausea(1st vaccination)	2	2		
Grade 3 Nausea(1st vaccination)	0	0		
Any Nausea(2nd vaccination)	0	0		
Grade 3 Nausea(2nd vaccination)	0	0		
Any Nausea(3rd vaccination)	0	1		
Grade 3 Nausea(3rd vaccination)	0	0		
Any Nausea(4th vaccination)	1	0		
Grade 3 Nausea(4th vaccination)	0	0		
Any Nausea(5th vaccination)	0	1		
Grade 3 Nausea(5th vaccination)	0	0		
Any Fatigue (1st vaccination)	2	1		
Grade 3 Fatigue(1st vaccination)	0	0		
Any Fatigue (2nd vaccination)	2	0		
Grade 3 Fatigue(2nd vaccination)	0	0		
Any Fatigue (3rd vaccination)	1	2		
Grade 3 Fatigue(3rd vaccination)	0	0		
Any Fatigue (4th vaccination)	1	3		
Grade 3 Fatigue(4th vaccination)	0	0		
Any Fatigue (5th vaccination)	1	1		
Grade 3 Fatigue(5th vaccination)	0	0		
Any Myalgia(1st vaccination)	0	0		
Grade 3 Myalgia(1st vaccination)	0	0		
Any Myalgia(2nd vaccination)	3	1		
Grade 3 Myalgia(2nd vaccination)	0	0		
Any Myalgia(3rd vaccination)	0	0		
Grade 3 Myalgia(3rd vaccination)	0	0		
Any Myalgia(4th vaccination)	1	0		
Grade 3 Myalgia(4th vaccination)	0	0		
Any Myalgia(5th vaccination)	1	0		
Grade 3 Myalgia(5th vaccination)	0	0		
Any Arthralgia(1st vaccination)	0	0		
Grade 3 Arthralgia(1st vaccination)	0	0		
Any Arthralgia(2nd vaccination)	0	0		
Grade 3 Arthralgia(2nd vaccination)	0	0		
Any Arthralgia(3rd vaccination)	0	0		
Grade 3 Arthralgia(3rd vaccination)	0	0		
Any Arthralgia(4th vaccination)	0	0		
Grade 3 Arthralgia(4th vaccination)	0	0		
Any Arthralgia(5th vaccination)	0	0		
Grade 3 Arthralgia(5th vaccination)	0	0		
Any Headache(1st vaccination)	1	0		
Grade 3 Headache(1st vaccination)	0	0		
Any Headache(2nd vaccination)	1	1		
Grade 3 Headache(2nd vaccination)	0	0		
Any Headache(3rd vaccination)	1	1		

Grade 3 Headache(3rd vaccination)	0	0		
Any Headache(4th vaccination)	1	1		
Grade 3 Headache(4th vaccination)	0	0		
Any Headache(5th vaccination)	0	1		
Grade 3 Headache(5th vaccination)	0	0		
Any Chills(1st vaccination)	2	2		
Grade 3 Chills(1st vaccination)	0	0		
Any Chills(2nd vaccination)	0	0		
Gradec3 Chills(2nd vaccination)	0	0		
Any Chills(3rd vaccination)	0	0		
Grade 3 Chills(3rd vaccination)	0	0		
Any Chills(4th vaccination)	0	0		
Grade 3 Chills(4th vaccination)	0	0		
Any Chills(5th vaccination)	0	0		
Grade 3 Chills(5th vaccination)	0	0		
Any Appetite Loss(1st vaccination)	0	0		
Grade 3 Appetite Loss(1st vaccination)	0	0		
Any Appetite Loss(2nd vaccination)	0	0		
Grade 3 Appetite Loss(2nd vaccination)	0	0		
Any Appetite Loss(3rd vaccination)	0	0		
Grade 3 Appetite Loss(3rd vaccination)	0	0		
Any Appetite Loss(4th vaccination)	0	0		
Grade 3 Appetite Loss(4th vaccination)	0	0		
AnyAppetiteLoss(5th vaccination)	0	0		
Grade 3 Appetite Loss(5th vaccination)	0	0		
Fever(1st vaccination)	0	0		
Fever(2nd vaccination)	0	0		
Fever(3rd vaccination)	0	0		
Fever(4th vaccination)	0	0		
Fever(5th vaccination)	0	0		
Pain/Fever prevention(1st vaccination)	0	0		
Pain/Fever prevention(2nd vaccination)	0	0		
Pain/Fever prevention(3rd vaccination)	0	0		
Pain/Fever prevention(4th vaccination)	0	0		
Pain/Fever prevention(5th vaccination)	0	0		
Pain/Fever treatment(1st vaccination)	0	0		
Pain/Fever treatment(2nd vaccination)	0	1		
Pain/Fever treatment(3rd vaccination)	0	0		
Pain/Fever treatment(4th vaccination)	0	0		
Pain/Fever treatment(5th vaccination)	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants reporting any unsolicited AEs within 30 minutes after vaccination.

End point title	Number of participants reporting any unsolicited AEs within 30 minutes after vaccination.

End point description:

An unsolicited adverse event is an adverse event that was not solicited and that was spontaneously communicated by a participant and/or parent/legal guardian who has signed the informed consent. Number of participants reporting any unsolicited AE within 30 minutes after each vaccination.

End point type	Secondary

End point timeframe:

Within 30 minutes after vaccination

End point values	rMenB_0_2 Group	ABCWY_ 0_2 Group	ABCWY_0_1 Group	ABCWY_0_6 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	221	228	151	129
Units: Participants				
Dizziness	3	0	1	2
Presyncope	2	1	0	0
Syncope	0	1	1	0
Injection site pain	1	0	0	0
Asthenia	0	0	0	0
Dyspnoea	1	0	0	0
Fatigue	0	0	0	0
Headache	0	0	0	0
Hypoaesthesia	0	0	0	0
Injection site bruising	1	0	0	0
Injection site warmth	0	1	0	0
Pain	0	0	0	0
Paraesthesia	1	0	0	0
Pruritus allergic	0	0	1	0

End point values	ABCWY_0_11 Group	ABCWY_0_2_6 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	147	157		
Units: Participants				
Dizziness	0	1		
Presyncope	0	0		
Syncope	1	0		
Injection site pain	0	1		
Asthenia	0	1		
Dyspnoea	0	0		
Fatigue	1	0		
Headache	1	0		
Hypoaesthesia	1	0		
Injection site bruising	0	0		
Injection site warmth	0	0		
Pain	1	0		
Paraesthesia	0	0		
Pruritus allergic	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants reporting unsolicited AEs from Day 1 to Day 30 after any vaccination.

End point title	Number of participants reporting unsolicited AEs from Day 1 to Day 30 after any vaccination.

End point description:

The number of participants reporting unsolicited AEs and possibly or probably related unsolicited AEs were assessed.

End point type	Secondary

End point timeframe:

Day 1 through Day 30 after any vaccination

End point values	rMenB_0_2 Group	ABCWY_ 0_2 Group	ABCWY_0_1 Group	ABCWY_0_6 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	221	228	151	129
Units: Participants				
Any AE(s)	146	148	93	76
Possibly or Probably Related AE(s)	25	31	23	16

End point values	ABCWY_0_11 Group	ABCWY_0_2_6 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	147	157		
Units: Participants				
Any AE(s)	97	104		
Possibly or Probably Related AE(s)	18	27		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants reporting any solicited local or systemic adverse events (AEs) and other indicators of reactogenicity from Day 1 to Day 7.

End point title	Number of participants reporting any solicited local or systemic adverse events (AEs) and other indicators of reactogenicity

	from Day 1 to Day 7.

End point description:

Number of participants reporting any solicited local or systemic AEs and other indicators of reactogenicity from Day 1 (6 hours) to Day 7 after any meningococcal vaccination is reported.

End point type	Secondary

End point timeframe:

At Day 1 (6 hours) to Day 7 after vaccination

End point values	rMenB_0_2 Group	ABCWY_ 0_2 Group	ABCWY_0_1 Group	ABCWY_0_6 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	228	231	155	134
Units: Participants				
Any AE	225	228	153	131
Any Local AE	224	227	148	129
Any Systemic AE	201	201	143	117
Any Pain (1st vacc)	213	223	142	126
Grade 3 Pain (1st vacc)	9	13	2	10
Any Pain (2nd vacc)	32	34	122	41
Grade 3 Pain (2nd vacc)	0	1	5	0
Any Pain (3rd vacc)	193	185	38	26
Grade 3 Pain (3rd vacc)	11	7	0	0
Any Pain (4th vacc)	79	77	19	106
Grade 3 Pain (4th vacc)	1	0	0	10
Any Pain (5th vacc)	83	80	58	48
Grade 3 Pain (5th vacc)	0	1	1	0
Any Erythema (1st vacc)	23	21	16	11
Grade 3 Erythema (1st vacc)	0	1	1	0
Any Erythema (2nd vacc)	3	5	8	1
Grade3Erythema(2ndvacc)	0	0	1	0
Any Erythema (3rd vacc)	32	27	0	2
Grade3Erythema(3rdvacc)	2	6	0	0
Any Erythema (4th vacc)	1	1	0	10
Grade3Erythema(4thvacc)	0	0	0	1
Any Erythema (5th vacc)	1	1	1	0
Grade3Erythema(5thvacc)	0	0	0	0
AnyInduration(1st vacc)	21	20	12	13
Grade3Induration(1vacc)	0	0	0	1
AnyInduration(2nd vacc)	2	2	10	0
Grade3Induration(2vacc)	0	0	0	0
AnyInduration(3rd vacc)	24	17	0	0
Grade3Induration(3vacc)	2	0	0	0
AnyInduration(4th vacc)	2	3	0	10
Grade3Induration(4vacc)	0	0	0	1
AnyInduration(5th vacc)	2	3	1	2
Grade 3 Induration(5th vacc)	0	0	0	1
Any Fatigue (1st vacc)	126	121	84	68
Grade 3 Fatigue(1st vacc)	7	7	4	3
Any Fatigue (2nd vacc)	61	64	64	40

Grade 3 Fatigue(2nd vacc)	0	3	4	2
Any Fatigue (3rd vacc)	106	96	44	32
Garde 3 Fatigue(3rd vacc)	4	5	1	0
Any Fatigue (4th vacc)	50	56	37	51
Grade 3 Fatigue(4th vacc)	2	3	0	5
Any Fatigue (5th vacc)	62	59	37	41
Grade3Fatigue(5th vacc)	1	2	4	0
Any Headache (1st vacc)	103	92	65	52
Grade3Headache(1stvacc)	4	3	5	2
Any Headache (2nd vacc)	67	47	70	36
Grade3Headache(2ndvacc)	1	2	3	2
Any Headache (3rd vacc)	90	76	42	28
Grade3Headache(3rdvacc)	3	4	1	0
Any Headache (4th vacc)	49	35	26	44
Grade3Headache(4thvacc)	3	3	0	2
Any Headache (5th vacc)	64	40	33	33
Grade3Headache(5thvacc)	1	1	2	1
Any Myalgia (1st vacc)	62	53	39	34
Grade3Myalgia(1st vacc)	2	4	2	2
Any Myalgia (2nd vacc)	15	20	27	15
Grade3Myalgia(2nd vacc)	0	3	1	1
Any Myalgia (3rd vacc)	52	40	13	10
Grade3Myalgia(3rd vacc)	2	2	0	0
Any Myalgia (4th vacc)	17	20	11	26
Grade3Myalgia(4th vacc)	1	1	1	2
Any Myalgia (5th vacc)	16	26	19	12
Grade3Myalgia(5th vacc)	0	1	0	0
AnyAppetite Loss(1vacc)	41	33	28	22
Grade3AppetiteLoss(1vacc)	2	3	0	0
AnyAppetiteLoss(2vacc)	17	11	15	12
Grade3AppetiteLoss(2vacc)	0	1	0	0
AnyAppetiteLoss(3vacc)	28	28	7	7
Grade3AppetiteLoss(3vacc)	1	0	1	0
AnyAppetiteLoss(4vacc)	11	10	4	13
Grade3AppetiteLoss(4vacc)	0	0	0	0
AnyAppetiteLoss(5vacc)	18	14	9	9
Grade3AppetiteLoss(5vacc)	0	0	1	0
Any Nausea (1st vacc)	42	36	28	17
Grade 3 Nausea(1stvacc)	1	0	0	0
Any Nausea (2nd vacc)	17	15	20	10
Grade 3 Nausea(2nd vacc)	0	0	0	0
Any Nausea (3rd vacc)	35	24	10	8
Grade 3 Nausea(3rd vacc)	0	0	0	0
Any Nausea (4th vacc)	21	13	9	11
Grade 3 Nausea(4th vacc)	1	0	0	0
Any Nausea (5th vacc)	16	15	8	11
Grade 3 Nausea(5th vacc)	0	0	0	0
Any Chills (1st vacc)	45	36	41	24
Grade 3 Chills(1stvacc)	1	0	1	1
Any Chills (2nd vacc)	17	26	26	12
Grade 3 Chills(2ndvacc)	0	1	1	0
Any Chills(3rd vacc)	33	33	9	7

Grade 3 Chills(3rdvacc)	1	1	0	0
Any Chills(4thvacc)	11	11	10	12
Grade 3 Chills(4thvacc)	2	0	0	0
Any Chills (5th vacc)	19	23	17	11
Grade 3 Chills(5vacc)	0	0	0	1
Fever (1st vacc)	5	4	5	1
Fever (2nd vacc)	2	6	4	2
Fever (3rd vacc)	6	3	2	0
Fever (4th vacc)	0	2	0	3
Fever (5th vacc)	5	1	2	0
Pain/Fever prevention(1)	28	34	21	26
Pain/Fever prevention(2)	5	7	18	5
Pain/Fever prevention(3)	32	34	3	2
Pain/Fever prevention(4)	6	5	3	19
Pain/Fever prevention(5)	5	9	4	1
Pain/Fever treatment(1)	31	45	27	32
Pain/Fever treatment(2)	3	4	20	3
Pain/Fever treatment(3)	38	37	2	4
Pain/Fever treatment(4)	7	4	2	22
Pain/Fever treatment(5)	3	8	2	3
Any Arthralgia(1st vacc)	25	14	13	17
Grade3Arthralgia(1stvacc)	0	1	0	0
Any Arthralgia (2nd vacc)	7	11	10	9
Grade3Arthralgia(2ndvacc)	0	0	0	1
Any Arthralgia(3rd vacc)	16	7	4	3
Grade3Arthralgia(3rdvacc)	0	1	0	0
Any Arthralgia(4th vacc)	8	10	5	10
Grade3Arthralgia(4thvacc)	1	0	0	0
Any Arthralgia(5th vacc)	8	9	8	6
Grade3Arthralgia(5thvacc)	0	0	0	0

End point values	ABCWY_0_11 Group	ABCWY_0_2_6 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	151	159		
Units: Participants				
Any AE	151	157		
Any Local AE	148	156		
Any Systemic AE	134	143		
Any Pain (1st vacc)	80	146		
Grade 3 Pain (1st vacc)	0	6		
Any Pain (2nd vacc)	135	51		
Grade 3 Pain (2nd vacc)	11	0		
Any Pain (3rd vacc)	16	133		
Grade 3 Pain (3rd vacc)	0	5		
Any Pain (4th vacc)	44	138		
Grade 3 Pain (4th vacc)	0	9		
Any Pain (5th vacc)	119	64		
Grade 3 Pain (5th vacc)	11	1		

Any Erythema (1st vacc)	1	23		
Grade 3 Erythema (1st vacc)	0	2		
Any Erythema (2nd vacc)	17	2		
Grade3Erythema(2ndvacc)	3	0		
Any Erythema (3rd vacc)	0	19		
Grade3Erythema(3rdvacc)	0	1		
Any Erythema (4th vacc)	0	13		
Grade3Erythema(4thvacc)	0	4		
Any Erythema (5th vacc)	11	0		
Grade3Erythema(5thvacc)	1	0		
AnyInduration(1st vacc)	3	19		
Grade3Induration(1vacc)	0	1		
AnyInduration(2nd vacc)	11	2		
Grade3Induration(2vacc)	0	0		
AnyInduration(3rd vacc)	1	20		
Grade3Induration(3vacc)	0	0		
AnyInduration(4th vacc)	0	14		
Grade3Induration(4vacc)	0	1		
AnyInduration(5th vacc)	16	1		
Grade 3 Induration(5th vacc)	1	0		
Any Fatigue (1st vacc)	68	76		
Grade 3 Fatigue(1st vacc)	3	4		
Any Fatigue (2nd vacc)	64	49		
Grade 3 Fatigue(2nd vacc)	1	0		
Any Fatigue (3rd vacc)	32	55		
Garde 3 Fatigue(3rd vacc)	1	1		
Any Fatigue (4th vacc)	35	73		
Grade 3 Fatigue(4th vacc)	2	3		
Any Fatigue (5th vacc)	51	46		
Grade3Fatigue(5th vacc)	6	3		
Any Headache (1st vacc)	63	64		
Grade3Headache(1stvacc)	2	3		
Any Headache (2nd vacc)	63	41		
Grade3Headache(2ndvacc)	4	2		
Any Headache (3rd vacc)	30	53		
Grade3Headache(3rdvacc)	3	0		
Any Headache (4th vacc)	26	52		
Grade3Headache(4thvacc)	0	4		
Any Headache (5th vacc)	52	37		
Grade3Headache(5thvacc)	2	2		
Any Myalgia (1st vacc)	33	40		
Grade3Myalgia(1st vacc)	0	3		
Any Myalgia (2nd vacc)	37	18		
Grade3Myalgia(2nd vacc)	1	0		
Any Myalgia (3rd vacc)	13	34		
Grade3Myalgia(3rd vacc)	2	2		
Any Myalgia (4th vacc)	13	39		
Grade3Myalgia(4th vacc)	0	2		
Any Myalgia (5th vacc)	21	19		
Grade3Myalgia(5th vacc)	1	1		
AnyAppetite Loss(1vacc)	14	18		
Grade3AppetiteLoss(1vacc)	0	0		

AnyAppetiteLoss(2vacc)	19	9		
Grade3AppetiteLoss(2vacc)	2	0		
AnyAppetiteLoss(3vacc)	11	17		
Grade3AppetiteLoss(3vacc)	1	0		
AnyAppetiteLoss(4vacc)	11	23		
Grade3AppetiteLoss(4vacc)	0	0		
AnyAppetiteLoss(5vacc)	22	7		
Grade3AppetiteLoss(5vacc)	0	0		
Any Nausea (1st vacc)	26	21		
Grade 3 Nausea(1stvacc)	0	1		
Any Nausea (2nd vacc)	26	15		
Grade 3 Nausea(2nd vacc)	0	0		
Any Nausea (3rd vacc)	4	21		
Grade 3 Nausea(3rd vacc)	0	0		
Any Nausea (4th vacc)	14	23		
Grade 3 Nausea(4th vacc)	0	0		
Any Nausea (5th vacc)	21	12		
Grade 3 Nausea(5th vacc)	0	0		
Any Chills (1st vacc)	27	40		
Grade 3 Chills(1stvacc)	2	1		
Any Chills (2nd vacc)	32	15		
Grade 3 Chills(2ndvacc)	0	0		
Any Chills(3rd vacc)	12	22		
Grade 3 Chills(3rdvacc)	1	0		
Any Chills(4thvacc)	9	31		
Grade 3 Chills(4thvacc)	0	1		
Any Chills (5th vacc)	22	13		
Grade 3 Chills(5vacc)	0	0		
Fever (1st vacc)	2	3		
Fever (2nd vacc)	9	3		
Fever (3rd vacc)	4	4		
Fever (4th vacc)	0	7		
Fever (5th vacc)	3	1		
Pain/Fever prevention(1)	5	34		
Pain/Fever prevention(2)	24	7		
Pain/Fever prevention(3)	3	21		
Pain/Fever prevention(4)	3	25		
Pain/Fever prevention(5)	26	3		
Pain/Fever treatment(1)	6	31		
Pain/Fever treatment(2)	29	4		
Pain/Fever treatment(3)	2	23		
Pain/Fever treatment(4)	2	27		
Pain/Fever treatment(5)	29	2		
Any Arthralgia(1st vacc)	12	14		
Grade3Arthralgia(1stvacc)	1	2		
Any Arthralgia (2nd vacc)	8	7		
Grade3Arthralgia(2ndvacc)	0	1		
Any Arthralgia(3rd vacc)	6	11		
Grade3Arthralgia(3rdvacc)	0	0		
Any Arthralgia(4th vacc)	7	18		
Grade3Arthralgia(4thvacc)	0	2		
Any Arthralgia(5th vacc)	11	11		

Grade3Arthralgia(5thvacc)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants reporting any serious AE (SAE), medically attended AEs (MAAEs), AEs leading to premature withdrawal

End point title	Number of participants reporting any serious AE (SAE), medically attended AEs (MAAEs), AEs leading to premature withdrawal

End point description:

The number of participants reporting any SAE, possibly or probably related SAE(s), medically-attended AEs, AEs leading to premature withdrawal, AEs leading to death, AEs leading to hospitalization and AEs leading to dose reduction, interruption and delay in study vaccination during the entire study period is reported.

End point type	Secondary

End point timeframe:

During the entire study period (Month 0 to Month 13)

End point values	rMenB_0_2 Group	ABCWY_ 0_2 Group	ABCWY_0_1 Group	ABCWY_0_6 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	221	228	151	129
Units: Participants				
Any SAE(s)	9	3	8	7
Possibly or Probably Related SAE(s)	0	1	1	0
Medically Attended AE(s)	103	97	68	57
AE(s) leading to premature withdrawal	2	6	4	2
AE(s) leading to Death	0	0	0	0
AE(s) leading to Hospitalization	9	1	7	6
AE(s)leadingtodosereduction,interruption,vaccdelay	8	8	7	2

End point values	ABCWY_0_11 Group	ABCWY_0_2_6 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	147	157		
Units: Participants				
Any SAE(s)	2	6		
Possibly or Probably Related SAE(s)	0	0		
Medically Attended AE(s)	67	79		
AE(s) leading to premature withdrawal	1	3		
AE(s) leading to Death	0	0		

AE(s) leading to Hospitalization	1	6		
AE(s)leadingtodosereduction,interruption,vaccdelay	4	5		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited AEs were collected from day 1 to day 7, Unsolicited AEs were collected from day 1 to day 30, SAEs were collected throughout the entire study period.

Adverse event reporting additional description:

Solicited AEs were collected by Systematic assessment; Unsolicited AEs were collected by non-systematic assessment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups

Reporting group title	rMenB_0_2 Group

Reporting group description:

Subjects received two injections of Bexsero vaccine at Visit Month 0 and Visit Month 2, Havrix vaccine at Visit Month 6 and Visit Month 12 and saline placebo at Visit Month 1.

Reporting group title	ABCWY_ 0_2 Group

Reporting group description:

Subjects received MenABCWY vaccine at Visit Month 0 and Visit Month 2, Havrix vaccine at Visit Month 6 and Visit Month 12 and saline placebo at Visit Month 1.

Reporting group title	ABCWY_0_1 Group

Reporting group description:

Subjects received MenABCWY vaccine at Visit Month 0 and Visit Month 1, Havrix vaccine at Visit Month 2 and Visit Month 12 and saline placebo at Visit Month 6.

Reporting group title	ABCWY_0_6 Group

Reporting group description:

Subjects received MenABCWY vaccine at Visit Month 0 and Visit Month 6, Havrix vaccine at Visit Month 1 and Visit Month 12 and saline placebo at Visit Month 2.

Reporting group title	ABCWY_0_11 Group

Reporting group description:

Subjects received MenABCWY vaccine at Visit Month 1 and Visit Month 12, Havrix vaccine at Visit Month 0 and Visit Month 6 and saline placebo at Visit Month 2.

Reporting group title	ABCWY_0_2_6 Group

Reporting group description:

Subjects received MenABCWY vaccine at Visit Month 0, Visit Month 2 and Visit Month 6 and Havrix vaccine at Visit Month 1 and Visit Month 12.

Serious adverse events	rMenB_0_2 Group	ABCWY_ 0_2 Group	ABCWY_0_1 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 228 (3.95%)	3 / 231 (1.30%)	8 / 155 (5.16%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibroadenoma of breast			

subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion incomplete			
subjects affected / exposed	1 / 228 (0.44%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 228 (0.44%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Testicular torsion			
subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 228 (0.44%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			

subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 228 (0.00%)	1 / 231 (0.43%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Carbon monoxide poisoning			
subjects affected / exposed	0 / 228 (0.00%)	1 / 231 (0.43%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			
subjects affected / exposed	1 / 228 (0.44%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrioventricular block second degree			
subjects affected / exposed	1 / 228 (0.44%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Partial seizures			
subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Seizure			
subjects affected / exposed	0 / 228 (0.00%)	1 / 231 (0.43%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	2 / 228 (0.88%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal migraine			
subjects affected / exposed	1 / 228 (0.44%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	1 / 228 (0.44%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Tubulointerstitial nephritis			

subjects affected / exposed	1 / 228 (0.44%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Connective tissue disorder			
subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Torticollis			
subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	1 / 228 (0.44%)	0 / 231 (0.00%)	2 / 155 (1.29%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	1 / 228 (0.44%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infectious mononucleosis			
subjects affected / exposed	1 / 228 (0.44%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	1 / 228 (0.44%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic inflammatory disease			
subjects affected / exposed	1 / 228 (0.44%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonsillar abscess			
subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 228 (0.44%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Failure to thrive			
subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	1 / 155 (0.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			

subjects affected / exposed	0 / 228 (0.00%)	0 / 231 (0.00%)	0 / 155 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	ABCWY_0_6 Group	ABCWY_0_11 Group	ABCWY_0_2_6 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 134 (5.22%)	2 / 151 (1.32%)	6 / 159 (3.77%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibroadenoma of breast			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	1 / 134 (0.75%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion incomplete			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 134 (0.75%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

Testicular torsion			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental disorder			
subjects affected / exposed	1 / 134 (0.75%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Carbon monoxide poisoning			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Forearm fracture			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Atrioventricular block second degree			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Partial seizures			
subjects affected / exposed	0 / 134 (0.00%)	1 / 151 (0.66%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 134 (0.00%)	1 / 151 (0.66%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal migraine			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	1 / 134 (0.75%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			

subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	1 / 134 (0.75%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Connective tissue disorder			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Torticollis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			

subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 134 (0.75%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious mononucleosis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic inflammatory disease			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonsillar abscess			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis			
subjects affected / exposed	1 / 134 (0.75%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Failure to thrive			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obesity			
subjects affected / exposed	0 / 134 (0.00%)	0 / 151 (0.00%)	1 / 159 (0.63%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	1 / 134 (0.75%)	0 / 151 (0.00%)	0 / 159 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	rMenB_0_2 Group	ABCWY_ 0_2 Group	ABCWY_0_1 Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	226 / 228 (99.12%)	229 / 231 (99.13%)	153 / 155 (98.71%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Arthralgia			
subjects affected / exposed	48 / 228 (21.05%)	48 / 231 (20.78%)	28 / 155 (18.06%)
occurrences (all)	109	125	57
Injury, poisoning and procedural complications			
Respiratory tract infection			
subjects affected / exposed	15 / 228 (6.58%)	12 / 231 (5.19%)	10 / 155 (6.45%)
occurrences (all)	24	15	16
Nervous system disorders			
Headache			
subjects affected / exposed	165 / 228 (72.37%)	149 / 231 (64.50%)	114 / 155 (73.55%)
occurrences (all)	830	593	496
General disorders and administration			

site conditions			
Chills			
subjects affected / exposed	80 / 228 (35.09%)	76 / 231 (32.90%)	61 / 155 (39.35%)
occurrences (all)	236	216	172
Fatigue			
subjects affected / exposed	169 / 228 (74.12%)	165 / 231 (71.43%)	119 / 155 (76.77%)
occurrences (all)	956	891	534
Injection site erythema			
subjects affected / exposed	131 / 228 (57.46%)	131 / 231 (56.71%)	80 / 155 (51.61%)
occurrences (all)	465	367	271
Injection site induration			
subjects affected / exposed	110 / 228 (48.25%)	98 / 231 (42.42%)	67 / 155 (43.23%)
occurrences (all)	437	359	260
Injection site pain			
subjects affected / exposed	221 / 228 (96.93%)	225 / 231 (97.40%)	148 / 155 (95.48%)
occurrences (all)	1870	1598	1003
Pyrexia			
subjects affected / exposed	27 / 228 (11.84%)	27 / 231 (11.69%)	20 / 155 (12.90%)
occurrences (all)	37	34	26
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	16 / 228 (7.02%)	9 / 231 (3.90%)	6 / 155 (3.87%)
occurrences (all)	22	9	6
Nausea			
subjects affected / exposed	74 / 228 (32.46%)	68 / 231 (29.44%)	51 / 155 (32.90%)
occurrences (all)	232	145	136
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	12 / 228 (5.26%)	5 / 231 (2.16%)	6 / 155 (3.87%)
occurrences (all)	14	6	7
Oropharyngeal pain			
subjects affected / exposed	12 / 228 (5.26%)	13 / 231 (5.63%)	9 / 155 (5.81%)
occurrences (all)	14	13	13
Musculoskeletal and connective tissue disorders			
Myalgia			

subjects affected / exposed	103 / 228 (45.18%)	99 / 231 (42.86%)	69 / 155 (44.52%)
occurrences (all)	271	315	169
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	15 / 228 (6.58%)	11 / 231 (4.76%)	13 / 155 (8.39%)
occurrences (all)	16	11	13
Nasopharyngitis			
subjects affected / exposed	37 / 228 (16.23%)	30 / 231 (12.99%)	28 / 155 (18.06%)
occurrences (all)	53	50	40
Pharyngitis			
subjects affected / exposed	16 / 228 (7.02%)	21 / 231 (9.09%)	7 / 155 (4.52%)
occurrences (all)	16	21	9
Rhinitis			
subjects affected / exposed	15 / 228 (6.58%)	18 / 231 (7.79%)	7 / 155 (4.52%)
occurrences (all)	18	21	10
Tonsillitis			
subjects affected / exposed	7 / 228 (3.07%)	10 / 231 (4.33%)	3 / 155 (1.94%)
occurrences (all)	9	11	4
Upper respiratory tract infection			
subjects affected / exposed	53 / 228 (23.25%)	58 / 231 (25.11%)	37 / 155 (23.87%)
occurrences (all)	74	92	52
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	69 / 228 (30.26%)	64 / 231 (27.71%)	45 / 155 (29.03%)
occurrences (all)	208	164	107

Non-serious adverse events	ABCWY_0_6 Group	ABCWY_0_11 Group	ABCWY_0_2_6 Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	131 / 134 (97.76%)	151 / 151 (100.00%)	158 / 159 (99.37%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Arthralgia			
subjects affected / exposed	31 / 134 (23.13%)	27 / 151 (17.88%)	38 / 159 (23.90%)
occurrences (all)	96	68	101
Injury, poisoning and procedural complications			

Respiratory tract infection			
subjects affected / exposed	5 / 134 (3.73%)	6 / 151 (3.97%)	10 / 159 (6.29%)
occurrences (all)	12	12	13
Nervous system disorders			
Headache			
subjects affected / exposed	93 / 134 (69.40%)	110 / 151 (72.85%)	117 / 159 (73.58%)
occurrences (all)	450	478	530
General disorders and administration site conditions			
Chills			
subjects affected / exposed	40 / 134 (29.85%)	62 / 151 (41.06%)	70 / 159 (44.03%)
occurrences (all)	136	173	208
Fatigue			
subjects affected / exposed	98 / 134 (73.13%)	105 / 151 (69.54%)	120 / 159 (75.47%)
occurrences (all)	533	559	633
Injection site erythema			
subjects affected / exposed	80 / 134 (59.70%)	89 / 151 (58.94%)	97 / 159 (61.01%)
occurrences (all)	268	284	398
Injection site induration			
subjects affected / exposed	53 / 134 (39.55%)	70 / 151 (46.36%)	85 / 159 (53.46%)
occurrences (all)	176	248	458
Injection site pain			
subjects affected / exposed	129 / 134 (96.27%)	148 / 151 (98.01%)	154 / 159 (96.86%)
occurrences (all)	1065	1087	1592
Pyrexia			
subjects affected / exposed	13 / 134 (9.70%)	25 / 151 (16.56%)	26 / 159 (16.35%)
occurrences (all)	16	33	32
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	5 / 134 (3.73%)	9 / 151 (5.96%)	9 / 159 (5.66%)
occurrences (all)	6	12	12
Nausea			
subjects affected / exposed	47 / 134 (35.07%)	56 / 151 (37.09%)	62 / 159 (38.99%)
occurrences (all)	85	167	149
Respiratory, thoracic and mediastinal disorders			
Cough			

subjects affected / exposed	1 / 134 (0.75%)	1 / 151 (0.66%)	3 / 159 (1.89%)
occurrences (all)	1	1	3
Oropharyngeal pain			
subjects affected / exposed	7 / 134 (5.22%)	5 / 151 (3.31%)	7 / 159 (4.40%)
occurrences (all)	9	6	8
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	54 / 134 (40.30%)	65 / 151 (43.05%)	81 / 159 (50.94%)
occurrences (all)	178	213	244
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	9 / 134 (6.72%)	10 / 151 (6.62%)	10 / 159 (6.29%)
occurrences (all)	11	12	10
Nasopharyngitis			
subjects affected / exposed	21 / 134 (15.67%)	24 / 151 (15.89%)	25 / 159 (15.72%)
occurrences (all)	38	34	44
Pharyngitis			
subjects affected / exposed	8 / 134 (5.97%)	11 / 151 (7.28%)	15 / 159 (9.43%)
occurrences (all)	8	14	15
Rhinitis			
subjects affected / exposed	6 / 134 (4.48%)	5 / 151 (3.31%)	11 / 159 (6.92%)
occurrences (all)	6	5	14
Tonsillitis			
subjects affected / exposed	6 / 134 (4.48%)	9 / 151 (5.96%)	5 / 159 (3.14%)
occurrences (all)	8	10	5
Upper respiratory tract infection			
subjects affected / exposed	31 / 134 (23.13%)	35 / 151 (23.18%)	37 / 159 (23.27%)
occurrences (all)	46	51	51
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	43 / 134 (32.09%)	45 / 151 (29.80%)	52 / 159 (32.70%)
occurrences (all)	91	131	121

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 April 2014	The protocol was amended primarily to address comments from CBER on the previous version of the protocol, relating to addition of secondary immunogenicity objective and inclusion of detail on safety data collection and randomization procedures. Additional changes were made to ensure that the subjects/parents/legal guardians were encouraged to contact sites during the entire study in case medically-attended AEs or any AEs which was perceived as being of concern. Additionally the placebo was provided as ampoules instead of the vials and the protocol text was amended accordingly.
03 February 2015	The protocol was amended to further clarify certain sections and to correct the content errors/typographical errors which were recognized in the protocol version 3.0.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported