Clinical trial results:
A Phase 3b, Single-Center, Open-label Study to Assess the Immunogenicity and Safety of Novartis Meningococcal B Recombinant Vaccine When Administered at a 0, 2-Month Schedule in Healthy at-Risk Adults Aged 18 to 65 Years Inclusive.

Summary

EudraCT number	2012-005815-25
Trial protocol	DE
Global end of trial date	14 April 2014

Results information

Result version number	v1 (current)
This version publication date	11 May 2016
First version publication date	03 May 2015

Trial information

Trial identification

Sponsor protocol code	V72_59

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01911221
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Vaccines and Diagnostics
Sponsor organisation address	Via Fiorentina 1, Siena, Italy, 53100
Public contact	Posting Director, Novartis Vaccines and Diagnostics, RegistryContactVaccinesUS@novartis.com
Scientific contact	Posting Director, Novartis Vaccines and Diagnostics, RegistryContactVaccinesUS@novartis.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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	16 September 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 April 2014
Global end of trial reached?	Yes
Global end of trial date	14 April 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the immune response, serum bactericidal assay (hSBA) will be performed against the N. meningitidis serogroup B indicator strains H44/76, NZ98/254, 5/99 M10713 strain at one month after a vaccination course of two doses of rMenB+OMV NZ administered two months apart.

Characterisation of the immune response against vaccine antigen 287-953, as measured by ELISA at one month after a vaccination course of two doses of rMenB+OMV NZ administered two months apart. To evaluate the safety and tolerability of two doses of rMenB+OMV NZ vaccine given two months apart, in healthy at-risk adults.

Protection of trial subjects:

This clinical study was designed and was to be implemented and reported in accordance with the International Conference on Harmonisation (ICH) Tripartite Guidelines for Good Clinical Practices (GCP), with applicable local regulations including European Directive 2001/20/EC, Novartis Vaccines and Diagnostics codes on protection of human rights, and with the ethical principles laid down in the Declaration of Helsinki.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 August 2013
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	Germany: 13
Worldwide total number of subjects	13
EEA total number of subjects	13

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)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	13
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited from single study center in Germany.

Pre-assignment

Screening details:

All enrolled subjects were included in the trial.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	rMenB+OMV NZ

Arm description:

Subjects received two doses of rMenB +OMV NZ at 0 month and 2 month schedule.

Arm type	Experimental
Investigational medicinal product name	rMenB+OMV NZ
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Each dose 0.5 mL of injectable solution was administered intramuscularly.

Number of subjects in period 1	rMenB+OMV NZ
Started	13
Completed	13

Baseline characteristics

Reporting groups	
Reporting group title	rMenB+OMV NZ
Reporting group description:	
Subjects received two doses of rMenB +OMV NZ at 0 month and 2 month schedule.	

Reporting group values	rMenB+OMV NZ	Total	
Number of subjects	13	13	
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)		0	
Adolescents (12-17 years)		0	
Adults (18-64 years)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
arithmetic mean	38.5		
standard deviation	± 12.2	-	
Gender categorical Units: Subjects			
Female	10	10	
Male	3	3	

End points

End points reporting groups

Reporting group title	rMenB+OMV NZ
Reporting group description:	
Subjects received two doses of rMenB +OMV NZ at 0 month and 2 month schedule.	
Subject analysis set title	All Enrolled Set
Subject analysis set type	Full analysis
Subject analysis set description:	
All screened subjects who provided informed consent and provided demographic and/or baseline screening assessments, regardless of the subject's treatment status in the study and received a subject ID.	
Subject analysis set title	Full Analysis Set (FAS)
Subject analysis set type	Full analysis
Subject analysis set description:	
All subjects in the enrolled set who received a study vaccination and provided an evaluable serum sample at 1 month after the second dose of rMenB+OMV NZ, with assay result available for at least 1 of the serogroup B indicator strains or M10713 strain or ELISA.	
Subject analysis set title	Safety Set (Solicited AEs & other solicited reactions)
Subject analysis set type	Safety analysis
Subject analysis set description:	
All subjects in the exposed set who provided postvaccination reactogenicity data.	
Subject analysis set title	Safety Set (unsolicited AEs)
Subject analysis set type	Safety analysis
Subject analysis set description:	
All subjects in the exposed set who had postvaccination unsolicited AE records.	
Subject analysis set title	Safety Set (Overall)
Subject analysis set type	Safety analysis
Subject analysis set description:	
All subjects in the exposed set who had either postvaccination AEs or reactogenicity records.	

Primary: 1. Geometric Mean Human Serum Bactericidal Activity Titers Against N Meningitidis Serogroup B Strains Following A Two-dose Vaccination Schedule

End point title	1. Geometric Mean Human Serum Bactericidal Activity Titers Against N Meningitidis Serogroup B Strains Following A Two-dose Vaccination Schedule[1]
End point description:	
The immunogenicity was assessed to evaluate the human serum bactericidal activity (hSBA) against the indicator strains of N meningitidis serogroup B (H44/76, 5/99, NZ98/254) and M10713 strain at baseline and at one month after the second vaccination. Analysis was done on Full Analysis Set.	
End point type	Primary
End point timeframe:	
Day 1 and Day 91	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analyses of immunogenicity and safety were descriptive.

End point values	rMenB+OMV NZ			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: Titers				
geometric mean (confidence interval 95%)				
H44/76 Prevaccination (Day 1)	1.18 (0.92 to 1.52)			
H44/76 Post 2nd vaccination (Day 91)	53 (34 to 84)			
5/99 Prevaccination (Day 1)	2.27 (1.34 to 3.85)			
5/99 Post 2nd vaccination (Day 91)(N=12)	143 (57 to 356)			
NZ98/254 Prevaccination (Day 1)	1.09 (0.91 to 1.31)			
NZ98/254 Post 2nd vaccination (Day 91)(N=12)	15 (5.41 to 43)			
M10713 Prevaccination (Day 1)	21 (12 to 39)			
M10713 Post 2nd vaccination (Day 91)(N=12)	56 (31 to 99)			

Statistical analyses

No statistical analyses for this end point

Primary: 2. Geometric Mean Ratios Against N Meningitidis Serogroup B Strains Following A Two-dose Vaccination Schedule

End point title	2. Geometric Mean Ratios Against N Meningitidis Serogroup B Strains Following A Two-dose Vaccination Schedule[2]

End point description:

The immunogenicity was assessed to evaluate the hSBA in terms of geometric mean ratios within subjects against the indicator strains of N meningitidis serogroup B (H44/76, 5/99, NZ98/254) and strain M10713 at one month after the second vaccination versus baseline.
Analysis was done on Full Analysis Set.

End point type	Primary

End point timeframe:

Day 1 and Day 91

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analyses of immunogenicity and safety were descriptive.

End point values	rMenB+OMV NZ			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: Ratio				
geometric mean (confidence interval 95%)				
H44/76 (Day 91/Day 1)	45 (29 to 70)			
5/99 (Day 91/Day 1)(N=12)	59 (21 to 166)			
NZ98/254 (Day 91/Day 1)(N=12)	14 (5.17 to 37)			

M10713 (Day 91/Day 1)(N=12)	2.99 (1.43 to 6.27)			

Statistical analyses

No statistical analyses for this end point

Primary: 3. Percentages Of Subjects With hSBA≥ 1:5 Titers Against N Meningitidis Serogroup B Strains Following Two-Dose Vaccination Schedule.

End point title	3. Percentages Of Subjects With hSBA≥ 1:5 Titers Against N Meningitidis Serogroup B Strains Following Two-Dose Vaccination Schedule.[3]

End point description:

The immunogenicity was assessed to evaluate the hSBA titers ≥ 1:5 in terms of percentages of subjects against N meningitidis serogroup B (H44/76, 5/99, NZ98/254) and strain M10713 following a two-dose vaccination schedule with rMenB+OMV NZ vaccine.
Analysis was done on Full Analysis Set.

End point type	Primary

End point timeframe:

Day 1 and Day 91

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analyses of immunogenicity and safety were descriptive.

End point values	rMenB+OMV NZ			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: Percentages of subjects				
number (confidence interval 95%)				
H44/76 Prevaccination (Day 1)	0 (0 to 25)			
H44/76 Post 2nd vaccination (Day 91)	100 (75 to 100)			
5/99 Prevaccination (Day 1)	31 (9 to 61)			
5/99 Post 2nd vaccination (Day 91)(N=12)	100 (74 to 100)			
NZ98/254 Prevaccination (Day 1)	0 (0 to 25)			
NZ98/254 Post 2nd vaccination (Day 91)(N=12)	75 (43 to 95)			
M10713 Prevaccination (Day 1)	92 (64 to 100)			
M10713 Post 2nd vaccination (Day 91)(N=12)	100 (74 to 100)			

Statistical analyses

No statistical analyses for this end point

Primary: 4. Percentages Of Subjects With hSBA≥ 1:8 Titers Against N Meningitidis

Serogroup B Strains Following Two-Dose Vaccination Schedule.

End point title	4. Percentages Of Subjects With hSBA≥ 1:8 Titers Against N Meningitidis Serogroup B Strains Following Two-Dose Vaccination Schedule.[4]

End point description:

The immunogenicity was assessed to evaluate the human serum bactericidal activity titers ≥ 1:8 in terms of percentages of subjects against N meningitidis serogroup B (H44/76, 5/99, NZ98/254) and strain M10713 following a two dose vaccination schedule with rMenB+OMV NZ vaccine.
Analysis was done on Full Analysis Set.

End point type	Primary

End point timeframe:

Day 1 and Day 91

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analyses of immunogenicity and safety were descriptive.

End point values	rMenB+OMV NZ			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: Percentages of subjects				
number (confidence interval 95%)				
H44/76 Prevaccination (Day 1)	0 (0 to 25)			
H44/76 Post 2nd vaccination (Day 91)	100 (75 to 100)			
5/99 Prevaccination (Day 1)	8 (0 to 36)			
5/99 Post 2nd vaccination (Day 91)(N=12)	92 (62 to 100)			
NZ98/254 Prevaccination (Day 1)	0 (0 to 25)			
NZ98/254 Post 2nd vaccination (Day 91)(N=12)	75 (43 to 95)			
M10713 Prevaccination (Day 1)	85 (55 to 98)			
M10713 Post 2nd vaccination (Day 91)(N=12)	92 (62 to 100)			

Statistical analyses

No statistical analyses for this end point

Primary: 5. Percentages Of Subjects With Four-Fold Increase In Human Serum Bactericidal Activity From Baseline Against N Meningitidis Serogroup B Strains Following a Two Dose Vaccination Schedule.

End point title	5. Percentages Of Subjects With Four-Fold Increase In Human Serum Bactericidal Activity From Baseline Against N Meningitidis Serogroup B Strains Following a Two Dose Vaccination Schedule.[5]

End point description:

The antibody responses were assessed to evaluate the four fold increase in human serum bactericidal activity titers in terms of percentages of subjects against N meningitidis serogroup B (H44/76, 5/99, NZ98/254) and strain M10713 following a two dose vaccination schedule with rMenB+OMV NZ vaccine.
Analysis was done on Full Analysis Set.

End point type	Primary

End point timeframe:

Day 91

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analyses of immunogenicity and safety were descriptive.

End point values	rMenB+OMV NZ			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: Percentages of subjects				
geometric mean (confidence interval 95%)				
H44/76	100 (75 to 100)			
5/99 (N=12)	92 (62 to 100)			
NZ98/254 (N=12)	75 (43 to 95)			
M10713 (N=12)	33 (10 to 65)			

Statistical analyses

No statistical analyses for this end point

Primary: 6. Geometric Mean Concentrations For Vaccine Antigen 287-953 Following A Two-dose Vaccination Schedule

End point title	6. Geometric Mean Concentrations For Vaccine Antigen 287-953 Following A Two-dose Vaccination Schedule[6]

End point description:

The antibody responses were assessed to evaluate the geometric mean concentrations as measured by Enzyme Linked Immunosorbent Assay (ELISA) in terms of percentages of subjects for the vaccine antigen 287-953 following a two dose vaccination schedule with rMenB+OMV NZ vaccine at baseline and at one month the second vaccination.
Analysis was done on Full Analysis Set.

End point type	Primary

End point timeframe:

Day 1 and Day 91

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analyses of immunogenicity and safety were descriptive.

End point values	rMenB+OMV NZ			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: IU/mL				
geometric mean (confidence interval 95%)				
Prevaccination (Day 1)	22 (18 to 28)			
Post second vaccination (Day 91)	1200 (537 to 2680)			

Statistical analyses

No statistical analyses for this end point

Primary: 7. Geometric Mean Ratios For Vaccine Antigen 287-953 Following A Two-dose Vaccination Schedule.

End point title	7. Geometric Mean Ratios For Vaccine Antigen 287-953 Following A Two-dose Vaccination Schedule.[7]

End point description:

The antibody responses were assessed to evaluate the geometric mean ratios as measured by ELISA within the subjects for the vaccine antigen 287-953 following a two dose vaccination schedule with rMenB+OMV NZ vaccine at one month after the second vaccination versus baseline.
Analysis was done on Full Analysis Set.

End point type	Primary

End point timeframe:

Day 1 and Day 91

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analyses of immunogenicity and safety were descriptive.

End point values	rMenB+OMV NZ			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: Ratio				
geometric mean (confidence interval 95%)				
Antigen 287-953 (Day 91/Day1)	54 (24 to 120)			

Statistical analyses

No statistical analyses for this end point

Primary: 8. Percentages of Subjects With Four Fold Increase From Baseline For Vaccine Antigen 287-953 Following A Two-dose Vaccination Schedule.

End point title	8. Percentages of Subjects With Four Fold Increase From Baseline For Vaccine Antigen 287-953 Following A Two-dose Vaccination Schedule.[8]

End point description:

The antibody responses were assessed to evaluate the four fold increases in ELISA concentrations as measured by ELISA to the vaccine antigen 287-953 following a two dose vaccination schedule with rMenB+OMV NZ vaccine at one month the second vaccination over baseline.
Analysis was done on Full Analysis Set.

End point type	Primary

End point timeframe:

Day 1 and Day 91

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analyses of immunogenicity and safety were descriptive.

End point values	rMenB+OMV NZ			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: Percentages of subjects				
number (confidence interval 95%)				
Antigen 287-953 (Day 91)	85 (55 to 98)			

Statistical analyses

No statistical analyses for this end point

Primary: 9. Number of Subjects Reporting Solicited Local and Systemic Adverse Events After Receiving rMenB+OMV NZ Vaccine (After Any Vaccination)

End point title	9. Number of Subjects Reporting Solicited Local and Systemic Adverse Events After Receiving rMenB+OMV NZ Vaccine (After Any Vaccination)[9]

End point description:

Number of Subjects Reporting Solicited Local and Systemic Adverse Events After Receiving rMenB+OMV NZ Vaccine (After Any Vaccination).
Analysis was done on Solicited Safety Set.

End point type	Primary

End point timeframe:

Day 1 through Day 7 postvaccination.

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analyses of immunogenicity and safety were descriptive.

End point values	rMenB+OMV NZ			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: Number of subjects				
Any local	13			
Injection site erythema	0			
Injection site swelling	0			
Injection site induration	1			
Injection site pain	13			
Any systemic	9			
Nausea	2			
Myalgia	3			
Arthralgia	3			
Fatigue	5			
Headache	8			
Fever (≥38°C)	1			

Prophylactic use of antipyretics/analgesics	0			
Therapeutic use of antipyretics/analgesics	4			

Statistical analyses

No statistical analyses for this end point

Primary: 10. Number of Subjects Reporting Unsolicited Adverse Events After Receiving rMenB+OMV NZ Vaccine (After Any Vaccination)

End point title	10. Number of Subjects Reporting Unsolicited Adverse Events After Receiving rMenB+OMV NZ Vaccine (After Any Vaccination)[10]

End point description:

Safety was assessed as the number of subjects who reported unsolicited adverse events as collected from Day 1 to Day 91 following rMenB+OMV vaccination (a two dose schedule). Unsolicited adverse events were collected from day 1 through day 7 after each vaccination, while serious adverse events, medically attended adverse events and adverse events leading to withdrawal from study were reported from day 1 through day 91.
Analysis was done on Unsolicited Safety Set.

End point type	Primary

End point timeframe:

Day 1 through Day 91 postvaccination

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analyses of immunogenicity and safety were descriptive.

End point values	rMenB+OMV NZ			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: Number of subjects				
Any unsolicited AEs	8			
At least possibly related unsolicited AEs	7			

Statistical analyses

No statistical analyses for this end point

Primary: 11. Number of Subjects Reporting Unsolicited Serious Adverse Events After Receiving rMenB+OMV NZ Vaccine (After Any Vaccination)

End point title	11. Number of Subjects Reporting Unsolicited Serious Adverse Events After Receiving rMenB+OMV NZ Vaccine (After Any Vaccination)[11]

End point description:

Safety was assessed as the number of subjects who reported Serious Adverse Events (SAEs), medically attended AEs, AEs leading to withdrawal from the study, as collected from day 1 to day 91 following vaccination with rMenB+OMV NZ (a two dose schedule) were reported.
Analysis was done on Unsolicited Safety Set.

End point type	Primary

End point timeframe:

Day 1 through Day 91 postvaccination.

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analyses of immunogenicity and safety were descriptive.

End point values	rMenB+OMV NZ			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: Number of subjects				
AEs leading to study withdrawal	0			
Medically attended AEs	2			
Any SAEs	0			
At least possibly related SAEs	0			
AEs leading to death	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Day 1 through Day 91 postvaccination.	
Adverse event reporting additional description:	
Safety was assessed as the number of subjects who reported Serious Adverse Events (SAEs), medically attended AEs, AEs leading to withdrawal from the study, as collected from day 1 to day 91 following vaccination with rMenB+OMV NZ (a two dose schedule) are reported.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups	
Reporting group title	rMenB+OMV NZ
Reporting group description:	
Subjects received two doses of rMenB +OMV NZ at 0 month and 2 month schedule.	

Serious adverse events	rMenB+OMV NZ		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 13 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	rMenB+OMV NZ		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 13 (100.00%)		
Nervous system disorders			
Headache			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 13 (61.54%)		
occurrences (all)	12		
General disorders and administration site conditions			
Chills			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Fatigue			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 13 (38.46%)		
occurrences (all)	10		
Injection site erythema			
alternative assessment type: Systematic			
subjects affected / exposed	10 / 13 (76.92%)		
occurrences (all)	18		
Injection site induration			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 13 (38.46%)		
occurrences (all)	7		
Injection site pain			
alternative assessment type: Systematic			
subjects affected / exposed	13 / 13 (100.00%)		
occurrences (all)	28		
Injection site swelling			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 13 (38.46%)		
occurrences (all)	7		
Pyrexia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Gastrointestinal disorders			
Nausea			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	2		
Musculoskeletal and connective tissue disorders			
Arthralgia			
alternative assessment type: Systematic			

subjects affected / exposed	3 / 13 (23.08%)		
occurrences (all)	5		
Myalgia			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 13 (23.08%)		
occurrences (all)	5		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		
Respiratory tract infection			
subjects affected / exposed	2 / 13 (15.38%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
25 June 2013	Addition of hSBA against the strain M10713 to evaluate the immunogenicity of rMenB+OMV NZ on the antigen NHBA (287-953), in addition to the ELISA.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported