Clinical trial results:
A Phase I/II, randomised, controlled study to assess the safety, effectiveness and immune response of meningococcal combined ABCWY vaccine when administered to healthy adults (Phase I) and to healthy adolescents and adults (Phase II).

Summary

EudraCT number	2020-004741-37
Trial protocol	BE FI Outside EU/EEA PL SE
Global end of trial date	15 November 2024

Results information

Result version number	v1 (current)
This version publication date	30 May 2025
First version publication date	30 May 2025

Trial information

Trial identification

Sponsor protocol code	212458

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04886154
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	Rue de l'Institut, 89,, Rixensart, Belgium, 1330
Public contact	GSK Response Center, GlaxoSmithKline, 044 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 044 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-003359-PIP01-22
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	03 December 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 February 2024
Global end of trial reached?	Yes
Global end of trial date	15 November 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Phase I:
•To evaluate the safety and reactogenicity of the 2 formulations of MenABCWY-2Gen vaccine

Phase II:
•To demonstrate the superiority of the effectiveness of MenABCWY-2Gen vaccine when administered at 0,2- or 0,6-months schedule, compared to the MenB vaccine administered at 0,6-months schedule
•To demonstrate the immunological non-inferiority (NI) of MenABCWY-2Gen vaccine administered at 0,2- or 0,6-months schedule compared to the MenACWY vaccine (single dose)
•To evaluate the safety and reactogenicity of the MenABCWY-2Gen, the MenB and the MenACWY vaccines

Phase II-Sourcing:
•To evaluate the safety and reactogenicity of the 2 formulations of MenABCWY-2Gen vaccine.

Protection of trial subjects:

All participants were followed for safety up to 6 months in Phase I and Phase II (Sourcing) and 12 months in Phase II (Formulation and Schedule-finding) after the last vaccination.

The participants were observed closely for at least 30 minutes following the administration of the vaccine(s)/product(s), with appropriate medical treatment readily available in case of anaphylaxis and/or syncope.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 June 2021
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	Australia: 227
Country: Number of subjects enrolled	Belgium: 169
Country: Number of subjects enrolled	Brazil: 147
Country: Number of subjects enrolled	Finland: 157
Country: Number of subjects enrolled	Poland: 596
Country: Number of subjects enrolled	Sweden: 35
Country: Number of subjects enrolled	Türkiye: 26
Country: Number of subjects enrolled	United States: 83
Worldwide total number of subjects	1440
EEA total number of subjects	957

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)	122
Adolescents (12-17 years)	272
Adults (18-64 years)	1046
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Out of 1440 participants enrolled, 3 participants from Phase II (Formulation and Schedule-finding) did not receive vaccination as they did not meet the eligibility criteria, therefore only 1437 participants were included in the Exposed Set and started the study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	ABCWY low dose Group

Arm description:

Participants received two doses of the MenABCWY-2Gen low-dose vaccine on Day 1 and Day 31, following a 0, 1-month schedule during Study Phase I (Safety Lead-In).

Arm type	Experimental
Investigational medicinal product name	MenABCWY-2Gen low dose vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenABCWY-2Gen low dose vaccine is administered intramuscularly as 2 doses to participants.

Arm title	Placebo low dose Group

Arm description:

Participants received two doses of a placebo on Day 1 and Day 31, following a 0, 1-month schedule during Study Phase I (Safety Lead-In), as the control group for the ABCWY low-dose group.

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

Dosage and administration details:

Placebo is administered intramuscularly as 2 doses to participants.

Arm title	ABCWY high dose Group

Arm description:

Participants received two doses of the MenABCWY-2Gen high-dose vaccine on Day 1 and Day 31, following a 0, 1-month schedule during Study Phase I (Safety Lead-In).

Arm type	Experimental

Investigational medicinal product name	MenABCWY-2Gen high dose vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenABCWY-2Gen high dose vaccine is administered intramuscularly as 2 doses to participants.

Arm title	Placebo high dose Group

Arm description:

Participants received two doses of a placebo on Day 1 and Day 31, following a 0, 1-month schedule during Study Phase I (Safety Lead-In), as the control group for the ABCWY high-dose group.

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

Dosage and administration details:

Placebo is administered intramuscularly as 2 doses to participants.

Arm title	ABCWY low dose_06 Group

Arm description:

Participants received two doses of the MenABCWY-2Gen low-dose vaccine on Day 1 and Day 181, following a 0, 6-month schedule, along with one dose of a placebo on Day 121 during Phase II (Formulation and Schedule-Finding).

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

Dosage and administration details:

Placebo is administered intramuscularly as 1 dose to participants.

Investigational medicinal product name	MenABCWY-2Gen low dose vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenABCWY-2Gen low dose vaccine is administered intramuscularly as 2 doses to participants.

Arm title	ABCWY low dose_02 Group

Arm description:

Participants received two doses of the MenABCWY-2Gen low-dose vaccine on Day 121 and Day 181, following a 0, 2-month schedule, along with one dose of a placebo on Day 1 during Phase II (Formulation and Schedule-Finding).

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

Dosage and administration details:

Placebo is administered intramuscularly as 1 dose to participants.

Investigational medicinal product name	MenABCWY-2Gen low dose vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenABCWY-2Gen low dose vaccine is administered intramuscularly as 2 doses to participants.

Arm title	ABCWY high dose_06 Group

Arm description:

Participants received two doses of the MenABCWY-2Gen high-dose vaccine on Day 1 and Day 181, following a 0, 6-month schedule, along with one dose of a placebo on Day 121 during Phase II (Formulation and Schedule-Finding).

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

Dosage and administration details:

Placebo is administered intramuscularly as 1 dose to participants.

Investigational medicinal product name	MenABCWY-2Gen high dose vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenABCWY-2Gen high dose vaccine is administered intramuscularly as 2 doses to participants.

Arm title	ABCWY high dose_02 Group

Arm description:

Participants received two doses of the MenABCWY-2Gen high-dose vaccine on Day 121 and Day 181, following a 0, 2-month schedule, along with one dose of a placebo on Day 1 during Phase II (Formulation and Schedule-Finding).

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

Dosage and administration details:

Placebo is administered intramuscularly as 1 dose to participants.

Investigational medicinal product name	MenABCWY-2Gen high dose vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenABCWY-2Gen high dose vaccine is administered intramuscularly as 2 doses to participants.

Arm title	Control Group

Arm description:

Participants randomized to the control group received two doses of the Bexsero (MenB) vaccine on Day 1 and Day 181, following a 0, 6-month schedule, and one dose of Menveo (MenACWY) on Day 1 during Study Phase II (Formulation and Schedule-Finding).

Arm type	Active comparator
Investigational medicinal product name	MenACWY
Investigational medicinal product code	
Other name	GSK's combined meningococcal groups A, C, Y and W-135 conjugate vaccine, Menveo
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenACWY vaccine is administered intramuscularly as 1 dose to participants.

Investigational medicinal product name	Meningococcal Group B Vaccine (rMenB+OMV NZ)
Investigational medicinal product code	
Other name	GSK’s meningococcal group B vaccine, Bexsero
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

MenB vaccine is administered intramuscularly as 2 doses in a 0,6-months schedule to participants.

Arm title	ABCWY low dose_01 Group

Arm description:

Participants received two doses of MenABCWY-2Gen low dose vaccine on Day 1 and Day 31, following a 0, 1-month schedule during study Phase II (Sourcing).

Arm type	Experimental
Investigational medicinal product name	MenABCWY-2Gen low dose vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenABCWY-2Gen low dose vaccine is administered intramuscularly as 2 doses to participants.

Arm title	ABCWY high dose_01 Group

Arm description:

Participants received two doses of MenABCWY-2Gen high dose vaccine on Day 1 and Day 31, following a 0, 1-month schedule during study Phase II (Sourcing).

Arm type	Experimental
Investigational medicinal product name	MenABCWY-2Gen high dose vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenABCWY-2Gen high dose vaccine is administered intramuscularly as 2 doses to participants.

Arm title	ABCWY low doseS_02 Group

Arm description:

Participants received two doses of MenABCWY-2Gen low dose vaccine on Day 1 and day 61 following a 0, 2-month schedule during study Phase II (Sourcing).

Arm type	Experimental
Investigational medicinal product name	MenABCWY-2Gen low dose vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenABCWY-2Gen low dose vaccine is administered intramuscularly as 2 doses to participants.

Arm title	ABCWY high doseS_02 Group
Arm description:	
Participants received two doses of MenABCWY-2Gen high dose vaccine on Day 1 and day 61 following a 0, 2-month schedule during study Phase II (Sourcing).	
Arm type	Experimental
Investigational medicinal product name	MenABCWY-2Gen high dose vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
MenABCWY-2Gen high dose vaccine is administered intramuscularly as 2 doses to participants.	
Arm title	ABCWY low doseS_06 Group
Arm description:	
Participants received two doses of MenABCWY-2Gen low dose vaccine on Day 1 and day 181 following a 0, 6-month schedule during study Phase II (Sourcing).	
Arm type	Experimental
Investigational medicinal product name	MenABCWY-2Gen low dose vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
MenABCWY-2Gen low dose vaccine is administered intramuscularly as 2 doses to participants.	
Arm title	ABCWY high doseS_06 Group
Arm description:	
Participants received two doses of MenABCWY-2Gen high dose vaccine on Day 1 and day 181 following a 0, 6-month schedule during study Phase II (Sourcing).	
Arm type	Experimental
Investigational medicinal product name	MenABCWY-2Gen high dose vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
MenABCWY-2Gen high dose vaccine is administered intramuscularly as 2 doses to participants.	

Number of subjects in period 1[1]	ABCWY low dose Group	Placebo low dose Group	ABCWY high dose Group
Started	12	4	13
Completed	11	4	11
Not completed	1	0	2
ADVERSE EVENT REQUIRING EXPEDITED REPORT	-	-	-
Adverse event, non-fatal	-	-	-
MIGRATED / MOVED FROM THE STUDY AREA	-	-	-
Lost to follow-up	1	-	2

Other, Not Specified	-	-	-

Number of subjects in period 1[1]	Placebo high dose Group	ABCWY low dose_06 Group	ABCWY low dose_02 Group
Started	3	239	181
Completed	3	209	166
Not completed	0	30	15
ADVERSE EVENT REQUIRING EXPEDITED REPORT	-	-	-
Adverse event, non-fatal	-	1	-
MIGRATED / MOVED FROM THE STUDY AREA	-	1	-
Lost to follow-up	-	17	7
Other, Not Specified	-	11	8

Number of subjects in period 1[1]	ABCWY high dose_06 Group	ABCWY high dose_02 Group	Control Group
Started	238	194	197
Completed	218	175	182
Not completed	20	19	15
ADVERSE EVENT REQUIRING EXPEDITED REPORT	1	-	-
Adverse event, non-fatal	-	1	1
MIGRATED / MOVED FROM THE STUDY AREA	2	1	-
Lost to follow-up	8	7	8
Other, Not Specified	9	10	6

Number of subjects in period 1[1]	ABCWY low dose_01 Group	ABCWY high dose_01 Group	ABCWY low doseS_02 Group
Started	54	53	62
Completed	53	50	59
Not completed	1	3	3
ADVERSE EVENT REQUIRING EXPEDITED REPORT	-	-	-
Adverse event, non-fatal	-	-	1
MIGRATED / MOVED FROM THE STUDY AREA	-	-	-
Lost to follow-up	-	2	-
Other, Not Specified	1	1	2

Number of subjects in period 1[1]	ABCWY high doseS_02 Group	ABCWY low doseS_06 Group	ABCWY high doseS_06 Group
Started	62	62	63
Completed	61	60	56
Not completed	1	2	7
ADVERSE EVENT REQUIRING EXPEDITED REPORT	-	-	-
Adverse event, non-fatal	-	-	3

MIGRATED / MOVED FROM THE STUDY AREA	-	-	1
Lost to follow-up	-	-	-
Other, Not Specified	1	2	3

Notes:

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

Justification: Out of 1440 participants enrolled, 3 participants from Phase II (Formulation and Schedule-finding) did not receive vaccination as they did not meet the eligibility criteria, therefore only 1437 participants were included in the Exposed Set and started the study.

Baseline characteristics

Reporting groups

Reporting group title	ABCWY low dose Group
Reporting group description:	
Participants received two doses of the MenABCWY-2Gen low-dose vaccine on Day 1 and Day 31, following a 0, 1-month schedule during Study Phase I (Safety Lead-In).	
Reporting group title	Placebo low dose Group
Reporting group description:	
Participants received two doses of a placebo on Day 1 and Day 31, following a 0, 1-month schedule during Study Phase I (Safety Lead-In), as the control group for the ABCWY low-dose group.	
Reporting group title	ABCWY high dose Group
Reporting group description:	
Participants received two doses of the MenABCWY-2Gen high-dose vaccine on Day 1 and Day 31, following a 0, 1-month schedule during Study Phase I (Safety Lead-In).	
Reporting group title	Placebo high dose Group
Reporting group description:	
Participants received two doses of a placebo on Day 1 and Day 31, following a 0, 1-month schedule during Study Phase I (Safety Lead-In), as the control group for the ABCWY high-dose group.	
Reporting group title	ABCWY low dose_06 Group
Reporting group description:	
Participants received two doses of the MenABCWY-2Gen low-dose vaccine on Day 1 and Day 181, following a 0, 6-month schedule, along with one dose of a placebo on Day 121 during Phase II (Formulation and Schedule-Finding).	
Reporting group title	ABCWY low dose_02 Group
Reporting group description:	
Participants received two doses of the MenABCWY-2Gen low-dose vaccine on Day 121 and Day 181, following a 0, 2-month schedule, along with one dose of a placebo on Day 1 during Phase II (Formulation and Schedule-Finding).	
Reporting group title	ABCWY high dose_06 Group
Reporting group description:	
Participants received two doses of the MenABCWY-2Gen high-dose vaccine on Day 1 and Day 181, following a 0, 6-month schedule, along with one dose of a placebo on Day 121 during Phase II (Formulation and Schedule-Finding).	
Reporting group title	ABCWY high dose_02 Group
Reporting group description:	
Participants received two doses of the MenABCWY-2Gen high-dose vaccine on Day 121 and Day 181, following a 0, 2-month schedule, along with one dose of a placebo on Day 1 during Phase II (Formulation and Schedule-Finding).	
Reporting group title	Control Group
Reporting group description:	
Participants randomized to the control group received two doses of the Bexsero (MenB) vaccine on Day 1 and Day 181, following a 0, 6-month schedule, and one dose of Menveo (MenACWY) on Day 1 during Study Phase II (Formulation and Schedule-Finding).	
Reporting group title	ABCWY low dose_01 Group
Reporting group description:	
Participants received two doses of MenABCWY-2Gen low dose vaccine on Day 1 and Day 31, following a 0, 1-month schedule during study Phase II (Sourcing).	
Reporting group title	ABCWY high dose_01 Group
Reporting group description:	
Participants received two doses of MenABCWY-2Gen high dose vaccine on Day 1 and Day 31, following a 0, 1-month schedule during study Phase II (Sourcing).	
Reporting group title	ABCWY low doseS_02 Group
Reporting group description:	
Participants received two doses of MenABCWY-2Gen low dose vaccine on Day 1 and day 61 following a 0, 2-month schedule during study Phase II (Sourcing).	

Reporting group title	ABCWY high doseS_02 Group
Reporting group description:	
Participants received two doses of MenABCWY-2Gen high dose vaccine on Day 1 and day 61 following a 0, 2-month schedule during study Phase II (Sourcing).	

Reporting group title	ABCWY low doseS_06 Group
Reporting group description:	
Participants received two doses of MenABCWY-2Gen low dose vaccine on Day 1 and day 181 following a 0, 6-month schedule during study Phase II (Sourcing).	

Reporting group title	ABCWY high doseS_06 Group
Reporting group description:	
Participants received two doses of MenABCWY-2Gen high dose vaccine on Day 1 and day 181 following a 0, 6-month schedule during study Phase II (Sourcing).	

Reporting group values	ABCWY low dose Group	Placebo low dose Group	ABCWY high dose Group
Number of subjects	12	4	13
Age categorical Units: Subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	1	0	0
Adults (18-64 years)	11	4	13
Age Continuous Units: years			
arithmetic mean	28.6	30.8	31.7
standard deviation	± 7.5	± 6.2	± 6.0
Sex: Female, Male Units: Participants			
Male	6	2	6
Female	6	2	7
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	11	4	13
Unknown or Not Reported	1	0	0

Reporting group values	Placebo high dose Group	ABCWY low dose_06 Group	ABCWY low dose_02 Group
Number of subjects	3	239	181
Age categorical Units: Subjects			
Children (2-11 years)	0	26	19
Adolescents (12-17 years)	0	59	49
Adults (18-64 years)	3	154	113
Age Continuous Units: years			
arithmetic mean	28.7	18.9	18.6
standard deviation	± 3.8	± 4.7	± 4.6
Sex: Female, Male Units: Participants			
Male	2	86	85
Female	1	153	96

Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	41	29
Not Hispanic or Latino	3	198	152
Unknown or Not Reported	0	0	0

Reporting group values	ABCWY high dose_06 Group	ABCWY high dose_02 Group	Control Group
Number of subjects	238	194	197
Age categorical Units: Subjects			
Children (2-11 years)	30	23	24
Adolescents (12-17 years)	59	48	55
Adults (18-64 years)	149	123	118
Age Continuous Units: years			
arithmetic mean	18.7	18.6	18.4
standard deviation	± 5.0	± 4.7	± 4.6
Sex: Female, Male Units: Participants			
Male	82	73	84
Female	156	121	113
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	30	29	35
Not Hispanic or Latino	208	165	162
Unknown or Not Reported	0	0	0

Reporting group values	ABCWY low dose_01 Group	ABCWY high dose_01 Group	ABCWY low doseS_02 Group
Number of subjects	54	53	62
Age categorical Units: Subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	54	53	62
Age Continuous Units: years			
arithmetic mean	34.6	31.7	35.2
standard deviation	± 8.9	± 7.3	± 9.1
Sex: Female, Male Units: Participants			
Male	26	19	24
Female	28	34	38
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	3	6	0
Not Hispanic or Latino	50	46	62
Unknown or Not Reported	1	1	0

Reporting group values	ABCWY high doseS_02 Group	ABCWY low doseS_06 Group	ABCWY high doseS_06 Group
Number of subjects	62	62	63

Age categorical Units: Subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	62	62	63
Age Continuous Units: years			
arithmetic mean	34.6	37.0	37.3
standard deviation	± 8.4	± 8.7	± 8.8
Sex: Female, Male Units: Participants			
Male	23	25	26
Female	39	37	37
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	3	0
Not Hispanic or Latino	62	59	63
Unknown or Not Reported	0	0	0

Reporting group values	Total		
Number of subjects	1437		
Age categorical Units: Subjects			
Children (2-11 years)	122		
Adolescents (12-17 years)	271		
Adults (18-64 years)	1044		
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male Units: Participants			
Male	569		
Female	868		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	176		
Not Hispanic or Latino	1258		
Unknown or Not Reported	3		

End points reporting groups

Reporting group title	ABCWY low dose Group
Reporting group description:	
Participants received two doses of the MenABCWY-2Gen low-dose vaccine on Day 1 and Day 31, following a 0, 1-month schedule during Study Phase I (Safety Lead-In).	
Reporting group title	Placebo low dose Group
Reporting group description:	
Participants received two doses of a placebo on Day 1 and Day 31, following a 0, 1-month schedule during Study Phase I (Safety Lead-In), as the control group for the ABCWY low-dose group.	
Reporting group title	ABCWY high dose Group
Reporting group description:	
Participants received two doses of the MenABCWY-2Gen high-dose vaccine on Day 1 and Day 31, following a 0, 1-month schedule during Study Phase I (Safety Lead-In).	
Reporting group title	Placebo high dose Group
Reporting group description:	
Participants received two doses of a placebo on Day 1 and Day 31, following a 0, 1-month schedule during Study Phase I (Safety Lead-In), as the control group for the ABCWY high-dose group.	
Reporting group title	ABCWY low dose_06 Group
Reporting group description:	
Participants received two doses of the MenABCWY-2Gen low-dose vaccine on Day 1 and Day 181, following a 0, 6-month schedule, along with one dose of a placebo on Day 121 during Phase II (Formulation and Schedule-Finding).	
Reporting group title	ABCWY low dose_02 Group
Reporting group description:	
Participants received two doses of the MenABCWY-2Gen low-dose vaccine on Day 121 and Day 181, following a 0, 2-month schedule, along with one dose of a placebo on Day 1 during Phase II (Formulation and Schedule-Finding).	
Reporting group title	ABCWY high dose_06 Group
Reporting group description:	
Participants received two doses of the MenABCWY-2Gen high-dose vaccine on Day 1 and Day 181, following a 0, 6-month schedule, along with one dose of a placebo on Day 121 during Phase II (Formulation and Schedule-Finding).	
Reporting group title	ABCWY high dose_02 Group
Reporting group description:	
Participants received two doses of the MenABCWY-2Gen high-dose vaccine on Day 121 and Day 181, following a 0, 2-month schedule, along with one dose of a placebo on Day 1 during Phase II (Formulation and Schedule-Finding).	
Reporting group title	Control Group
Reporting group description:	
Participants randomized to the control group received two doses of the Bexsero (MenB) vaccine on Day 1 and Day 181, following a 0, 6-month schedule, and one dose of Menveo (MenACWY) on Day 1 during Study Phase II (Formulation and Schedule-Finding).	
Reporting group title	ABCWY low dose_01 Group
Reporting group description:	
Participants received two doses of MenABCWY-2Gen low dose vaccine on Day 1 and Day 31, following a 0, 1-month schedule during study Phase II (Sourcing).	
Reporting group title	ABCWY high dose_01 Group
Reporting group description:	
Participants received two doses of MenABCWY-2Gen high dose vaccine on Day 1 and Day 31, following a 0, 1-month schedule during study Phase II (Sourcing).	
Reporting group title	ABCWY low doseS_02 Group
Reporting group description:	
Participants received two doses of MenABCWY-2Gen low dose vaccine on Day 1 and day 61 following a 0, 2-month schedule during study Phase II (Sourcing).	

Reporting group title	ABCWY high doseS_02 Group

Reporting group description:

Participants received two doses of MenABCWY-2Gen high dose vaccine on Day 1 and day 61 following a 0, 2-month schedule during study Phase II (Sourcing).

Reporting group title	ABCWY low doseS_06 Group

Reporting group description:

Participants received two doses of MenABCWY-2Gen low dose vaccine on Day 1 and day 181 following a 0, 6-month schedule during study Phase II (Sourcing).

Reporting group title	ABCWY high doseS_06 Group

Reporting group description:

Participants received two doses of MenABCWY-2Gen high dose vaccine on Day 1 and day 181 following a 0, 6-month schedule during study Phase II (Sourcing).

Subject analysis set title	Control (MenACWY) Group
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants randomized to Control Group received a single dose of Menveo (MenACWY) on Day 1 during study Phase II (Formulation and Schedule-finding).

Subject analysis set title	Control (MenB_06) Group
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants randomized to Control Group received 2 doses of Bexsero (MenB) vaccine on Day 1 and Day 181 following in a 0, 6- month schedule during study Phase II (Formulation and Schedule-finding).

Subject analysis set title	Control (MenB_06) Group
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants randomized to Control Group received 2 doses of Bexsero (MenB) vaccine on Day 1 and Day 181 following in a 0, 6- month schedule during study Phase II (Formulation and Schedule-finding).

Primary: Number of participants with solicited administration site events in study Phase I (Safety Lead-in) Day 1

End point title	Number of participants with solicited administration site events in study Phase I (Safety Lead-in) Day 1[1][2]

End point description:

The solicited administration site events include injection site pain, erythema (redness), swelling and induration. Any solicited administration site AEs = occurrence of the symptom regardless of intensity grade. Analysis was performed on the Phase I Exposed set (ES), which included all participants who received at least one dose of the study treatment and have post-vaccination data for the specified analysis at specified timepoints. Allocation per group using the enrolled set is based on the treatment administered.

End point type	Primary

End point timeframe:

During the 7 days (including the day of vaccination) following vaccination at Day 1

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase I (Safety Lead-in) groups.

End point values	ABCWY low dose Group	Placebo low dose Group	ABCWY high dose Group	Placebo high dose Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	3
Units: Participants				
Erythema (N= 12, 4,13, 3)	0	0	0	0
Induration (N= 12, 4,13, 3)	1	0	0	0
Pain (N= 12, 4,13, 3)	11	1	13	0
Swelling (N= 12, 4,13, 3)	1	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with solicited administration site events in study Phase I (Safety Lead-in) at Day 31

End point title	Number of participants with solicited administration site events in study Phase I (Safety Lead-in) at Day 31[3][4]

End point description:

The solicited administration site events include injection site pain, erythema (redness), swelling and induration. Any solicited administration site AEs = occurrence of the symptom regardless of intensity grade. Analysis was performed on the Phase I Exposed set (ES), which included all participants who received at least one dose of the study treatment and have post-vaccination data for the specified analysis at specified timepoints. Allocation per group using the enrolled set is based on the treatment administered.

End point type	Primary

End point timeframe:

During the 7 days (including the day of vaccination) following vaccination at Day 31

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase I (Safety Lead-in) groups.

End point values	ABCWY low dose Group	Placebo low dose Group	ABCWY high dose Group	Placebo high dose Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	11	3
Units: Participants				
Erythema (N=12,4,11,3)	2	0	0	0
Induration (N=12,4,11,3)	0	0	0	0
Pain (N=12,4,11,3)	8	1	8	1
Swelling (N=12,4,11,3)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with solicited systemic events in study Phase I (Safety Lead-in) Day 1

End point title	Number of participants with solicited systemic events in study Phase I (Safety Lead-in) Day 1[5][6]

End point description:

The solicited systemic events include fever (temperature ≥ 38.0°C), nausea, fatigue, myalgia, arthralgia, and headache.
Analysis was performed on the Phase I Exposed set (ES), which included all participants who received at least one dose of the study treatment and have post-vaccination data for the specified analysis at specified timepoints. Allocation per group using the enrolled set is based on the treatment administered.

End point type	Primary

End point timeframe:

During the 7 days (including the day of vaccination) following vaccination at Day 1

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase I (Safety Lead-in) groups.

End point values	ABCWY low dose Group	Placebo low dose Group	ABCWY high dose Group	Placebo high dose Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	3
Units: Participants				
Arthralgia (N=12,4,13,3)	1	1	2	1
Fatigue (N=12,4,13,3)	4	1	11	2
Headache (N=12,4,13,3)	4	0	4	1
Myalgia (N=12,4,13,3)	4	0	3	1
Nausea (N=12,4,13,3)	0	0	3	0
Fever (N=12,4,13,3)	1	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with solicited systemic events in study Phase I (Safety Lead-in) Day 31

End point title	Number of participants with solicited systemic events in study Phase I (Safety Lead-in) Day 31[7][8]

End point description:

The solicited systemic events include fever (temperature ≥ 38.0°C), nausea, fatigue, myalgia, arthralgia and headache. Analysis was performed on the Phase I Exposed set (ES), which included all participants who received at least one dose of the study treatment and have post-vaccination data for the specified analysis at specified timepoints. Allocation per group using the enrolled set is based on the treatment administered.

End point type	Primary

End point timeframe:

During the 7 days (including the day of vaccination) following vaccination at Day 31

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase I (Safety Lead-in) groups.

End point values	ABCWY low dose Group	Placebo low dose Group	ABCWY high dose Group	Placebo high dose Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	11	3
Units: Participants				
Arthralgia (N= 12, 4, 11, 3)	1	2	2	0
Fatigue (N= 12, 4, 11, 3)	1	2	7	2
Headache (N= 12, 4, 11, 3)	4	2	3	1
Myalgia (N= 12, 4, 11, 3)	1	1	2	0
Nausea (N= 12, 4, 11, 3)	1	1	2	0
Fever (N= 12, 4, 11, 3)	1	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with any unsolicited adverse events (AEs), including all serious adverse events (SAEs), AEs leading to withdrawal and AEs of special interest (AESIs) in study Phase I (Safety Lead-in)

End point title	Number of participants with any unsolicited adverse events (AEs), including all serious adverse events (SAEs), AEs leading to withdrawal and AEs of special interest (AESIs) in study Phase I (Safety Lead-in)[9][10]

End point description:

Unsolicited AEs includes any AE reported in addition to those solicited during the clinical study. Any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms is reported as an unsolicited AE. A SAE is any untoward medical occurrence that results in death, is life-threatening, requires or prolongs hospitalization, results in disability/incapacity and is a congenital anomaly/birth defect in a subject’s offspring. AESIs are predefined (serious or non-serious) AEs of scientific and medical concern specific to the product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor can be appropriate, because such an event might warrant further investigation to characterize and understand it. A participant was considered withdrawn if no study procedures occurred, and no follow-up or further information has been collected from the date of withdrawal or last contact. Analysis was performed on the Phase I ES.

End point type	Primary

End point timeframe:

During the 30 days (including the day of vaccination) following vaccination at Day 1

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 analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase I (Safety Lead-in) groups.

End point values	ABCWY low dose Group	Placebo low dose Group	ABCWY high dose Group	Placebo high dose Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	3
Units: Participants	4	1	8	1

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with SAEs, AEs leading to withdrawal and AESIs in study Phase I (Safety Lead-in)

End point title	Number of participants with SAEs, AEs leading to withdrawal and AESIs in study Phase I (Safety Lead-in)[11][12]

End point description:

A SAEs is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity and is a congenital anomaly/birth defect in the offspring of a study subject. AESIs are predefined (serious or non-serious) AEs of scientific and medical concern specific to the product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor can be appropriate, because such an event might warrant further investigation to characterize and understand it. A participant was considered withdrawn if no study procedures occurred, and no follow-up or further information has been collected from the date of withdrawal or last contact. Analysis was performed on the Phase I ES.

End point type	Primary

End point timeframe:

Throughout the Phase 1 study period (Day 1 through Day 211)

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 analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase I (Safety Lead-in) groups.

End point values	ABCWY low dose Group	Placebo low dose Group	ABCWY high dose Group	Placebo high dose Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	3
Units: Participants				
SAEs (N=12, 4, 13, 3)	0	0	0	0
AEs leading to withdrawal (N=12, 4, 13, 3)	0	0	0	0
AESIs (N=12, 4, 13, 3)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with any unsolicited AEs, including all SAEs, AEs

leading to withdrawal and AESIs in study Phase I (Safety Lead-in)	
End point title	Number of participants with any unsolicited AEs, including all SAEs, AEs leading to withdrawal and AESIs in study Phase I (Safety Lead-in)[13][14]

End point description:

Unsolicited AEs includes any AE reported in addition to those solicited during the clinical study. Any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms is reported as unsolicited AE. A SAE is any untoward medical occurrence that results in death, is life-threatening, requires or prolongs hospitalization, results in disability/incapacity and is a congenital anomaly/birth defect in a subject's offspring. AESIs are predefined (serious or non-serious) AEs of scientific and medical concern specific to the product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor can be appropriate, because such an event might warrant further investigation to characterize and understand it. A participant was considered withdrawn if no study procedures occurred, and no follow-up or further information has been collected from the date of withdrawal or last contact. Analysis was performed on the Phase I ES.

End point type	Primary

End point timeframe:

During the 30 days (including the day of vaccination) following vaccination at Day 31

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[14] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase I (Safety Lead-in) groups.

End point values	ABCWY low dose Group	Placebo low dose Group	ABCWY high dose Group	Placebo high dose Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	11	3
Units: Participants	6	1	7	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with change from baseline in haematological and biochemical laboratory values, in study Phase I (Safety Lead-in)	
End point title	Number of participants with change from baseline in haematological and biochemical laboratory values, in study Phase I (Safety Lead-in)[15][16]

End point description:

The safety laboratory data included haematological parameters [basophils, eosinophils, Erythrocytes, hemoglobin (Hb), leukocytes, lymphocytes, monocytes, platelets, and neutrophils], and chemical parameters (Alanine Aminotransferase [ALT], Aspartate Aminotransferase [AST], Creatinine)
Below = value below the laboratory reference range defined for the specified visit and laboratory parameter; Within = value within the laboratory reference range defined for the specified visit and laboratory parameter; Above = value above the laboratory reference range defined for the specified visit and laboratory parameter. Analysis was performed on the Phase I ES.

End point type	Primary

End point timeframe:

At Day (D) 8 (7 days after the first vaccination)

Notes:

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

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

[16] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase I (Safety Lead-in) groups.

End point values	ABCWY low dose Group	Placebo low dose Group	ABCWY high dose Group	Placebo high dose Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	3
Units: Participants				
Basophils|Below(baseline)-below(D8)N=12,4,13,3	0	0	0	0
Eosinophils|Below(baseline)-below(D8)N=12,4,13,3	0	0	0	0
Erythrocytes|Below(baseline)-below(D8)N=12,4,13,3	0	0	0	0
Hb|Below(baseline)-below(D8)N=12,4,13,3	0	0	0	0
Leukocytes|Below(baseline)-below(D8)N=12,4,13,3	0	0	0	0
Lymphocytes|Below(baseline)-below(D8)N=12,4,13,3	0	0	0	0
Monocytes|Below(baseline)-below(D8)N=12,4,13,3	0	0	0	0
Neutrophils|Below(baseline)-below(D8)N=12,4,13,3	0	0	0	0
Platelets|Below(baseline)-below(D8)N=12,4,13,3	0	0	0	0
ALT|Below(baseline)-below(D8)N=12,4,13,3	0	0	0	0
AST|Below(baseline)-below(D8)N=12,4,13,3	0	0	0	0
Creatinine|Below(baseline)-below(D8)N=12,4,13,3	0	0	0	0
Basophils|Within(baseline)-below(D8)N=12,4,13,3	0	0	0	0
Eosinophils|Within(baseline)-below(D8)N=12,4,13,3	0	0	0	0
Erythrocyte|Within(baseline)-below(D8)N=12,4,13,3	0	0	0	0
Hb|Within(baseline)-below(D8)N=12,4,13,3	0	0	2	0
Leukocytes|Within(baseline)-below(D8)N=12,4,13,3	0	0	0	0
Lymphocytes|Within(baseline)-below(D8)N=12,4,13,3	0	0	0	0
Monocytes|Within(baseline)-below(D8)N=12,4,13,3	0	0	0	0
Neutrophils|Within(baseline)-below(D8)N=12,4,13,3	0	1	0	0
Platelets|Within(baseline)-below(D8)N=12,4,13,3	0	0	0	0
ALT|Within(baseline)-below(D8)N=12,4,13,3	0	0	0	0
AST|Within(baseline)-below(D8)N=12,4,13,3	0	0	0	0

Creatinine|Within(baseline)-below (D8)N=12,4,13,3	0	0	0	0
Basophils|Above(baseline)-below (D8)N=12,4,13,3	0	0	0	0
Eosinophils|Above(baseline)-below(D8)N=12,4,13,3	0	0	0	0
Erythrocytes|Above(baseline)-below(D8)N=12,4,13,3	0	0	0	0
Hb|Above(baseline)-below(D8)N=12,4,13,3	0	0	0	0
Leukocytes|Above(baseline)-below (D8)N=12,4,13,3	0	0	0	0
Lymphocytes|Above(baseline)-below (D8)N=12,4,13,3	0	0	0	0
Monocytes|Above(baseline)-below (D8)N=12,4,13,3	0	0	0	0
Neutrophils|Above(baseline)-below (D8)N=12,4,13,3	0	0	0	0
Platelets|Above(baseline)-below (D8)N=12,4,13,3	0	0	0	0
ALT|Above(baseline)-below (D8)N=12,4,13,3	0	0	0	0
AST|Above(baseline)-below (D8)N=12,4,13,3	0	0	0	0
Creatinine|Above(baseline)-below (D8)N=12,4,13,3	0	0	0	0
Basophils|Below(baseline)-within (D8)N=12,4,13,3	0	0	0	0
Eosinophil|Below(baseline)-within(D8)N=12,4,13,3	0	0	0	0
Erythrocyte|Below(baseline)-within (D8)N=12,4,13,3	0	0	1	0
Hb|Below(baseline)-within (D8)N=12,4,13,3	0	0	0	0
Leukocytes|Below(baseline)-within (D8)N=12,4,13,3	0	0	0	0
Lymphocytes|Below(baseline)-within (D8)N=12,4,13,3	0	0	0	0
Monocytes|Below(baseline)-within (D8)N=12,4,13,3	0	0	0	0
Neutrophils|Below(baseline)-within (D8)N=12,4,13,3	0	0	1	0
Platelets|Below(baseline)-within (D8)N=12,4,13,3	1	0	1	0
ALT|Below(baseline)-within (D8)N=12,4,13,3	0	0	0	0
AST|Below(baseline)-within (D8)N=12,4,13,3	0	0	0	0
Creatinine|Below(baseline)-within (D8)N=12,4,13,3	0	0	1	0
Basophils|Within(baseline)-within (D8)N=12,4,13,3	12	4	13	3
Eosinophil|Within(baseline)-within(D8)N=12,4,13,3	11	4	13	3
Erythrocyte|Within(baseline)-within(D8)N=12,4,13,3	12	4	12	3
Hb|Within(baseline)-within (D8)N=12,4,13,3	12	4	11	3
Leukocytes|Within(baseline)-within (D8)N=12,4,13,3	12	4	13	3
Lymphocytes|Within(baseline)-within(D8)N=12,4,13,3	12	4	13	3

Monocytes|Within(baseline)-within (D8)N=12,4,13,3	12	4	13	3
Neutrophils|Within(baseline)-within(D8)N=12,4,13,3	12	3	12	3
Platelets|Within(baseline)-within (D8)N=12,4,13,3	11	4	12	3
ALT|Within(baseline)-within (D8)N=12,4,13,3	10	4	10	2
AST|Within(baseline)-within (D8)N=12,4,13,3	12	4	12	2
Creatinine|Within(baseline)-within (D8)N=12,4,13,3	12	3	12	2
Basophils|Above(baseline)-within (D8)N=12,4,13,3	0	0	0	0
Eosinophil|Above(baseline)-within(D8)N=12,4,13,3	0	0	0	0
Erythrocyte|Above(baseline)-within (D8)N=12,4,13,3	0	0	0	0
Hb|Above(baseline)-within (D8)N=12,4,13,3	0	0	0	0
Leukocytes|Above(baseline)-within (D8)N=12,4,13,3	0	0	0	0
Lymphocytes|Above(baseline)-within (D8)N=12,4,13,3	0	0	0	0
Monocytes|Above(baseline)-within (D8)N=12,4,13,3	0	0	0	0
Neutrophils|Above(baseline)-within (D8)N=12,4,13,3	0	0	0	0
Platelets|Above(baseline)-within (D8)N=12,4,13,3	0	0	0	0
ALT|Above(baseline)-within (D8)N=12,4,13,3	1	0	0	0
AST|Above(baseline)-within (D8)N=12,4,13,3	0	0	0	0
Creatinine|Above(baseline)-within (D8)N=12,4,13,3	0	1	0	1
Basophils|Below(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Eosinophil|Below(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Erythrocytes|Below(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Hb|Below(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Leukocytes|Below(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Lymphocytes|Below(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Monocytes|Below(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Neutrophils|Below(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Platelets|Below(baseline)-above(D8)N=12,4,13,3	0	0	0	0
ALT|Below(baseline)-above(D8)N=12,4,13,3	0	0	0	0
AST|Below(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Creatinine|Below(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Basophils|Within(baseline)-above(D8)N=12,4,13,3	0	0	0	0

Eosinophils|Within (baseline)-above(D8)N=12,4,13,3	1	0	0	0
Erythrocyte|Within(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Hb|Within(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Leukocytes|Within(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Lymphocytes|Within(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Monocytes|Within(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Neutrophils|Within(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Platelets|Within(baseline)-above(D8)N=12,4,13,3	0	0	0	0
ALT|Within(baseline)-above(D8)N=12,4,13,3	0	0	1	1
AST|Within(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Creatinine|Within(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Basophils|Above(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Eosinophils|Above(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Erythrocytes|Above(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Hemoglobin|Above(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Leukocytes|Above(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Lymphocytes|Above(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Monocytes|Above(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Neutrophils|Above(baseline)-above(D8)N=12,4,13,3	0	0	0	0
Platelets|Above(baseline)-above(D8)N=12,4,13,3	0	0	0	0
ALT|Above(baseline)-above(D8)N=12,4,13,3	1	0	2	0
AST|Above(baseline)-above(D8)N=12,4,13,3	0	0	1	1
Creatinine|Above(baseline)-above(D8)N=12,4,13,3	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Clinically Significant Haematological and Biochemical Laboratory Values, in study Phase I (Safety Lead-in)

End point title	Number of Participants with Clinically Significant Haematological and Biochemical Laboratory Values, in study Phase I (Safety Lead-in)[17][18]

End point description:

Clinical laboratory testing included hematological and biochemical laboratory values. Any abnormal

laboratory test result (e.g., in hematology or clinical chemistry) that was deemed clinically significant by the investigator's medical and scientific judgment, and not related to an underlying disease, was reported as an unsolicited adverse event (AE) unless it was considered by the investigator to be more severe than expected for the participant's condition. The safety laboratory data included hematological parameters (basophils, eosinophils, erythrocytes, hemoglobin, leukocytes, lymphocytes, monocytes, platelets, and neutrophils) and chemical parameters (Alanine Aminotransferase [ALT], Aspartate Aminotransferase [AST], and creatinine).

End point type	Primary

End point timeframe:

At Day 8 (7 days after the first vaccination)

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[18] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase I (Safety Lead-in) groups.

End point values	ABCWY low dose Group	Placebo low dose Group	ABCWY high dose Group	Placebo high dose Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	12	4	13	3
Units: Participants				
Basophils (N=12,4,13,3)	0	0	0	0
Eosinophils (N=12,4,13,3)	0	0	0	0
Erythrocytes (N=12,4,13,3)	0	0	0	0
Hemoglobin (N=12,4,13,3)	0	0	0	0
Leukocytes (N=12,4,13,3)	0	0	0	0
Lymphocytes (N=12,4,13,3)	0	0	0	0
Monocytes (N=12,4,13,3)	0	0	0	0
Neutrophils (N=12,4,13,3)	0	0	0	0
Platelets (N=12,4,13,3)	0	0	0	0
ALT (N=12,4,13,3)	0	0	0	0
AST (N=12,4,13,3)	0	0	0	0
Creatinine (N=12,4,13,3)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of blood samples with bactericidal serum activity using enc-hSBA against a panel of 110 randomly selected endemic US N. meningitidis serogroup B invasive disease strains at study Phase II (Formulation and Schedule-finding)

End point title	Percentage of blood samples with bactericidal serum activity using enc-hSBA against a panel of 110 randomly selected endemic US N. meningitidis serogroup B invasive disease strains at study Phase II (Formulation and Schedule-finding)[19]

End point description:

The effectiveness of the MenABCWY-2Gen (low & high dose) vaccine when administered at 0,2- or 0,6-months schedule compared to MenB vaccine administered at 0,6-months schedule, against a panel of 110 randomly selected endemic N. meningitidis serogroup B strains is measured in terms of percentage

of samples with bactericidal activity using endogenous complement human Serum Bactericidal Assay (enc-hSBA), which provides a qualitative assessment (yes/no) of the presence of sufficient bactericidal antibodies in human sera to kill a meningococcal strain at a specific dilution of 1:4.

End point type	Primary

End point timeframe:

At Day 211 (1 month after the last vaccination)

Notes:

[19] - 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: As specified in the Protocol, the analysis assesses the immune response to the MenABCWY-2Gen and Men B vaccine against serogroup B indicator strains in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	230[20]	177[21]	235[22]	189[23]
Units: Percentage of blood Samples				
number (not applicable)				
Number Analyzed	91.0	86.2	91.0	88.4

Notes:

[20] - Number of Samples Analyzed:6714

[21] - Number of Samples Analyzed:5383

[22] - Number of Samples Analyzed:7063

[23] - Number of Samples Analyzed:5540,

End point values	Control Group			
Subject group type	Reporting group			
Number of subjects analysed	194[24]			
Units: Percentage of blood Samples				
number (not applicable)				
Number Analyzed	86.4			

Notes:

[24] - Number of Samples Analyzed:5620

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

To demonstrate the superiority of the effectiveness of the MenABCWY-2Gen vaccine (low dose) when administered at 0,6-months schedule, compared to the MenB vaccine administered at 0,6-months schedule.

Comparison groups	ABCWY low dose_06 Group v Control Group
Number of subjects included in analysis	424
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	4.67
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	3.38
upper limit	5.97

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

To demonstrate the superiority of the effectiveness of the MenABCWY-2Gen vaccine (low dose) when administered at 0,2- months schedule, compared to the MenB vaccine administered at 0,6-months schedule.

Comparison groups	ABCWY low dose_02 Group v Control Group
Number of subjects included in analysis	371
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	-0.17
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-1.65
upper limit	1.3

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

To demonstrate the superiority of the effectiveness of the MenABCWY-2Gen vaccine (high dose) when administered at 0,6- months schedule, compared to the MenB vaccine administered at 0,6-months schedule.

Comparison groups	ABCWY high dose_06 Group v Control Group
Number of subjects included in analysis	429
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	4.6
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	3.33
upper limit	5.89

Statistical analysis title	Statistical Analysis 4

Statistical analysis description:

To demonstrate the superiority of the effectiveness of the MenABCWY-2Gen vaccine (high dose) when administered at 0,2- months schedule, compared to the MenB vaccine administered at 0,6-months schedule.

Comparison groups	ABCWY high dose_02 Group v Control Group

Number of subjects included in analysis	383
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	2.01
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	0.6
upper limit	3.42

Primary: Number of participants with a 4-fold rise in hSBA titers against serogroups A, C, W and Y in study Phase II (Formulation and Schedule-finding) At Day 211

End point title	Number of participants with a 4-fold rise in hSBA titers against serogroups A, C, W and Y in study Phase II (Formulation and Schedule-finding) At Day 211[25]

End point description:

The immune response to the MenABCWY-2Gen (low and high dose) vaccine when administered at 0,2- or 0,6-months schedule compared to MenACWY vaccine (single dose), relative to day 1 in the ABCWY and control groups (0, 6 month schedule) and day 31 in ABCWY (0, 2 month schedule) is measured in terms of number of participants achieving a 4-fold rise in hSBA titers against serogroups A, C, W and Y. The 4-fold rise is defined as: -a post-vaccination hSBA titer ≥ 16 for participants with a pre-vaccination hSBA titer < 4, -a post-vaccination hSBA titer ≥ 4 times the lower limit of quantitation (LLOQ) for participants with a pre-vaccination hSBA titer ≥LOD but <LLOQ, and. -a post-vaccination hSBA titer ≥ 4 times the pre-vaccination hSBA titer for participants with a pre-vaccination hSBA titer ≥LLOQ.

End point type	Primary

End point timeframe:

At Day 211 for ABCWY groups (1 month after the last MenABCWY-2Gen vaccination) and at Day 31 for Control group (1 month after the last MenACWY vaccination)

Notes:

[25] - 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: As specified in the Protocol, the analysis assesses the immune response to the MenABCWY-2Gen and Men B vaccine against serogroup A, C, W and Y in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	135	116	147	118
Units: Participants				
Men A (N= 132,109,140,112,156)	125	105	136	107
Men C (N=135,113,146,118,152)	129	107	132	111
Men W (N=134,114,143,116,156)	129	108	135	105
Men Y (N=131,116,147,115,159)	122	102	131	100

End point values	Control Group			
Subject group type	Reporting group			
Number of subjects analysed	159			
Units: Participants				

Men A (N= 132,109,140,112,156)	143			
Men C (N=135,113,146,118,152)	92			
Men W (N=134,114,143,116,156)	102			
Men Y (N=131,116,147,115,159)	95			

Statistical analyses

Statistical analysis title	Statistical Analysis 3
Statistical analysis description:	
To demonstrate the immunological non-inferiority of the MenABCWY-2Gen vaccine (high dose) administered at 0,6-months schedule compared to the MenACWY vaccine administered at month 0 in the control group (Men A).	
Comparison groups	ABCWY high dose_06 Group v Control Group
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	5.48
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-0.71
upper limit	12.25

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
To demonstrate the immunological non-inferiority of the MenABCWY-2Gen vaccine (low dose) administered at 0,2-months schedule compared to the MenACWY vaccine administered at month 0 in the control group (Men A).	
Comparison groups	ABCWY low dose_02 Group v Control Group
Number of subjects included in analysis	275
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	4.66
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-2.71
upper limit	11.64

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
To demonstrate the immunological non-inferiority of the MenABCWY-2Gen vaccine (low dose) administered at 0,6-months schedule compared to the MenACWY vaccine administered at month 0 in the control group (Men A).	

Comparison groups	ABCWY low dose_06 Group v Control Group
Number of subjects included in analysis	294
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	3.03
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-4.21
upper limit	10.17

Statistical analysis title	Statistical Analysis 4

Statistical analysis description:

To demonstrate the immunological non-inferiority of the MenABCWY-2Gen vaccine (high dose) administered at 0,2-months schedule compared to the MenACWY vaccine administered at month 0 in the control group (Men A).

Comparison groups	ABCWY high dose_02 Group v Control Group
Number of subjects included in analysis	277
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	3.87
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-3.7
upper limit	10.97

Statistical analysis title	Statistical Analysis 7

Statistical analysis description:

To demonstrate the immunological non-inferiority of the MenABCWY-2Gen vaccine (high dose) administered at 0,6-months schedule compared to the MenACWY vaccine administered at month 0 in the control group (Men C).

Comparison groups	ABCWY high dose_06 Group v Control Group
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	29.88
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	19.26
upper limit	40.19

Statistical analysis title	Statistical Analysis 6

Statistical analysis description:

To demonstrate the immunological non-inferiority of the MenABCWY-2Gen vaccine (low dose) administered at 0,2-months schedule compared to the MenACWY vaccine administered at month 0 in the control group (Men C).

Comparison groups	ABCWY low dose_02 Group v Control Group
Number of subjects included in analysis	275
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	34.16
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	23.76
upper limit	44.1

Statistical analysis title	Statistical Analysis 5

Statistical analysis description:

To demonstrate the immunological non-inferiority of the MenABCWY-2Gen vaccine (low dose) administered at 0,6-months schedule compared to the MenACWY vaccine administered at month 0 in the control group (Men C).

Comparison groups	ABCWY low dose_06 Group v Control Group
Number of subjects included in analysis	294
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	35.03
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	25.22
upper limit	44.75

Statistical analysis title	Statistical Analysis 8

Statistical analysis description:

To demonstrate the immunological non-inferiority of the MenABCWY-2Gen vaccine (high dose) administered at 0,2-months schedule compared to the MenACWY vaccine administered at month 0 in the control group (Men C).

Comparison groups	ABCWY high dose_02 Group v Control Group

Number of subjects included in analysis	277
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	33.54
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	23.09
upper limit	43.54

Statistical analysis title	Statistical Analysis 11

Statistical analysis description:

To demonstrate the immunological non-inferiority of the MenABCWY-2Gen vaccine (high dose) administered at 0,6-months schedule compared to the MenACWY vaccine administered at month 0 in the control group (Men W).

Comparison groups	ABCWY high dose_06 Group v Control Group
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	29.02
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	19.42
upper limit	38.67

Statistical analysis title	Statistical Analysis 10

Statistical analysis description:

To demonstrate the immunological non-inferiority of the MenABCWY-2Gen vaccine (low dose) administered at 0,2-months schedule compared to the MenACWY vaccine administered at month 0 in the control group (Men W).

Comparison groups	ABCWY low dose_02 Group v Control Group
Number of subjects included in analysis	275
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	29.35
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	19.31
upper limit	39.08

Statistical analysis title	Statistical Analysis 9

Statistical analysis description:

To demonstrate the immunological non-inferiority of the MenABCWY-2Gen vaccine (low dose) administered at 0,6-months schedule compared to the MenACWY vaccine administered at month 0 in the control group (Men W).

Comparison groups	ABCWY low dose_06 Group v Control Group
Number of subjects included in analysis	294
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	30.88
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	21.61
upper limit	40.32

Statistical analysis title	Statistical Analysis 12

Statistical analysis description:

To demonstrate the immunological non-inferiority of the MenABCWY-2Gen vaccine (high dose) administered at 0,2-months schedule compared to the MenACWY vaccine administered at month 0 in the control group (Men W).

Comparison groups	ABCWY high dose_02 Group v Control Group
Number of subjects included in analysis	277
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	25.13
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	14.2
upper limit	35.45

Statistical analysis title	Statistical Analysis 15

Statistical analysis description:

To demonstrate the immunological non-inferiority of the MenABCWY-2Gen vaccine (high dose) administered at 0,6-months schedule compared to the MenACWY vaccine administered at month 0 in the control group (Men Y).

Comparison groups	ABCWY high dose_06 Group v Control Group
Number of subjects included in analysis	306
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	29.37

Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	18.67
upper limit	39.63

Statistical analysis title	Statistical Analysis 14

Statistical analysis description:

To demonstrate the immunological non-inferiority of the MenABCWY-2Gen vaccine (low dose) administered at 0,2-months schedule compared to the MenACWY vaccine administered at month 0 in the control group (Men Y).

Comparison groups	ABCWY low dose_02 Group v Control Group
Number of subjects included in analysis	275
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	28.18
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	16.61
upper limit	38.86

Statistical analysis title	Statistical Analysis 13

Statistical analysis description:

To demonstrate the immunological non-inferiority of the MenABCWY-2Gen vaccine (low dose) administered at 0,6-months schedule compared to the MenACWY vaccine administered at month 0 in the control group (Men Y).

Comparison groups	ABCWY low dose_06 Group v Control Group
Number of subjects included in analysis	294
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	33.38
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	23.08
upper limit	43.26

Statistical analysis title	Statistical Analysis 16

Statistical analysis description:

To demonstrate the immunological non-inferiority of the MenABCWY-2Gen vaccine (high dose) administered at 0,2-months schedule compared to the MenACWY vaccine administered at month 0 in the control group (Men Y).

Comparison groups	ABCWY high dose_02 Group v Control Group
Number of subjects included in analysis	277
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in percentage
Point estimate	27.21
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	15.46
upper limit	38.02

Primary: Number of participants with solicited administration site events in study Phase II (Formulation and Schedule-finding) at Day 1

End point title	Number of participants with solicited administration site events in study Phase II (Formulation and Schedule-finding) at Day 1[26][27]

End point description:

Assessed solicited administration site events included injection site pain, erythema (redness), swelling and induration. Any = occurrence of the event regardless of intensity grade.

End point type	Primary

End point timeframe:

During the 7 days (including the day of vaccination) following vaccination at Day 1

Notes:

[26] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[27] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen and Men B vaccine in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	239	181	238	194
Units: Participants				
Erythema (N=239, 181, 238, 194 178, 178)	32	0	29	0
Induration (N=239, 181, 238, 194 178, 178)	22	1	30	1
Pain (N=239, 181, 238, 194, 178 ,178)	217	39	220	42
Swelling (N=239, 181, 238, 194 178,178)	34	0	32	0

End point values	Control (MenACWY) Group	Control (MenB_06) Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	178	178		

Units: Participants				
Erythema (N=239, 181, 238, 194 178, 178)	6	13		
Induration (N=239, 181, 238, 194 178, 178)	6	11		
Pain (N=239, 181, 238, 194, 178 ,178)	76	145		
Swelling (N=239, 181, 238, 194 178,178)	4	8		

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with solicited administration site events in study Phase II (Formulation and Schedule-finding) at Day 121

End point title	Number of participants with solicited administration site events in study Phase II (Formulation and Schedule-finding) at Day 121[28][29]

End point description:

Assessed solicited administration site events included injection site pain, erythema (redness), swelling and induration. Any = occurrence of the event regardless of intensity grade.

End point type	Primary

End point timeframe:

During the 7 days (including the day of vaccination) following vaccination at Day 121

Notes:

[28] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[29] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen and Men B vaccine in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	220	170	224	182
Units: Participants				
Erythema (N=220,170,224, 182,0,0)	0	17	0	14
Induration (N=220,170,224, 182,0,0)	1	15	0	18
Pain (N=220,170,224,182,0,0)	28	143	26	153
Swelling (N=220,170,224,182,0,0)	1	21	0	21

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with solicited administration site events in study Phase II (Formulation and Schedule-finding) at Day 181

End point title	Number of participants with solicited administration site events in study Phase II (Formulation and Schedule-finding) at Day 181[30][31]

End point description:

Assessed solicited administration site events included injection site pain, erythema (redness), swelling and induration. Any = occurrence of the event regardless of intensity grade.

End point type	Primary

End point timeframe:

During the 7 days (including the day of vaccination) following vaccination at Day 181

Notes:

[30] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[31] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen and Men B vaccine in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	216	163	220	176
Units: Participants				
Erythema(N=216,163,220,176,0,187)	23	15	21	17
Induration(N=216,163,220,176,0,187)	18	17	20	15
Pain(N=216,163,220,176,0,187)	191	134	187	146
Swelling(N=216,163,220,176,0,187)	27	25	27	23

End point values	Control (MenB_06) Group			
Subject group type	Subject analysis set			
Number of subjects analysed	187			
Units: Participants				
Erythema(N=216,163,220,176,0,187)	18			
Induration(N=216,163,220,176,0,187)	16			
Pain(N=216,163,220,176,0,187)	154			
Swelling(N=216,163,220,176,0,187)	23			

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with solicited systemic events in study Phase II (Formulation and Schedule-finding) at Day 1

End point title	Number of participants with solicited systemic events in study Phase II (Formulation and Schedule-finding) at Day 1[32][33]

End point description:

Assessed solicited systemic events included fever (temperature ≥ 38.0°C), nausea, fatigue, myalgia,

arthralgia and headache. Any = occurrence of the event regardless of intensity grade or relation to the study vaccination.

End point type	Primary

End point timeframe:

During the 7 days (including the day of vaccination) following vaccination at Day 1

Notes:

[32] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[33] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen and Men B vaccine in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	239	181	238	194
Units: Participants				
Arthralgia (N=239, 181, 238, 194,197)	17	6	16	6
Fatigue (N=239, 181, 238, 194,197)	123	60	109	73
Headache (N=239, 181, 238, 194,197)	92	60	102	63
Myalgia (N=239, 181, 238, 194,197)	28	6	23	9
Nausea (N=239, 181, 238, 194,197)	30	16	23	13
Fever (N=239, 181, 238, 194,197)	4	2	8	1

End point values	Control Group			
Subject group type	Reporting group			
Number of subjects analysed	197			
Units: Participants				
Arthralgia (N=239, 181, 238, 194,197)	11			
Fatigue (N=239, 181, 238, 194,197)	91			
Headache (N=239, 181, 238, 194,197)	78			
Myalgia (N=239, 181, 238, 194,197)	18			
Nausea (N=239, 181, 238, 194,197)	19			
Fever (N=239, 181, 238, 194,197)	8			

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with solicited systemic events in study Phase II (Formulation and Schedule-finding) at Day 121

End point title	Number of participants with solicited systemic events in study Phase II (Formulation and Schedule-finding) at Day 121[34][35]

End point description:

Assessed solicited systemic events included fever (temperature ≥ 38.0°C), nausea, fatigue, myalgia, arthralgia and headache. Any = occurrence of the event regardless of intensity grade or relation to the

study vaccination.

End point type	Primary

End point timeframe:

During the 7 days (including the day of vaccination) following vaccination at Day 121

Notes:

[34] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[35] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen and Men B vaccine in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	220	170	224	182
Units: Participants				
Arthralgia(N=220, 170, 224, 182,0)	2	13	4	8
Fatigue(N=220, 170, 224, 182,0)	46	72	42	68
Headache(N=220, 170, 224, 182,0)	46	56	47	58
Myalgia(N=220, 170, 224, 182,0)	4	21	8	23
Nausea(N=220, 170, 224, 182,0)	13	8	14	19
Fever (N=220, 170, 224, 182,0)	1	5	2	5

End point values	Control Group			
Subject group type	Reporting group			
Number of subjects analysed	0[36]			
Units: Participants				
Arthralgia(N=220, 170, 224, 182,0)				
Fatigue(N=220, 170, 224, 182,0)				
Headache(N=220, 170, 224, 182,0)				
Myalgia(N=220, 170, 224, 182,0)				
Nausea(N=220, 170, 224, 182,0)				
Fever (N=220, 170, 224, 182,0)				

Notes:

[36] - At Day 121 no participants received vaccination.

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with solicited systemic events in study Phase II (Formulation and Schedule-finding) at Day 181

End point title	Number of participants with solicited systemic events in study Phase II (Formulation and Schedule-finding) at Day 181[37][38]

End point description:

Assessed solicited systemic events included fever (temperature ≥ 38.0°C), nausea, fatigue, myalgia, arthralgia and headache. Any = occurrence of the event regardless of intensity grade or relation to the study vaccination.

End point type	Primary

End point timeframe:

During the 7 days (including the day of vaccination) following vaccination at Day 181

Notes:

[37] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[38] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen and Men B vaccine in in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	216	163	220	176
Units: Participants				
Arthralgia(N=216,163,220,176,187)	14	8	22	13
Fatigue(N=216,163,220,176,187)	86	59	98	62
Headache(N=216,163,220,176,187)	75	59	90	59
Myalgia(N=216,163,220,176,187)	26	18	36	20
Nausea(N=216,163,220,176,187)	22	11	31	12
Fever(N=216,163,220,176,187)	4	6	8	3

End point values	Control Group			
Subject group type	Reporting group			
Number of subjects analysed	187			
Units: Participants				
Arthralgia(N=216,163,220,176,187)	6			
Fatigue(N=216,163,220,176,187)	75			
Headache(N=216,163,220,176,187)	64			
Myalgia(N=216,163,220,176,187)	33			
Nausea(N=216,163,220,176,187)	15			
Fever(N=216,163,220,176,187)	5			

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with any unsolicited AEs (including all SAEs, AEs leading to withdrawal, and AESIs) in study Phase II (Formulation and Schedule-finding) at Day 1

End point title	Number of participants with any unsolicited AEs (including all SAEs, AEs leading to withdrawal, and AESIs) in study Phase II (Formulation and Schedule-finding) at Day 1[39][40]

End point description:

Unsolicited AEs includes any AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms is

reported as an unsolicited adverse event. A SAE is any untoward medical occurrence that results in death, is life-threatening, requires or prolongs hospitalization, results in disability/incapacity and is a congenital anomaly/birth defect in a subject's offspring. AESIs are predefined (serious or non-serious) AEs of scientific and medical concern specific to the product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor can be appropriate, because such an event might warrant further investigation to characterize and understand it. A participant was considered withdrawn if no study procedures occurred, and no follow-up or further information has been collected from the date of withdrawal or last contact.

End point type	Primary

End point timeframe:

During the 30 days (including the day of vaccination) following vaccination at Day 1

Notes:

[39] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[40] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen and Men B vaccine in in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	239	181	238	194
Units: Participants	51	34	52	35

End point values	Control Group			
Subject group type	Reporting group			
Number of subjects analysed	197			
Units: Participants	27			

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with any unsolicited AEs (including all SAEs, AEs leading to withdrawal, and AESIs) in study Phase II (Formulation and Schedule-finding) at Day 121

End point title	Number of participants with any unsolicited AEs (including all SAEs, AEs leading to withdrawal, and AESIs) in study Phase II (Formulation and Schedule-finding) at Day 121[41][42]

End point description:

Unsolicited AEs includes any AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms is reported as an unsolicited adverse event. A SAE is any untoward medical occurrence that results in death, is life-threatening, requires or prolongs hospitalization, results in disability/incapacity and is a congenital anomaly/birth defect in a subject's offspring. AESIs are predefined (serious or non-serious) AEs of scientific and medical concern specific to the product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor can be appropriate, because such an event might warrant further investigation to characterize and understand it. A participant was considered withdrawn if no study procedures occurred, and no follow-up or further information has been collected from the date of withdrawal or last contact.

End point type	Primary

End point timeframe:

During the 30 days (including the day of vaccination) following vaccination at Day 121

Notes:

[41] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[42] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen and Men B vaccine in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	220	170	224	182
Units: Participants	16	19	22	18

End point values	Control Group			
Subject group type	Reporting group			
Number of subjects analysed	0[43]			
Units: Participants				

Notes:

[43] - At Day 121 no participant received vaccination in Control group.

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with SAEs, AEs leading to withdrawal and AESIs in study Phase II (Formulation and Schedule-Finding)

End point title	Number of participants with SAEs, AEs leading to withdrawal and AESIs in study Phase II (Formulation and Schedule-Finding)[44][45]

End point description:

A SAEs is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity and is a congenital anomaly/birth defect in the offspring of a study subject. AESIs are predefined (serious or non-serious) AEs of scientific and medical concern specific to the product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor can be appropriate, because such an event might warrant further investigation to characterize and understand it. A participant was considered withdrawn if no study procedures occurred, and no follow-up or further information has been collected from the date of withdrawal or last contact.

End point type	Primary

End point timeframe:

Throughout the Phase II FSF study period (Day 1 through Day 541)

Notes:

[44] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[45] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen and Men B vaccine in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	239	181	238	194
Units: Participants				
SAEs(N= 239,181,238,194,197)	9	7	4	4
AEs leading to withdrawal(N= 239,181,238,194,197)	1	0	1	1
AESIs(N=239,181,238,194,197)	4	1	2	0

End point values	Control Group			
Subject group type	Reporting group			
Number of subjects analysed	197			
Units: Participants				
SAEs(N= 239,181,238,194,197)	2			
AEs leading to withdrawal(N= 239,181,238,194,197)	0			
AESIs(N=239,181,238,194,197)	1			

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with any unsolicited AEs (including all SAEs, AEs leading to withdrawal, and AESIs) in study Phase II (Formulation and Schedule-finding) at Day 181

End point title	Number of participants with any unsolicited AEs (including all SAEs, AEs leading to withdrawal, and AESIs) in study Phase II (Formulation and Schedule-finding) at Day 181[46][47]

End point description:

Unsolicited AEs includes any AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms is reported as an unsolicited adverse event. A SAE is any untoward medical occurrence that results in death, is life-threatening, requires or prolongs hospitalization, results in disability/incapacity and is a congenital anomaly/birth defect in a subject’s offspring. AESIs are predefined (serious or non-serious) AEs of scientific and medical concern specific to the product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor can be appropriate, because such an event might warrant further investigation to characterize and understand it. A participant was considered withdrawn if no study procedures occurred, and no follow-up or further information has been collected from the date of withdrawal or last contact.

End point type	Primary

End point timeframe:

During the 30 days (including the day of vaccination) following vaccination at Day 181

Notes:

[46] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[47] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen and Men B vaccine in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	216	163	220	176
Units: Participants	28	24	42	27

End point values	Control Group			
Subject group type	Reporting group			
Number of subjects analysed	187			
Units: Participants	28			

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with solicited administration site events in study Phase II (Sourcing) at Day 1

End point title	Number of participants with solicited administration site events in study Phase II (Sourcing) at Day 1[48][49]

End point description:

Assessed solicited administration site events included injection site pain, erythema (redness), swelling and induration. Any = occurrence of the event regardless of intensity grade.

End point type	Primary

End point timeframe:

During the 7 days (including the day of vaccination) following vaccination at Day 1

Notes:

[48] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[49] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen in study Phase II (Sourcing) groups.

End point values	ABCWY low dose_01 Group	ABCWY high dose_01 Group	ABCWY low doseS_02 Group	ABCWY high doseS_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	54	53	62	62
Units: Participants				
Erythema (N=54,53,62,62,62,63)	0	0	0	0
Induration(N=54,53,62,62,62,63)	0	0	0	0
Pain(N=54,53,62,62,62,63)	2	4	3	1
Swelling(N=54,53,62,62,62,63)	0	0	0	0

End point values	ABCWY low doseS_06 Group	ABCWY high doseS_06 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	62	63		
Units: Participants				
Erythema (N=54,53,62,62,62,63)	0	0		
Induration(N=54,53,62,62,62,63)	0	0		
Pain(N=54,53,62,62,62,63)	1	2		
Swelling(N=54,53,62,62,62,63)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with solicited administration site events in study Phase II (Sourcing) at Day 31

End point title	Number of participants with solicited administration site events in study Phase II (Sourcing) at Day 31[50][51]

End point description:

Assessed solicited administration site events included injection site pain, erythema (redness), swelling and induration. Any = occurrence of the event regardless of intensity grade.

End point type	Primary

End point timeframe:

During the 7 days (including the day of vaccination) following vaccination at Day 31

Notes:

[50] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[51] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase II (Sourcing) groups.

End point values	ABCWY low dose_01 Group	ABCWY high dose_01 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	47		
Units: Participants				
Erythema (N=50,47)	0	1		
Induration(N=50,47)	0	0		
Pain(N=50,47)	0	1		
Swelling(N=50,47)	0	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with solicited administration site events in study Phase II (Sourcing) at Day 61

End point title	Number of participants with solicited administration site events in study Phase II (Sourcing) at Day 61[52][53]

End point description:

Assessed solicited administration site events included injection site pain, erythema (redness), swelling and induration. Any = occurrence of the event regardless of intensity grade.

End point type	Primary

End point timeframe:

During the 7 days (including the day of vaccination) following vaccination at Day 61

Notes:

[52] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[53] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase II (Sourcing) groups.

End point values	ABCWY low doseS_02 Group	ABCWY high doseS_02 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58	60		
Units: Participants				
Erythema (N=58,60)	0	0		
Induration(N=58,60)	0	0		
Pain(N=58,60)	2	3		
Swelling(N=58,60)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with solicited administration site events in study Phase II (Sourcing) at Day 181

End point title	Number of participants with solicited administration site events in study Phase II (Sourcing) at Day 181[54][55]

End point description:

Assessed solicited administration site events included injection site pain, erythema (redness), swelling and induration. Any = occurrence of the event regardless of intensity grade.

End point type	Primary

End point timeframe:

During the 7 days (including the day of vaccination) following vaccination at Day 181

Notes:

[54] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[55] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase II (Sourcing) groups.

End point values	ABCWY low doseS_06 Group	ABCWY high doseS_06 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60	55		
Units: Participants				
Erythema(N=60,55)	0	0		
Induration(N=60,55)	0	0		
Pain(N=60,55)	4	3		
Swelling(N=60,55)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with solicited systemic events in study Phase II (Sourcing) at Day 1

End point title	Number of participants with solicited systemic events in study Phase II (Sourcing) at Day 1[56][57]

End point description:

Assessed solicited systemic events included fever (temperature ≥ 38.0°C), nausea, fatigue, myalgia, arthralgia and headache. Any = occurrence of the event regardless of intensity grade or relation to the study vaccination.

End point type	Primary

End point timeframe:

During the 7 days (including the day of vaccination) following vaccination at Day 1

Notes:

[56] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[57] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase II (Sourcing) groups.

End point values	ABCWY low dose_01 Group	ABCWY high dose_01 Group	ABCWY low doseS_02 Group	ABCWY high doseS_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	54	53	62	62
Units: Participants				
Arthralgia (N=54,53,62,62,62,63)	1	0	1	0
Fatigue (N=54,53,62,62,62,63)	2	1	2	0
Headache (N=54,53,62,62,62,63)	3	0	0	0
Myalgia (N=54,53,62,62,62,63)	1	0	1	0
Nausea (N=54,53,62,62,62,63)	2	1	0	0
Fever (N=54,53,62,62,62,63)	0	0	0	0

End point values	ABCWY low doseS_06 Group	ABCWY high doseS_06 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	62	63		
Units: Participants				
Arthralgia (N=54,53,62,62,62,63)	0	0		
Fatigue (N=54,53,62,62,62,63)	0	1		
Headache (N=54,53,62,62,62,63)	0	3		
Myalgia (N=54,53,62,62,62,63)	0	1		
Nausea (N=54,53,62,62,62,63)	1	0		
Fever (N=54,53,62,62,62,63)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with solicited systemic events in study Phase II (Sourcing) at Day 31

End point title	Number of participants with solicited systemic events in study Phase II (Sourcing) at Day 31[58][59]

End point description:

Assessed solicited systemic events included fever (temperature ≥ 38.0°C), nausea, fatigue, myalgia, arthralgia and headache. Any = occurrence of the event regardless of intensity grade or relation to the study vaccination.

End point type	Primary

End point timeframe:

During the 7 days (including the day of vaccination) following vaccination at Day 31

Notes:

[58] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[59] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase II (Sourcing) groups.

End point values	ABCWY low dose_01 Group	ABCWY high dose_01 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	47		
Units: Participants				
Arthralgia (N=50,47)	0	0		
Fatigue(N=50,47)	1	0		
Headache(N=50,47)	0	3		
Myalgia(N=50,47)	0	0		
Nausea(N=50,47)	0	2		
Fever (N=50,47)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with solicited systemic events in study Phase II (Sourcing) at Day 61

End point title	Number of participants with solicited systemic events in study Phase II (Sourcing) at Day 61[60][61]

End point description:

Assessed solicited systemic events included fever (temperature ≥ 38.0°C), nausea, fatigue, myalgia, arthralgia and headache. Any = occurrence of the event regardless of intensity grade or relation to the study vaccination.

End point type	Primary

End point timeframe:

During the 7 days (including the day of vaccination) following vaccination at Day 61

Notes:

[60] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[61] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase II (Sourcing) groups.

End point values	ABCWY low doseS_02 Group	ABCWY high doseS_02 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58	60		
Units: Participants				
Arthralgia(N=58,60)	0	0		
Fatigue(N=58,60)	0	0		
Headache(N=58,60)	0	0		
Myalgia(N=58,60)	1	0		

Nausea(N=58,60)	0	0		
Fever (N=58,60)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with solicited systemic events in study Phase II (Sourcing) at Day 181

End point title	Number of participants with solicited systemic events in study Phase II (Sourcing) at Day 181[62][63]

End point description:

Assessed solicited systemic events included fever (temperature ≥ 38.0°C), nausea, fatigue, myalgia, arthralgia and headache. Any = occurrence of the event regardless of intensity grade or relation to the study vaccination.

End point type	Primary

End point timeframe:

During the 7 days (including the day of vaccination) following vaccination at Day 181

Notes:

[62] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[63] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase II (Sourcing) groups.

End point values	ABCWY low doseS_06 Group	ABCWY high doseS_06 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60	55		
Units: Participants				
Arthralgia(N=60,55)	0	0		
Fatigue(N=60,55)	0	0		
Headache(N=60,55)	0	0		
Myalgia(N=60,55)	0	0		
Nausea(N=60,55)	0	0		
Fever (N=60,55)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with any unsolicited AEs (including all SAEs, AEs leading to withdrawal, and AESIs) in study Phase II (Sourcing) at Day 1

End point title	Number of participants with any unsolicited AEs (including all SAEs, AEs leading to withdrawal, and AESIs) in study Phase II

	(Sourcing) at Day 1[64][65]

End point description:

Unsolicited AEs includes any AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms is reported as an unsolicited adverse event. A SAE is any untoward medical occurrence that results in death, is life-threatening, requires or prolongs hospitalization, results in disability/incapacity and is a congenital anomaly/birth defect in a subject's offspring. AESIs are predefined (serious or non-serious) AEs of scientific and medical concern specific to the product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor can be appropriate, because such an event might warrant further investigation to characterize and understand it. A participant was considered withdrawn if no study procedures occurred, and no follow-up or further information has been collected from the date of withdrawal or last contact.

End point type	Primary

End point timeframe:

During the 30 days (including the day of vaccination) following vaccination at Day 1

Notes:

[64] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen in study Phase II (Sourcing) groups.
[65] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase II (Sourcing) groups.

End point values	ABCWY low dose_01 Group	ABCWY high dose_01 Group	ABCWY low doseS_02 Group	ABCWY high doseS_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	54	53	62	62
Units: Participants	10	12	14	8

End point values	ABCWY low doseS_06 Group	ABCWY high doseS_06 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	62	63		
Units: Participants	10	18		

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with any unsolicited AEs (including all SAEs, AEs leading to withdrawal, and AESIs) in study Phase II (Sourcing) at Day 31

End point title	Number of participants with any unsolicited AEs (including all SAEs, AEs leading to withdrawal, and AESIs) in study Phase II (Sourcing) at Day 31[66][67]

End point description:

Unsolicited AEs includes any AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms is reported as an unsolicited adverse event. A SAE is any untoward medical occurrence that results in death, is life-threatening, requires or prolongs hospitalization, results in disability/incapacity and is a

congenital anomaly/birth defect in a subject's offspring. AESIs are predefined (serious or non-serious) AEs of scientific and medical concern specific to the product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor can be appropriate, because such an event might warrant further investigation to characterize and understand it. A participant was considered withdrawn if no study procedures occurred, and no follow-up or further information has been collected from the date of withdrawal or last contact.

End point type	Primary

End point timeframe:

During the 30 days (including the day of vaccination) following vaccination at Day 31

Notes:

[66] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[67] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase II (Sourcing) groups.

End point values	ABCWY low dose_01 Group	ABCWY high dose_01 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	47		
Units: Participants	11	16		

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with any unsolicited AEs (including all SAEs, AEs leading to withdrawal, and AESIs) in study Phase II (Sourcing) at Day 61

End point title	Number of participants with any unsolicited AEs (including all SAEs, AEs leading to withdrawal, and AESIs) in study Phase II (Sourcing) at Day 61[68][69]

End point description:

Unsolicited AEs includes any AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms is reported as an unsolicited adverse event. A SAE is any untoward medical occurrence that results in death, is life-threatening, requires or prolongs hospitalization, results in disability/incapacity and is a congenital anomaly/birth defect in a subject's offspring. AESIs are predefined (serious or non-serious) AEs of scientific and medical concern specific to the product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor can be appropriate, because such an event might warrant further investigation to characterize and understand it. A participant was considered withdrawn if no study procedures occurred, and no follow-up or further information has been collected from the date of withdrawal or last contact.

End point type	Primary

End point timeframe:

During the 30 days (including the day of vaccination) following vaccination at Day 61

Notes:

[68] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[69] - 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 analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was

performed.

End point values	ABCWY low doseS_02 Group	ABCWY high doseS_02 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58	60		
Units: Participants	8	7		

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with SAEs, AEs leading to withdrawal and AESIs in study Phase II (Sourcing) Day 1 through Day 211

End point title	Number of participants with SAEs, AEs leading to withdrawal and AESIs in study Phase II (Sourcing) Day 1 through Day 211[70][71]

End point description:

A SAEs is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity and is a congenital anomaly/birth defect in the offspring of a study subject. AESIs are predefined (serious or non-serious) AEs of scientific and medical concern specific to the product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor can be appropriate, because such an event might warrant further investigation to characterize and understand it. A participant was considered withdrawn if no study procedures occurred, and no follow-up or further information has been collected from the date of withdrawal or last contact.

End point type	Primary

End point timeframe:

Throughout the study period (Day 1 through Day 211)

Notes:

[70] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[71] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase II (Sourcing) groups.

End point values	ABCWY low dose_01 Group	ABCWY high dose_01 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54	53		
Units: Participants				
SAEs(N=54,53)	0	0		
AEs leading to withdrawal(N=54,53)	0	0		
AESIs(N=54,53)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with any unsolicited AEs (including all SAEs, AEs leading to withdrawal, and AESIs) in study Phase II (Sourcing) at Day 181

End point title	Number of participants with any unsolicited AEs (including all SAEs, AEs leading to withdrawal, and AESIs) in study Phase II (Sourcing) at Day 181[72][73]

End point description:

Unsolicited AEs includes any AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms is reported as an unsolicited adverse event. A SAE is any untoward medical occurrence that results in death, is life-threatening, requires or prolongs hospitalization, results in disability/incapacity and is a congenital anomaly/birth defect in a subject's offspring. AESIs are predefined (serious or non-serious) AEs of scientific and medical concern specific to the product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor can be appropriate, because such an event might warrant further investigation to characterize and understand it. A participant was considered withdrawn if no study procedures occurred, and no follow-up or further information has been collected from the date of withdrawal or last contact.

End point type	Primary

End point timeframe:

During the 30 days (including the day of vaccination) following vaccination at Day 181

Notes:

[72] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[73] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase II (Sourcing) groups.

End point values	ABCWY low doseS_06 Group	ABCWY high doseS_06 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60	55		
Units: Participants	10	9		

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with SAEs, AEs leading to withdrawal and AESIs in study Phase II (Sourcing) Day 1 through Day 241

End point title	Number of participants with SAEs, AEs leading to withdrawal and AESIs in study Phase II (Sourcing) Day 1 through Day 241[74][75]

End point description:

A SAEs is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity and is a congenital anomaly/birth defect in the offspring of a study subject. AESIs are predefined (serious or non-serious) AEs of scientific and medical concern specific to the product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor can be appropriate, because such an event might warrant further investigation to characterize and understand it. A participant was considered withdrawn if no study procedures occurred, and no follow-up or further information has been

collected from the date of withdrawal or last contact.

End point type	Primary

End point timeframe:

Throughout the study period (Day 1 through Day 241)

Notes:

[74] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[75] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase II (Sourcing) groups.

End point values	ABCWY low doseS_02 Group	ABCWY high doseS_02 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	62	62		
Units: Participants				
SAEs (N=62,62)	2	1		
AEs leading to withdrawal(N=62,62)	1	0		
AESIs(N=62,62)	0	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with SAEs, AEs leading to withdrawal and AESIs in study Phase II (Sourcing) Day 1 through Day 361

End point title	Number of participants with SAEs, AEs leading to withdrawal and AESIs in study Phase II (Sourcing) Day 1 through Day 361[76][77]

End point description:

A SAEs is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity and is a congenital anomaly/birth defect in the offspring of a study subject. AESIs are predefined (serious or non-serious) AEs of scientific and medical concern specific to the product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor can be appropriate, because such an event might warrant further investigation to characterize and understand it. A participant was considered withdrawn if no study procedures occurred, and no follow-up or further information has been collected from the date of withdrawal or last contact.

End point type	Primary

End point timeframe:

Throughout the study period (Day 1 through Day 361)

Notes:

[76] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of this primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[77] - 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: As specified in the Protocol, the analysis assesses the Safety of the MenABCWY-2Gen vaccine in study Phase II (Sourcing) groups.

End point values	ABCWY low doseS_06 Group	ABCWY high doseS_06 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	62	63		
Units: Participants				
SAEs(N=62,63)	0	4		
AEs leading to withdrawal(N=62,63)	0	2		
AESIs(N=62,63)	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants classified by percentages of serogroup B invasive disease strains killed using enc-hSBA in each participant in study Phase II (Formulation and Schedule-finding)

End point title	Percentage of participants classified by percentages of serogroup B invasive disease strains killed using enc-hSBA in each participant in study Phase II (Formulation and Schedule-finding)[78]

End point description:

The percentages of strains killed measured by enc-hSBA against a randomly selected panel of strains and the corresponding exact 2-sided 95% CIs based on Clopper-Pearson method is calculated in all groups at 1 month after the last vaccination of MenABCWY-2Gen (low and high dose) vaccine administered at 0,2 and 0,6-months schedule and of the MenB vaccine administered at 0,6-months schedule.

End point type	Secondary

End point timeframe:

At Day 211 (1 month after the last vaccination)

Notes:

[78] - 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: As specified in the Protocol, the analysis describes the distribution of participants by percentages of serogroup B invasive disease strains killed using enc-hSBA of the MenABCWY-2Gen and Men B vaccine in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	205	161	215	169
Units: Percentage of participants				
number (confidence interval 95%)				
>= 50% killed strains(N=205, 161, 215,169,176)	98.5 (95.8 to 99.7)	97.5 (93.8 to 99.3)	97.7 (94.7 to 99.2)	98.8 (95.8 to 99.9)
>=55% killed strains(N=205, 161, 215,169,176)	98.0 (95.1 to 99.5)	95.7 (91.2 to 98.2)	97.7 (94.7 to 99.2)	98.2 (94.9 to 99.6)
>=60% killed strains(N=205, 161, 215,169,176)	96.6 (93.1 to 98.6)	95.0 (90.4 to 97.8)	97.2 (94.0 to 99.0)	97.0 (93.2 to 99.0)
>=65% killed strains(N=205, 161, 215,169,176)	95.6 (91.8 to 98.0)	92.5 (87.3 to 96.1)	96.3 (92.8 to 98.4)	95.9 (91.7 to 98.3)
>=70% killed strains(N=205, 161, 215,169,176)	94.1 (90.0 to 96.9)	89.4 (83.6 to 93.7)	94.4 (90.5 to 97.1)	94.7 (90.1 to 97.5)
>=75% killed strains(N=205, 161, 215,169,176)	91.2 (86.5 to 94.7)	82.0 (75.2 to 87.6)	90.2 (85.5 to 93.9)	88.8 (83.0 to 93.1)

>=80% killed strains(N=205, 161, 215,169,176)	88.8 (83.6 to 92.8)	77.6 (70.4 to 83.8)	87.4 (82.3 to 91.6)	82.8 (76.3 to 88.2)
>=85% killed strains(N=205, 161, 215,169,176)	82.9 (77.1 to 87.8)	64.6 (56.7 to 72.0)	82.8 (77.1 to 87.6)	75.1 (67.9 to 81.5)
>=90% killed strains(N=205, 161, 215,169,176)	71.2 (64.5 to 77.3)	53.4 (45.4 to 61.3)	70.7 (64.1 to 76.7)	55.0 (47.2 to 62.7)
>=95% killed strains(N=205, 161, 215,169,176)	43.4 (36.5 to 50.5)	29.2 (22.3 to 36.9)	44.2 (37.4 to 51.1)	34.3 (27.2 to 42.0)
100% killed strains(N=205, 161, 215,169,176)	23.4 (17.8 to 29.8)	14.3 (9.3 to 20.7)	24.2 (18.6 to 30.5)	17.2 (11.8 to 23.7)

End point values	Control Group			
Subject group type	Reporting group			
Number of subjects analysed	176			
Units: Percentage of participants				
number (confidence interval 95%)				
>= 50% killed strains(N=205, 161, 215,169,176)	98.3 (95.1 to 99.6)			
>=55% killed strains(N=205, 161, 215,169,176)	96.6 (92.7 to 98.7)			
>=60% killed strains(N=205, 161, 215,169,176)	95.5 (91.2 to 98.0)			
>=65% killed strains(N=205, 161, 215,169,176)	93.8 (89.1 to 96.8)			
>=70% killed strains(N=205, 161, 215,169,176)	88.6 (83.0 to 92.9)			
>=75% killed strains(N=205, 161, 215,169,176)	80.7 (74.1 to 86.2)			
>=80% killed strains(N=205, 161, 215,169,176)	75.6 (68.5 to 81.7)			
>=85% killed strains(N=205, 161, 215,169,176)	63.6 (56.1 to 70.7)			
>=90% killed strains(N=205, 161, 215,169,176)	52.3 (44.6 to 59.8)			
>=95% killed strains(N=205, 161, 215,169,176)	26.1 (19.8 to 33.3)			
100% killed strains(N=205, 161, 215,169,176)	15.3 (10.4 to 21.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with hSBA titers ≥ LLOQ for each and all serogroup B indicator strains in study Phase II (Formulation and Schedule-finding)

End point title	Number of participants with hSBA titers ≥ LLOQ for each and all serogroup B indicator strains in study Phase II (Formulation and Schedule-finding)[79]

End point description:

The immune response to MenABCWY-2Gen (low and high dose) administered at 0,2 and 0,6-months schedule and MenB vaccine administered at 0,6-months schedule is evaluated by measuring bactericidal activity using a qualified AO hSBA against a standard panel of serogroup B indicator strains.

End point type	Secondary

End point timeframe:

At Day 1 in ABCWY (0,6-months) and Control groups, Day 31 in ABCWY groups (0,2-months) and Day 211 in all study groups

Notes:

[79] - 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: As specified in the Protocol, the analysis assesses the immune response to the MenABCWY-2Gen and Men B vaccine against serogroup B indicator strains in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	209	173	214	189
Units: Participants				
fHbp, Day 1 (N=209,214,0,0,194)	9	99999	10	99999
fHbp, Day 31 (N=0,0,173,189,0)	99999	14	99999	14
fHbp, Day 211 (N=201,213,159,168,179)	175	112	184	137
NadA, Day 1 (201,211,0,0,189)	16	99999	23	99999
NadA, Day 31 (N=0,0,168,185,0)	99999	18	99999	14
NadA, Day 211 (N=197,201,150,162,171)	175	120	169	131
NHBA, Day 1 (N=207,213,0,0,189)	43	99999	49	99999
NHBA, Day 31 (N=0,0,172,186,0)	99999	46	99999	44
NHBA, Day 211 (199, 212, 155,167,177)	197	148	208	163
PorA, Day 1 (N=208,213,0,0,190)	7	99999	9	99999
PorA, Day 31 (N=0,0,161,173,0)	99999	8	99999	8
PorA, Day 211 (N=200,214,153,169,178)	171	106	179	136
fHbp V1.13, Day 1 (N=203,209,0,0,184)	32	99999	31	99999
fHbp V1.13, Day 31 (N=0,0,171,184 ,0)	99999	31	99999	31
fHbp V1.13, Day 211 (N=188,194,142,148,168)	162	97	169	111
fHbp V2, Day 1 (N=203,209,0,0,185)	8	99999	12	99999
fHbp V2, Day 31 (N=0 ,0,171,184,0)	99999	12	99999	21
fHbp V2, Day 211 (N=195,204,150, 161,172)	186	128	192	144
fHbp V3, Day 1 (N=203,209,0,0,185)	15	99999	16	99999
fHbp V3, Day 31 (N=0,0,172,184,0)	99999	13	99999	21
fHbp V3, Day 211(N=1 94,204,151,162,172)	155	95	168	107
Composite Response, Day 1 (N=194,206,0,0,179)	1	99999	1	99999
Composite Response,Day 31 (N=0,0,51,164,0)	99999	3	99999	3
Composite Response,Day 211(N=180, 181,131,134,158)	121	60	126	73

End point values	Control Group			

Subject group type	Reporting group			
Number of subjects analysed	194			
Units: Participants				
fHbp, Day 1 (N=209,214,0,0,194)	12			
fHbp, Day 31 (N=0,0,173,189,0)	99999			
fHbp, Day 211 (N=201,213,159,168,179)	137			
NadA, Day 1 (201,211,0,0,189)	14			
NadA, Day 31 (N=0,0,168,185,0)	99999			
NadA, Day 211 (N=197,201,150,162,171)	147			
NHBA, Day 1 (N=207,213,0,0,189)	40			
NHBA, Day 31 (N=0,0,172,186,0)	99999			
NHBA, Day 211 (199, 212, 155,167,177)	172			
PorA, Day 1 (N=208,213,0,0,190)	8			
PorA, Day 31 (N=0,0,161,173,0)	99999			
PorA, Day 211 (N=200,214,153,169,178)	136			
fHbp V1.13, Day 1 (N=203,209,0,0,184)	34			
fHbp V1.13, Day 31 (N=0,0,171,184 ,0)	99999			
fHbp V1.13, Day 211 (N=188,194,142,148,168)	130			
fHbp V2, Day 1 (N=203,209,0,0,185)	13			
fHbp V2, Day 31 (N=0 ,0,171,184,0)	99999			
fHbp V2, Day 211 (N=195,204,150, 161,172)	72			
fHbp V3, Day 1 (N=203,209,0,0,185)	11			
fHbp V3, Day 31 (N=0,0,172,184,0)	99999			
fHbp V3, Day 211(N=1 94,204,151,162,172)	41			
Composite Response, Day 1 (N=194,206,0,0,179)	1			
Composite Response,Day 31 (N=0,0,51,164,0)	99999			
Composite Response,Day 211(N=180, 181,131,134,158)	30			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with 4-fold rise in hSBA titers against serogroup B indicator strains in study Phase II (Formulation and Schedule-finding)

End point title	Number of participants with 4-fold rise in hSBA titers against serogroup B indicator strains in study Phase II (Formulation and Schedule-finding)[80]

End point description:

The immune response to MenABCWY-2Gen (low and high dose) vaccine when administered at 0,2- or 0,6-months schedule and to MenB vaccine administered at 0,6-months schedule, relative to day 1 in ABCWY (0,6 month schedule) and control groups and day 31 in ABCWY (0,2 month schedule) is measured in terms of number of participants achieving a 4-fold rise in hSBA titers against serogroup B indicator strains. The 4-fold rise is defined as: -a post-vaccination hSBA titer ≥ 16 for participants with a pre-vaccination hSBA titre < 4, -a post-vaccination hSBA titer ≥ 4 times the LLOQ for participants with a

pre-vaccination hSBA titer ≥LOD but <LLOQ, and. -a post-vaccination hSBA titer ≥ 4 times the pre-vaccination hSBA titer for participants with a pre-vaccination hSBA titer ≥ LLOQ.

End point type	Secondary

End point timeframe:

At Day 211 (1 month after the last vaccination)

Notes:

[80] - 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: As specified in the Protocol, the analysis assesses the immune response to the MenABCWY-2Gen and Men B vaccine against serogroup B indicator strains in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	178	155	193	168
Units: Participants				
fHbp (N=78,155,193,168,177)	144	89	155	122
NadA (N=166,141,179,159,167)	135	104	133	113
NHBA (N=174,150,191,164,171)	162	122	175	136
PorA (N=175,140,193,157,172)	124	69	133	92
fHbp V1.13 (N=161,137,173,144,158)	126	82	140	92
fHbp V2 (N=168,144,182,157,163)	119	69	138	91
fHbp V3 (N=167,146,182,158,163)	92	62	120	77

End point values	Control Group			
Subject group type	Reporting group			
Number of subjects analysed	177			
Units: Participants				
fHbp (N=78,155,193,168,177)	119			
NadA (N=166,141,179,159,167)	135			
NHBA (N=174,150,191,164,171)	139			
PorA (N=175,140,193,157,172)	109			
fHbp V1.13 (N=161,137,173,144,158)	97			
fHbp V2 (N=168,144,182,157,163)	21			
fHbp V3 (N=167,146,182,158,163)	7			

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA Geometric mean titers (GMTs) against serogroup B indicator strains in study Phase II (Formulation and Schedule-finding)

End point title	hSBA Geometric mean titers (GMTs) against serogroup B indicator strains in study Phase II (Formulation and Schedule-finding)[81]

End point description:

For each B strains, the GMTs are calculated with their associated 2-sided 95% CIs, by exponentiating

the corresponding log-transformed means and their 95% CIs.

End point type	Secondary

End point timeframe:

At Day 1 in ABCWY groups (0,6-months) and Control groups, Day 31 in ABCWY groups (0,2-months) and Day 211 in all study groups

Notes:

[81] - 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: As specified in the Protocol, the analysis assesses the immune response to the MenABCWY-2Gen and Men B vaccine against serogroup B indicator strains in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	209	173	214	189
Units: Titers				
geometric mean (confidence interval 95%)				
fHbp, Day 1(N=209,214,0,0,194)	8.7 (8.1 to 9.3)	99999 (99999 to 99999)	8.8 (8.2 to 9.4)	99999 (99999 to 99999)
fHbp, Day 31(N=0,0,173,189,0)	99999 (99999 to 99999)	9.4 (8.7 to 10.1)	99999 (99999 to 99999)	9.5 (8.8 to 10.2)
fHbp, Day 211(N=201,213,159,168,179)	109.1 (86.0 to 138.3)	47.7 (37.0 to 61.5)	140.2 (110.9 to 177.4)	82.4 (63.8 to 106.4)
NadA, Day 1 (N=201,213,159,168,179)	7.8 (7.2 to 8.4)	99999 (99999 to 99999)	8.1 (7.5 to 8.7)	99999 (99999 to 99999)
NadA, Day 31(N=0,0,168,185,0)	99999 (99999 to 99999)	8.2 (7.6 to 8.9)	99999 (99999 to 99999)	8.1 (7.5 to 8.8)
NadA, Day 211(N=197,201,150,162,171)	82.5 (64.8 to 105.1)	58.9 (45.2 to 76.7)	88.5 (69.5 to 112.7)	56.8 (43.7 to 73.8)
NHBA, Day 1(N=207,213,0,0,189)	5.0 (4.2 to 6.0)	99999 (99999 to 99999)	5.2 (4.4 to 6.2)	99999 (99999 to 99999)
NHBA, Day 31 (N=0,0,172,186,0)	99999 (99999 to 99999)	6.3 (5.3 to 7.7)	99999 (99999 to 99999)	6.0 (5.0 to 7.2)
NHBA, Day 211 (199, 212, 155,167,177)	128.4 (106.4 to 155.0)	75.1 (61.4 to 91.9)	169.5 (141.0 to 203.9)	101.0 (82.6 to 123.4)
PorA, Day 1 (N=208,213,0,0,190)	4.5 (4.2 to 4.8)	99999 (99999 to 99999)	4.4 (4.1 to 4.8)	99999 (99999 to 99999)
PorA, Day 31 (N=0,0,161,173,0)	99999 (99999 to 99999)	4.6 (4.3 to 5.0)	99999 (99999 to 99999)	4.6 (4.3 to 5.0)
PorA, Day 211 (N=200,214,153,169,178)	35.7 (28.3 to 45.2)	18.4 (14.3 to 23.7)	41.1 (32.7 to 51.6)	28.2 (21.9 to 36.1)
fHbp V1.13, Day 1 (N=203,209,0,0,184)	5.1 (4.3 to 6.1)	99999 (99999 to 99999)	5.2 (4.3 to 6.2)	99999 (99999 to 99999)
fHbp V1.13, Day 31 (N=0,0,171,184 ,0)	99999 (99999 to 99999)	5.6 (4.6 to 6.7)	99999 (99999 to 99999)	5.8 (4.8 to 7.0)
fHbp V1.13, Day 211 (N=188,194,142,148,168)	88.3 (63.4 to 122.9)	39.7 (27.8 to 56.7)	122.1 (88.3 to 169.0)	54.9 (38.2 to 78.9)
fHbp V2, Day 1 (N=203,209,0,0,185)	2.7 (2.5 to 2.9)	99999 (99999 to 99999)	2.7 (2.6 to 2.9)	99999 (99999 to 99999)
fHbp V2, Day 31 (N=0 ,0,171,184,0)	99999 (99999 to 99999)	2.8 (2.7 to 3.0)	99999 (99999 to 99999)	3.0 (2.8 to 3.2)
fHbp V2, Day 211 (N=195,204,150, 161,172)	31.7 (25.2 to 39.8)	17.3 (13.5 to 22.1)	44.0 (35.1 to 55.2)	23.2 (18.1 to 29.7)
fHbp V3, Day 1 (N=203,209,0,0,185)	8.7 (7.9 to 9.5)	99999 (99999 to 99999)	8.7 (7.9 to 9.5)	99999 (99999 to 99999)
fHbp V3, Day 31 (N=0,0,172,184,0)	99999 (99999 to 99999)	8.7 (7.9 to 9.6)	99999 (99999 to 99999)	8.9 (8.2 to 9.8)

fHbp V3, Day 211(N=1 94,204,151,162,172)	50.7 (40.4 to 63.7)	27.0 (21.1 to 34.4)	65.7 (52.5 to 82.3)	33.2 (25.9 to 42.4)

End point values	Control Group			
Subject group type	Reporting group			
Number of subjects analysed	194			
Units: Titers				
geometric mean (confidence interval 95%)				
fHbp, Day 1(N=209,214,0,0,194)	8.9 (8.3 to 9.6)			
fHbp, Day 31(N=0,0,173,189,0)	99999 (99999 to 99999)			
fHbp, Day 211(N=201,213,159,168,179)	62.0 (48.3 to 79.5)			
NadA, Day 1 (N=201,213,159,168,179)	7.7 (7.1 to 8.3)			
NadA, Day 31(N=0,0,168,185,0)	99999 (99999 to 99999)			
NadA, Day 211(N=197,201,150,162,171)	109.1 (84.5 to 140.9)			
NHBA, Day 1(N=207,213,0,0,189)	5.3 (4.4 to 6.4)			
NHBA, Day 31 (N=0,0,172,186,0)	99999 (99999 to 99999)			
NHBA, Day 211 (199, 212, 155,167,177)	58.2 (47.9 to 70.7)			
PorA, Day 1 (N=208,213,0,0,190)	4.3 (4.0 to 4.6)			
PorA, Day 31 (N=0,0,161,173,0)	99999 (99999 to 99999)			
PorA, Day 211 (N=200,214,153,169,178)	30.4 (23.9 to 38.8)			
fHbp V1.13, Day 1 (N=203,209,0,0,184)	5.2 (4.3 to 6.3)			
fHbp V1.13, Day 31 (N=0,0,171,184 ,0)	99999 (99999 to 99999)			
fHbp V1.13, Day 211 (N=188,194,142,148,168)	36.9 (26.3 to 51.9)			
fHbp V2, Day 1 (N=203,209,0,0,185)	2.7 (2.6 to 2.9)			
fHbp V2, Day 31 (N=0 ,0,171,184,0)	99999 (99999 to 99999)			
fHbp V2, Day 211 (N=195,204,150, 161,172)	5.2 (4.1 to 6.6)			
fHbp V3, Day 1 (N=203,209,0,0,185)	8.3 (7.5 to 9.1)			
fHbp V3, Day 31 (N=0,0,172,184,0)	99999 (99999 to 99999)			
fHbp V3, Day 211(N=1 94,204,151,162,172)	10.8 (8.6 to 13.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA Geometric mean ratios (GMRs) against serogroup B indicator strains in study Phase II (Formulation and Schedule-finding)

End point title	hSBA Geometric mean ratios (GMRs) against serogroup B indicator strains in study Phase II (Formulation and Schedule-finding)[82]

End point description:

For each B strains, the GMRs (post-vaccination/ Baseline) are calculated with their associated 2-sided 95% CIs, by exponentiating the corresponding log-transformed means and their 95% CIs.

End point type	Secondary

End point timeframe:

At Day 211 in all study groups versus Day 1 in ABCWY (0,6-months) and Control groups and Day 31 in ABCWY groups (0,2-months)

Notes:

[82] - 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: As specified in the Protocol, the analysis assesses the immune response to the MenABCWY-2Gen and Men B vaccine against serogroup B indicator strains in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	178	155	193	168
Units: Ratio				
geometric mean (confidence interval 95%)				
fHbp (N=78,155,193,168,177)	13.4 (10.5 to 17.2)	5.6 (4.3 to 7.2)	16.5 (12.9 to 21.0)	9.0 (6.9 to 11.6)
NadA (N=166,141,179,159,167)	11.1 (8.5 to 14.3)	7.1 (5.4 to 9.3)	10.8 (8.4 to 14.0)	7.1 (5.4 to 9.3)
NHBA (N=174,150,191,164,171)	29.3 (23.5 to 36.7)	14.0 (11.1 to 17.6)	34.2 (27.5 to 42.5)	18.4 (14.6 to 23.1)
PorA (N=175,140,193,157,172)	8.6 (6.7 to 10.9)	4.5 (3.5 to 5.8)	10.1 (8.1 to 12.8)	6.3 (4.9 to 8.1)
fHbp V1.13 (N=161,137,173,144,158)	17.8 (12.8 to 24.9)	8.2 (5.8 to 11.7)	24.9 (18.0 to 34.6)	9.8 (6.9 to 14.0)
fHbp V2(N=168,144,182,157,163)	12.7 (10.1 to 16.1)	6.9 (5.4 to 8.8)	17.1 (13.6 to 21.5)	8.0 (6.2 to 10.2)
fHbp V3(N=167,146,182,158,163)	5.9 (4.7 to 7.4)	3.5 (2.7 to 4.4)	7.7 (6.1 to 9.7)	3.7 (2.9 to 4.8)

End point values	Control Group			
Subject group type	Reporting group			
Number of subjects analysed	177			
Units: Ratio				
geometric mean (confidence interval 95%)				
fHbp (N=78,155,193,168,177)	7.0 (5.5 to 9.1)			
NadA (N=166,141,179,159,167)	14.7 (11.3 to 19.1)			
NHBA (N=174,150,191,164,171)	11.5 (9.1 to 14.4)			
PorA (N=175,140,193,157,172)	7.4 (5.8 to 9.4)			
fHbp V1.13 (N=161,137,173,144,158)	7.0 (5.0 to 9.8)			
fHbp V2(N=168,144,182,157,163)	2.0 (1.5 to 2.5)			
fHbp V3(N=167,146,182,158,163)	1.3 (1.0 to 1.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with hSBA titers ≥ LLOQ for serogroups A, C, W and Y in study Phase II (Formulation and Schedule-finding)

End point title	Number of participants with hSBA titers ≥ LLOQ for serogroups A, C, W and Y in study Phase II (Formulation and Schedule-finding)[83]

End point description:

The number of participants with hSBA titers ≥ LLOQ and the corresponding exact 2-sided 95% CIs based on Clopper-Pearson method are calculated. Baseline (pre-vaccination) was evaluated at Day 1 for 0,6 schedules and Control, at Month 1 for 0,2 schedules. Post vaccination was evaluated at Month 7 for all MenABCWY groups, at Month 1 for Control group.

End point type	Secondary

End point timeframe:

Day 1 in ABCWY (0,6 Months) & Control; Day 31 pre-vaccination in ABCWY (0,2 Months); Day 31 post-first MenABCWY-2Gen in ABCWY (0,6 Months); Day 211 post-last MenABCWY-2Gen in all ABCWY; Day 31 post-MenACWY in Control

Notes:

[83] - 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: As specified in the Protocol, the analysis assesses the immune response to the MenABCWY-2Gen and Men B vaccine against serogroup A, C, W and Y in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	222	175	226	189
Units: Participants				
Men A, Day 1 (N=208,201,0,0,190)	23	99999	12	99999
Men A, Day 31 (Pre vaccination) (N=0,0,170,184,0)	99999	19	99999	16
Men A, Day 31(Post vaccination)N=204,221,0,0,187	170	99999	180	99999
Men A,Day 211(Post vaccination)N=202,212,159,167,0	198	155	208	166
Men C, Day 1 (N=209,211,0,0,193)	83	99999	85	99999
Men C,Day 31(Pre vaccination)(N=0,0,173,189,0)	99999	69	99999	76
Men C, Day 31(Post vaccination)N=219,217,0,0,181	160	99999	162	99999
Men C,Day 211(Post vaccination)N=204,213,160,171,0	199	158	207	167
Men W, Day 1 (N=207,210,0,0,192)	40	99999	37	99999
Men W, Day 31(Pre vaccination)N=0,0,173,187,0	99999	36	99999	36
Men W, Day 31 Post vaccination)N=222,221,0,0,188	165	99999	173	99999

Men W,Day 211(Post vaccination)N=204,211,157,168,0	203	157	211	168
Men Y, Day 1 (N=207,211,0,0,193)	22	99999	26	99999
Men Y, Day 31(Pre vaccination)N=0,0,175,187,0	99999	31	99999	24
Men Y, Day 31(Post vaccination)N=222,226,0,0,190	135	99999	139	99999
Men Y,Day 211(Post vaccination)N=203,214,161,169,0	198	152	201	158

End point values	Control Group			
Subject group type	Reporting group			
Number of subjects analysed	193			
Units: Participants				
Men A, Day 1 (N=208,201,0,0,190)	20			
Men A, Day 31 (Pre vaccination) (N=0,0,170,184,0)	99999			
Men A, Day 31(Post vaccination)N=204,221,0,0,187	174			
Men A,Day 211(Post vaccination)N=202,212,159,167,0	99999			
Men C, Day 1 (N=209,211,0,0,193)	88			
Men C,Day 31(Pre vaccination)(N=0,0,173,189,0)	99999			
Men C, Day 31(Post vaccination)N=219,217,0,0,181	141			
Men C,Day 211(Post vaccination)N=204,213,160,171,0	99999			
Men W, Day 1 (N=207,210,0,0,192)	36			
Men W, Day 31(Pre vaccination)N=0,0,173,187,0	99999			
Men W, Day 31 Post vaccination)N=222,221,0,0,188	140			
Men W,Day 211(Post vaccination)N=204,211,157,168,0	99999			
Men Y, Day 1 (N=207,211,0,0,193)	33			
Men Y, Day 31(Pre vaccination)N=0,0,175,187,0	99999			
Men Y, Day 31(Post vaccination)N=222,226,0,0,190	141			
Men Y,Day 211(Post vaccination)N=203,214,161,169,0	99999			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with a 4-fold rise in hSBA titers against serogroups A, C, W and Y in study Phase II (Formulation and Schedule-finding) At Day 31

End point title	Number of participants with a 4-fold rise in hSBA titers against serogroups A, C, W and Y in study Phase II (Formulation and

	Schedule-finding) At Day 31[84]

End point description:

The immune response to the MenABCWY-2Gen (low and high dose) vaccine when administered at 0,6-months schedule, relative to day 1 was measured in terms of percentage of participants achieving a 4-fold rise in hSBA titers against serogroups A, C, W and Y. Serum bactericidal activity against MenACWY were determined by using a validated AO hSBA. The 4-fold rise is defined as: -a post-vaccination hSBA titre ≥ 16 for participants with a pre-vaccination hSBA titre < 4, -a post-vaccination hSBA titre ≥ 4 times the LLOQ for participants with a pre-vaccination hSBA titre ≥ LOD but < LLOQ, and. -a post-vaccination hSBA titre ≥4 times the pre-vaccination hSBA titre for participants with a pre-vaccination hSBA titre ≥ LLOQ.

End point type	Secondary

End point timeframe:

At Day 31 (1 month after the first MenABCWY-2Gen vaccination) in ABCWY (0,6-months) groups

Notes:

[84] - 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: As specified in the Protocol, the analysis assesses the immune response to the MenABCWY-2Gen and Men B vaccine against serogroup A, C, W and Y in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY high dose_06 Group	Control Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	194	201	186	
Units: Participants				
Men A (N=176,186,180)	145	145	166	
Men C (N=193,192,178)	125	119	113	
Men W (N=194,195,183)	132	139	124	
Men Y (N=193,201,186)	105	104	116	

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA GMTs against serogroups A, C, W and Y in study Phase II (Formulation and Schedule-finding)

End point title	hSBA GMTs against serogroups A, C, W and Y in study Phase II (Formulation and Schedule-finding)[85]

End point description:

The immune response to the MenABCWY-2Gen (low and high dose) vaccine (0,2- and 0,6-months schedule) and MenACWY vaccine (single dose) was evaluated by hSBA titers which are logarithmically transformed (base10) to fulfil the normal distribution assumption. For each serogroup A, C, W and Y, the GMTs are calculated with their associated 2-sided 95% CIs, by exponentiating the corresponding log-transformed means and their 95% CIs.

End point type	Secondary

End point timeframe:

Day 1 in ABCWY (0,6 Months) & Control; Day 31 pre-vaccination in ABCWY (0,2 Months); Day 31 post-first MenABCWY-2Gen in ABCWY (0,6 Months); Day 211 post-last MenABCWY-2Gen in all ABCWY; Day 31 post-MenACWY in Control

Notes:

[85] - 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: As specified in the Protocol, the analysis assesses the immune response to the MenABCWY-2Gen and Men B vaccine against serogroup A, C, W and Y in study Phase II (Formulation and Schedule-

finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	222	181	226	194
Units: Titers				
geometric mean (confidence interval 95%)				
Men A, Day 1 (N=208,201,0,0,190)	9.7 (8.5 to 11.2)	99999 (99999 to 99999)	8.7 (7.5 to 10.0)	99999 (99999 to 99999)
Men A,Day 31 (Pre vaccination) (N=0,0,181,194,0)	99999 (99999 to 99999)	9.9 (8.5 to 11.4)	99999 (99999 to 99999)	8.7 (7.5 to 10.1)
Men A,Day 31(Post vaccination)N=204,221,0,0,187	174.3 (127.6 to 238.1)	99999 (99999 to 99999)	169.5 (124.6 to 230.5)	99999 (99999 to 99999)
Men A,Day 211(Post vaccination)N=202,212,159,167,0	356.3 (296.7 to 427.9)	339.5 (278.9 to 413.1)	422.8 (352.8 to 506.7)	356.9 (293.8 to 433.4)
Men C, Day 1 (N=209,211,0,0,193)	10.7 (8.6 to 13.3)	99999 (99999 to 99999)	10.3 (8.2 to 12.8)	99999 (99999 to 99999)
Men C,Day 31(Pre vaccination)(N=0,0,173,189,0)	99999 (99999 to 99999)	10.4 (8.3 to 13.1)	99999 (99999 to 99999)	10.9 (8.7 to 13.6)
Men C, Day 31(Post vaccination)N=219,217,0,0,181	170.4 (106.8 to 272.0)	99999 (99999 to 99999)	162.0 (100.9 to 259.9)	99999 (99999 to 99999)
Men C,Day 211(Post vaccination)N=204,213,160,171,0	768.4 (601.2 to 982.0)	677.6 (521.0 to 881.2)	738.9 (579.1 to 942.8)	652.5 (502.5 to 847.3)
Men W, Day 1 (N=207,210,0,0,192)	8.0 (6.5 to 9.9)	99999 (99999 to 99999)	7.2 (5.8 to 8.9)	99999 (99999 to 99999)
Men W, Day 31(Pre vaccination)N=0,0,173,187,0	99999 (99999 to 99999)	8.5 (6.8 to 10.7)	99999 (99999 to 99999)	8.1 (6.5 to 10.0)
Men W, Day 31 Post vaccination)N=222,221,0,0,188	89.9 (61.9 to 130.7)	99999 (99999 to 99999)	122.6 (84.1 to 178.6)	99999 (99999 to 99999)
Men W,Day 211(Post vaccination)N=204,213,161,169,0	683.2 (572.6 to 815.1)	366.4 (303.4 to 442.5)	800.6 (671.8 to 954.1)	481.0 (398.2 to 580.9)
Men Y, Day 1 (N=207,211,0,0,193)	7.4 (6.3 to 8.7)	99999 (99999 to 99999)	7.7 (6.5 to 9.0)	99999 (99999 to 99999)
Men Y, Day 31(Pre vaccination)N=0,0,175,187,0	99999 (99999 to 99999)	8.8 (7.4 to 10.4)	99999 (99999 to 99999)	7.7 (6.5 to 9.1)
Men Y, Day 31(Post vaccination)N=222,226,0,0,190	62.8 (43.8 to 90.2)	99999 (99999 to 99999)	64.2 (44.7 to 92.2)	99999 (99999 to 99999)
Men Y,Day 211(Post vaccination)N=203,214,161,169,0	406.9 (315.8 to 524.4)	239.5 (182.7 to 314.0)	353.1 (274.6 to 454.0)	215.1 (164.1 to 281.9)

End point values	Control Group			
Subject group type	Reporting group			
Number of subjects analysed	193			
Units: Titers				
geometric mean (confidence interval 95%)				
Men A, Day 1 (N=208,201,0,0,190)	9.3 (8.0 to 10.7)			
Men A,Day 31 (Pre vaccination) (N=0,0,181,194,0)	99999 (99999 to 99999)			
Men A,Day 31(Post vaccination)N=204,221,0,0,187	410.6 (299.0 to 564.1)			

Men A,Day 211(Post vaccination)N=202,212,159,167,0	99999 (99999 to 99999)			
Men C, Day 1 (N=209,211,0,0,193)	11.5 (9.2 to 14.3)			
Men C,Day 31(Pre vaccination)(N=0,0,173,189,0)	99999 (99999 to 99999)			
Men C, Day 31(Post vaccination)N=219,217,0,0,181	209.5 (128.4 to 341.9)			
Men C,Day 211(Post vaccination)N=204,213,160,171,0	99999 (99999 to 99999)			
Men W, Day 1 (N=207,210,0,0,192)	7.6 (6.1 to 9.5)			
Men W, Day 31(Pre vaccination)N=0,0,173,187,0	99999 (99999 to 99999)			
Men W, Day 31 Post vaccination)N=222,221,0,0,188	87.0 (59.0 to 128.3)			
Men W,Day 211(Post vaccination)N=204,213,161,169,0	99999 (99999 to 99999)			
Men Y, Day 1 (N=207,211,0,0,193)	8.7 (7.4 to 10.3)			
Men Y, Day 31(Pre vaccination)N=0,0,175,187,0	99999 (99999 to 99999)			
Men Y, Day 31(Post vaccination)N=222,226,0,0,190	100.0 (68.7 to 145.5)			
Men Y,Day 211(Post vaccination)N=203,214,161,169,0	99999 (99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA GMRs against serogroups A, C, W and Y in study Phase II (Formulation and Schedule-finding)

End point title	hSBA GMRs against serogroups A, C, W and Y in study Phase II (Formulation and Schedule-finding)[86]

End point description:

For each serogroup A, C, W and Y, the GMRs (post-vaccination/ Day 1 (Month 0)) are calculated with their associated 2-sided 95% CIs, by exponentiating the corresponding log-transformed means and their 95% CIs.

End point type	Secondary

End point timeframe:

At Day 31 [for ABCWY (0,6-months) and Control group compared to Day 1 (Baseline)], at Day 211 [for ABCWY (0,6-months) groups compared to Day 1 (baseline) and for ABCWY (0,2-months) groups compared to Day 31]

Notes:

[86] - 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: As specified in the Protocol, the analysis assesses the immune response to the MenABCWY-2Gen and Men B vaccine against serogroup A, C, W and Y in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	194	159	201	171
Units: Ratio				
geometric mean (confidence interval 95%)				
Men A, Day 31(N=176,186,0,0,180)	19.1 (14.2 to 25.8)	99999 (99999 to 99999)	17.0 (12.5 to 22.9)	99999 (99999 to 99999)
Men A, Day 211 (N=177,181,152,163,0)	43.0 (35.3 to 52.5)	38.4 (31.2 to 47.4)	53.3 (43.6 to 65.3)	45.8 (37.3 to 56.3)
Men C, Day 31 (N=193,192,0,0,178)	14.8 (9.6 to 22.7)	99999 (99999 to 99999)	13.9 (8.9 to 21.6)	99999 (99999 to 99999)
Men C, Day 211 (N=180,190,156,171,0)	91.5 (68.4 to 122.5)	77.3 (57.0 to 104.8)	78.4 (58.5 to 105.1)	66.2 (49.1 to 89.4)
Men W, Day 31 (N=194,195,10,0,83)	13.2 (9.3 to 18.8)	99999 (99999 to 99999)	17.5 (12.2 to 24.9)	99999 (99999 to 99999)
Men W, Day 211 (N=178,189,157,167,0)	101.6 (78.7 to 131.2)	54.0 (41.4 to 70.4)	127.9 (99.4 to 164.7)	69.8 (53.6 to 90.9)
Men Y, Day 31 (N=193,201,0,0,186)	9.5 (6.6 to 13.7)	99999 (99999 to 99999)	9.3 (6.4 to 13.4)	99999 (99999 to 99999)
Men Y, Day 211 (N=177,192,159,167,0)	61.6 (46.3 to 81.8)	32.2 (24.0 to 43.2)	51.7 (39.0 to 68.4)	31.6 (23.5 to 42.3)

End point values	Control Group			
Subject group type	Reporting group			
Number of subjects analysed	186			
Units: Ratio				
geometric mean (confidence interval 95%)				
Men A, Day 31(N=176,186,0,0,180)	42.9 (31.9 to 57.8)			
Men A, Day 211 (N=177,181,152,163,0)	99999 (99999 to 99999)			
Men C, Day 31 (N=193,192,0,0,178)	15.6 (10.0 to 24.2)			
Men C, Day 211 (N=180,190,156,171,0)	99999 (99999 to 99999)			
Men W, Day 31 (N=194,195,10,0,83)	12.5 (8.7 to 17.9)			
Men W, Day 211 (N=178,189,157,167,0)	99999 (99999 to 99999)			
Men Y, Day 31 (N=193,201,0,0,186)	13.1 (9.0 to 19.0)			
Men Y, Day 211 (N=177,192,159,167,0)	99999 (99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Immunoglobulin G (IgG) antibodies against serogroups A, C, W and Y in study Phase II (Formulation and Schedule-finding)

End point title	Immunoglobulin G (IgG) antibodies against serogroups A, C, W and Y in study Phase II (Formulation and Schedule-finding)[87]

End point description:

The immune responses to MenABCWY-2Gen (low and high dose) and MenACWY vaccines are evaluated by measuring the total IgG in terms of electrochemiluminescence-based (ECL) multiplex assay Geometric Mean Concentrations (GMCs).

End point type	Secondary

End point timeframe:

Day 1 in ABCWY (0,6 Months) & Control; Day 31 pre-vaccination in ABCWY (0,2 Months); Day 31 post-first MenABCWY-2Gen in ABCWY (0,6 Months); Day 211 post-last MenABCWY-2Gen in all ABCWY; Day 31 post-MenACWY in Control

Notes:

[87] - 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: As specified in the Protocol, the analysis assesses the immune response to the MenABCWY-2Gen and Men B vaccine against serogroup A, C, W and Y in study Phase II (Formulation and Schedule-finding) groups.

End point values	ABCWY low dose_06 Group	ABCWY low dose_02 Group	ABCWY high dose_06 Group	ABCWY high dose_02 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	211	170	223	184
Units: Microgram per milliliter(µg/mL)				
geometric mean (confidence interval 95%)				
Men A Ab, Day 1 (N=197,201,0,0,176)	2.3 (2.0 to 2.6)	99999 (99999 to 99999)	2.1 (1.8 to 2.4)	99999 (99999 to 99999)
Men A Ab,Day 31 (Pre vaccination)N=0,0,168,184,0	99999 (99999 to 99999)	2.4 (2.1 to 2.8)	99999 (99999 to 99999)	2.3 (2.0 to 2.7)
Men A Ab,Day 31(Post vaccination)N=207,221,0,0,183	10.5 (8.0 to 13.8)	99999 (99999 to 99999)	9.3 (7.1 to 12.2)	99999 (99999 to 99999)
MenA Ab,Day211(Postvaccination)N=178,189,	14.6 (11.5 to 18.6)	14.0 (10.9 to 18.1)	13.1 (10.4 to 16.5)	14.0 (10.9 to 18.1)
Men C Ab, Day 1(N=197,202,0,0,178)	1.1 (1.0 to 1.2)	99999 (99999 to 99999)	1.1 (1.0 to 1.2)	99999 (99999 to 99999)
Men C Ab, Day 31 (Pre vaccination)N=0,0,169,183,0	99999 (99999 to 99999)	1.0 (0.9 to 1.1)	99999 (99999 to 99999)	1.1 (1.0 to 1.2)
Men C Ab,Day 31(Post vaccination)N=208,217,0,0,181	8.0 (6.1 to 10.6)	99999 (99999 to 99999)	8.1 (6.2 to 10.7)	99999 (99999 to 99999)
MenC Ab,Day211(Postvaccination)N=164,172,	8.6 (6.9 to 10.7)	11.7 (9.3 to 14.8)	8.0 (6.5 to 9.8)	11.2 (8.9 to 14.1)
Men W Ab, Day 1(N=197,201,0,0,178)	1.3 (1.1 to 1.4)	99999 (99999 to 99999)	1.2 (1.1 to 1.3)	99999 (99999 to 99999)
Men W Ab, Day 31 (Pre vaccination)N=0,0,170,182,0	99999 (99999 to 99999)	1.2 (1.1 to 1.4)	99999 (99999 to 99999)	1.2 (1.1 to 1.4)
Men W Ab,Day 31(Post vaccination)N=211,223,0,0,187	4.6 (3.5 to 6.1)	99999 (99999 to 99999)	4.3 (3.3 to 5.7)	99999 (99999 to 99999)
MenWAb,Day 211(Postvaccination)N=180,187,125,13	8.2 (6.4 to 10.5)	6.2 (4.7 to 8.1)	8.7 (6.8 to 11.1)	7.2 (5.5 to 9.5)
Men Y Ab, Day 1(N=196,202,0,0,177)	1.3 (1.2 to 1.5)	99999 (99999 to 99999)	1.3 (1.2 to 1.4)	99999 (99999 to 99999)
Men Y Ab, Day 31(Pre vaccination)N=0,0,169,183,0	99999 (99999 to 99999)	1.4 (1.2 to 1.5)	99999 (99999 to 99999)	1.3 (1.2 to 1.4)
Men Y Ab,Day 31(Post vaccination)N=208,221,0,0,185	4.2 (3.2 to 5.5)	99999 (99999 to 99999)	4.4 (3.4 to 5.8)	99999 (99999 to 99999)
MenYAb,Day211(Post vaccination)N=180,189,136,139,0	10.1 (7.8 to 13.1)	11.3 (8.6 to 15.0)	10.0 (7.8 to 12.9)	9.8 (7.4 to 12.9)

End point values	Control Group			
Subject group type	Reporting group			
Number of subjects analysed	187			
Units: Microgram per milliliter(µg/mL)				
geometric mean (confidence interval 95%)				
Men A Ab, Day 1 (N=197,201,0,0,176)	2.3 (2.0 to 2.6)			
Men A Ab,Day 31 (Pre vaccination)N=0,0,168,184,0	99999 (99999 to 99999)			
Men A Ab,Day 31(Post vaccination)N=207,221,0,0,183	20.3 (15.4 to 26.7)			
MenA Ab,Day211(Postvaccination)N=178,189,	99999 (99999 to 99999)			
Men C Ab, Day 1(N=197,202,0,0,178)	1.1 (1.0 to 1.3)			
Men C Ab, Day 31 (Pre vaccination)N=0,0,169,183,0	99999 (99999 to 99999)			
Men C Ab,Day 31(Post vaccination)N=208,217,0,0,181	8.6 (6.5 to 11.4)			
MenC Ab,Day211(Postvaccination)N=164,172,	99999 (99999 to 99999)			
Men W Ab, Day 1(N=197,201,0,0,178)	1.2 (1.1 to 1.4)			
Men W Ab, Day 31 (Pre vaccination)N=0,0,170,182,0	99999 (99999 to 99999)			
Men W Ab,Day 31(Post vaccination)N=211,223,0,0,187	3.6 (2.7 to 4.8)			
MenWAb,Day 211(Postvaccination)N=180,187,125,13	99999 (99999 to 99999)			
Men Y Ab, Day 1(N=196,202,0,0,177)	1.3 (1.2 to 1.5)			
Men Y Ab, Day 31(Pre vaccination)N=0,0,169,183,0	99999 (99999 to 99999)			
Men Y Ab,Day 31(Post vaccination)N=208,221,0,0,185	5.3 (4.0 to 7.0)			
MenYAb,Day211(Post vaccination)N=180,189,136,139,0	99999 (99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Solicited AEs: up to day 7 post vaccination; Unsolicited AEs: up to day 30 post vaccination, SAEs: from Day 1 to Day 211 (Phase I Safety Lead-in); from Day 1 to Day 541(Phase II Formulation and Schedule-Finding); from Day 1 to Day 361 (Phase II Sourcing)

Assessment type	Systematic

Dictionary used

Dictionary name	v27.0
Dictionary version	27.0

Reporting groups

Reporting group title	ABCWY low dose Group

Reporting group description:

Participants received two doses of the MenABCWY-2Gen low-dose vaccine on Day 1 and Day 31, following a 0, 1-month schedule during Study Phase I (Safety Lead-In).

Reporting group title	ABCWY high dose Group

Reporting group description:

Participants received two doses of the MenABCWY-2Gen high-dose vaccine on Day 1 and Day 31, following a 0, 1-month schedule during Study Phase I (Safety Lead-In).

Reporting group title	Placebo low dose Group

Reporting group description:

Participants received two doses of a placebo on Day 1 and Day 31, following a 0, 1-month schedule during Study Phase I (Safety Lead-In), as the control group for the ABCWY low-dose group.

Reporting group title	ABCWY high dose_06 Group

Reporting group description:

Participants received two doses of the MenABCWY-2Gen high-dose vaccine on Day 1 and Day 181, following a 0, 6-month schedule, along with one dose of a placebo on Day 121 during Phase II (Formulation and Schedule-Finding).

Reporting group title	ABCWY low dose_02 Group

Reporting group description:

Participants received two doses of the MenABCWY-2Gen low-dose vaccine on Day 121 and Day 181, following a 0, 2-month schedule, along with one dose of a placebo on Day 1 during Phase II (Formulation and Schedule-Finding).

Reporting group title	ABCWY low dose_06 Group

Reporting group description:

Participants received two doses of the MenABCWY-2Gen low-dose vaccine on Day 1 and Day 181, following a 0, 6-month schedule, along with one dose of a placebo on Day 121 during Phase II (Formulation and Schedule-Finding).

Reporting group title	Placebo high dose Group

Reporting group description:

Participants received two doses of a placebo on Day 1 and Day 31, following a 0, 1-month schedule during Study Phase I (Safety Lead-In), as the control group for the ABCWY high-dose group.

Reporting group title	ABCWY high dose_02 Group

Reporting group description:

Participants received two doses of the MenABCWY-2Gen high-dose vaccine on Day 121 and Day 181, following a 0, 2-month schedule, along with one dose of a placebo on Day 1 during Phase II (Formulation and Schedule-Finding).

Reporting group title	ABCWY high doseS_02 Group

Reporting group description:

Participants received two doses of MenABCWY-2Gen high dose vaccine on Day 1 and day 61 following a 0, 2-month schedule during study Phase II (Sourcing).

Reporting group title	Control Group

Reporting group description:

Participants randomized to the control group received two doses of the Bexsero (MenB) vaccine on Day

1 and Day 181, following a 0, 6-month schedule, and one dose of Menveo (MenACWY) on Day 1 during Study Phase II (Formulation and Schedule-Finding).

Reporting group title	ABCWY low dose_01 Group
Reporting group description:	
Participants received two doses of MenABCWY-2Gen low dose vaccine on Day 1 and Day 31, following a 0, 1-month schedule during study Phase II (Sourcing).	
Reporting group title	ABCWY high dose_01 Group
Reporting group description:	
Participants received two doses of MenABCWY-2Gen high dose vaccine on Day 1 and Day 31, following a 0, 1-month schedule during study Phase II (Sourcing).	
Reporting group title	ABCWY low doseS_02 Group
Reporting group description:	
Participants received two doses of MenABCWY-2Gen low dose vaccine on Day 1 and day 61 following a 0, 2-month schedule during study Phase II (Sourcing).	
Reporting group title	ABCWY low doseS_06 Group
Reporting group description:	
Participants received two doses of MenABCWY-2Gen low dose vaccine on Day 1 and day 181 following a 0, 6-month schedule during study Phase II (Sourcing).	
Reporting group title	ABCWY high doseS_06 Group
Reporting group description:	
Participants received two doses of MenABCWY-2Gen high dose vaccine on Day 1 and day 181 following a 0, 6-month schedule during study Phase II (Sourcing).	

Serious adverse events	ABCWY low dose Group	ABCWY high dose Group	Placebo low dose Group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate cancer			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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 spontaneous			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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
Ectopic pregnancy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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

Premature labour			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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			
Cyst			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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
Bronchospasm			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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
Paranoid personality disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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
Psychotic disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Benign familial haematuria			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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			
Arrhythmia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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
Atrial fibrillation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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
Myocarditis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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			
Bell's palsy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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
Epilepsy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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
Migraine			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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			
Blood loss anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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

Mesenteric lymphadenitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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			
Colitis ulcerative			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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
Cholelithiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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			
Nephrolithiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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
Ureteric stenosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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
Cellulitis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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
Enterobiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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
Pharyngeal abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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
Pilonidal disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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
Pyelonephritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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 bacterial			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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
Vestibular neuronitis			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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
Viral infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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			
Hyperlipidaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (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 high dose_06 Group	ABCWY low dose_02 Group	ABCWY low dose_06 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 238 (1.68%)	7 / 181 (3.87%)	9 / 239 (3.77%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate cancer			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (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 spontaneous			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (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
Ectopic pregnancy			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (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
Premature labour			

subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (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			
Cyst			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (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
Bronchospasm			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
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 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (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
Paranoid personality disorder			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (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
Congenital, familial and genetic disorders			
Benign familial haematuria			

subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (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
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (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
Myocarditis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Bell's palsy			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (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
Migraine			
subjects affected / exposed	0 / 238 (0.00%)	2 / 181 (1.10%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Blood loss anaemia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Mesenteric lymphadenitis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (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			
Colitis ulcerative			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (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
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (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
Cholelithiasis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (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			
Nephrolithiasis			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (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
Ureteric stenosis			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			

subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (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
Enterobiasis			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (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
Pharyngeal abscess			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (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
Pilonidal disease			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (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
Pyelonephritis			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (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
Tonsillitis bacterial			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular neuronitis			

subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (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			
Hyperlipidaemia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (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	Placebo high dose Group	ABCWY high dose_02 Group	ABCWY high doseS_02 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	4 / 194 (2.06%)	1 / 62 (1.61%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate cancer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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 spontaneous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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
Ectopic pregnancy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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
Premature labour			

subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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			
Cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (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
Bronchospasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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
Paranoid personality disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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
Psychotic disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Benign familial haematuria			

subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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			
Arrhythmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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
Myocarditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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			
Bell's palsy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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
Epilepsy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (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
Migraine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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			
Blood loss anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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

Mesenteric lymphadenitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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			
Colitis ulcerative			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	1 / 62 (1.61%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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
Cholelithiasis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (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
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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
Ureteric stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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
Cellulitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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
Enterobiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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
Pharyngeal abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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
Pilonidal disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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
Pyelonephritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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 bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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
Vestibular neuronitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (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			
Hyperlipidaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (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

Serious adverse events	Control Group	ABCWY low dose_01 Group	ABCWY high dose_01 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 197 (1.02%)	0 / 54 (0.00%)	0 / 53 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate cancer			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ectopic pregnancy			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature labour			

subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Cyst			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paranoid personality disorder			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Benign familial haematuria			

subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Bell's palsy			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Blood loss anaemia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Mesenteric lymphadenitis			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (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
Cholelithiasis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureteric stenosis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			

subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (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
Enterobiasis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngeal abscess			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal disease			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis bacterial			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vestibular neuronitis			

subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyperlipidaemia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	ABCWY low doseS_02 Group	ABCWY low doseS_06 Group	ABCWY high doseS_06 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 62 (3.23%)	0 / 62 (0.00%)	4 / 63 (6.35%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate cancer			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ectopic pregnancy			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Premature labour			

subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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			
Cyst			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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
Bronchospasm			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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
Paranoid personality disorder			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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
Psychotic disorder			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Benign familial haematuria			

subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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			
Arrhythmia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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
Atrial fibrillation			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (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
Myocarditis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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			
Bell's palsy			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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
Epilepsy			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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
Migraine			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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			
Blood loss anaemia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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

Mesenteric lymphadenitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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			
Colitis ulcerative			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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
Cholelithiasis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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			
Nephrolithiasis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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
Ureteric stenosis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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
Cellulitis			

subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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
Enterobiasis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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
Pharyngeal abscess			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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
Pilonidal disease			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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
Pyelonephritis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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 bacterial			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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
Vestibular neuronitis			

subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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
Viral infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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			
Hyperlipidaemia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (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

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	ABCWY low dose Group	ABCWY high dose Group	Placebo low dose Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 12 (100.00%)	13 / 13 (100.00%)	3 / 4 (75.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Uterine leiomyoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Administration site erythema			
subjects affected / exposed	2 / 12 (16.67%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Administration site hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Administration site pain			
subjects affected / exposed	11 / 12 (91.67%)	13 / 13 (100.00%)	2 / 4 (50.00%)
occurrences (all)	19	21	2
Administration site induration			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Administration site swelling			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Axillary pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Administration site warmth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hangover			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	6 / 12 (50.00%)	12 / 13 (92.31%)	3 / 4 (75.00%)
occurrences (all)	7	18	3

Influenza like illness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Injection site haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Injection site lymphadenopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site mass			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site oedema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site nodule			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Injection site pain			
subjects affected / exposed	2 / 12 (16.67%)	5 / 13 (38.46%)	0 / 4 (0.00%)
occurrences (all)	5	5	0
Injection site pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site warmth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Medical device site pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 12 (0.00%)	2 / 13 (15.38%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Peripheral swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	2 / 12 (16.67%)	2 / 13 (15.38%)	0 / 4 (0.00%)
occurrences (all)	2	2	0

Swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaccination site erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaccination site pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaccination site swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaccination site warmth			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mite allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mycotic allergy			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Adenomyosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cervical polyp			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Heavy menstrual bleeding			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endometriosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Menstrual disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ovarian cyst			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Allergic sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Cough			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal obstruction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal septum deviation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasal septum perforation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Oropharyngeal pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pharyngeal swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tonsillolith			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anger			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eating disorder			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Initial insomnia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mixed anxiety and depressive disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neurosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Obsessive-compulsive disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Social anxiety disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Suicidal ideation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood iron decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Human metapneumovirus test positive			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Streptococcus test positive			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Accident			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Accidental exposure to product			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ankle fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cartilage injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eyelid injury			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epicondylitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Craniofacial fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Forearm fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Heat exhaustion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ligament rupture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immunisation reaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			

subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Limb injury			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Post procedural complication			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Post-traumatic neck syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Procedural complication			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Radius fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Repetitive strain injury			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Skin laceration			
subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Skin abrasion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin injury			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Stress fracture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tendon rupture			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Traumatic pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	7 / 12 (58.33%)	5 / 13 (38.46%)	2 / 4 (50.00%)
occurrences (all)	11	9	2
Dizziness			

subjects affected / exposed	1 / 12 (8.33%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Migraine with aura			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Trigeminal neuralgia			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphadenitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Inner ear inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Motion sickness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tinnitus			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctival hyperaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Panophthalmitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Anal fissure			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Colitis ulcerative			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Coeliac disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lip swelling			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 12 (8.33%)	4 / 13 (30.77%)	1 / 4 (25.00%)
occurrences (all)	2	5	2
Odynophagia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth impacted			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alopecia areata			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dyshidrotic eczema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Lichen planus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Onychalgia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Parapsoriasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sea bather's eruption			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Solar dermatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Transient acantholytic dermatosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Urticaria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urticaria papular			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urticaria chronic			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Cystitis noninfective			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urethral haemorrhage			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urethral pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urge incontinence			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperprolactinaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Polycystic ovarian syndrome			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Axillary mass			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	2 / 12 (16.67%)	4 / 13 (30.77%)	2 / 4 (50.00%)
occurrences (all)	2	4	3
Back pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Inguinal mass			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Jaw disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle disorder			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			

subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	4 / 12 (33.33%)	6 / 13 (46.15%)	1 / 4 (25.00%)
occurrences (all)	5	7	1
Musculoskeletal stiffness			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pain in jaw			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess neck			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Acarodermatitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Acute sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Adenovirus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alveolar osteitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chlamydial infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Coronavirus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dengue fever			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Ear infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Enterovirus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Helicobacter infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infectious mononucleosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Laryngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metapneumovirus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lyme disease			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Norovirus infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ovarian bacterial infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Paronychia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pharyngitis bacterial			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Post-acute COVID-19 syndrome			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pustule			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinusitis bacterial			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Suspected COVID-19			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tinea versicolour			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tonsillitis bacterial			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tonsillitis streptococcal			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 12 (16.67%)	2 / 13 (15.38%)	0 / 4 (0.00%)
occurrences (all)	2	2	0
Viral infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral pharyngitis			
subjects affected / exposed	0 / 12 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Viral rash			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Vulval abscess			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vulvovaginitis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypovitaminosis			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insulin resistance			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 12 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	ABCWY high dose_06 Group	ABCWY low dose_02 Group	ABCWY low dose_06 Group

Total subjects affected by non-serious adverse events			
subjects affected / exposed	234 / 238 (98.32%)	170 / 181 (93.92%)	229 / 239 (95.82%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Uterine leiomyoma			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Administration site erythema			
subjects affected / exposed	45 / 238 (18.91%)	25 / 181 (13.81%)	46 / 239 (19.25%)
occurrences (all)	51	33	56
Administration site hypoaesthesia			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Administration site pain			
subjects affected / exposed	232 / 238 (97.48%)	160 / 181 (88.40%)	226 / 239 (94.56%)
occurrences (all)	440	321	443
Administration site induration			
subjects affected / exposed	44 / 238 (18.49%)	27 / 181 (14.92%)	32 / 239 (13.39%)
occurrences (all)	50	34	41
Administration site swelling			
subjects affected / exposed	52 / 238 (21.85%)	34 / 181 (18.78%)	48 / 239 (20.08%)
occurrences (all)	59	47	62
Axillary pain			
subjects affected / exposed	2 / 238 (0.84%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	2	0	1
Administration site warmth			

subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Asthenia			
subjects affected / exposed	1 / 238 (0.42%)	2 / 181 (1.10%)	0 / 239 (0.00%)
occurrences (all)	1	2	0
Chills			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	2 / 239 (0.84%)
occurrences (all)	0	0	2
Chest pain			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	2
Hangover			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	147 / 238 (61.76%)	104 / 181 (57.46%)	152 / 239 (63.60%)
occurrences (all)	252	193	256
Influenza like illness			
subjects affected / exposed	12 / 238 (5.04%)	8 / 181 (4.42%)	4 / 239 (1.67%)
occurrences (all)	17	14	6
Inflammation			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Injection site bruising			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Injection site discomfort			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Injection site erythema			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Injection site haemorrhage			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	1	0	1
Injection site hypoaesthesia			

subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Injection site lymphadenopathy			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Injection site mass			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Injection site oedema			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Injection site nodule			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	4
Injection site pruritus			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	2 / 239 (0.84%)
occurrences (all)	1	0	2
Injection site paraesthesia			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Injection site rash			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Injection site swelling			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	2 / 238 (0.84%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	2	1	0
Injection site warmth			

subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	1	0	1
Malaise			
subjects affected / exposed	1 / 238 (0.42%)	1 / 181 (0.55%)	1 / 239 (0.42%)
occurrences (all)	1	1	1
Medical device site pruritus			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	18 / 238 (7.56%)	12 / 181 (6.63%)	14 / 239 (5.86%)
occurrences (all)	21	13	15
Swelling			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Vaccination site erythema			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Vaccination site pruritus			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Vaccination site swelling			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site pain			

subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Vaccination site warmth			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Mite allergy			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Hypersensitivity			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Mycotic allergy			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Seasonal allergy			
subjects affected / exposed	2 / 238 (0.84%)	1 / 181 (0.55%)	1 / 239 (0.42%)
occurrences (all)	2	2	1
Reproductive system and breast disorders			
Adenomyosis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Cervical polyp			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Heavy menstrual bleeding			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Endometriosis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			

subjects affected / exposed	3 / 238 (1.26%)	3 / 181 (1.66%)	1 / 239 (0.42%)
occurrences (all)	3	3	1
Menstrual disorder			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Menstruation irregular			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Ovarian cyst			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Allergic sinusitis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Dyspnoea exertional			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	4 / 238 (1.68%)	0 / 181 (0.00%)	4 / 239 (1.67%)
occurrences (all)	4	0	4
Epistaxis			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	1 / 239 (0.42%)
occurrences (all)	0	1	1
Asthma			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Nasal pruritus			

subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Nasal obstruction			
subjects affected / exposed	1 / 238 (0.42%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	1	1	0
Nasal congestion			
subjects affected / exposed	1 / 238 (0.42%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	1	1	0
Nasal septum deviation			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Nasal septum perforation			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Paranasal sinus discomfort			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	6 / 238 (2.52%)	7 / 181 (3.87%)	1 / 239 (0.42%)
occurrences (all)	7	8	1
Rhinorrhoea			
subjects affected / exposed	6 / 238 (2.52%)	1 / 181 (0.55%)	1 / 239 (0.42%)
occurrences (all)	6	1	1
Rhinitis allergic			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	2 / 239 (0.84%)
occurrences (all)	1	0	2
Pharyngeal swelling			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Tonsillolith			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Anxiety disorder			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Anger			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Attention deficit hyperactivity disorder			
subjects affected / exposed	2 / 238 (0.84%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	2	0	1
Depression			
subjects affected / exposed	3 / 238 (1.26%)	0 / 181 (0.00%)	2 / 239 (0.84%)
occurrences (all)	3	0	2
Eating disorder			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Initial insomnia			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	1	0	1
Insomnia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Mixed anxiety and depressive disorder			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Neurosis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Obsessive-compulsive disorder			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Social anxiety disorder			

subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Sleep disorder			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Suicidal ideation			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood iron decreased			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Human metapneumovirus test positive			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Streptococcus test positive			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Accident			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Accidental exposure to product			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Animal bite			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Ankle fracture			

subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Arthropod bite			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Concussion			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Cartilage injury			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Bone contusion			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Eyelid injury			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Epicondylitis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Craniofacial fracture			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Contusion			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Foot fracture			
subjects affected / exposed	1 / 238 (0.42%)	1 / 181 (0.55%)	1 / 239 (0.42%)
occurrences (all)	1	1	1
Forearm fracture			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Heat exhaustion			

subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Ligament rupture			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Joint dislocation			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Immunisation reaction			
subjects affected / exposed	1 / 238 (0.42%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	1	1	0
Ligament sprain			
subjects affected / exposed	2 / 238 (0.84%)	2 / 181 (1.10%)	0 / 239 (0.00%)
occurrences (all)	2	2	0
Limb injury			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Muscle strain			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Post procedural complication			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Post-traumatic neck syndrome			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Procedural complication			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Procedural pain			
subjects affected / exposed	1 / 238 (0.42%)	3 / 181 (1.66%)	1 / 239 (0.42%)
occurrences (all)	1	3	1
Radius fracture			

subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Repetitive strain injury			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Skin abrasion			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Skin injury			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Spinal fracture			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Stress fracture			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Sunburn			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Tendon rupture			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Traumatic pain			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Cardiac disorders			

Sinus tachycardia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	157 / 238 (65.97%)	110 / 181 (60.77%)	140 / 239 (58.58%)
occurrences (all)	250	180	234
Dizziness			
subjects affected / exposed	1 / 238 (0.42%)	2 / 181 (1.10%)	0 / 239 (0.00%)
occurrences (all)	1	2	0
Hyperaesthesia			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Lethargy			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	4 / 238 (1.68%)	1 / 181 (0.55%)	2 / 239 (0.84%)
occurrences (all)	4	1	2
Migraine with aura			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Presyncope			

subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	1 / 239 (0.42%)
occurrences (all)	0	1	1
Tension headache			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Trigeminal neuralgia			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Lymphadenitis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	3 / 238 (1.26%)	1 / 181 (0.55%)	1 / 239 (0.42%)
occurrences (all)	4	1	1
Lymph node pain			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Cerumen impaction			

subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	1 / 238 (0.42%)	1 / 181 (0.55%)	2 / 239 (0.84%)
occurrences (all)	1	1	2
Inner ear inflammation			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Motion sickness			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	1	0	1
Tinnitus			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Tympanic membrane perforation			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Vertigo			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	2	0	1
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	2 / 239 (0.84%)
occurrences (all)	0	0	2
Eye irritation			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Conjunctival hyperaemia			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0

Panophthalmitis			
subjects affected / exposed	2 / 238 (0.84%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	2	0	0
Eye pain			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Photophobia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	4 / 238 (1.68%)	1 / 181 (0.55%)	2 / 239 (0.84%)
occurrences (all)	5	1	2
Anal fissure			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 238 (0.42%)	2 / 181 (1.10%)	2 / 239 (0.84%)
occurrences (all)	1	2	2
Colitis ulcerative			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Coeliac disease			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	6 / 238 (2.52%)	2 / 181 (1.10%)	5 / 239 (2.09%)
occurrences (all)	6	2	7
Dyspepsia			
subjects affected / exposed	0 / 238 (0.00%)	2 / 181 (1.10%)	2 / 239 (0.84%)
occurrences (all)	0	2	2
Enteritis			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Dental caries			

subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Food poisoning			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Gastrointestinal inflammation			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Gingival swelling			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Lip swelling			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	57 / 238 (23.95%)	34 / 181 (18.78%)	57 / 239 (23.85%)
occurrences (all)	69	37	68
Odynophagia			

subjects affected / exposed	2 / 238 (0.84%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	2	1	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	1 / 238 (0.42%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	1	1	0
Stomatitis			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	2 / 238 (0.84%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	2	3	0
Tooth impacted			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	4 / 238 (1.68%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	4	0	0
Alopecia			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Alopecia areata			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Blister			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	2 / 238 (0.84%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	2	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0

Dermatitis atopic			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	1	0	1
Drug eruption			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Dyshidrotic eczema			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	1 / 238 (0.42%)	2 / 181 (1.10%)	0 / 239 (0.00%)
occurrences (all)	1	2	0
Lichen planus			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Onychalgia			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Parapsoriasis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Psoriasis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	3 / 239 (1.26%)
occurrences (all)	0	0	3
Sea bather's eruption			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0

Rash macular			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Rash erythematous			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Solar dermatitis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Transient acantholytic dermatosis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	2 / 238 (0.84%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	2	1	0
Urticaria papular			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Urticaria chronic			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Cystitis noninfective			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Urethral haemorrhage			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Urethral pain			

subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Urge incontinence			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Hypothyroidism			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	2 / 239 (0.84%)
occurrences (all)	0	0	2
Hyperprolactinaemia			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Polycystic ovarian syndrome			
subjects affected / exposed	2 / 238 (0.84%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal and connective tissue disorders			
Axillary mass			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Arthralgia			
subjects affected / exposed	44 / 238 (18.49%)	26 / 181 (14.36%)	27 / 239 (11.30%)
occurrences (all)	51	29	33
Back pain			
subjects affected / exposed	2 / 238 (0.84%)	3 / 181 (1.66%)	0 / 239 (0.00%)
occurrences (all)	2	3	0
Flank pain			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Inguinal mass			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc protrusion			

subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Jaw disorder			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Muscle disorder			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	1 / 238 (0.42%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	1	1	0
Myalgia			
subjects affected / exposed	57 / 238 (23.95%)	34 / 181 (18.78%)	53 / 239 (22.18%)
occurrences (all)	71	45	63
Musculoskeletal stiffness			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	1 / 238 (0.42%)	2 / 181 (1.10%)	3 / 239 (1.26%)
occurrences (all)	1	2	3
Rotator cuff syndrome			

subjects affected / exposed	1 / 238 (0.42%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	1	1	0
Synovial cyst			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	2 / 239 (0.84%)
occurrences (all)	0	0	2
Infections and infestations			
Abscess neck			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Acarodermatitis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Acute sinusitis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Adenovirus infection			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Alveolar osteitis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	2 / 238 (0.84%)	4 / 181 (2.21%)	3 / 239 (1.26%)
occurrences (all)	2	5	3
Cellulitis			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
COVID-19			
subjects affected / exposed	12 / 238 (5.04%)	14 / 181 (7.73%)	14 / 239 (5.86%)
occurrences (all)	12	16	14

Chlamydial infection			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Coronavirus infection			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	2 / 239 (0.84%)
occurrences (all)	0	0	2
Conjunctivitis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	3 / 238 (1.26%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	3	0	0
Dengue fever			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	2 / 239 (0.84%)
occurrences (all)	0	0	2
Ear infection			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Folliculitis			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Enterovirus infection			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	1 / 238 (0.42%)	3 / 181 (1.66%)	4 / 239 (1.67%)
occurrences (all)	1	3	4
Gastrointestinal infection			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Helicobacter infection			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1

Hordeolum			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Herpes simplex			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Impetigo			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Infectious mononucleosis			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	7 / 238 (2.94%)	4 / 181 (2.21%)	9 / 239 (3.77%)
occurrences (all)	7	4	10
Laryngitis			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	3 / 239 (1.26%)
occurrences (all)	1	0	3
Metapneumovirus infection			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Lyme disease			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	17 / 238 (7.14%)	14 / 181 (7.73%)	21 / 239 (8.79%)
occurrences (all)	22	18	26
Onychomycosis			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	1	0	1
Oral fungal infection			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	2 / 239 (0.84%)
occurrences (all)	0	0	4

Norovirus infection			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Otitis externa			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Ovarian bacterial infection			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Otitis media acute			
subjects affected / exposed	2 / 238 (0.84%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	2	0	0
Otitis media			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	2 / 239 (0.84%)
occurrences (all)	0	1	2
Paronychia			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	1	0	1
Pharyngitis			
subjects affected / exposed	3 / 238 (1.26%)	1 / 181 (0.55%)	5 / 239 (2.09%)
occurrences (all)	4	1	5
Pharyngitis bacterial			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Pharyngitis streptococcal			
subjects affected / exposed	2 / 238 (0.84%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	2	0	0
Post-acute COVID-19 syndrome			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	2 / 238 (0.84%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	2	0	0
Pustule			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0

Respiratory tract infection			
subjects affected / exposed	1 / 238 (0.42%)	4 / 181 (2.21%)	2 / 239 (0.84%)
occurrences (all)	1	4	2
Rhinitis			
subjects affected / exposed	3 / 238 (1.26%)	2 / 181 (1.10%)	2 / 239 (0.84%)
occurrences (all)	3	2	2
Sinusitis			
subjects affected / exposed	5 / 238 (2.10%)	6 / 181 (3.31%)	1 / 239 (0.42%)
occurrences (all)	7	6	1
Skin infection			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Sinusitis bacterial			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Suspected COVID-19			
subjects affected / exposed	3 / 238 (1.26%)	3 / 181 (1.66%)	2 / 239 (0.84%)
occurrences (all)	3	3	2
Tonsillitis			
subjects affected / exposed	0 / 238 (0.00%)	3 / 181 (1.66%)	6 / 239 (2.51%)
occurrences (all)	0	3	6
Tinea versicolour			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Tonsillitis bacterial			
subjects affected / exposed	2 / 238 (0.84%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	2	0	1
Tooth abscess			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Tonsillitis streptococcal			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0

Upper respiratory tract infection			
subjects affected / exposed	12 / 238 (5.04%)	8 / 181 (4.42%)	16 / 239 (6.69%)
occurrences (all)	15	11	19
Viral infection			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Urinary tract infection			
subjects affected / exposed	4 / 238 (1.68%)	3 / 181 (1.66%)	0 / 239 (0.00%)
occurrences (all)	5	3	0
Viral pharyngitis			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	1 / 239 (0.42%)
occurrences (all)	0	1	1
Viral rash			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Vulval abscess			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	0	0	1
Vulvovaginal mycotic infection			
subjects affected / exposed	1 / 238 (0.42%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	1	2	0
Vulvovaginitis			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	1	0	0
Decreased appetite			

subjects affected / exposed	1 / 238 (0.42%)	2 / 181 (1.10%)	0 / 239 (0.00%)
occurrences (all)	1	2	0
Hypovitaminosis			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Insulin resistance			
subjects affected / exposed	1 / 238 (0.42%)	0 / 181 (0.00%)	1 / 239 (0.42%)
occurrences (all)	1	0	1
Vitamin D deficiency			
subjects affected / exposed	0 / 238 (0.00%)	1 / 181 (0.55%)	0 / 239 (0.00%)
occurrences (all)	0	1	0
Iron deficiency			
subjects affected / exposed	0 / 238 (0.00%)	0 / 181 (0.00%)	0 / 239 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Placebo high dose Group	ABCWY high dose_02 Group	ABCWY high doseS_02 Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	182 / 194 (93.81%)	58 / 62 (93.55%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Uterine leiomyoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Administration site erythema			
subjects affected / exposed	0 / 3 (0.00%)	29 / 194 (14.95%)	20 / 62 (32.26%)
occurrences (all)	0	32	28

Administration site hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Administration site pain			
subjects affected / exposed	1 / 3 (33.33%)	173 / 194 (89.18%)	55 / 62 (88.71%)
occurrences (all)	1	346	98
Administration site induration			
subjects affected / exposed	0 / 3 (0.00%)	27 / 194 (13.92%)	18 / 62 (29.03%)
occurrences (all)	0	35	20
Administration site swelling			
subjects affected / exposed	0 / 3 (0.00%)	33 / 194 (17.01%)	22 / 62 (35.48%)
occurrences (all)	0	45	28
Axillary pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Administration site warmth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Hangover			
subjects affected / exposed	1 / 3 (33.33%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	2 / 3 (66.67%)	115 / 194 (59.28%)	37 / 62 (59.68%)
occurrences (all)	4	206	51
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	8 / 194 (4.12%)	0 / 62 (0.00%)
occurrences (all)	0	14	0

Inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 3 (0.00%)	2 / 194 (1.03%)	0 / 62 (0.00%)
occurrences (all)	0	2	0
Injection site discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Injection site haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Injection site hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Injection site induration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Injection site lymphadenopathy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Injection site mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Injection site oedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Injection site nodule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0

Injection site pruritus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Injection site paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Injection site rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
Injection site swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Injection site warmth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Medical device site pruritus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	10 / 194 (5.15%)	3 / 62 (4.84%)
occurrences (all)	0	10	3
Swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0

Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
Vaccination site erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Vaccination site pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Vaccination site swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Vaccination site warmth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Mite allergy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Mycotic allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			

subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Adenomyosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Cervical polyp			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Heavy menstrual bleeding			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Endometriosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Dysmenorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	3 / 194 (1.55%)	0 / 62 (0.00%)
occurrences (all)	0	3	0
Menstrual disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Ovarian cyst			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Allergic sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			

subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Cough			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Nasal pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Nasal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Nasal septum deviation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
Nasal septum perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	7 / 194 (3.61%)	0 / 62 (0.00%)
occurrences (all)	0	7	0
Rhinorrhoea			

subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	1 / 62 (1.61%)
occurrences (all)	0	1	1
Rhinitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Pharyngeal swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Tonsillolith			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Anxiety disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	3 / 194 (1.55%)	1 / 62 (1.61%)
occurrences (all)	0	3	1
Anger			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Eating disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Initial insomnia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Mixed anxiety and depressive disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Neurosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Obsessive-compulsive disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Social anxiety disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Stress			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
Suicidal ideation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Investigations			
Blood iron decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Human metapneumovirus test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Streptococcus test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Accidental exposure to product			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Ankle fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	2	0
Cartilage injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Eyelid injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Epicondylitis			

subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Craniofacial fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Forearm fracture			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Heat exhaustion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Ligament rupture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Joint dislocation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Immunisation reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 3 (0.00%)	3 / 194 (1.55%)	0 / 62 (0.00%)
occurrences (all)	0	3	0
Limb injury			

subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Muscle strain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	1 / 62 (1.61%)
occurrences (all)	0	1	1
Post procedural complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Post-traumatic neck syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Procedural complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 194 (1.03%)	0 / 62 (0.00%)
occurrences (all)	0	2	0
Radius fracture			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Road traffic accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Repetitive strain injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Skin injury			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Spinal fracture			

subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Stress fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Tendon rupture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Traumatic pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 3 (66.67%)	112 / 194 (57.73%)	31 / 62 (50.00%)
occurrences (all)	2	190	44
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	4 / 194 (2.06%)	0 / 62 (0.00%)
occurrences (all)	0	4	0
Hyperaesthesia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 3 (0.00%)	2 / 194 (1.03%)	0 / 62 (0.00%)
occurrences (all)	0	2	0
Migraine with aura			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Trigeminal neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			

Iron deficiency anaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 194 (1.03%)	0 / 62 (0.00%)
occurrences (all)	0	2	0
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Lymphadenitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Lymphadenopathy			
subjects affected / exposed	0 / 3 (0.00%)	3 / 194 (1.55%)	1 / 62 (1.61%)
occurrences (all)	0	3	1
Lymph node pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Ear discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 194 (1.03%)	0 / 62 (0.00%)
occurrences (all)	0	2	0
Inner ear inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Motion sickness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Eye irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Conjunctival hyperaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Panophthalmitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
Anal fissure			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			

subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Colitis ulcerative			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Coeliac disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
Food poisoning			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Gingival swelling			

subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
Haematemesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Lip swelling			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	35 / 194 (18.04%)	10 / 62 (16.13%)
occurrences (all)	0	47	11
Odynophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	2 / 194 (1.03%)	1 / 62 (1.61%)
occurrences (all)	0	2	1
Tooth impacted			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			

Acne			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Alopecia areata			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Drug eruption			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Dyshidrotic eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Lichen planus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0

Onychalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Parapsoriasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Sea bather's eruption			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Skin mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Solar dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Transient acantholytic dermatosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0

Urticaria papular			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Urticaria chronic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Cystitis noninfective			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Urethral haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Urethral pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Urge incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Hyperprolactinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Polycystic ovarian syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

Axillary mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	1 / 3 (33.33%)	21 / 194 (10.82%)	13 / 62 (20.97%)
occurrences (all)	1	27	14
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 194 (1.03%)	0 / 62 (0.00%)
occurrences (all)	0	2	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Inguinal mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Jaw disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Muscle disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	2	0
Muscle tightness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	3 / 194 (1.55%)	1 / 62 (1.61%)
occurrences (all)	0	3	1

Myalgia			
subjects affected / exposed	1 / 3 (33.33%)	41 / 194 (21.13%)	17 / 62 (27.42%)
occurrences (all)	1	55	20
Musculoskeletal stiffness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Tendonitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Abscess neck			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Acarodermatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Adenovirus infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Alveolar osteitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Body tinea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	1 / 62 (1.61%)
occurrences (all)	0	1	1
Cellulitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	16 / 194 (8.25%)	4 / 62 (6.45%)
occurrences (all)	0	17	4
Chlamydial infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Coronavirus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Dengue fever			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Ear infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Folliculitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Enterovirus infection			
subjects affected / exposed	0 / 3 (0.00%)	2 / 194 (1.03%)	0 / 62 (0.00%)
occurrences (all)	0	3	0
Gastroenteritis viral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	1 / 62 (1.61%)
occurrences (all)	0	1	1
Gastrointestinal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Helicobacter infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Infectious mononucleosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	7 / 194 (3.61%)	0 / 62 (0.00%)
occurrences (all)	0	7	0
Laryngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Metapneumovirus infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Lyme disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	12 / 194 (6.19%)	2 / 62 (3.23%)
occurrences (all)	0	15	3
Onychomycosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Norovirus infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Ovarian bacterial infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Otitis media			
subjects affected / exposed	0 / 3 (0.00%)	2 / 194 (1.03%)	0 / 62 (0.00%)
occurrences (all)	0	2	0
Paronychia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			

subjects affected / exposed	0 / 3 (0.00%)	2 / 194 (1.03%)	2 / 62 (3.23%)
occurrences (all)	0	2	2
Pharyngitis bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Post-acute COVID-19 syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Pustule			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	0 / 3 (0.00%)	3 / 194 (1.55%)	0 / 62 (0.00%)
occurrences (all)	0	3	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	4 / 194 (2.06%)	0 / 62 (0.00%)
occurrences (all)	0	4	0
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Sinusitis bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Suspected COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	3 / 194 (1.55%)	0 / 62 (0.00%)
occurrences (all)	0	3	0
Tonsillitis			

subjects affected / exposed	0 / 3 (0.00%)	2 / 194 (1.03%)	0 / 62 (0.00%)
occurrences (all)	0	2	0
Tinea versicolour			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Tonsillitis bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Tonsillitis streptococcal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
Tracheitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	8 / 194 (4.12%)	4 / 62 (6.45%)
occurrences (all)	0	8	5
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Viral pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Vulval abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	1 / 62 (1.61%)
occurrences (all)	0	0	1
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	2	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Vulvovaginitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	1 / 194 (0.52%)	0 / 62 (0.00%)
occurrences (all)	0	1	0
Hypovitaminosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Insulin resistance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 194 (0.00%)	0 / 62 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Control Group	ABCWY low dose_01 Group	ABCWY high dose_01 Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	192 / 197 (97.46%)	50 / 54 (92.59%)	53 / 53 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Basal cell carcinoma			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Uterine leiomyoma			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Hot flush			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Administration site erythema			
subjects affected / exposed	32 / 197 (16.24%)	14 / 54 (25.93%)	8 / 53 (15.09%)
occurrences (all)	37	16	11
Administration site hypoaesthesia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Administration site pain			
subjects affected / exposed	186 / 197 (94.42%)	50 / 54 (92.59%)	51 / 53 (96.23%)
occurrences (all)	340	91	86
Administration site induration			
subjects affected / exposed	29 / 197 (14.72%)	8 / 54 (14.81%)	9 / 53 (16.98%)
occurrences (all)	32	9	12
Administration site swelling			
subjects affected / exposed	31 / 197 (15.74%)	10 / 54 (18.52%)	14 / 53 (26.42%)
occurrences (all)	35	11	22
Axillary pain			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Administration site warmth			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Asthenia			

subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	1	0	1
Chest pain			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Hangover			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	118 / 197 (59.90%)	31 / 54 (57.41%)	36 / 53 (67.92%)
occurrences (all)	167	45	51
Influenza like illness			
subjects affected / exposed	5 / 197 (2.54%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	8	0	0
Inflammation			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	2 / 197 (1.02%)	1 / 54 (1.85%)	0 / 53 (0.00%)
occurrences (all)	2	1	0
Injection site discomfort			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Injection site haemorrhage			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Injection site hypoaesthesia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Injection site induration			

subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Injection site lymphadenopathy			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Injection site mass			
subjects affected / exposed	0 / 197 (0.00%)	1 / 54 (1.85%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Injection site oedema			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Injection site nodule			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Injection site pain			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Injection site pruritus			
subjects affected / exposed	3 / 197 (1.52%)	1 / 54 (1.85%)	1 / 53 (1.89%)
occurrences (all)	3	1	1
Injection site paraesthesia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Injection site rash			
subjects affected / exposed	2 / 197 (1.02%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	3	0	0
Injection site swelling			
subjects affected / exposed	0 / 197 (0.00%)	1 / 54 (1.85%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Injection site reaction			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Injection site warmth			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Malaise			

subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	1	0	1
Medical device site pruritus			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 197 (0.00%)	1 / 54 (1.85%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	15 / 197 (7.61%)	3 / 54 (5.56%)	7 / 53 (13.21%)
occurrences (all)	16	3	7
Swelling			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Swelling face			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Vaccination site erythema			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Vaccination site pruritus			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Vaccination site pain			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Vaccination site swelling			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site pain			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Vaccination site warmth			

subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Mite allergy			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Mycotic allergy			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Adenomyosis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Cervical polyp			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Heavy menstrual bleeding			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Endometriosis			
subjects affected / exposed	0 / 197 (0.00%)	1 / 54 (1.85%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Dysmenorrhoea			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Menstrual disorder			

subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	2	0	0
Menstruation irregular			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Ovarian cyst			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Vaginal haemorrhage			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Allergic sinusitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	3 / 197 (1.52%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	3	0	0
Epistaxis			
subjects affected / exposed	0 / 197 (0.00%)	1 / 54 (1.85%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Asthma			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Nasal pruritus			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Nasal obstruction			

subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Nasal septum deviation			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Nasal septum perforation			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	4 / 197 (2.03%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	4	0	1
Rhinorrhoea			
subjects affected / exposed	3 / 197 (1.52%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	5	0	0
Rhinitis allergic			
subjects affected / exposed	2 / 197 (1.02%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	3	0	0
Pharyngeal swelling			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Tonsillolith			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety disorder			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0

Anxiety			
subjects affected / exposed	1 / 197 (0.51%)	1 / 54 (1.85%)	0 / 53 (0.00%)
occurrences (all)	1	1	0
Anger			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	2 / 53 (3.77%)
occurrences (all)	0	0	2
Depression			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Eating disorder			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Initial insomnia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Mixed anxiety and depressive disorder			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Neurosis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Obsessive-compulsive disorder			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Social anxiety disorder			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			

subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Stress			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Suicidal ideation			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood iron decreased			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Human metapneumovirus test positive			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Streptococcus test positive			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Accident			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Accidental exposure to product			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Ankle fracture			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			

subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Concussion			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Cartilage injury			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Eyelid injury			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Epicondylitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Craniofacial fracture			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	1 / 197 (0.51%)	1 / 54 (1.85%)	0 / 53 (0.00%)
occurrences (all)	1	1	0
Fall			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	2	0	0
Foot fracture			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Forearm fracture			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Heat exhaustion			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Ligament rupture			

subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Joint injury			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Joint dislocation			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Immunisation reaction			
subjects affected / exposed	0 / 197 (0.00%)	1 / 54 (1.85%)	1 / 53 (1.89%)
occurrences (all)	0	1	1
Ligament sprain			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Limb injury			
subjects affected / exposed	2 / 197 (1.02%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	2	0	0
Muscle strain			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Post procedural complication			
subjects affected / exposed	2 / 197 (1.02%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	2	0	0
Post-traumatic neck syndrome			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Procedural complication			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Radius fracture			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			

subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Repetitive strain injury			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Skin injury			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Stress fracture			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Sunburn			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Tendon rupture			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Traumatic pain			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0

Tachycardia			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 197 (0.00%)	1 / 54 (1.85%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	104 / 197 (52.79%)	33 / 54 (61.11%)	29 / 53 (54.72%)
occurrences (all)	146	43	41
Dizziness			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Migraine			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Migraine with aura			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Presyncope			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Sciatica			

subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Trigeminal neuralgia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Lymphadenitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			

subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Inner ear inflammation			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Motion sickness			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Conjunctival hyperaemia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Panophthalmitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0

Eye pain			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	3 / 197 (1.52%)	2 / 54 (3.70%)	0 / 53 (0.00%)
occurrences (all)	3	2	0
Anal fissure			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Colitis ulcerative			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Coeliac disease			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	3 / 197 (1.52%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	3	0	1
Dyspepsia			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	1	0	1
Enteritis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Constipation			

subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Haematemesis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Lip swelling			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	30 / 197 (15.23%)	9 / 54 (16.67%)	13 / 53 (24.53%)
occurrences (all)	35	11	15
Odynophagia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			

subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	3 / 197 (1.52%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	3	0	0
Toothache			
subjects affected / exposed	0 / 197 (0.00%)	1 / 54 (1.85%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Tooth impacted			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Alopecia areata			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0

Drug eruption			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Dyshidrotic eczema			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 197 (0.00%)	1 / 54 (1.85%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Lichen planus			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Onychalgia			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Parapsoriasis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	2 / 53 (3.77%)
occurrences (all)	0	0	2
Sea bather's eruption			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Rash macular			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0

Rash erythematous			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	2 / 53 (3.77%)
occurrences (all)	0	0	2
Skin mass			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Solar dermatitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Transient acantholytic dermatosis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Urticaria papular			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Urticaria chronic			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Cystitis noninfective			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Urethral haemorrhage			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Urethral pain			
subjects affected / exposed	0 / 197 (0.00%)	1 / 54 (1.85%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Urge incontinence			

subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Hyperprolactinaemia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Polycystic ovarian syndrome			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Axillary mass			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	20 / 197 (10.15%)	10 / 54 (18.52%)	11 / 53 (20.75%)
occurrences (all)	21	11	15
Back pain			
subjects affected / exposed	0 / 197 (0.00%)	1 / 54 (1.85%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Flank pain			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Inguinal mass			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			

subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Joint range of motion decreased			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Jaw disorder			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Muscle disorder			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	47 / 197 (23.86%)	18 / 54 (33.33%)	18 / 53 (33.96%)
occurrences (all)	51	21	25
Musculoskeletal stiffness			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 197 (0.00%)	1 / 54 (1.85%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Synovial cyst			

subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess neck			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Acarodermatitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Adenovirus infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Alveolar osteitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 197 (0.00%)	1 / 54 (1.85%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
COVID-19			
subjects affected / exposed	6 / 197 (3.05%)	4 / 54 (7.41%)	5 / 53 (9.43%)
occurrences (all)	6	4	5
Chlamydial infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0

Coronavirus infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Dengue fever			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Folliculitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Enterovirus infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	2 / 197 (1.02%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	2	0	1
Gastrointestinal infection			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Helicobacter infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0

Herpes simplex			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	1 / 197 (0.51%)	1 / 54 (1.85%)	0 / 53 (0.00%)
occurrences (all)	1	1	0
Infectious mononucleosis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	3 / 197 (1.52%)	1 / 54 (1.85%)	0 / 53 (0.00%)
occurrences (all)	3	1	0
Laryngitis			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Metapneumovirus infection			
subjects affected / exposed	0 / 197 (0.00%)	1 / 54 (1.85%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Lyme disease			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	5 / 197 (2.54%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	5	0	0
Onychomycosis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Norovirus infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0

Otitis externa			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Ovarian bacterial infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	2 / 197 (1.02%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	2	0	0
Pharyngitis bacterial			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Post-acute COVID-19 syndrome			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Pustule			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0

Rhinitis			
subjects affected / exposed	2 / 197 (1.02%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	2	0	0
Sinusitis			
subjects affected / exposed	3 / 197 (1.52%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	3	0	0
Skin infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	0	0	1
Sinusitis bacterial			
subjects affected / exposed	0 / 197 (0.00%)	1 / 54 (1.85%)	0 / 53 (0.00%)
occurrences (all)	0	1	0
Suspected COVID-19			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	4 / 197 (2.03%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	4	0	1
Tinea versicolour			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Tonsillitis bacterial			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Tooth abscess			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Tonsillitis streptococcal			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	12 / 197 (6.09%)	2 / 54 (3.70%)	2 / 53 (3.77%)
occurrences (all)	12	2	2

Viral infection			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Viral pharyngitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Vulval abscess			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Vulvovaginitis			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	1 / 53 (1.89%)
occurrences (all)	1	0	2
Hypovitaminosis			

subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Insulin resistance			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	1 / 197 (0.51%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	1	0	0
Iron deficiency			
subjects affected / exposed	0 / 197 (0.00%)	0 / 54 (0.00%)	0 / 53 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	ABCWY low doseS_02 Group	ABCWY low doseS_06 Group	ABCWY high doseS_06 Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	61 / 62 (98.39%)	60 / 62 (96.77%)	62 / 63 (98.41%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 62 (0.00%)	1 / 62 (1.61%)	0 / 63 (0.00%)
occurrences (all)	0	1	0
Uterine leiomyoma			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Administration site erythema			
subjects affected / exposed	22 / 62 (35.48%)	26 / 62 (41.94%)	24 / 63 (38.10%)
occurrences (all)	33	31	28
Administration site hypoaesthesia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0

Administration site pain			
subjects affected / exposed	61 / 62 (98.39%)	59 / 62 (95.16%)	60 / 63 (95.24%)
occurrences (all)	110	107	102
Administration site induration			
subjects affected / exposed	18 / 62 (29.03%)	16 / 62 (25.81%)	20 / 63 (31.75%)
occurrences (all)	26	21	25
Administration site swelling			
subjects affected / exposed	25 / 62 (40.32%)	24 / 62 (38.71%)	26 / 63 (41.27%)
occurrences (all)	36	31	34
Axillary pain			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Administration site warmth			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Hangover			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	50 / 62 (80.65%)	49 / 62 (79.03%)	41 / 63 (65.08%)
occurrences (all)	78	71	56
Influenza like illness			
subjects affected / exposed	0 / 62 (0.00%)	1 / 62 (1.61%)	1 / 63 (1.59%)
occurrences (all)	0	1	1
Inflammation			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0

Injection site bruising			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Injection site haemorrhage			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Injection site hypoaesthesia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Injection site lymphadenopathy			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Injection site mass			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Injection site oedema			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Injection site nodule			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Injection site pruritus			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	1	0	1

Injection site paraesthesia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Injection site rash			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	2 / 63 (3.17%)
occurrences (all)	0	0	2
Injection site swelling			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Injection site warmth			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Medical device site pruritus			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	3 / 62 (4.84%)	5 / 62 (8.06%)	5 / 63 (7.94%)
occurrences (all)	3	5	5
Swelling			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Swelling face			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0

Vaccination site erythema			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Vaccination site pruritus			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Vaccination site swelling			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Vessel puncture site pain			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Vaccination site warmth			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Immune system disorders			
Food allergy			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Mite allergy			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Mycotic allergy			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Seasonal allergy			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			

Adenomyosis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 62 (1.61%)	0 / 63 (0.00%)
occurrences (all)	0	1	0
Cervical polyp			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Heavy menstrual bleeding			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	2	0	0
Endometriosis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 62 (1.61%)	0 / 63 (0.00%)
occurrences (all)	0	1	0
Dysmenorrhoea			
subjects affected / exposed	1 / 62 (1.61%)	1 / 62 (1.61%)	0 / 63 (0.00%)
occurrences (all)	1	1	0
Menstrual disorder			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Menstruation irregular			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Ovarian cyst			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Allergic sinusitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			

subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 62 (1.61%)	1 / 63 (1.59%)
occurrences (all)	0	1	2
Asthma			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	1	0	1
Nasal pruritus			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Nasal obstruction			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Nasal septum deviation			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Nasal septum perforation			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	2 / 63 (3.17%)
occurrences (all)	0	0	2
Rhinorrhoea			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			

subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Pharyngeal swelling			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Throat irritation			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Tonsillolith			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety disorder			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 62 (0.00%)	1 / 62 (1.61%)	0 / 63 (0.00%)
occurrences (all)	0	1	0
Anger			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Attention deficit hyperactivity disorder			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	2 / 63 (3.17%)
occurrences (all)	0	0	2
Depression			
subjects affected / exposed	0 / 62 (0.00%)	2 / 62 (3.23%)	0 / 63 (0.00%)
occurrences (all)	0	2	0
Eating disorder			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Initial insomnia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Insomnia			

subjects affected / exposed	0 / 62 (0.00%)	2 / 62 (3.23%)	0 / 63 (0.00%)
occurrences (all)	0	2	0
Mixed anxiety and depressive disorder			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Neurosis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Obsessive-compulsive disorder			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Social anxiety disorder			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Sleep disorder			
subjects affected / exposed	0 / 62 (0.00%)	1 / 62 (1.61%)	0 / 63 (0.00%)
occurrences (all)	0	1	0
Stress			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Suicidal ideation			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood iron decreased			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Human metapneumovirus test positive			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Body temperature increased			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Streptococcus test positive			

subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Accident			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Accidental exposure to product			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Animal bite			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Ankle fracture			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Arthropod bite			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Concussion			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Cartilage injury			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Eyelid injury			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Epicondylitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Craniofacial fracture			

subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Foot fracture			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Forearm fracture			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Heat exhaustion			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Ligament rupture			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Joint injury			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Immunisation reaction			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Limb injury			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Muscle strain			

subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Post procedural complication			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Post-traumatic neck syndrome			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Procedural complication			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Radius fracture			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Repetitive strain injury			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Skin injury			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Spinal fracture			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Stress fracture			

subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Sunburn			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Tendon rupture			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Thermal burn			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Traumatic pain			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Disturbance in attention			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	38 / 62 (61.29%)	36 / 62 (58.06%)	37 / 63 (58.73%)
occurrences (all)	52	49	47
Dizziness			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Hyperaesthesia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			

subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Migraine with aura			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	0 / 62 (0.00%)	1 / 62 (1.61%)	1 / 63 (1.59%)
occurrences (all)	0	2	1
Tension headache			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Trigeminal neuralgia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0

Anaemia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Lymphadenitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	1 / 62 (1.61%)	1 / 62 (1.61%)	0 / 63 (0.00%)
occurrences (all)	1	2	0
Lymph node pain			
subjects affected / exposed	1 / 62 (1.61%)	1 / 62 (1.61%)	0 / 63 (0.00%)
occurrences (all)	1	2	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Ear pain			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Inner ear inflammation			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Motion sickness			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Tympanic membrane perforation			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Vertigo			

subjects affected / exposed	0 / 62 (0.00%)	1 / 62 (1.61%)	0 / 63 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Blepharitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis allergic			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Conjunctival hyperaemia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Panophthalmitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Colitis ulcerative			

subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Coeliac disease			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 62 (1.61%)	2 / 62 (3.23%)	2 / 63 (3.17%)
occurrences (all)	1	2	2
Dyspepsia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Food poisoning			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 62 (1.61%)	0 / 63 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal inflammation			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Gingival swelling			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Haematemesis			

subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia oral			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Lip swelling			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	10 / 62 (16.13%)	11 / 62 (17.74%)	11 / 63 (17.46%)
occurrences (all)	12	12	14
Odynophagia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Tooth impacted			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0

Alopecia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Alopecia areata			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Drug eruption			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Dyshidrotic eczema			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Lichen planus			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Onychalgia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0

Parapsoriasis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Psoriasis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Sea bather's eruption			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Skin mass			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Solar dermatitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Transient acantholytic dermatosis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	0 / 62 (0.00%)	1 / 62 (1.61%)	0 / 63 (0.00%)
occurrences (all)	0	1	0
Urticaria papular			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0

Urticaria chronic			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Cystitis noninfective			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Urethral haemorrhage			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Urethral pain			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Urge incontinence			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Hyperprolactinaemia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Polycystic ovarian syndrome			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Axillary mass			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0

Arthralgia			
subjects affected / exposed	11 / 62 (17.74%)	15 / 62 (24.19%)	20 / 63 (31.75%)
occurrences (all)	15	20	29
Back pain			
subjects affected / exposed	2 / 62 (3.23%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	2	0	0
Flank pain			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Inguinal mass			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Intervertebral disc protrusion			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Limb discomfort			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Joint range of motion decreased			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Jaw disorder			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Muscle disorder			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	19 / 62 (30.65%)	25 / 62 (40.32%)	23 / 63 (36.51%)
occurrences (all)	23	27	30

Musculoskeletal stiffness			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	1	0	1
Rotator cuff syndrome			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Synovial cyst			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Tendonitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess neck			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Acarodermatitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Acute sinusitis			
subjects affected / exposed	0 / 62 (0.00%)	1 / 62 (1.61%)	0 / 63 (0.00%)
occurrences (all)	0	1	0
Adenovirus infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Alveolar osteitis			

subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 62 (0.00%)	2 / 62 (3.23%)	0 / 63 (0.00%)
occurrences (all)	0	2	0
Cellulitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	3 / 62 (4.84%)	2 / 62 (3.23%)	3 / 63 (4.76%)
occurrences (all)	3	2	3
Chlamydial infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Coronavirus infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Cystitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Dengue fever			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Enterovirus infection			

subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	2 / 63 (3.17%)
occurrences (all)	0	0	2
Gastrointestinal infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Helicobacter infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Hordeolum			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Herpes simplex			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Infectious mononucleosis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Laryngitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Metapneumovirus infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Lyme disease			

subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	3 / 62 (4.84%)	4 / 62 (6.45%)	4 / 63 (6.35%)
occurrences (all)	3	4	5
Onychomycosis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Oral fungal infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Norovirus infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Otitis externa			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Ovarian bacterial infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Pharyngitis bacterial			

subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Post-acute COVID-19 syndrome			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1
Pustule			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	2 / 62 (3.23%)	1 / 62 (1.61%)	0 / 63 (0.00%)
occurrences (all)	2	1	0
Skin infection			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Sinusitis bacterial			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Suspected COVID-19			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	1 / 62 (1.61%)	1 / 62 (1.61%)	1 / 63 (1.59%)
occurrences (all)	1	2	1
Tinea versicolour			

subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Tonsillitis bacterial			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Tonsillitis streptococcal			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 62 (1.61%)	2 / 62 (3.23%)	7 / 63 (11.11%)
occurrences (all)	2	2	7
Viral infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	2	0	0
Viral pharyngitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Viral rash			
subjects affected / exposed	0 / 62 (0.00%)	1 / 62 (1.61%)	0 / 63 (0.00%)
occurrences (all)	0	1	0
Vulval abscess			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal candidiasis			

subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Vulvovaginitis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Decreased appetite			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Hypovitaminosis			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Insulin resistance			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	0	0	0
Vitamin D deficiency			
subjects affected / exposed	1 / 62 (1.61%)	0 / 62 (0.00%)	0 / 63 (0.00%)
occurrences (all)	1	0	0
Iron deficiency			
subjects affected / exposed	0 / 62 (0.00%)	0 / 62 (0.00%)	1 / 63 (1.59%)
occurrences (all)	0	0	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
21 June 2021	This protocol was amended primarily for 3 reasons: 1. To eliminate the Tdap vaccine in the Phase II Formulation and Schedule-finding and replace by placebo to avoid potential confounding factors that might impact selection of dosage and schedule for further development which is one of the primary aims of the study. 2. Due to the decision to parallelly test low and high dose in Phase II Formulation and Schedule-finding, the alpha has been split leading to an increase in the sample size to maintain the power of the analysis. 3. Increasing the number of participants in Phase II sourcing to support the meningitis assay development, clinical testing and maintenance strategies. Additionally, considering that some of the study interventions are combination products constituted of a device and biologic product (pre-filled syringes), the amended protocol provides instructions for collection of safety information related to the use of medical devices. Additional changes have been made to align with the current guidelines or to improve the clarity of the text.
29 September 2021	The study design for Phase II Formulation and Schedule Findings has been updated.
22 March 2022	This protocol has been amended to add dosing schedules in the Phase II Sourcing part to support the further assay development.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported