Clinical trial results:
Safety and Immunogenicity Study of VLA15, a Multivalent Recombinant OspA Based Vaccine Candidate Against Lyme Borreliosis: a Randomized, Controlled, Observer-Blind Phase 2 Study in a Healthy Pediatric and Adult Study Population

Summary

EudraCT number	2025-000381-28
Trial protocol	Outside EU/EEA
Global end of trial date	02 July 2025

Results information

Result version number	v1 (current)
This version publication date	01 March 2026
First version publication date	01 March 2026

Trial information

Trial identification

Sponsor protocol code	C4601008

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04801420
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	66 Hudson Boulevard East, New York, United States, NY 10001
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-003130-PIP02-23
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	06 October 2025
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	02 July 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to assess the safety and tolerability profile of VLA15, given in a three- or two dose primary immunisation schedule (Month 0-2-6 or Month 0-6), in a healthy study population aged 5 to 65 years up to Day 208 (Month 7) and to assess the immune response to VLA15, given in a three- or two dose primary immunisation schedule (Month 0-2-6 or Month 0-6), in a healthy study population aged 5 to 65 years at Day 208 (Month 7).

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) guidelines. In addition, all the local regulatory requirements were followed, in particular, those affording greater protection to the safety of participants.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 March 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 625
Worldwide total number of subjects	625
EEA total number of subjects	0

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)	155
Adolescents (12-17 years)	150
Adults (18-64 years)	312
From 65 to 84 years	8

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were recruited for Part A and then continued into Part B

Pre-assignment

Screening details:

A total of 714 participants were screened of which 89 failed screening, and 625 participants were randomised into 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	Investigator, Monitor, Assessor, Subject

Blinding implementation details:

The study was an observer-blinded study, which was conducted in a blinded manner for the study investigators, the sponsor including laboratory personnel, and the participants.

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1: VLA15

Arm description:

Participants aged 5 to 65 years received three intramuscular (IM) vaccinations of 180 microgram (mcg) VLA15 at Months 0, 2 and 6 during the Main Study Phase and received three IM vaccinations of 180 mcg VLA15 at Months 18, 30 and 42 during the Booster Phase.

Arm type	Experimental
Investigational medicinal product name	PF-07307405
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Participants received VLA15 180 mcg IM injection at Months 0, 2 and 6. Eligible participants received booster dose at Months 18, 30 and 42.

Arm title	Group 2: VLA15 + Placebo

Arm description:

Participants aged 5 to 65 years received two IM vaccinations of 180 mcg VLA15 at Months 0 and 6 and a placebo injection at Month 2 during the Main Study Phase and received three IM vaccinations of 180 mcg VLA15 at Months 18, 30 and 42 during the Booster Phase.

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:

Participants received normal saline 0.5 milliliter (mL) IM injection at Month 2.

Investigational medicinal product name	PF-07307405
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection

Routes of administration	Intramuscular use

Dosage and administration details:

Participants received VLA15 180 mcg IM injection at Months 0 and 6. Eligible participants received booster dose at Months 18, 30 and 42.

Arm title	Group 3: Placebo

Arm description:

Participants aged 5 to 65 years received three IM injections of placebo at Months 0, 2 and 6 during the Main Study Phase and received three IM injections of placebo at Months 18, 30 and 42 during the Booster Phase.

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:

Participants received normal saline 0.5 mL IM injection at Months 0, 2 and 6. Eligible participants received booster dose at Months 18, 30 and 42.

Number of subjects in period 1	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo
Started	208	209	208
Completed	128	118	113
Not completed	80	91	95
Adverse event, serious fatal	1	-	-
Consent withdrawn by subject	20	17	18
Physician decision	7	9	10
Individual Stopping Criteria Reached	-	2	-
Adverse event, non-fatal	1	1	4
Unspecified	18	28	24
Lost to follow-up	26	27	29
Moved From Study Area	7	7	10

Baseline characteristics

Reporting groups	
Reporting group title	Group 1: VLA15
Reporting group description:	
Participants aged 5 to 65 years received three intramuscular (IM) vaccinations of 180 microgram (mcg) VLA15 at Months 0, 2 and 6 during the Main Study Phase and received three IM vaccinations of 180 mcg VLA15 at Months 18, 30 and 42 during the Booster Phase.	
Reporting group title	Group 2: VLA15 + Placebo
Reporting group description:	
Participants aged 5 to 65 years received two IM vaccinations of 180 mcg VLA15 at Months 0 and 6 and a placebo injection at Month 2 during the Main Study Phase and received three IM vaccinations of 180 mcg VLA15 at Months 18, 30 and 42 during the Booster Phase.	
Reporting group title	Group 3: Placebo
Reporting group description:	
Participants aged 5 to 65 years received three IM injections of placebo at Months 0, 2 and 6 during the Main Study Phase and received three IM injections of placebo at Months 18, 30 and 42 during the Booster Phase.	

Reporting group values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo
Number of subjects	208	209	208
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	28.7	28.9	29.0
standard deviation	± 19.09	± 19.56	± 19.72
Gender categorical Units: Subjects			
Male	96	101	107
Female	112	108	101
Ethnicity Units: Subjects			
Hispanic or Latino	23	15	18
Not Hispanic or Latino	185	194	190
Race Units: Subjects			
American Indian or Alaska Native	1	0	0
Asian	4	3	6
Black or African American	27	17	24
White	172	184	176
Other	4	5	2

Reporting group values	Total		
Number of subjects	625		
Age Categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	- 		
Gender categorical Units: Subjects			
Male	304		
Female	321		
Ethnicity Units: Subjects			
Hispanic or Latino	56		
Not Hispanic or Latino	569		
Race Units: Subjects			
American Indian or Alaska Native	1		
Asian	13		
Black or African American	68		
White	532		
Other	11		

End points reporting groups

Reporting group title	Group 1: VLA15
Reporting group description:	
Participants aged 5 to 65 years received three intramuscular (IM) vaccinations of 180 microgram (mcg) VLA15 at Months 0, 2 and 6 during the Main Study Phase and received three IM vaccinations of 180 mcg VLA15 at Months 18, 30 and 42 during the Booster Phase.	
Reporting group title	Group 2: VLA15 + Placebo
Reporting group description:	
Participants aged 5 to 65 years received two IM vaccinations of 180 mcg VLA15 at Months 0 and 6 and a placebo injection at Month 2 during the Main Study Phase and received three IM vaccinations of 180 mcg VLA15 at Months 18, 30 and 42 during the Booster Phase.	
Reporting group title	Group 3: Placebo
Reporting group description:	
Participants aged 5 to 65 years received three IM injections of placebo at Months 0, 2 and 6 during the Main Study Phase and received three IM injections of placebo at Months 18, 30 and 42 during the Booster Phase.	
Subject analysis set title	Group 1: VLA15
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants aged 5 to 65 years received three IM vaccinations of 180 mcg VLA15 at Months 0, 2 and 6 during the Main Study Phase and received three IM vaccinations of 180 mcg VLA15 at Months 18, 30 and 42 during the Booster Phase.	
Subject analysis set title	Group 2: VLA15 + Placebo
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants aged 5 to 65 years received two IM vaccinations of 180 mcg VLA15 at Months 0 and 6 and a placebo injection at Month 2 during the Main Study Phase and received three IM vaccinations of 180 mcg VLA15 at Months 18, 30 and 42 during the Booster Phase.	
Subject analysis set title	Group 3: Placebo
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants aged 5 to 65 years received three IM injections of placebo at Months 0, 2 and 6 during the Main Study Phase and received three IM injections of placebo at Months 18, 30 and 42 during the Booster Phase.	
Subject analysis set title	Received any VLA15
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants aged 5 to 65 years who received IM vaccination of 180 mcg VLA15 or placebo injections, but could not be assigned to Group 1, 2 or 3 as participants received wrong vaccination or missed a vaccination.	
Subject analysis set title	All Participants
Subject analysis set type	Safety analysis
Subject analysis set description:	
Participants aged 5 to 65 years who received either IM vaccination of 180 mcg VLA15 or placebo injections during the Main Study Phase were included. This arm also included participants who received wrong vaccination or missed a vaccination.	
Subject analysis set title	Group 1: VLA15
Subject analysis set type	Per protocol
Subject analysis set description:	
Participants aged 5 to 65 years received three IM vaccinations of 180 mcg VLA15 at Months 0, 2 and 6 during the Main Study Phase and received three IM vaccinations of 180 mcg VLA15 at Months 18, 30 and 42 during the Booster Phase.	
Subject analysis set title	Group 2: VLA15 + Placebo
Subject analysis set type	Per protocol

Subject analysis set description:

Participants aged 5 to 65 years received two IM vaccinations of 180 mcg VLA15 at Months 0 and 6 and a placebo injection at Month 2 during the Main Study Phase and received three IM vaccinations of 180 mcg VLA15 at Months 18, 30 and 42 during the Booster Phase.

Subject analysis set title	Group 3: Placebo
Subject analysis set type	Per protocol

Subject analysis set description:

Participants aged 5 to 65 years received three IM injections of placebo at Months 0, 2 and 6 during the Main Study Phase and received three IM injections of placebo at Months 18, 30 and 42 during the Booster Phase.

Subject analysis set title	Group 1: VLA15
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants aged 5 to 65 years received three IM vaccinations of 180 mcg VLA15 at Months 0, 2 and 6 during the Main Study Phase and received three IM vaccinations of 180 mcg VLA15 at Months 18, 30 and 42 during the Booster Phase. Participants in this subject analysis set received any vaccination.

Subject analysis set title	Group 2: VLA15 + Placebo
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants aged 5 to 65 years received two IM vaccinations of 180 mcg VLA15 at Months 0 and 6 and a placebo injection at Month 2 during the Main Study Phase and received three IM vaccinations of 180 mcg VLA15 at Months 18, 30 and 42 during the Booster Phase.

Subject analysis set title	Group 3: Placebo
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants aged 5 to 65 years received three IM injections of placebo at Months 0, 2 and 6 during the Main Study Phase and received three IM injections of placebo at Months 18, 30 and 42 during the Booster Phase.

Subject analysis set title	Received any VLA15
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants aged 5 to 65 years who received IM vaccination of 180 mcg VLA15 or placebo injections, but could not be assigned to Group 1, 2 or 3 as participants received wrong vaccination or missed a vaccination.

Primary: Percentage of Participants With Solicited Local and Solicited Systemic Adverse Events (AEs) Within 7 Days After Vaccination 1

End point title	Percentage of Participants With Solicited Local and Solicited Systemic Adverse Events (AEs) Within 7 Days After Vaccination 1[1]

End point description:

Participants or their legal guardians were required to record any solicited local and systemic AEs in the electronic diary. Solicited symptoms were pre-defined symptoms which were collected via an electronic diary. Solicited local AEs included pain, tenderness, erythema/redness meeting grading scale (MGS), swelling MGS and induration/hardening MGS. Solicited systemic AEs included headache, muscle pain, joint pain, nausea, vomiting, fatigue and fever. Two-sided 95% confidence intervals were calculated according to Altman method. Safety Analysis Set (SAS) included all participants who entered into the study and received at least one vaccination. All participants reported under 'Subjects Analyzed' contributed data to the table but may not have evaluable data for every row. Here, "number analysed (n)" signifies number of participants evaluable for the specified rows.

End point type	Primary

End point timeframe:

From Day 1 to Day 7 after vaccination 1 at Month 0

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: Only descriptive data was planned for this endpoint

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	Received any VLA15
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	127	112	206	419
Units: Percentage of participants				
number (confidence interval 95%)				
Pain (n=123, 108, 199, 403, 602)	61.0 (52.1 to 69.1)	52.8 (43.4 to 61.9)	12.6 (8.7 to 17.9)	60.3 (55.4 to 65.0)
Tenderness (n=123, 109, 199, 407, 606)	80.5 (72.6 to 86.5)	80.7 (72.3 to 87.0)	19.6 (14.7 to 25.7)	81.6 (77.5 to 85.0)
Erythema/Redness MGS (n=120, 109, 198, 398, 596)	10.0 (5.8 to 16.7)	10.1 (5.7 to 17.2)	2.5 (1.1 to 5.8)	13.1 (10.1 to 16.7)
Swelling MGS (n=119, 109, 199, 395, 594)	5.9 (2.9 to 11.6)	4.6 (2.0 to 10.3)	0.5 (0.1 to 2.8)	9.1 (6.7 to 12.4)
Induration/Hardening MGS (n=119,109,198,396,594)	9.2 (5.2 to 15.8)	3.7 (1.4 to 9.1)	1.0 (0.3 to 3.6)	8.8 (6.4 to 12.0)
Headache (n=121, 108, 199, 397, 596)	27.3 (20.1 to 35.8)	23.1 (16.2 to 31.9)	19.6 (14.7 to 25.7)	23.4 (19.5 to 27.8)
Muscle pain (n=121, 109, 199, 402, 601)	36.4 (28.3 to 45.2)	33.0 (24.9 to 42.3)	11.1 (7.4 to 16.2)	35.6 (31.0 to 40.4)
Joint pain (n=121, 108, 199, 397, 596)	10.7 (6.4 to 17.5)	3.7 (1.4 to 9.1)	6.0 (3.5 to 10.2)	7.8 (5.6 to 10.9)
Nausea (n=119, 108, 199, 393, 592)	2.5 (0.9 to 7.2)	4.6 (2.0 to 10.4)	6.0 (3.5 to 10.2)	5.3 (3.5 to 8.0)
Vomiting (n=119, 108, 198, 393, 591)	0.8 (0.1 to 4.6)	0.0 (0.0 to 3.4)	1.0 (0.3 to 3.6)	0.8 (0.3 to 2.2)
Fatigue (n=120, 109, 200, 396, 596)	20.0 (13.8 to 28.0)	15.6 (10.0 to 23.6)	16.5 (12.0 to 22.3)	19.7 (16.1 to 23.9)
Fever (n=112, 98, 187, 364, 551)	1.8 (0.5 to 6.3)	0.0 (0.0 to 3.8)	0.5 (0.1 to 3.0)	1.1 (0.4 to 2.8)

End point values	All Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	625			
Units: Percentage of participants				
number (confidence interval 95%)				
Pain (n=123, 108, 199, 403, 602)	44.5 (40.6 to 48.5)			
Tenderness (n=123, 109, 199, 407, 606)	61.2 (57.3 to 65.0)			
Erythema/Redness MGS (n=120, 109, 198, 398, 596)	9.6 (7.5 to 12.2)			
Swelling MGS (n=119, 109, 199, 395, 594)	6.2 (4.6 to 8.5)			
Induration/Hardening MGS (n=119,109,198,396,594)	6.2 (4.6 to 8.5)			
Headache (n=121, 108, 199, 397, 596)	22.1 (19.0 to 25.7)			
Muscle pain (n=121, 109, 199, 402, 601)	27.5 (24.0 to 31.2)			
Joint pain (n=121, 108, 199, 397, 596)	7.2 (5.4 to 9.6)			
Nausea (n=119, 108, 199, 393, 592)	5.6 (4.0 to 7.7)			
Vomiting (n=119, 108, 198, 393, 591)	0.8 (0.4 to 2.0)			
Fatigue (n=120, 109, 200, 396, 596)	18.6 (15.7 to 21.9)			
Fever (n=112, 98, 187, 364, 551)	0.9 (0.4 to 2.1)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Solicited Local and Solicited Systemic AEs Within 7 Days After Vaccination 2

End point title	Percentage of Participants With Solicited Local and Solicited Systemic AEs Within 7 Days After Vaccination 2[2]

End point description:

Participants or their legal guardians were required to record any solicited local and systemic AEs in the electronic diary. Solicited symptoms were pre-defined symptoms which were collected via an electronic diary. Solicited local AEs included pain, tenderness, erythema/redness MGS, swelling MGS and induration/hardening MGS. Solicited systemic AEs included headache, muscle pain, joint pain, nausea, vomiting, fatigue and fever. Two-sided 95% confidence intervals were calculated according to Altman method. SAS included all participants who entered into the study and received at least one vaccination. All participants reported under 'Subjects Analyzed' contributed data to the table but may not have evaluable data for every row. Here, "n" signifies number of participants evaluable for the specified rows.

End point type	Primary

End point timeframe:

From Day 1 to Day 7 after vaccination 2 at Month 2

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned for this endpoint

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	Received any VLA15
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	127	112	206	419
Units: Percentage of participants				
number (confidence interval 95%)				
Pain (n=124, 105, 189, 392, 581)	55.6 (46.9 to 64.1)	4.8 (2.1 to 10.7)	8.5 (5.3 to 13.3)	31.9 (27.5 to 36.7)
Tenderness (n=126, 105, 191, 395, 586)	81.0 (73.2 to 86.9)	9.5 (5.3 to 16.6)	14.7 (10.3 to 20.4)	47.3 (42.5 to 52.3)
Erythema/Redness MGS (n=123, 105, 189, 390, 579)	16.3 (10.8 to 23.8)	0.0 (0.0 to 3.5)	1.6 (0.5 to 4.6)	7.4 (5.2 to 10.5)
Swelling MGS (n=123, 105, 189, 389, 578)	13.8 (8.8 to 21.0)	0.0 (0.0 to 3.5)	0.5 (0.1 to 2.9)	5.4 (3.6 to 8.1)
Induration/Hardening MGS (n=124,105,189,392,581)	12.1 (7.5 to 19.0)	0.0 (0.0 to 3.5)	0.0 (0.0 to 2.0)	5.4 (3.5 to 8.1)
Headache (n=123, 104, 190, 388, 578)	20.3 (14.2 to 28.3)	10.6 (6.0 to 18.0)	12.6 (8.6 to 18.1)	15.5 (12.2 to 19.4)
Muscle pain (n=124, 104, 189, 390, 579)	25.8 (18.9 to 34.2)	3.8 (1.5 to 9.5)	3.7 (1.8 to 7.4)	14.1 (11.0 to 17.9)
Joint pain (n=123, 104, 189, 388, 577)	4.9 (2.3 to 10.2)	2.9 (1.0 to 8.1)	1.6 (0.5 to 4.6)	4.6 (3.0 to 7.2)
Nausea (n=123, 104, 191, 387, 578)	4.9 (2.3 to 10.2)	1.9 (0.5 to 6.7)	5.8 (3.2 to 10.0)	3.6 (2.2 to 6.0)
Vomiting (n=123, 104, 189, 387, 576)	0.0 (0.0 to 3.0)	1.0 (0.2 to 5.2)	0.0 (0.0 to 2.0)	1.3 (0.6 to 3.0)

Fatigue (n=123, 104, 190, 387, 577)	13.8 (8.8 to 21.0)	8.7 (4.6 to 15.6)	12.1 (8.2 to 17.5)	11.9 (9.0 to 15.5)
Fever (n=118, 98, 181, 369, 550)	2.5 (0.9 to 7.2)	0.0 (0.0 to 3.8)	0.0 (0.0 to 2.1)	0.8 (0.3 to 2.4)

End point values	All Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	625			
Units: Percentage of participants				
number (confidence interval 95%)				
Pain (n=124, 105, 189, 392, 581)	24.3 (21.0 to 27.9)			
Tenderness (n=126, 105, 191, 395, 586)	36.7 (32.9 to 40.7)			
Erythema/Redness MGS (n=123, 105, 189, 390, 579)	5.5 (3.9 to 7.7)			
Swelling MGS (n=123, 105, 189, 389, 578)	3.8 (2.5 to 5.7)			
Induration/Hardening MGS (n=124,105,189,392,581)	3.6 (2.4 to 5.5)			
Headache (n=123, 104, 190, 388, 578)	14.5 (11.9 to 17.6)			
Muscle pain (n=124, 104, 189, 390, 579)	10.7 (8.4 to 13.5)			
Joint pain (n=123, 104, 189, 388, 577)	3.6 (2.4 to 5.5)			
Nausea (n=123, 104, 191, 387, 578)	4.3 (2.9 to 6.3)			
Vomiting (n=123, 104, 189, 387, 576)	0.9 (0.4 to 2.0)			
Fatigue (n=123, 104, 190, 387, 577)	12.0 (9.6 to 14.9)			
Fever (n=118, 98, 181, 369, 550)	0.5 (0.2 to 1.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Solicited Local and Solicited Systemic AEs Within 7 Days After Vaccination 3

End point title	Percentage of Participants With Solicited Local and Solicited Systemic AEs Within 7 Days After Vaccination 3[3]

End point description:

Participants or their legal guardians were required to record any solicited local and systemic AEs in the electronic diary. Solicited symptoms were pre-defined symptoms which were collected via an electronic diary. Solicited local AEs included pain, tenderness, erythema/redness MGS, swelling MGS and induration/hardening MGS. Solicited systemic AEs included headache, muscle pain, joint pain, nausea, vomiting, fatigue and fever. Two-sided 95% confidence intervals were calculated according to Altman method. SAS included all participants who entered into the study and received at least one vaccination. All participants reported under 'Subjects Analyzed' contributed data to the table but may not have evaluable data for every row. Here, "n" signifies number of participants evaluable for the specified rows.

End point type	Primary

End point timeframe:

From Day 1 to Day 7 after vaccination 3 at Month 6

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: Only descriptive data was planned for this endpoint

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	Received any VLA15
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	127	112	206	419
Units: Percentage of participants				
number (confidence interval 95%)				
Pain (n=120, 105, 177, 365, 542)	57.5 (48.6 to 66.0)	60.0 (50.4 to 68.9)	5.6 (3.1 to 10.1)	59.2 (54.1 to 64.1)
Tenderness (n=121, 106, 177, 367, 544)	73.6 (65.1 to 80.6)	82.1 (73.7 to 88.2)	13.0 (8.8 to 18.7)	78.2 (73.7 to 82.1)
Erythema/Redness MGS (n=120, 106, 177, 364, 541)	11.7 (7.1 to 18.6)	7.5 (3.9 to 14.2)	1.1 (0.3 to 4.0)	9.6 (7.0 to 13.1)
Swelling MGS (n=119, 106, 177, 363, 540)	8.4 (4.6 to 14.8)	11.3 (6.6 to 18.8)	0.6 (0.1 to 3.1)	9.1 (6.5 to 12.5)
Induration/Hardening MGS (n=119,106,177,364,541)	8.4 (4.6 to 14.8)	6.6 (3.2 to 13.0)	0.6 (0.1 to 3.1)	8.2 (5.8 to 11.5)
Headache (n=117, 106, 178, 362, 540)	15.4 (10.0 to 23.0)	18.9 (12.6 to 27.4)	9.0 (5.6 to 14.1)	18.5 (14.8 to 22.8)
Muscle pain (n=118, 106, 177, 364, 541)	27.1 (19.9 to 35.8)	29.2 (21.4 to 38.5)	7.3 (4.3 to 12.2)	28.3 (23.9 to 33.1)
Joint pain (n=117, 106, 178, 362, 540)	8.5 (4.7 to 15.0)	2.8 (1.0 to 8.0)	3.4 (1.6 to 7.2)	5.0 (3.2 to 7.7)
Nausea (n=117, 105, 177, 361, 538)	1.7 (0.5 to 6.0)	2.9 (1.0 to 8.1)	2.3 (0.9 to 5.7)	3.0 (1.7 to 5.4)
Vomiting (n=117, 105, 177, 361, 538)	0.9 (0.2 to 4.7)	1.9 (0.5 to 6.7)	0.0 (0.0 to 2.1)	1.1 (0.4 to 2.8)
Fatigue (n=117, 106, 178, 362, 540)	17.9 (12.0 to 25.9)	16.0 (10.3 to 24.2)	11.8 (7.8 to 17.4)	17.1 (13.6 to 21.3)
Fever (n=114, 101, 171, 348, 519)	0.0 (0.0 to 3.3)	1.0 (0.2 to 5.4)	0.6 (0.1 to 3.2)	0.9 (0.3 to 2.5)

End point values	All Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	625			
Units: Percentage of participants				
number (confidence interval 95%)				
Pain (n=120, 105, 177, 365, 542)	41.7 (37.6 to 45.9)			
Tenderness (n=121, 106, 177, 367, 544)	57.0 (52.8 to 61.1)			
Erythema/Redness MGS (n=120, 106, 177, 364, 541)	6.8 (5.0 to 9.3)			
Swelling MGS (n=119, 106, 177, 363, 540)	6.3 (4.5 to 8.7)			
Induration/Hardening MGS (n=119,106,177,364,541)	5.7 (4.1 to 8.0)			
Headache (n=117, 106, 178, 362, 540)	15.4 (12.6 to 18.7)			
Muscle pain (n=118, 106, 177, 364, 541)	21.4 (18.2 to 25.1)			
Joint pain (n=117, 106, 178, 362, 540)	4.4 (3.0 to 6.5)			
Nausea (n=117, 105, 177, 361, 538)	2.8 (1.7 to 4.5)			

Vomiting (n=117, 105, 177, 361, 538)	0.7 (0.3 to 1.9)			
Fatigue (n=117, 106, 178, 362, 540)	15.4 (12.6 to 18.7)			
Fever (n=114, 101, 171, 348, 519)	0.8 (0.3 to 2.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Solicited Local and Solicited Systemic AEs Within 7 Days After Any Vaccination During the Main Study Phase

End point title	Percentage of Participants With Solicited Local and Solicited Systemic AEs Within 7 Days After Any Vaccination During the Main Study Phase[4]

End point description:

Participants or their legal guardians were required to record any solicited local and systemic AEs in the electronic diary. Solicited symptoms were pre-defined symptoms which were collected via an electronic diary. Solicited local AEs included pain, tenderness, erythema/redness MGS, swelling MGS and induration/hardening MGS. Solicited systemic AEs included headache, muscle pain, joint pain, nausea, vomiting, fatigue and fever. Two-sided 95% confidence intervals were calculated according to Altman method. SAS included all participants who entered into the study and received at least one vaccination.

End point type	Primary

End point timeframe:

From Day 1 to Day 7 after vaccination 1, 2 or 3 at Month 0, 2 and 6, respectively

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned for this endpoint

End point values	All Participants	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	625	190	187	208
Units: Percentage of participants				
number (confidence interval 95%)				
Pain	57.0 (53.0 to 60.8)	80.5 (74.3 to 85.5)	77.0 (70.5 to 82.5)	16.8 (12.4 to 22.5)
Tenderness	69.9 (66.2 to 73.4)	92.6 (88.0 to 95.6)	92.5 (87.8 to 95.5)	28.4 (22.7 to 34.8)
Erythema/Redness MGS	15.7 (13.0 to 18.7)	26.8 (21.0 to 33.6)	18.7 (13.8 to 24.9)	3.4 (1.6 to 6.8)
Swelling MGS	12.5 (10.1 to 15.3)	20.5 (15.4 to 26.8)	16.6 (11.9 to 22.6)	1.4 (0.5 to 4.2)
Induration/Hardening MGS	11.5 (9.2 to 14.3)	19.5 (14.5 to 25.7)	14.4 (10.1 to 20.2)	1.4 (0.5 to 4.2)
Headache	34.6 (30.9 to 38.4)	38.4 (31.8 to 45.5)	36.4 (29.8 to 43.5)	28.8 (23.1 to 35.3)
Muscle pain	37.1 (33.4 to 41.0)	45.8 (38.9 to 52.9)	48.1 (41.1 to 55.3)	17.8 (13.2 to 23.6)
Joint pain	11.5 (9.2 to 14.3)	15.3 (10.8 to 21.1)	9.6 (6.2 to 14.7)	8.2 (5.2 to 12.7)
Nausea	9.6 (7.5 to 12.2)	8.4 (5.2 to 13.2)	11.2 (7.5 to 16.6)	9.6 (6.3 to 14.4)
Vomiting	2.2 (1.3 to 3.7)	3.2 (1.5 to 6.7)	3.2 (1.5 to 6.8)	1.0 (0.3 to 3.4)

Fatigue	30.4 (26.9 to 34.1)	33.2 (26.9 to 40.1)	29.9 (23.8 to 36.9)	28.4 (22.7 to 34.8)
Fever	1.9 (1.1 to 3.3)	3.2 (1.5 to 6.7)	1.6 (0.5 to 4.6)	1.0 (0.3 to 3.4)

End point values	Received any VLA15			
Subject group type	Subject analysis set			
Number of subjects analysed	417			
Units: Percentage of participants				
number (confidence interval 95%)				
Pain	77.0 (72.7 to 80.8)			
Tenderness	90.6 (87.5 to 93.1)			
Erythema/Redness MGS	21.8 (18.1 to 26.0)			
Swelling MGS	18.0 (14.6 to 22.0)			
Induration/Hardening MGS	16.5 (13.3 to 20.4)			
Headache	37.4 (32.9 to 42.1)			
Muscle pain	46.8 (42.0 to 51.6)			
Joint pain	13.2 (10.3 to 16.8)			
Nausea	9.6 (7.1 to 12.8)			
Vomiting	2.9 (1.7 to 5.0)			
Fatigue	31.4 (27.1 to 36.0)			
Fever	2.4 (1.3 to 4.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Geometric Mean Titers (GMTs) for Immunoglobulin G (IgG) Against Each Outer Surface Protein A (OspA) Serotype (ST1 to ST6) at Day 208 During the Main Study Phase

End point title	Geometric Mean Titers (GMTs) for Immunoglobulin G (IgG) Against Each Outer Surface Protein A (OspA) Serotype (ST1 to ST6) at Day 208 During the Main Study Phase[5]

End point description:

GMTs for IgG against each OspA serotype ST1 to ST6, determined by an IgG binding assay at Day 208 was presented in this outcome measure. Per-Protocol Analysis Set (PPAS) consisted of the Full Analysis Set (FAS, included all participants enrolled who received at least one vaccination) population excluding those participants with at least one relevant protocol deviation (i.e., a protocol deviation with possible impact on immunogenicity). All participants reported under 'Subjects Analyzed' contributed data to the table but may not have evaluable data for every row. Here, "n" signifies participants with available results for each serotype.

End point type	Primary

End point timeframe:

At Day 208 (Month 7)

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: Only descriptive data was planned for this endpoint

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	176	162	175	
Units: Titers				
geometric mean (confidence interval 95%)				
ST1 (n=171, 158, 165)	331.4 (273.5 to 401.5)	197.3 (156.2 to 249.3)	23.8 (21.6 to 26.2)	
ST2 (n=171, 158, 165)	653.9 (557.9 to 766.3)	460.3 (370.6 to 571.8)	21.9 (20.2 to 23.7)	
ST3 (n=171, 158, 165)	583.2 (494.4 to 688.0)	436.2 (344.8 to 551.8)	21.9 (20.2 to 23.9)	
ST4 (n=171, 158, 165)	420.6 (353.2 to 500.9)	245.8 (196.1 to 308.2)	23.5 (21.3 to 25.9)	
ST5 (n=171, 158, 165)	442.3 (374.2 to 522.7)	239.4 (190.5 to 301.0)	22.4 (20.6 to 24.4)	
ST6 (n=171, 158, 165)	428.5 (358.8 to 511.8)	222.0 (177.4 to 277.8)	24.3 (22.2 to 26.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Solicited Local and Solicited Systemic AEs Within 7 Days After 1st Booster Dose

End point title	Percentage of Participants With Solicited Local and Solicited Systemic AEs Within 7 Days After 1st Booster Dose

End point description:

Participants or their legal guardians were required to record any solicited local and systemic AEs in the electronic diary. Solicited symptoms were pre-defined symptoms which were collected via an electronic diary. Solicited local AEs included pain, tenderness, erythema/redness MGS, swelling MGS and induration/hardening MGS. Solicited systemic AEs included headache, muscle pain, joint pain, nausea, vomiting, fatigue and fever. Two-sided 95% confidence intervals were calculated according to Altman method. SAS included all participants who entered into the study and received at least one vaccination. All participants reported under 'Subjects Analyzed' contributed data to the table but may not have evaluable data for every row. Here, "n" signifies number of participants evaluable for the specified rows.

End point type	Secondary

End point timeframe:

Within 7 Days after 1st booster dose at Month 18

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	Received any VLA15
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	127	112	206	419
Units: Percentage of participants				
number (confidence interval 95%)				
Pain (n=121, 108, 133, 291, 424)	53.7 (44.9 to 62.4)	51.9 (42.5 to 61.0)	6.0 (3.1 to 11.4)	53.6 (47.9 to 59.3)
Tenderness (n=122, 110, 134, 296, 430)	74.6 (66.2 to 81.5)	76.4 (67.6 to 83.3)	14.9 (9.9 to 21.9)	75.7 (70.5 to 80.2)
Erythema/Redness MGS (n=119, 109, 135, 290, 425)	7.6 (4.0 to 13.8)	5.5 (2.5 to 11.5)	2.2 (0.8 to 6.3)	7.9 (5.3 to 11.6)
Swelling MGS (n=119, 108, 135, 289, 424)	8.4 (4.6 to 14.8)	6.5 (3.2 to 12.8)	1.5 (0.4 to 5.2)	8.7 (5.9 to 12.5)
Induration/Hardening MGS (n=121,108,135,291,426)	5.0 (2.3 to 10.4)	4.6 (2.0 to 10.4)	1.5 (0.4 to 5.2)	6.2 (3.9 to 9.6)
Headache (n=117, 109, 136, 288, 424)	18.8 (12.8 to 26.8)	11.9 (7.1 to 19.3)	13.2 (8.5 to 20.0)	15.3 (11.6 to 19.9)
Muscle pain (n=119, 108, 135, 291, 426)	21.8 (15.4 to 30.1)	33.3 (25.2 to 42.7)	8.9 (5.2 to 14.9)	28.9 (24.0 to 34.3)
Joint pain (n=118, 107, 135, 287, 422)	5.9 (2.9 to 11.7)	0.9 (0.2 to 5.1)	1.5 (0.4 to 5.2)	3.1 (1.7 to 5.9)
Nausea (n=118, 107, 135, 287, 422)	5.1 (2.4 to 10.7)	2.8 (1.0 to 7.9)	1.5 (0.4 to 5.2)	5.6 (3.5 to 8.9)
Vomiting (n=118, 107, 135, 287, 422)	0.8 (0.1 to 4.6)	0.9 (0.2 to 5.1)	0.0 (0.0 to 2.8)	1.0 (0.4 to 3.0)
Fatigue (n=118, 108, 135, 288, 423)	13.6 (8.5 to 20.9)	13.9 (8.6 to 21.7)	7.4 (4.1 to 13.1)	14.6 (11.0 to 19.1)
Fever (n=110, 105, 132, 272, 404)	0.9 (0.2 to 5.0)	0.0 (0.0 to 3.5)	0.8 (0.1 to 4.2)	0.4 (0.1 to 2.1)

End point values	All Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	625			
Units: Percentage of participants				
number (confidence interval 95%)				
Pain (n=121, 108, 133, 291, 424)	38.7 (34.2 to 43.4)			
Tenderness (n=122, 110, 134, 296, 430)	56.7 (52.0 to 61.3)			
Erythema/Redness MGS (n=119, 109, 135, 290, 425)	6.1 (4.2 to 8.8)			
Swelling MGS (n=119, 108, 135, 289, 424)	6.4 (4.4 to 9.1)			
Induration/Hardening MGS (n=121,108,135,291,426)	4.7 (3.1 to 7.1)			
Headache (n=117, 109, 136, 288, 424)	14.6 (11.6 to 18.3)			
Muscle pain (n=119, 108, 135, 291, 426)	22.5 (18.8 to 26.7)			
Joint pain (n=118, 107, 135, 287, 422)	2.6 (1.5 to 4.6)			
Nausea (n=118, 107, 135, 287, 422)	4.3 (2.7 to 6.6)			
Vomiting (n=118, 107, 135, 287, 422)	0.7 (0.2 to 2.1)			
Fatigue (n=118, 108, 135, 288, 423)	12.3 (9.5 to 15.8)			
Fever (n=110, 105, 132, 272, 404)	0.5 (0.1 to 1.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Serious Adverse Events (SAEs)

End point title	Percentage of Participants With Serious Adverse Events (SAEs)

End point description:

A SAE was any untoward medical occurrence that at any dose: resulted in death; required inpatient hospitalisation or prolongation of existing hospitalisation; was life-threatening; resulted in persistent or significant disability/incapacity; was a congenital anomaly/birth defect; was another medically important condition. SAS included all participants who entered into the study and received at least one vaccination.

End point type	Secondary

End point timeframe:

From Day 1 of vaccination up to Month 48

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	Received any VLA15
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	127	112	206	419
Units: Percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 2.9)	3.6 (1.4 to 8.8)	6.8 (4.1 to 11.1)	3.3 (2.0 to 5.5)

End point values	All Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	625			
Units: Percentage of participants				
number (confidence interval 95%)	4.5 (3.1 to 6.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Adverse Events of Special Interest (AESIs)

End point title	Percentage of Participants With Adverse Events of Special Interest (AESIs)

End point description:

An AESI (serious or non-serious) was one of scientific and medical concern specific to the sponsor's product or program, for which ongoing monitoring and rapid communication by the investigator to the sponsor were appropriate. SAS included all participants who entered into the study and received at least one vaccination.

End point type	Secondary

End point timeframe:

From Day 1 of vaccination up to Month 48

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	Received any VLA15
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	127	112	206	419
Units: Percentage of participants				
number (confidence interval 95%)	0.8 (0.1 to 4.3)	2.7 (0.9 to 7.6)	0.5 (0.1 to 2.7)	3.3 (2.0 to 5.5)

End point values	All Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	625			
Units: Percentage of participants				
number (confidence interval 95%)	2.4 (1.5 to 3.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Unsolicited AE

End point title	Percentage of Participants With Unsolicited AE

End point description:

An AE was any untoward medical occurrence in a participant administered an investigational product, whether or not related to this treatment. Unsolicited AEs were defined as any solicited local or systemic AE if it had an onset date more than 6 days after vaccination or any other symptom or untoward medical event. SAS included all participants who entered into the study and received at least one vaccination.

End point type	Secondary

End point timeframe:

Up to 28 Days after vaccination

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	Received any VLA15
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	127	112	206	419
Units: Percentage of participants				
number (confidence interval 95%)	29.1 (21.9 to 37.6)	36.6 (28.3 to 45.8)	35.0 (28.8 to 41.7)	30.8 (26.6 to 35.4)

End point values	All Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	625			
Units: Percentage of participants				
number (confidence interval 95%)	32.2 (28.6 to 35.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With SAEs, AESIs, Solicited and Unsolicited AEs Stratified by Age Group

End point title	Percentage of Participants With SAEs, AESIs, Solicited and Unsolicited AEs Stratified by Age Group

End point description:

Percentage of participants with SAEs, AESIs, solicited & unsolicited AEs stratified by age group 5-11, 12-17 & 18-65 years (yrs) were reported. SAE: any untoward medical occurrence that at any dose: resulted in death; required inpatient hospitalisation or prolongation of existing hospitalisation; was life-threatening; resulted in persistent or significant disability/incapacity; was a congenital anomaly/birth defect; was another medically important condition. AESI: scientific & medical concern specific to the sponsor's product or program. Solicited AE: predefined reactions at injection site or systemic reactions after each vaccination. Unsolicited AEs: any solicited local or systemic AE if it had an onset date more than 6 days after vaccination or any other symptom or untoward medical event. Safety set was analysed. Here, "n" signifies participants evaluable for specified rows.

End point type	Secondary

End point timeframe:

SAEs and AESIs From Day 1 of vaccination up to Month 48; Solicited AEs: Within 7 Days after each booster vaccination; Unsolicited AEs: up to 28 Days after vaccination

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	Received any VLA15
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	127	112	206	419
Units: Percentage of participants				
number (confidence interval 95%)				
18-65 yrs, SAEs (n=67, 63, 105, 215, 320)	0.0 (0.0 to 5.4)	4.8 (1.6 to 13.1)	8.6 (4.6 to 15.5)	3.7 (1.9 to 7.2)

18-65 yrs, AESIs (n=67, 63, 105, 215, 320)	1.5 (0.3 to 8.0)	1.6 (0.3 to 8.5)	0.0 (0.0 to 3.5)	4.2 (2.2 to 7.8)
18-65 yrs, Solicited AEs (n=67,63,105,215,320)	98.5 (92.0 to 99.7)	100 (94.3 to 100)	68.6 (59.2 to 76.7)	96.7 (93.4 to 98.4)
18-65 yrs, Unsolicited AEs (n=67,63,105,215,320)	32.8 (22.8 to 44.7)	44.4 (32.8 to 56.7)	40.0 (31.1 to 49.6)	39.1 (32.8 to 45.7)
12-17 yrs, SAEs (n=28, 24, 50, 100, 150)	0.0 (0.0 to 12.1)	0.0 (0.0 to 13.8)	6.0 (2.1 to 16.2)	3.0 (1.0 to 8.5)
12-17 yrs, AESIs (n=28, 24, 50, 100, 150)	0.0 (0.0 to 12.1)	0.0 (0.0 to 13.8)	2.0 (0.4 to 10.5)	2.0 (0.6 to 7.0)
12-17 yrs, Solicited AEs (n=28, 24, 50, 100, 150)	96.4 (82.3 to 99.4)	100 (86.2 to 100)	64.0 (50.1 to 75.9)	97.0 (91.5 to 99.0)
12-17 yrs, Unsolicited AEs (n=28,24,50,100,150)	35.7 (20.7 to 54.2)	20.8 (9.2 to 40.5)	30.0 (19.1 to 43.8)	25.0 (17.5 to 34.3)
5-11 yrs, SAEs (n=32, 25, 51, 104, 155)	0.0 (0.0 to 10.7)	4.0 (0.7 to 19.5)	3.9 (1.1 to 13.2)	2.9 (1.0 to 8.1)
5-11 yrs, AESIs (n=32, 25, 51, 104, 155)	0.0 (0.0 to 10.7)	8.0 (2.2 to 25.0)	0.0 (0.0 to 7.0)	2.9 (1.0 to 8.1)
5-11 yrs, Solicited AEs (n=32, 25, 51, 104, 155)	93.8 (79.9 to 98.3)	96.0 (80.5 to 99.3)	76.5 (63.2 to 86.0)	94.2 (88.0 to 97.3)
5-11 yrs, Unsolicited AEs (n=32,25,51,104,155)	15.6 (6.9 to 31.8)	32.0 (17.2 to 51.6)	29.4 (18.7 to 43.0)	19.2 (12.8 to 27.8)

End point values	All Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	625			
Units: Percentage of participants				
number (confidence interval 95%)				
18-65 yrs, SAEs (n=67, 63, 105, 215, 320)	5.3 (3.3 to 8.3)			
18-65 yrs, AESIs (n=67, 63, 105, 215, 320)	2.8 (1.5 to 5.3)			
18-65 yrs, Solicited AEs (n=67,63,105,215,320)	87.5 (83.4 to 90.7)			
18-65 yrs, Unsolicited AEs (n=67,63,105,215,320)	39.4 (34.2 to 44.8)			
12-17 yrs, SAEs (n=28, 24, 50, 100, 150)	4.0 (1.8 to 8.5)			
12-17 yrs, AESIs (n=28, 24, 50, 100, 150)	2.0 (0.7 to 5.7)			
12-17 yrs, Solicited AEs (n=28, 24, 50, 100, 150)	86.0 (79.5 to 90.7)			
12-17 yrs, Unsolicited AEs (n=28,24,50,100,150)	26.7 (20.2 to 34.3)			
5-11 yrs, SAEs (n=32, 25, 51, 104, 155)	3.2 (1.4 to 7.3)			
5-11 yrs, AESIs (n=32, 25, 51, 104, 155)	1.9 (0.7 to 5.5)			
5-11 yrs, Solicited AEs (n=32, 25, 51, 104, 155)	88.4 (82.4 to 92.5)			
5-11 yrs, Unsolicited AEs (n=32,25,51,104,155)	22.6 (16.7 to 29.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: GMTs for IgG Against Each OspA Serotype (ST1 to ST6) at Baseline, Days 85, 180, 365 and Month 18 During the Main Study Phase

End point title	GMTs for IgG Against Each OspA Serotype (ST1 to ST6) at Baseline, Days 85, 180, 365 and Month 18 During the Main Study Phase

End point description:

GMTs for IgG against each OspA serotype ST1 to ST6, determined by an IgG binding assay were evaluated. PPAS consisted of the FAS population excluding those participants with at least one relevant protocol deviation (i.e., a protocol deviation with possible impact on immunogenicity). All participants reported under 'Subjects Analyzed' contributed data to the table but may not have evaluable data for every row. Here, "n" signifies participants with available results for each serotype at specified time points.

End point type	Secondary

End point timeframe:

At Baseline, Days 85, 180, 365 and Month 18

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	176	162	175	
Units: Titers				
geometric mean (confidence interval 95%)				
ST1: Baseline (n=175, 162, 175)	21.2 (20.3 to 22.1)	20.3 (19.9 to 20.7)	21.9 (20.7 to 23.2)	
ST1: Day 85 (n=169, 155, 170)	116.5 (96.4 to 140.8)	20.8 (20.1 to 21.5)	21.8 (20.5 to 23.3)	
ST1: Day 180 (n=172, 161, 172)	38.2 (33.6 to 43.4)	21.4 (20.5 to 22.3)	22.0 (20.8 to 23.2)	
ST1: Day 365 (n=163, 156, 158)	40.8 (35.3 to 47.1)	30.2 (27.1 to 33.6)	21.3 (20.3 to 22.4)	
ST1: Month 18 (n=158, 144, 156)	27.3 (24.2 to 30.7)	22.7 (21.3 to 24.2)	21.2 (20.2 to 22.3)	
ST2: Baseline (n=175, 162, 175)	20.8 (20.0 to 21.6)	20.0 (20.0 to 20.0)	21.3 (20.4 to 22.3)	
ST2: Day 85 (n=169, 155, 170)	262.8 (217.6 to 317.3)	21.8 (20.6 to 23.1)	21.0 (19.9 to 22.1)	
ST2: Day 180 (n=172, 161, 172)	70.4 (60.4 to 82.1)	21.9 (20.8 to 23.1)	21.1 (20.3 to 22.1)	
ST2: Day 365 (n=163, 156, 158)	67.8 (58.2 to 78.9)	54.1 (46.8 to 62.7)	20.9 (20.1 to 21.7)	
ST2: Month 18 (n=157, 144, 156)	35.4 (31.1 to 40.2)	30.3 (27.2 to 33.8)	20.3 (19.9 to 20.9)	
ST3: Baseline (n=175, 162, 175)	20.6 (20.0 to 21.3)	20.3 (19.9 to 20.7)	20.9 (20.2 to 21.7)	
ST3: Day 85 (n=169, 155, 170)	249.8 (205.1 to 304.2)	22.7 (21.5 to 24.1)	20.9 (19.8 to 22.2)	
ST3: Day 180 (n=172, 161, 172)	65.4 (55.8 to 76.6)	22.3 (21.2 to 23.6)	21.1 (20.4 to 21.8)	
ST3: Day 365 (n=163, 156, 158)	63.1 (53.8 to 74.0)	58.1 (49.8 to 67.8)	20.6 (20.0 to 21.1)	

ST3: Month 18 (n=158, 144, 156)	34.3 (29.8 to 39.4)	33.8 (30.1 to 37.9)	20.1 (19.9 to 20.3)	
ST4: Baseline (n=175, 162, 175)	20.8 (20.0 to 21.6)	20.4 (20.0 to 20.9)	21.7 (20.6 to 22.8)	
ST4: Day 85 (n=169, 155, 170)	147.4 (122.6 to 177.3)	21.7 (20.7 to 22.7)	21.6 (20.3 to 23.0)	
ST4: Day 180 (n=172, 161, 172)	47.5 (41.7 to 54.1)	22.1 (21.1 to 23.2)	22.4 (21.1 to 23.7)	
ST4: Day 365 (n=163, 156, 158)	52.6 (45.5 to 60.8)	37.2 (33.1 to 41.9)	20.9 (20.0 to 21.8)	
ST4: Month 18 (n=158, 144, 156)	32.3 (28.5 to 36.7)	25.8 (23.7 to 28.1)	21.0 (20.1 to 22.0)	
ST5: Baseline (n=175, 162, 175)	20.6 (19.8 to 21.4)	20.2 (19.9 to 20.6)	20.7 (20.1 to 21.4)	
ST5: Day 85 (n=169, 155, 170)	164.2 (135.7 to 198.8)	21.2 (20.3 to 22.0)	20.9 (19.9 to 22.1)	
ST5: Day 180 (n=172, 161, 172)	52.3 (45.5 to 60.1)	21.7 (20.7 to 22.7)	20.8 (20.2 to 21.5)	
ST5: Day 365 (n=163, 156, 158)	54.6 (47.0 to 63.5)	38.4 (33.9 to 43.5)	20.4 (19.9 to 20.9)	
ST5: Month 18 (n=157, 144, 156)	29.3 (25.9 to 33.1)	24.9 (23.0 to 27.0)	20.2 (19.9 to 20.5)	
ST6: Baseline (n=176, 162, 175)	22.5 (20.9 to 24.2)	21.3 (20.4 to 22.2)	22.1 (21.0 to 23.2)	
ST6: Day 85 (n=169, 155, 170)	143.7 (119.2 to 173.1)	22.5 (21.2 to 23.9)	22.3 (20.9 to 23.9)	
ST6: Day 180 (n=172, 161, 172)	49.3 (42.8 to 56.8)	23.2 (21.9 to 24.7)	22.5 (21.4 to 23.7)	
ST6: Day 365 (n=163, 156, 158)	57.2 (49.2 to 66.6)	38.1 (33.8 to 42.9)	21.9 (20.9 to 23.1)	
ST6: Month 18 (n=158, 144, 156)	32.2 (28.1 to 36.9)	25.7 (23.5 to 28.0)	21.2 (20.4 to 22.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Seroconversion at Days 85, 180, 208, 365 and Month 18 After Vaccination During the Main Study Phase

End point title	Percentage of Participants With Seroconversion at Days 85, 180, 208, 365 and Month 18 After Vaccination During the Main Study Phase

End point description:

Seroconversion Rate (SCR) for each OspA serotype specific IgG ST1 to ST6, determined by enzyme linked immunosorbent assay (ELISA) were evaluated. Seroconversion for ELISA: 1) For participants who were seronegative at screening: percentage of participants with a change from seronegative at screening to seropositive (i.e. antibody titer of >=40 Units per milliliter [U/mL]) at a certain time point. 2) For participants who were seropositive at screening: percentage of participants with a >= 4-fold rise in OspA IgG antibody titer from screening. PPAS consisted of the FAS population excluding those participants with at least one relevant protocol deviation (i.e., a protocol deviation with possible impact on immunogenicity). All participants reported under 'Subjects Analyzed' contributed data to the table but may not have evaluable data for every row. Here, "n" signifies participants with available results for each serotype at specified time points.

End point type	Secondary

End point timeframe:

At Days 85, 180, 208, 365 and Month 18

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	176	162	175	
Units: Percentage of participants				
number (confidence interval 95%)				
ST1: Day 85 (n=168, 155, 170)	75.0 (67.9 to 80.9)	2.6 (1.0 to 6.4)	1.8 (0.6 to 5.1)	
ST1: Day 180 (n=171, 161, 172)	40.4 (33.3 to 47.8)	5.0 (2.5 to 9.5)	2.9 (1.2 to 6.6)	
ST1: Day 208 (n=170, 158, 165)	92.9 (88.1 to 95.9)	83.5 (77.0 to 88.5)	6.7 (3.8 to 11.5)	
ST1: Day 365 (n=162, 156, 158)	43.2 (35.8 to 50.9)	28.8 (22.3 to 36.4)	0.6 (0.1 to 3.5)	
ST1: Month 18 (n=157, 144, 156)	16.6 (11.6 to 23.2)	9.7 (5.9 to 15.7)	0.0 (0.0 to 2.4)	
ST2: Day 85 (n=168, 155, 170)	89.9 (84.4 to 93.6)	6.5 (3.5 to 11.5)	0.6 (0.1 to 3.3)	
ST2: Day 180 (n=171, 161, 172)	66.7 (59.3 to 73.3)	7.5 (4.3 to 12.6)	1.2 (0.3 to 4.1)	
ST2: Day 208 (n=170, 158, 165)	97.6 (94.1 to 99.1)	94.3 (89.5 to 97.0)	2.4 (0.9 to 6.1)	
ST2: Day 365 (n=162, 156, 158)	64.8 (57.2 to 71.7)	59.0 (51.1 to 66.4)	1.3 (0.3 to 4.5)	
ST2: Month 18 (n=157, 144, 156)	36.3 (29.2 to 44.1)	31.3 (24.2 to 39.2)	0.0 (0.0 to 2.4)	
ST3: Day 85 (n=168, 155, 170)	90.5 (85.1 to 94.1)	11.0 (7.0 to 16.9)	0.6 (0.1 to 3.3)	
ST3: Day 180 (n=171, 161, 172)	63.7 (56.3 to 70.6)	8.7 (5.3 to 14.1)	4.1 (2.0 to 8.2)	
ST3: Day 208 (n=170, 158, 165)	98.8 (95.8 to 99.7)	91.8 (86.4 to 95.1)	4.2 (2.1 to 8.5)	
ST3: Day 365 (n=162, 156, 158)	63.0 (55.3 to 70.0)	61.5 (53.7 to 68.8)	0.6 (0.1 to 3.5)	
ST3: Month 18 (n=157, 144, 156)	31.2 (24.5 to 38.8)	40.3 (32.6 to 48.4)	0.6 (0.1 to 3.5)	
ST4: Day 85 (n=168, 155, 170)	83.9 (77.6 to 88.7)	5.2 (2.6 to 9.9)	2.4 (0.9 to 5.9)	
ST4: Day 180 (n=171, 161, 172)	55.0 (47.5 to 62.2)	8.1 (4.8 to 13.3)	6.4 (3.6 to 11.1)	
ST4: Day 208 (n=170, 158, 165)	95.9 (91.7 to 98.0)	88.6 (82.7 to 92.7)	6.7 (3.8 to 11.5)	
ST4: Day 365 (n=162, 156, 158)	57.4 (49.7 to 64.8)	42.9 (35.4 to 50.8)	1.3 (0.3 to 4.5)	
ST4: Month 18 (n=157, 144, 156)	31.2 (24.5 to 38.8)	19.4 (13.8 to 26.7)	1.3 (0.4 to 4.6)	
ST5: Day 85 (n=168, 155, 170)	82.7 (76.3 to 87.7)	4.5 (2.2 to 9.0)	2.4 (0.9 to 5.9)	
ST5: Day 180 (n=171, 161, 172)	57.9 (50.4 to 65.0)	5.6 (3.0 to 10.3)	4.1 (2.0 to 8.2)	
ST5: Day 208 (n=170, 158, 165)	97.1 (93.3 to 98.7)	86.7 (80.5 to 91.1)	6.7 (3.8 to 11.5)	
ST5: Day 365 (n=162, 156, 158)	57.4 (49.7 to 64.8)	43.6 (36.1 to 51.4)	1.3 (0.3 to 4.5)	
ST5: Month 18 (n=157, 144, 156)	23.6 (17.6 to 30.8)	17.4 (12.0 to 24.4)	1.3 (0.4 to 4.6)	

ST6: Day 85 (n=169, 155, 170)	79.9 (73.2 to 85.2)	4.5 (2.2 to 9.0)	2.4 (0.9 to 5.9)	
ST6: Day 180 (n=172, 161, 172)	50.0 (42.6 to 57.4)	8.7 (5.3 to 14.1)	5.2 (2.8 to 9.6)	
ST6: Day 208 (n=171, 158, 165)	95.3 (91.0 to 97.6)	85.4 (79.1 to 90.1)	8.5 (5.1 to 13.7)	
ST6: Day 365 (n=163, 156, 158)	57.1 (49.4 to 64.4)	41.7 (34.2 to 49.5)	3.2 (1.4 to 7.2)	
ST6: Month 18 (n=158, 144, 156)	22.2 (16.4 to 29.2)	16.7 (11.5 to 23.6)	2.6 (1.0 to 6.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean of the Fold Rise (GMFR) for IgG When Compared to Baseline Against Each OspA Serotype (ST1 to ST6) at Days 85 and 208 During the Main Study Phase

End point title	Geometric Mean of the Fold Rise (GMFR) for IgG When Compared to Baseline Against Each OspA Serotype (ST1 to ST6) at Days 85 and 208 During the Main Study Phase

End point description:

GMFR for IgG when compared to baseline against each OspA serotype ST1 to ST6, determined by IgG binding assay at Day 85 and Day 208 were evaluated. PPAS consisted of the FAS population excluding those participants with at least one relevant protocol deviation (i.e., a protocol deviation with possible impact on immunogenicity). All participants reported under 'Subjects Analyzed' contributed data to the table but may not have evaluable data for every row. Here, "n" signifies participants with available results for each serotype at specified time points.

End point type	Secondary

End point timeframe:

At Days 85 and 208

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	176	162	175	
Units: Fold rise				
geometric mean (confidence interval 95%)				
ST1: Day 85 (n=168, 155, 170)	5.5 (4.5 to 6.6)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	
ST1: Day 208 (n=170, 158, 165)	15.5 (12.8 to 18.8)	9.7 (7.7 to 12.3)	1.1 (1.0 to 1.2)	
ST2: Day 85 (n=168, 155, 170)	12.5 (10.4 to 15.2)	1.1 (1.0 to 1.2)	1.0 (1.0 to 1.0)	
ST2: Day 208 (n=170, 158, 165)	31.4 (26.6 to 36.9)	23.0 (18.5 to 28.6)	1.0 (1.0 to 1.1)	
ST3: Day 85 (n=168, 155, 170)	12.0 (9.8 to 14.6)	1.1 (1.1 to 1.2)	1.0 (1.0 to 1.0)	
ST3: Day 208 (n=170, 158, 165)	28.1 (23.8 to 33.2)	21.7 (17.1 to 27.4)	1.0 (1.0 to 1.1)	
ST4: Day 85 (n=168, 155, 170)	7.0 (5.8 to 8.4)	1.1 (1.0 to 1.1)	1.0 (1.0 to 1.0)	

ST4: Day 208 (n=170, 158, 165)	20.0 (16.8 to 23.9)	12.0 (9.6 to 15.0)	1.1 (1.0 to 1.2)	
ST5: Day 85 (n=168, 155, 170)	7.9 (6.5 to 9.6)	1.0 (1.0 to 1.1)	1.0 (1.0 to 1.1)	
ST5: Day 208 (n=170, 158, 165)	21.3 (17.9 to 25.2)	11.8 (9.4 to 14.8)	1.1 (1.0 to 1.2)	
ST6: Day 85 (n=169, 155, 170)	6.4 (5.3 to 7.7)	1.1 (1.0 to 1.1)	1.0 (1.0 to 1.1)	
ST6: Day 208 (n=171, 158, 165)	19.0 (15.9 to 22.8)	10.4 (8.3 to 13.0)	1.1 (1.0 to 1.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: GMTs for IgG Against Each OspA Serotype (ST1 to ST6) Stratified by Age Group at Baseline, Days 85, 180, 194, 365 and Month 18 During the Main Study Phase

End point title	GMTs for IgG Against Each OspA Serotype (ST1 to ST6) Stratified by Age Group at Baseline, Days 85, 180, 194, 365 and Month 18 During the Main Study Phase

End point description:

GMTs for IgG against each OspA serotype ST1 to ST6, determined by an IgG binding assay stratified by age group (5-11, 12-17 & 18-65 yrs) were evaluated. PPAS consisted of the FAS population excluding those participants with at least one relevant protocol deviation (i.e., a protocol deviation with possible impact on immunogenicity). All participants reported under 'Subjects Analyzed' contributed data to the table but may not have evaluable data for every row. Here, "n" signifies participants with available results for each serotype at specified time points.

End point type	Secondary

End point timeframe:

At Baseline, Days 85, 180, 194 (18 to 65 years only), 365 and Month 18

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	176	162	175	
Units: Titers				
geometric mean (confidence interval 95%)				
18-65 yrs, ST1: Baseline (n=96, 84, 93)	21.4 (20.0 to 23.0)	20.0 (20.0 to 20.0)	21.9 (20.1 to 23.8)	
18-65 yrs, ST1: Day 85 (n=93, 81, 93)	66.4 (51.8 to 85.1)	20.3 (19.7 to 20.8)	21.9 (20.2 to 23.7)	
18-65 yrs, ST1: Day 180 (n=95, 83, 92)	29.4 (25.0 to 34.6)	20.4 (19.8 to 21.1)	22.3 (20.5 to 24.2)	
18-65 yrs, ST1: Day 194 (n=51, 44, 44)	360.8 (238.2 to 546.6)	91.6 (60.0 to 139.6)	20.8 (19.7 to 22.0)	
18-65 yrs, ST1: Day 365 (n=92, 81, 87)	33.4 (27.8 to 40.0)	23.1 (21.0 to 25.4)	21.8 (20.1 to 23.6)	
18-65 yrs, ST1: Month 18 (n=86, 73, 85)	24.6 (21.2 to 28.4)	21.6 (20.2 to 23.2)	21.6 (19.9 to 23.4)	
18-65 yrs, ST2: Baseline (n=96, 84, 93)	21.2 (19.8 to 22.7)	20.0 (20.0 to 20.0)	21.3 (20.0 to 22.7)	

18-65 yrs, ST2: Day 85 (n=93, 81, 93)	152.4 (120.0 to 193.6)	20.4 (19.8 to 21.0)	21.0 (19.9 to 22.1)	
18-65 yrs, ST2: Day 180 (n=95, 83, 92)	44.5 (37.3 to 53.1)	21.0 (19.8 to 22.1)	21.3 (20.0 to 22.6)	
18-65 yrs, ST2: Day 194 (n=51, 44, 44)	691.5 (519.0 to 921.3)	216.7 (143.9 to 326.2)	21.0 (19.5 to 22.7)	
18-65 yrs, ST2: Day 365 (n=92, 81, 87)	50.9 (42.3 to 61.4)	35.9 (30.6 to 42.3)	21.3 (20.0 to 22.8)	
18-65 yrs, ST2: Month 18 (n=86, 73, 85)	29.5 (25.6 to 34.0)	23.5 (21.4 to 25.9)	20.6 (19.7 to 21.6)	
18-65 yrs, ST3: Baseline (n=96, 84, 93)	20.8 (19.7 to 22.0)	20.3 (19.7 to 20.9)	20.7 (19.9 to 21.5)	
18-65 yrs, ST3: Day 85 (n=93, 81, 93)	135.2 (106.4 to 171.9)	21.2 (20.1 to 22.3)	20.5 (19.8 to 21.3)	
18-65 yrs, ST3: Day 180 (n=95, 83, 92)	40.2 (33.8 to 47.9)	21.2 (20.0 to 22.6)	21.3 (20.3 to 22.4)	
18-65 yrs, ST3: Day 194 (n=51, 44, 44)	589.2 (428.7 to 809.9)	196.6 (129.9 to 297.6)	21.2 (19.8 to 22.8)	
18-65 yrs, ST3: Day 365 (n=92, 81, 87)	46.6 (38.6 to 56.3)	34.6 (29.4 to 40.6)	20.5 (19.8 to 21.3)	
18-65 yrs, ST3: Month 18 (n=86, 73, 85)	27.0 (23.5 to 31.1)	24.2 (22.0 to 26.6)	20.0 (20.0 to 20.0)	
18-65 yrs, ST4: Baseline (n=96, 84, 93)	21.3 (19.9 to 22.8)	20.0 (20.0 to 20.0)	21.6 (20.0 to 23.4)	
18-65 yrs, ST4: Day 85 (n=93, 81, 93)	81.8 (65.3 to 102.6)	20.5 (19.8 to 21.1)	21.5 (20.0 to 23.2)	
18-65 yrs, ST4: Day 180 (n=95, 83, 92)	32.5 (28.1 to 37.6)	21.4 (20.3 to 22.7)	22.9 (20.9 to 25.0)	
18-65 yrs, ST4: Day 194 (n=51, 44, 44)	434.4 (306.2 to 616.3)	112.4 (75.7 to 166.9)	22.5 (19.7 to 25.7)	
18-65 yrs, ST4: Day 365 (n=92, 81, 87)	39.9 (33.5 to 47.6)	25.9 (23.1 to 29.0)	21.4 (19.9 to 23.2)	
18-65 yrs, ST4: Month 18 (n=86, 73, 85)	26.8 (23.4 to 30.8)	22.3 (20.5 to 24.3)	21.5 (19.9 to 23.3)	
18-65 yrs, ST5: Baseline (n=96, 84, 93)	21.1 (19.7 to 22.6)	20.0 (20.0 to 20.0)	20.2 (19.8 to 20.6)	
18-65 yrs, ST5: Day 85 (n=93, 81, 93)	88.6 (70.4 to 111.4)	20.2 (19.8 to 20.6)	20.2 (19.8 to 20.7)	
18-65 yrs, ST5: Day 180 (n=95, 83, 92)	34.1 (29.5 to 39.5)	20.6 (19.8 to 21.5)	20.8 (20.0 to 21.7)	
18-65 yrs, ST5: Day 194 (n=51, 44, 44)	450.5 (328.9 to 617.2)	117.1 (78.1 to 175.7)	21.1 (19.9 to 22.4)	
18-65 yrs, ST5: Day 365 (n=92, 81, 87)	39.2 (32.9 to 46.7)	27.2 (24.0 to 30.7)	20.4 (19.8 to 21.1)	
18-65 yrs, ST5: Month 18 (n=86, 73, 85)	24.2 (21.4 to 27.4)	21.7 (20.3 to 23.1)	20.2 (19.8 to 20.5)	
18-65 yrs, ST6: Baseline (n=96, 84, 93)	21.7 (20.0 to 23.6)	20.5 (19.8 to 21.1)	21.0 (20.0 to 21.9)	
18-65 yrs, ST6: Day 85 (n=93, 81, 93)	79.3 (63.5 to 98.9)	20.8 (19.9 to 21.9)	21.4 (20.3 to 22.6)	
18-65 yrs, ST6: Day 180 (n=95, 83, 92)	33.4 (28.7 to 38.9)	21.1 (20.0 to 22.3)	21.8 (20.5 to 23.1)	
18-65 yrs, ST6: Day 194 (n=51, 44, 44)	405.5 (289.5 to 568.1)	104.8 (70.1 to 156.5)	21.7 (20.0 to 23.5)	
18-65 yrs, ST6: Day 365 (n=92, 81, 87)	41.4 (34.5 to 49.7)	26.2 (23.4 to 29.2)	22.0 (20.5 to 23.6)	
18-65 yrs, ST6: Month 18 (n=86, 73, 85)	26.5 (23.0 to 30.6)	21.8 (20.3 to 23.3)	21.1 (20.0 to 22.3)	
12-17 yrs, ST1: Baseline (n=40, 40, 42)	20.0 (20.0 to 20.0)	20.0 (20.0 to 20.0)	21.0 (19.6 to 22.6)	
12-17 yrs, ST1: Day 85 (n=37, 40, 39)	198.4 (136.9 to 287.7)	20.8 (19.7 to 21.9)	20.6 (19.4 to 21.9)	

12-17 yrs, ST1: Day 180 (n=39, 40, 41)	48.3 (36.8 to 63.5)	22.6 (20.3 to 25.2)	21.9 (20.0 to 24.1)	
12-17 yrs, ST1: Day 365 (n=35, 38, 36)	43.9 (31.8 to 60.5)	36.5 (28.7 to 46.4)	20.6 (19.4 to 22.0)	
12-17 yrs, ST1: Month 18 (n=36, 37, 34)	31.0 (22.8 to 42.1)	24.6 (20.9 to 28.9)	20.6 (19.4 to 22.0)	
12-17 yrs, ST2: Baseline (n=40, 40, 42)	20.0 (20.0 to 20.0)	20.0 (20.0 to 20.0)	20.0 (20.0 to 20.0)	
12-17 yrs, ST2: Day 85 (n=37, 40, 39)	414.3 (284.2 to 604.1)	23.7 (19.9 to 28.2)	20.0 (20.0 to 20.0)	
12-17 yrs, ST2: Day 180 (n=39, 40, 41)	102.3 (74.0 to 141.4)	24.6 (21.0 to 28.9)	21.2 (19.5 to 22.9)	
12-17 yrs, ST2: Day 365 (n=35, 38, 36)	68.6 (47.9 to 98.2)	72.8 (53.6 to 98.8)	20.7 (19.3 to 22.2)	
12-17 yrs, ST2: Month 18 (n=36, 37, 34)	39.8 (28.2 to 56.2)	39.3 (30.4 to 50.9)	20.0 (20.0 to 20.0)	
12-17 yrs, ST3: Baseline (n=40, 40, 42)	20.0 (20.0 to 20.0)	20.5 (19.5 to 21.5)	20.4 (19.6 to 21.2)	
12-17 yrs, ST3: Day 85 (n=37, 40, 39)	426.3 (288.0 to 631.2)	24.8 (21.5 to 28.6)	20.0 (20.0 to 20.0)	
12-17 yrs, ST3: Day 180 (n=39, 40, 41)	104.5 (75.8 to 143.9)	25.1 (21.5 to 29.4)	21.5 (19.8 to 23.5)	
12-17 yrs, ST3: Day 365 (n=35, 38, 36)	73.2 (50.8 to 105.5)	86.1 (63.4 to 116.8)	20.7 (19.3 to 22.3)	
12-17 yrs, ST3: Month 18 (n=36, 37, 34)	41.5 (28.3 to 61.0)	44.8 (34.4 to 58.3)	20.0 (20.0 to 20.0)	
12-17 yrs, ST4: Baseline (n=40, 40, 42)	20.0 (20.0 to 20.0)	21.8 (20.0 to 23.7)	21.4 (19.8 to 23.1)	
12-17 yrs, ST4: Day 85 (n=37, 40, 39)	256.6 (181.0 to 363.7)	23.7 (20.7 to 27.0)	21.1 (19.5 to 22.8)	
12-17 yrs, ST4: Day 180 (n=39, 40, 41)	68.0 (52.3 to 88.5)	24.1 (21.3 to 27.2)	22.2 (20.0 to 24.7)	
12-17 yrs, ST4: Day 365 (n=35, 38, 36)	58.6 (42.6 to 80.7)	52.4 (40.0 to 68.6)	20.0 (20.0 to 20.0)	
12-17 yrs, ST4: Month 18 (n=36, 37, 34)	38.0 (27.7 to 52.2)	33.6 (26.8 to 42.0)	21.0 (19.6 to 22.5)	
12-17 yrs, ST5: Baseline (n=40, 40, 42)	20.0 (20.0 to 20.0)	21.0 (19.6 to 22.6)	21.0 (19.6 to 22.5)	
12-17 yrs, ST5: Day 85 (n=37, 40, 39)	237.7 (190.5 to 393.4)	22.8 (20.1 to 25.9)	21.0 (19.6 to 22.5)	
12-17 yrs, ST5: Day 180 (n=39, 40, 41)	71.7 (53.2 to 96.7)	24.2 (21.1 to 27.7)	20.6 (19.4 to 21.8)	
12-17 yrs, ST5: Day 365 (n=35, 38, 36)	60.0 (42.6 to 84.4)	56.4 (43.1 to 73.8)	20.0 (20.0 to 20.0)	
12-17 yrs, ST5: Month 18 (n=36, 37, 34)	35.8 (25.5 to 50.1)	29.5 (23.9 to 36.4)	20.6 (19.4 to 21.9)	
12-17 yrs, ST6: Baseline (n=40, 40, 42)	20.9 (19.6 to 22.4)	23.6 (20.4 to 27.2)	23.2 (20.4 to 26.4)	
12-17 yrs, ST6: Day 85 (n=37, 40, 39)	229.4 (157.8 to 333.4)	26.3 (21.6 to 31.8)	22.8 (20.1 to 26.0)	
12-17 yrs, ST6: Day 180 (n=39, 40, 41)	66.2 (49.0 to 89.4)	27.3 (23.0 to 32.5)	23.8 (20.9 to 27.0)	
12-17 yrs, ST6: Day 365 (n=35, 38, 36)	66.5 (47.4 to 93.2)	51.2 (39.4 to 66.5)	21.7 (19.7 to 23.8)	
12-17 yrs, ST6: Month 18 (n=36, 37, 34)	37.5 (26.8 to 52.3)	31.9 (25.2 to 40.5)	22.3 (20.1 to 24.9)	
5-11 yrs, ST1: Baseline (n=39, 38, 40)	21.8 (19.7 to 24.0)	21.3 (19.4 to 23.4)	22.9 (20.1 to 26.2)	
5-11 yrs, ST1: Day 85 (n=39, 34, 38)	269.5 (219.8 to 330.5)	22.2 (19.7 to 25.1)	23.0 (18.6 to 28.6)	
5-11 yrs, ST1: Day 180 (n=38, 38, 39)	57.6 (44.8 to 74.0)	22.3 (19.6 to 25.3)	21.4 (19.4 to 23.6)	

5-11 yrs, ST1: Day 365 (n=36, 37, 35)	63.4 (46.7 to 86.1)	44.3 (33.5 to 58.6)	20.8 (19.2 to 22.5)	
5-11 yrs, ST1: Month 18 (n=36, 34, 37)	30.8 (23.6 to 40.1)	23.2 (20.0 to 26.9)	20.8 (19.2 to 22.6)	
5-11 yrs, ST2: Baseline (n=39, 38, 40)	20.6 (19.4 to 22.0)	20.0 (20.0 to 20.0)	22.9 (20.0 to 26.3)	
5-11 yrs, ST2: Day 85 (n=39, 34, 38)	625.2 (482.4 to 810.3)	23.1 (20.0 to 26.6)	22.0 (18.1 to 26.7)	
5-11 yrs, ST2: Day 180 (n=38, 38, 39)	151.0 (117.2 to 194.5)	21.3 (19.5 to 23.3)	20.8 (19.2 to 22.7)	
5-11 yrs, ST2: Day 365 (n=36, 37, 35)	138.9 (107.7 to 179.2)	98.0 (73.2 to 131.2)	20.0 (20.0 to 20.0)	
5-11 yrs, ST2: Month 18 (n=35, 34, 37)	48.7 (36.4 to 65.1)	39.5 (30.5 to 51.0)	20.0 (20.0 to 20.0)	
5-11 yrs, ST3: Baseline (n=39, 38, 40)	20.8 (19.7 to 22.1)	20.0 (20.0 to 20.0)	22.2 (19.7 to 24.9)	
5-11 yrs, ST3: Day 85 (n=39, 34, 38)	649.6 (494.7 to 853.1)	24.4 (20.8 to 28.5)	23.0 (18.1 to 29.3)	
5-11 yrs, ST3: Day 180 (n=38, 38, 39)	135.9 (100.2 to 184.5)	22.0 (20.0 to 24.3)	20.0 (20.0 to 20.0)	
5-11 yrs, ST3: Day 365 (n=36, 37, 35)	118.6 (85.0 to 165.5)	120.6 (91.1 to 159.6)	20.4 (19.6 to 21.4)	
5-11 yrs, ST3: Month 18 (n=36, 34, 37)	50.0 (36.4 to 68.8)	50.9 (39.6 to 65.6)	20.5 (19.5 to 21.5)	
5-11 yrs, ST4: Baseline (n=39, 38, 40)	20.5 (19.5 to 21.6)	20.0 (20.0 to 20.0)	22.1 (19.7 to 24.9)	
5-11 yrs, ST4: Day 85 (n=39, 34, 38)	354.9 (275.2 to 457.7)	22.5 (20.0 to 25.2)	22.6 (18.4 to 27.8)	
5-11 yrs, ST4: Day 180 (n=38, 38, 39)	84.7 (65.3 to 109.8)	21.6 (19.8 to 23.6)	21.3 (19.5 to 23.3)	
5-11 yrs, ST4: Day 365 (n=36, 37, 35)	96.1 (71.8 to 128.4)	58.0 (46.0 to 73.1)	20.5 (19.5 to 21.4)	
5-11 yrs, ST4: Month 18 (n=36, 34, 37)	42.9 (31.3 to 58.8)	26.6 (22.5 to 31.3)	20.0 (20.0 to 20.0)	
5-11 yrs, ST5: Baseline (n=39, 38, 40)	20.0 (20.0 to 20.0)	20.0 (20.0 to 20.0)	21.9 (19.7 to 24.2)	
5-11 yrs, ST5: Day 85 (n=39, 34, 38)	441.2 (339.3 to 573.7)	21.6 (19.7 to 23.6)	22.8 (18.3 to 28.4)	
5-11 yrs, ST5: Day 180 (n=38, 38, 39)	109.9 (84.1 to 143.6)	21.5 (19.3 to 23.9)	21.2 (19.5 to 22.9)	
5-11 yrs, ST5: Day 365 (n=36, 37, 35)	116.6 (87.9 to 154.7)	55.1 (41.6 to 73.0)	20.8 (19.2 to 22.4)	
5-11 yrs, ST5: Month 18 (n=35, 34, 37)	38.1 (28.6 to 50.8)	28.1 (23.2 to 34.1)	20.0 (20.0 to 20.0)	
5-11 yrs, ST6: Baseline (n=40, 38, 40)	26.2 (20.6 to 33.4)	20.9 (19.7 to 22.2)	23.8 (20.7 to 27.3)	
5-11 yrs, ST6: Day 85 (n=39, 34, 38)	380.4 (293.3 to 493.5)	22.6 (20.1 to 25.4)	24.2 (19.0 to 30.9)	
5-11 yrs, ST6: Day 180 (n=38, 38, 39)	96.6 (71.4 to 130.6)	24.1 (21.1 to 27.5)	23.0 (20.3 to 26.0)	
5-11 yrs, ST6: Day 365 (n=36, 37, 35)	113.1 (84.7 to 151.1)	64.0 (50.3 to 81.4)	22.0 (19.6 to 24.7)	
5-11 yrs, ST6: Month 18 (n=36, 34, 37)	44.2 (31.1 to 62.8)	28.8 (23.6 to 35.2)	20.5 (19.5 to 21.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Seroconversion Stratified by Age Group at Days 85, 180, 194, 208, 365 and Month 18 After Vaccination During the Main Study Phase

End point title	Percentage of Participants With Seroconversion Stratified by Age Group at Days 85, 180, 194, 208, 365 and Month 18 After Vaccination During the Main Study Phase

End point description:

Seroconversion rate (SCR) for each OspA serotype specific IgG ST1 to ST6, determined by ELISA stratified by age group (5-11, 12-17 & 18-65 yrs) were evaluated. Seroconversion for ELISA was defined as: 1) For participants who were seronegative at screening: percentage of participants with a change from seronegative at screening to seropositive (i.e. antibody titer of >=40 U/mL) at a certain time point. 2) For participants who were seropositive at screening: percentage of participants with a >= 4-fold rise in OspA IgG antibody titer from screening. PPAS consisted of the FAS population excluding those participants with at least one relevant protocol deviation (i.e., a protocol deviation with possible impact on immunogenicity). All participants reported under 'Subjects Analyzed' contributed data to the table but may not have evaluable data for every row. Here, "n" signifies participants with available results for each serotype at specified time points.

End point type	Secondary

End point timeframe:

At Days 85, 180, 194 (18 to 65 years only), 208, 365 and Month 18

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	176	162	175	
Units: Percentage of participants				
number (confidence interval 95%)				
18-65 yrs, ST1: Day 85 (n=93, 81, 93)	59.1 (49.0 to 68.6)	1.2 (0.2 to 6.7)	2.2 (0.6 to 7.5)	
18-65 yrs, ST1: Day 180 (n=95, 83, 92)	22.1 (14.9 to 31.4)	2.4 (0.7 to 8.4)	2.2 (0.6 to 7.6)	
18-65 yrs, ST1: Day 194 (n=51, 44, 44)	92.2 (81.5 to 96.9)	65.9 (51.1 to 78.1)	4.5 (1.3 to 15.1)	
18-65 yrs, ST1: Day 208 (n=93, 81, 88)	89.2 (81.3 to 94.1)	70.4 (59.7 to 79.2)	9.1 (4.7 to 16.9)	
18-65 yrs, ST1: Day 365 (n=92, 81, 87)	32.6 (23.9 to 42.7)	11.1 (6.0 to 19.8)	1.1 (0.2 to 6.2)	
18-65 yrs, ST1: Month 18 (n=86, 73, 85)	10.5 (5.6 to 18.7)	6.8 (3.0 to 15.1)	0.0 (0.0 to 4.3)	
18-65 yrs, ST2: Day 85 (n=93, 81, 93)	84.9 (76.3 to 90.8)	2.5 (0.7 to 8.6)	0.0 (0.0 to 4.0)	
18-65 yrs, ST2: Day 180 (n=95, 83, 92)	49.5 (39.6 to 59.4)	3.6 (1.2 to 10.1)	0.0 (0.0 to 4.0)	
18-65 yrs, ST2: Day 194 (n=51, 44, 44)	100 (93.0 to 100)	88.6 (76.0 to 95.0)	2.3 (0.4 to 11.8)	
18-65 yrs, ST2: Day 208 (n=93, 81, 88)	96.8 (90.9 to 98.9)	90.1 (81.7 to 94.9)	2.3 (0.6 to 7.9)	
18-65 yrs, ST2: Day 365 (n=92, 81, 87)	54.3 (44.2 to 64.1)	42.0 (31.8 to 52.8)	1.1 (0.2 to 6.2)	
18-65 yrs, ST2: Month 18 (n=86, 73, 85)	25.6 (17.5 to 35.7)	13.7 (7.6 to 23.4)	0.0 (0.0 to 4.3)	
18-65 yrs, ST3: Day 85 (n=93, 81, 93)	86.0 (77.5 to 91.6)	4.9 (1.9 to 12.0)	0.0 (0.0 to 4.0)	

18-65 yrs, ST3: Day 180 (n=95, 83, 92)	45.3 (35.6 to 55.3)	3.6 (1.2 to 10.1)	4.3 (1.7 to 10.7)	
18-65 yrs, ST3: Day 194 (n=51, 44, 44)	100 (93.0 to 100)	86.4 (73.3 to 93.6)	4.5 (1.3 to 15.1)	
18-65 yrs, ST3: Day 208 (n=93, 81, 88)	98.9 (94.2 to 99.8)	85.2 (75.9 to 91.3)	3.4 (1.2 to 9.5)	
18-65 yrs, ST3: Day 365 (n=92, 81, 87)	53.3 (43.1 to 63.1)	39.5 (29.6 to 50.4)	1.1 (0.2 to 6.2)	
18-65 yrs, ST3: Month 18 (n=86, 73, 85)	18.6 (11.8 to 28.1)	19.2 (11.8 to 29.7)	0.0 (0.0 to 4.3)	
18-65 yrs, ST4: Day 85 (n=93, 81, 93)	73.1 (63.3 to 81.1)	2.5 (0.7 to 8.6)	2.2 (0.6 to 7.5)	
18-65 yrs, ST4: Day 180 (n=95, 83, 92)	31.6 (23.1 to 41.5)	7.2 (3.4 to 14.9)	7.6 (3.7 to 14.9)	
18-65 yrs, ST4: Day 194 (n=51, 44, 44)	98.0 (89.7 to 99.7)	77.3 (63.0 to 87.2)	6.8 (2.3 to 18.2)	
18-65 yrs, ST4: Day 208 (n=93, 81, 88)	93.5 (86.6 to 97.0)	79.0 (68.9 to 86.5)	6.8 (3.2 to 14.1)	
18-65 yrs, ST4: Day 365 (n=92, 81, 87)	43.5 (33.8 to 53.7)	22.2 (14.5 to 32.4)	2.3 (0.6 to 8.0)	
18-65 yrs, ST4: Month 18 (n=86, 73, 85)	18.6 (11.8 to 28.1)	9.6 (4.7 to 18.5)	2.4 (0.6 to 8.2)	
18-65 yrs, ST5: Day 85 (n=93, 81, 93)	72.0 (62.2 to 80.1)	1.2 (0.2 to 6.7)	1.1 (0.2 to 5.8)	
18-65 yrs, ST5: Day 180 (n=95, 83, 92)	37.9 (28.8 to 47.9)	2.4 (0.7 to 8.4)	4.3 (1.7 to 10.7)	
18-65 yrs, ST5: Day 194 (n=51, 44, 44)	98.0 (89.7 to 99.7)	77.3 (63.0 to 87.2)	4.5 (1.3 to 15.1)	
18-65 yrs, ST5: Day 208 (n=93, 81, 88)	95.7 (89.5 to 98.3)	75.3 (64.9 to 83.4)	6.8 (3.2 to 14.1)	
18-65 yrs, ST5: Day 365 (n=92, 81, 87)	41.3 (31.8 to 51.5)	24.7 (16.6 to 35.1)	2.3 (0.6 to 8.0)	
18-65 yrs, ST5: Month 18 (n=86, 73, 85)	11.6 (6.4 to 20.1)	8.2 (3.8 to 16.8)	1.2 (0.2 to 6.4)	
18-65 yrs, ST6: Day 85 (n=93, 81, 93)	68.8 (58.8 to 77.3)	2.5 (0.7 to 8.6)	3.2 (1.1 to 9.1)	
18-65 yrs, ST6: Day 180 (n=95, 83, 92)	31.6 (23.1 to 41.5)	3.6 (1.2 to 10.1)	4.3 (1.7 to 10.7)	
18-65 yrs, ST6: Day 194 (n=51, 44, 44)	98.0 (89.7 to 99.7)	77.3 (63.0 to 87.2)	6.8 (2.3 to 18.2)	
18-65 yrs, ST6: Day 208 (n=93, 81, 88)	93.5 (86.6 to 97.0)	74.1 (63.6 to 82.4)	8.0 (3.9 to 15.5)	
18-65 yrs, ST6: Day 365 (n=92, 81, 87)	42.4 (32.8 to 52.6)	22.2 (14.5 to 32.4)	4.6 (1.8 to 11.2)	
18-65 yrs, ST6: Month 18 (n=86, 73, 85)	15.1 (9.1 to 24.2)	6.8 (3.0 to 15.1)	3.5 (1.2 to 9.9)	
12-17 yrs, ST1: Day 85 (n=37, 40, 39)	91.9 (78.7 to 97.2)	5.0 (1.4 to 16.5)	0.0 (0.0 to 9.0)	
12-17 yrs, ST1: Day 180 (n=39, 40, 41)	59.0 (43.4 to 72.9)	12.5 (5.5 to 26.1)	7.3 (2.5 to 19.4)	
12-17 yrs, ST1: Day 208 (n=39, 40, 38)	97.4 (86.8 to 99.5)	97.5 (87.1 to 99.6)	5.3 (1.5 to 17.3)	
12-17 yrs, ST1: Day 365 (n=35, 38, 36)	48.6 (33.0 to 64.4)	44.7 (30.1 to 60.3)	0.0 (0.0 to 9.6)	
12-17 yrs, ST1: Month 18 (n=36, 37, 34)	27.8 (15.8 to 44.0)	16.2 (7.7 to 31.1)	0.0 (0.0 to 10.2)	
12-17 yrs, ST2: Day 85 (n=37, 40, 39)	94.6 (82.3 to 98.5)	10.0 (4.0 to 23.1)	0.0 (0.0 to 9.0)	
12-17 yrs, ST2: Day 180 (n=39, 40, 41)	82.1 (67.3 to 91.0)	17.5 (8.7 to 31.9)	4.9 (1.3 to 16.1)	
12-17 yrs, ST2: Day 208 (n=39, 40, 38)	100 (91.0 to 100)	97.5 (87.1 to 99.6)	2.6 (0.5 to 13.5)	

12-17 yrs, ST2: Day 365 (n=35, 38, 36)	65.7 (49.2 to 79.2)	71.1 (55.2 to 83.0)	2.8 (0.5 to 14.2)	
12-17 yrs, ST2: Month 18 (n=36, 37, 34)	41.7 (27.1 to 57.8)	48.6 (33.4 to 64.1)	0.0 (0.0 to 10.2)	
12-17 yrs, ST3: Day 85 (n=37, 40, 39)	94.6 (82.3 to 98.5)	17.5 (8.7 to 31.9)	0.0 (0.0 to 9.0)	
12-17 yrs, ST3: Day 180 (n=39, 40, 41)	84.6 (70.3 to 92.8)	17.5 (8.7 to 31.9)	7.3 (2.5 to 19.4)	
12-17 yrs, ST3: Day 208 (n=39, 40, 38)	100 (91.0 to 100)	97.5 (87.1 to 99.6)	7.9 (2.7 to 20.8)	
12-17 yrs, ST3: Day 365 (n=35, 38, 36)	71.4 (54.9 to 83.7)	78.9 (63.7 to 88.9)	0.0 (0.0 to 9.6)	
12-17 yrs, ST3: Month 18 (n=36, 37, 34)	38.9 (24.8 to 55.1)	54.1 (38.4 to 69.0)	0.0 (0.0 to 10.2)	
12-17 yrs, ST4: Day 85 (n=37, 40, 39)	97.3 (86.2 to 99.5)	5.0 (1.4 to 16.5)	0.0 (0.0 to 9.0)	
12-17 yrs, ST4: Day 180 (n=39, 40, 41)	79.5 (64.5 to 89.2)	10.0 (4.0 to 23.1)	4.9 (1.3 to 16.1)	
12-17 yrs, ST4: Day 208 (n=39, 40, 38)	100 (91.0 to 100)	97.5 (87.1 to 99.6)	7.9 (2.7 to 20.8)	
12-17 yrs, ST4: Day 365 (n=35, 38, 36)	65.7 (49.2 to 79.2)	55.3 (39.7 to 69.9)	0.0 (0.0 to 9.6)	
12-17 yrs, ST4: Month 18 (n=36, 37, 34)	44.4 (29.5 to 60.4)	29.7 (17.5 to 45.8)	0.0 (0.0 to 10.2)	
12-17 yrs, ST5: Day 85 (n=37, 40, 39)	94.6 (82.3 to 98.5)	7.5 (2.6 to 19.9)	2.6 (0.5 to 13.2)	
12-17 yrs, ST5: Day 180 (n=39, 40, 41)	74.4 (58.9 to 85.4)	12.5 (5.5 to 26.1)	2.4 (0.4 to 12.6)	
12-17 yrs, ST5: Day 208 (n=39, 40, 38)	100 (91.0 to 100)	97.5 (87.1 to 99.6)	5.3 (1.5 to 17.3)	
12-17 yrs, ST5: Day 365 (n=35, 38, 36)	65.7 (49.2 to 79.2)	63.2 (47.3 to 76.6)	0.0 (0.0 to 9.6)	
12-17 yrs, ST5: Month 18 (n=36, 37, 34)	33.3 (20.2 to 49.7)	24.3 (13.4 to 40.1)	2.9 (0.5 to 14.9)	
12-17 yrs, ST6: Day 85 (n=37, 40, 39)	91.9 (78.7 to 97.2)	5.0 (1.4 to 16.5)	0.0 (0.0 to 9.0)	
12-17 yrs, ST6: Day 180 (n=39, 40, 41)	66.7 (51.0 to 79.4)	15.0 (7.1 to 29.1)	7.3 (2.5 to 19.4)	
12-17 yrs, ST6: Day 208 (n=39, 40, 38)	100 (91.0 to 100)	95.0 (83.5 to 98.6)	10.5 (4.2 to 24.1)	
12-17 yrs, ST6: Day 365 (n=35, 38, 36)	68.6 (52.0 to 81.4)	52.6 (37.3 to 67.5)	2.8 (0.5 to 14.2)	
12-17 yrs, ST6: Month 18 (n=36, 37, 34)	33.3 (20.2 to 49.7)	21.6 (11.4 to 37.2)	2.9 (0.5 to 14.9)	
5-11 yrs, ST1: Day 85 (n=38, 34, 38)	97.4 (86.5 to 99.5)	2.9 (0.5 to 14.9)	2.6 (0.5 to 13.5)	
5-11 yrs, ST1: Day 180 (n=37, 38, 39)	67.6 (51.5 to 80.4)	2.6 (0.5 to 13.5)	0.0 (0.0 to 9.0)	
5-11 yrs, ST1: Day 208 (n=38, 37, 39)	97.4 (86.5 to 99.5)	97.3 (86.2 to 99.5)	2.6 (0.5 to 13.2)	
5-11 yrs, ST1: Day 365 (n=35, 37, 35)	65.7 (49.2 to 79.2)	51.4 (35.9 to 66.6)	0.0 (0.0 to 9.9)	
5-11 yrs, ST1: Month 18 (n=35, 34, 37)	20.0 (10.0 to 35.9)	8.8 (3.0 to 23.0)	0.0 (0.0 to 9.4)	
5-11 yrs, ST2: Day 85 (n=38, 34, 38)	97.4 (86.5 to 99.5)	11.8 (4.7 to 26.6)	2.6 (0.5 to 13.5)	
5-11 yrs, ST2: Day 180 (n=37, 38, 39)	94.6 (82.3 to 98.5)	5.3 (1.5 to 17.3)	0.0 (0.0 to 9.0)	
5-11 yrs, ST2: Day 208 (n=38, 37, 39)	97.4 (86.5 to 99.5)	100 (90.6 to 100)	2.6 (0.5 to 13.2)	
5-11 yrs, ST2: Day 365 (n=35, 37, 35)	91.4 (77.6 to 97.0)	83.8 (68.9 to 92.3)	0.0 (0.0 to 9.9)	

5-11 yrs, ST2: Month 18 (n=35, 34, 37)	57.1 (40.9 to 72.0)	50.0 (34.1 to 65.9)	0.0 (0.0 to 9.4)	
5-11 yrs, ST3: Day 85 (n=38, 34, 38)	97.4 (86.5 to 99.5)	17.6 (8.3 to 33.5)	2.6 (0.5 to 13.5)	
5-11 yrs, ST3: Day 180 (n=37, 38, 39)	89.2 (75.3 to 95.7)	10.5 (4.2 to 24.1)	0.0 (0.0 to 9.0)	
5-11 yrs, ST3: Day 208 (n=38, 37, 39)	97.4 (86.5 to 99.5)	100 (90.6 to 100)	2.6 (0.5 to 13.2)	
5-11 yrs, ST3: Day 365 (n=35, 37, 35)	80.0 (64.1 to 90.0)	91.9 (78.7 to 97.2)	0.0 (0.0 to 9.9)	
5-11 yrs, ST3: Month 18 (n=35, 34, 37)	54.3 (38.2 to 69.5)	70.6 (53.8 to 83.2)	2.7 (0.5 to 13.8)	
5-11 yrs, ST4: Day 85 (n=38, 34, 38)	97.4 (86.5 to 99.5)	11.8 (4.7 to 26.6)	5.3 (1.5 to 17.3)	
5-11 yrs, ST4: Day 180 (n=37, 38, 39)	89.2 (75.3 to 95.7)	7.9 (2.7 to 20.8)	5.1 (1.4 to 16.9)	
5-11 yrs, ST4: Day 208 (n=38, 37, 39)	97.4 (86.5 to 99.5)	100 (90.6 to 100)	5.1 (1.4 to 16.9)	
5-11 yrs, ST4: Day 365 (n=35, 37, 35)	85.7 (70.6 to 93.7)	75.7 (59.9 to 86.6)	0.0 (0.0 to 9.9)	
5-11 yrs, ST4: Month 18 (n=35, 34, 37)	48.6 (33.0 to 64.4)	29.4 (16.8 to 46.2)	0.0 (0.0 to 9.4)	
5-11 yrs, ST5: Day 85 (n=38, 34, 38)	97.4 (86.5 to 99.5)	8.8 (3.0 to 23.0)	5.3 (1.5 to 17.3)	
5-11 yrs, ST5: Day 180 (n=37, 38, 39)	91.9 (78.7 to 97.2)	5.3 (1.5 to 17.3)	5.1 (1.4 to 16.9)	
5-11 yrs, ST5: Day 208 (n=38, 37, 39)	97.4 (86.5 to 99.5)	100 (90.6 to 100)	7.7 (2.7 to 20.3)	
5-11 yrs, ST5: Day 365 (n=35, 37, 35)	91.4 (77.6 to 97.0)	64.9 (48.8 to 78.2)	0.0 (0.0 to 9.9)	
5-11 yrs, ST5: Month 18 (n=35, 34, 37)	42.9 (28.0 to 59.1)	29.4 (16.8 to 46.2)	0.0 (0.0 to 9.4)	
5-11 yrs, ST6: Day 85 (n=39, 34, 38)	94.9 (83.1 to 98.6)	8.8 (3.0 to 23.0)	2.6 (0.5 to 13.5)	
5-11 yrs, ST6: Day 180 (n=38, 38, 39)	78.9 (63.7 to 88.9)	13.2 (5.8 to 27.3)	5.1 (1.4 to 16.9)	
5-11 yrs, ST6: Day 208 (n=39, 37, 39)	94.9 (83.1 to 98.6)	100 (90.6 to 100)	7.7 (2.7 to 20.3)	
5-11 yrs, ST6: Day 365 (n=36, 37, 35)	83.3 (68.1 to 92.1)	73.0 (57.0 to 84.6)	0.0 (0.0 to 9.9)	
5-11 yrs, ST6: Month 18 (n=36, 34, 37)	27.8 (15.8 to 44.0)	32.4 (19.1 to 49.2)	0.0 (0.0 to 9.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: GMFR for IgG Against Each OspA Serotype (ST1 to ST6) Stratified by Age Group at Days 85 and 208 During the Main Study Phase

End point title	GMFR for IgG Against Each OspA Serotype (ST1 to ST6) Stratified by Age Group at Days 85 and 208 During the Main Study Phase

End point description:

GMFR for IgG when compared to baseline against each OspA serotype ST1 to ST6, stratified by age group (5-11, 12-17 & 18-65 yrs) determined by IgG binding assay at Day 85 and Day 208 were evaluated. PPAS consisted of the FAS population excluding those participants with at least one relevant protocol deviation (i.e., a protocol deviation with possible impact on immunogenicity). All participants reported under 'Subjects Analyzed' contributed data to the table but may not have evaluable data for

every row. Here, “n” signifies participants with available results for each serotype at specified time points.

End point type	Secondary
End point timeframe:	
At Days 85 and 208	

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	176	162	175	
Units: Fold rise				
geometric mean (confidence interval 95%)				
18-65 yrs, ST1: Day 85 (n=93, 81, 93)	3.1 (2.4 to 3.9)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	
18-65 yrs, ST1: Day 208 (n=93, 81, 88)	9.4 (7.2 to 12.2)	4.0 (3.1 to 5.3)	1.1 (1.0 to 1.3)	
18-65 yrs, ST2: Day 85 (n=93, 81, 93)	7.2 (5.7 to 9.1)	1.0 (1.0 to 1.1)	1.0 (1.0 to 1.0)	
18-65 yrs, ST2: Day 208 (n=93, 81, 88)	19.7 (15.9 to 24.4)	10.6 (8.1 to 13.7)	1.0 (0.9 to 1.1)	
18-65 yrs, ST3: Day 85 (n=93, 81, 93)	6.5 (5.1 to 8.2)	1.0 (1.0 to 1.1)	1.0 (1.0 to 1.0)	
18-65 yrs, ST3: Day 208 (n=93, 81, 88)	17.7 (14.3 to 22.0)	9.0 (6.8 to 11.8)	1.1 (1.0 to 1.2)	
18-65 yrs, ST4: Day 85 (n=93, 81, 93)	3.8 (3.1 to 4.8)	1.0 (1.0 to 1.1)	1.0 (1.0 to 1.0)	
18-65 yrs, ST4: Day 208 (n=93, 81, 88)	11.9 (9.5 to 15.0)	5.2 (4.0 to 6.7)	1.1 (1.0 to 1.2)	
18-65 yrs, ST5: Day 85 (n=93, 81, 93)	4.2 (3.3 to 5.2)	1.0 (1.0 to 1.0)	1.0 (1.0 to 1.0)	
18-65 yrs, ST5: Day 208 (n=93, 81, 88)	12.7 (10.3 to 15.8)	4.9 (3.8 to 6.4)	1.1 (1.0 to 1.2)	
18-65 yrs, ST6: Day 85 (n=93, 81, 93)	3.6 (2.9 to 4.5)	1.0 (1.0 to 1.1)	1.0 (1.0 to 1.1)	
18-65 yrs, ST6: Day 208 (n=93, 81, 88)	11.6 (9.2 to 14.7)	4.6 (3.6 to 5.9)	1.1 (1.0 to 1.2)	
12-17 yrs, ST1: Day 85 (n=37, 40, 39)	9.9 (6.8 to 14.4)	1.0 (1.0 to 1.1)	1.0 (0.9 to 1.0)	
12-17 yrs, ST1: Day 208 (n=39, 40, 38)	25.4 (18.1 to 35.7)	23.4 (15.7 to 34.8)	1.1 (1.0 to 1.2)	
12-17 yrs, ST2: Day 85 (n=37, 40, 39)	20.7 (14.2 to 30.2)	1.2 (1.0 to 1.4)	1.0 (1.0 to 1.0)	
12-17 yrs, ST2: Day 208 (n=39, 40, 38)	45.2 (34.8 to 58.8)	45.3 (31.0 to 66.4)	1.0 (1.0 to 1.1)	
12-17 yrs, ST3: Day 85 (n=37, 40, 39)	21.3 (14.4 to 31.6)	1.2 (1.1 to 1.4)	1.0 (0.9 to 1.0)	
12-17 yrs, ST3: Day 208 (n=39, 40, 38)	43.9 (32.5 to 59.3)	46.9 (31.3 to 70.2)	1.0 (1.0 to 1.1)	
12-17 yrs, ST4: Day 85 (n=37, 40, 39)	12.8 (9.1 to 18.2)	1.1 (1.0 to 1.2)	1.0 (0.9 to 1.0)	
12-17 yrs, ST4: Day 208 (n=39, 40, 38)	32.0 (23.8 to 43.0)	26.1 (17.7 to 38.4)	1.1 (1.0 to 1.2)	
12-17 yrs, ST5: Day 85 (n=37, 40, 39)	13.7 (9.5 to 19.7)	1.1 (1.0 to 1.2)	1.0 (0.9 to 1.1)	
12-17 yrs, ST5: Day 208 (n=39, 40, 38)	31.7 (24.1 to 41.7)	25.8 (17.7 to 37.7)	1.0 (0.9 to 1.2)	
12-17 yrs, ST6: Day 85 (n=37, 40, 39)	11.2 (7.8 to 16.2)	1.1 (1.0 to 1.2)	1.0 (0.9 to 1.0)	
12-17 yrs, ST6: Day 208 (n=39, 40, 38)	30.0 (22.5 to 39.9)	19.7 (13.4 to 28.8)	1.1 (1.0 to 1.3)	

5-11 yrs, ST1: Day 85 (n=38, 34, 38)	12.3 (9.8 to 15.3)	1.0 (1.0 to 1.1)	1.0 (0.8 to 1.2)	
5-11 yrs, ST1: Day 208 (n=38, 37, 39)	32.3 (24.3 to 42.9)	25.7 (17.8 to 37.1)	1.0 (0.8 to 1.2)	
5-11 yrs, ST2: Day 85 (n=38, 34, 38)	30.2 (23.4 to 39.0)	1.2 (1.0 to 1.3)	1.0 (0.8 to 1.2)	
5-11 yrs, ST2: Day 208 (n=38, 37, 39)	66.9 (50.5 to 88.6)	60.7 (44.9 to 81.9)	1.0 (0.8 to 1.2)	
5-11 yrs, ST3: Day 85 (n=38, 34, 38)	30.7 (23.1 to 40.8)	1.2 (1.0 to 1.4)	1.0 (0.9 to 1.2)	
5-11 yrs, ST3: Day 208 (n=38, 37, 39)	54.7 (40.5 to 74.0)	65.1 (47.1 to 89.9)	1.0 (0.8 to 1.2)	
5-11 yrs, ST4: Day 85 (n=38, 34, 38)	16.9 (13.0 to 22.1)	1.1 (1.0 to 1.3)	1.0 (0.8 to 1.2)	
5-11 yrs, ST4: Day 208 (n=38, 37, 39)	43.9 (33.0 to 58.6)	33.1 (23.7 to 46.4)	1.0 (0.8 to 1.3)	
5-11 yrs, ST5: Day 85 (n=38, 34, 38)	21.7 (16.6 to 28.4)	1.1 (1.0 to 1.2)	1.0 (0.9 to 1.3)	
5-11 yrs, ST5: Day 208 (n=38, 37, 39)	49.6 (37.3 to 65.9)	34.5 (24.9 to 47.7)	1.1 (0.9 to 1.3)	
5-11 yrs, ST6: Day 85 (n=39, 34, 38)	14.4 (10.9 to 19.0)	1.1 (1.0 to 1.2)	1.0 (0.8 to 1.2)	
5-11 yrs, ST6: Day 208 (n=39, 37, 39)	38.8 (26.9 to 56.0)	31.5 (22.4 to 44.3)	1.1 (0.9 to 1.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: GMTs for IgG Against Each OspA Serotype (ST1 to ST6) at Months 19, 23, 26, 30, 31, 39, 42, 43 and 48 During the Booster Phase

End point title	GMTs for IgG Against Each OspA Serotype (ST1 to ST6) at Months 19, 23, 26, 30, 31, 39, 42, 43 and 48 During the Booster Phase

End point description:

GMTs for IgG against each OspA serotype ST1 to ST6, determined by an IgG binding assay were evaluated. PPAS consisted of the FAS population excluding those participants with at least one relevant protocol deviation (i.e., a protocol deviation with possible impact on immunogenicity). All participants reported under 'Subjects Analyzed' contributed data to the table but may not have evaluable data for every row. Here, "n" signifies participants with available results for each serotype at specified time points.

End point type	Secondary

End point timeframe:

At Months 19, 23, 26, 30, 31, 39, 42, 43 and 48

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	176	162	175	
Units: Titers				
geometric mean (confidence interval 95%)				

ST1: Month 19 (n=127, 111, 123)	1057.0 (843.1 to 1325.1)	830.0 (621.3 to 1108.9)	20.9 (20.0 to 21.9)	
ST1: Month 23 (n=115, 109, 118)	178.2 (142.9 to 222.2)	136.9 (107.3 to 174.6)	21.4 (20.1 to 22.9)	
ST1 Month 26 (n=110, 103, 112)	91.0 (74.4 to 111.4)	71.1 (56.3 to 89.8)	21.9 (20.5 to 23.4)	
ST1: Month 30 (n=107, 97, 97)	61.1 (49.0 to 76.2)	52.6 (42.0 to 65.7)	20.3 (19.7 to 20.9)	
ST1: Month 31 (n=113, 98, 97)	1193.1 (967.1 to 1471.8)	941.4 (729.8 to 1214.4)	21.0 (19.0 to 23.3)	
ST1: Month 39 (n=107, 83, 86)	97.3 (81.5 to 116.2)	89.5 (69.7 to 114.8)	21.2 (19.6 to 23.1)	
ST1: Month 42 (n=105, 82, 85)	78.3 (66.1 to 92.6)	68.6 (54.6 to 86.2)	20.6 (19.7 to 21.6)	
ST1: Month 43 (n=112, 91, 88)	1044.8 (888.5 to 1228.5)	969.8 (768.9 to 1223.2)	21.5 (19.1 to 24.2)	
ST1: Month 48 (n=92, 79, 75)	201.1 (159.9 to 252.8)	173.8 (136.8 to 220.9)	20.0 (20.0 to 20.0)	
ST2: Month 19 (n=127, 111, 123)	1807.9 (1486.2 to 2199.3)	1603.1 (1239.7 to 2073.0)	20.5 (19.8 to 21.2)	
ST2: Month 23 (n=115, 109, 118)	350.5 (294.0 to 417.9)	282.6 (228.2 to 349.9)	20.9 (19.8 to 22.1)	
ST2: Month 26 (n=110, 103, 112)	177.1 (148.6 to 211.0)	140.6 (112.7 to 175.6)	21.5 (20.3 to 22.8)	
ST2: Month 30 (n=107, 97, 97)	106.9 (85.8 to 133.2)	95.2 (76.4 to 118.5)	20.3 (19.7 to 20.8)	
ST2: Month 31 (n=113, 98, 97)	1788.6 (1501.0 to 2131.2)	1489.7 (1197.1 to 1853.8)	21.4 (19.2 to 23.9)	
ST2: Month 39 (n=107, 83, 86)	172.5 (144.4 to 206.0)	150.3 (118.7 to 190.3)	20.8 (19.5 to 22.2)	
ST2: Month 42 (n=105, 82, 85)	132.9 (110.9 to 159.3)	115.5 (92.7 to 143.9)	20.5 (19.5 to 21.6)	
ST2: Month 43 (n=112, 91, 88)	1622.3 (1407.9 to 1869.4)	1555.9 (1253.9 to 1930.7)	21.2 (18.9 to 23.9)	
ST2: Month 48 (n=92, 79, 75)	324.6 (264.4 to 398.5)	306.0 (250.4 to 373.8)	20.0 (20.0 to 20.0)	
ST3: Month 19 (n=127, 111, 123)	1628.0 (1331.6 to 1990.2)	1418.0 (1094.3 to 1837.4)	20.8 (20.1 to 21.6)	
ST3: Month 23 (n=115, 109, 118)	319.5 (261.3 to 390.8)	283.6 (225.2 to 357.2)	21.0 (19.7 to 22.4)	
ST3: Month 26 (n=110, 103, 112)	160.9 (133.7 to 193.5)	143.9 (114.7 to 180.6)	21.6 (20.3 to 23.0)	
ST3: Month 30 (n=107, 97, 97)	97.9 (77.6 to 123.6)	102.6 (82.0 to 128.2)	21.2 (20.2 to 22.2)	
ST3: Month 31 (n=113, 98, 97)	1592.0 (1327.3 to 1909.6)	1396.0 (1099.7 to 1772.2)	21.9 (19.6 to 24.5)	
ST3: Month 39 (n=107, 83, 86)	155.5 (129.6 to 186.6)	151.9 (117.7 to 196.0)	21.5 (19.3 to 23.9)	
ST3: Month 42 (n=105, 82, 85)	118.6 (99.0 to 142.0)	119.1 (95.4 to 148.7)	20.7 (19.7 to 21.8)	
ST3: Month 43 (n=112, 91, 88)	1388.1 (1192.5 to 1615.9)	1393.0 (1104.4 to 1756.9)	21.8 (19.3 to 24.5)	
ST3: Month 48 (n=92, 79, 75)	320.2 (258.0 to 397.5)	317.4 (253.5 to 397.4)	20.7 (19.7 to 21.8)	
ST4: Month 19 (n=127, 111, 123)	1334.1 (1086.0 to 1639.0)	1032.9 (786.1 to 1357.3)	21.7 (20.5 to 23.0)	

ST4: Month 23 (n=115, 109, 118)	227.5 (185.0 to 279.8)	170.4 (135.1 to 215.0)	22.0 (20.3 to 23.8)	
ST4: Month 26 (n=110, 103, 112)	122.9 (102.6 to 147.2)	90.6 (72.4 to 113.5)	22.7 (21.0 to 24.6)	
ST4: Month 30 (n=107, 97, 97)	81.1 (65.3 to 100.7)	63.9 (51.4 to 79.5)	21.4 (20.0 to 22.9)	
ST4: Month 31 (n=113, 98, 97)	1493.2 (1242.7 to 1794.2)	1123.3 (877.9 to 1437.2)	23.2 (20.5 to 26.3)	
ST4: Month 39 (n=107, 83, 86)	125.1 (104.5 to 149.7)	113.6 (89.1 to 144.9)	21.9 (19.7 to 24.4)	
ST4: Month 42 (n=105, 82, 85)	101.8 (85.6 to 121.1)	88.0 (70.1 to 110.4)	21.9 (20.2 to 23.8)	
ST4: Month 43 (n=112, 91, 88)	1327.6 (1143.7 to 1541.0)	1199.4 (964.0 to 1492.3)	22.5 (19.8 to 25.6)	
ST4: Month 48 (n=92, 79, 75)	260.0 (209.3 to 323.0)	226.7 (184.2 to 279.1)	20.6 (19.5 to 21.7)	
ST5: Month 19 (n=127, 111, 123)	1266.2 (1024.3 to 1565.2)	980.1 (745.0 to 1289.4)	20.2 (19.8 to 20.7)	
ST5: Month 23 (n=115, 109, 118)	226.5 (186.1 to 275.7)	150.6 (117.6 to 193.0)	21.0 (19.8 to 22.2)	
ST5: Month 26 (n=110, 103, 112)	121.5 (101.1 to 146.1)	86.6 (69.2 to 108.4)	21.6 (20.3 to 23.0)	
ST5: Month 30 (n=107, 97, 97)	72.6 (57.8 to 91.2)	65.7 (52.8 to 81.7)	20.3 (19.7 to 20.9)	
ST5: Month 31 (n=113, 98, 97)	1354.6 (1130.8 to 1622.7)	1044.5 (829.9 to 1314.7)	22.1 (19.7 to 24.9)	
ST5: Month 39 (n=107, 83, 86)	119.8 (100.7 to 142.7)	106.7 (84.5 to 134.9)	21.4 (19.6 to 23.4)	
ST5: Month 42 (n=105, 82, 85)	91.8 (77.1 to 109.3)	83.7 (67.7 to 103.5)	20.3 (19.7 to 20.9)	
ST5: Month 43 (n=112, 91, 88)	1195.4 (1030.9 to 1386.3)	1097.4 (884.8 to 1361.1)	21.5 (19.1 to 24.2)	
ST5: Month 48 (n=92, 79, 75)	226.0 (181.5 to 281.4)	181.2 (141.0 to 232.9)	20.3 (19.7 to 21.0)	
ST6: Month 19 (n=127, 111, 123)	1254.9 (1020.7 to 1542.8)	957.2 (726.8 to 1260.5)	22.3 (21.0 to 23.7)	
ST6: Month 23 (n=115, 109, 118)	226.3 (184.3 to 277.8)	165.7 (131.3 to 209.0)	22.2 (20.7 to 23.9)	
ST6: Month 26 (n=110, 103, 112)	128.0 (106.5 to 153.9)	88.6 (70.9 to 110.7)	22.6 (21.0 to 24.2)	
ST6: Month 30 (n=107, 97, 97)	76.3 (60.7 to 95.9)	67.3 (54.3 to 83.5)	22.1 (20.6 to 23.7)	
ST6: Month 31 (n=113, 98, 97)	1358.1 (1132.7 to 1628.3)	1026.8 (813.9 to 1295.3)	23.5 (20.7 to 26.7)	
ST6: Month 39 (n=107, 83, 86)	124.0 (103.4 to 148.8)	103.7 (81.8 to 131.4)	22.1 (20.0 to 24.5)	
ST6: Month 42 (n=105, 82, 85)	98.2 (81.8 to 118.0)	82.7 (66.2 to 103.5)	20.8 (19.7 to 22.0)	
ST6: Month 43 (n=112, 91, 88)	1195.8 (1028.0 to 1391.0)	1072.7 (862.9 to 1333.6)	22.4 (19.8 to 25.4)	
ST6: Month 48 (n=92, 79, 75)	240.9 (192.4 to 301.7)	203.7 (164.6 to 252.2)	21.0 (19.8 to 22.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Seroconversion at Months 19, 23, 26, 30, 31, 39, 42, 43 and 48 After Vaccination During the Booster Phase

End point title	Percentage of Participants With Seroconversion at Months 19, 23, 26, 30, 31, 39, 42, 43 and 48 After Vaccination During the Booster Phase

End point description:

SCR for each OspA serotype specific IgG ST1 to ST6, determined by ELISA were evaluated. Seroconversion for ELISA was defined as: 1) For participants who were seronegative at screening: percentage of participants with a change from seronegative at screening to seropositive (i.e. antibody titer of >=40 U/mL) at a certain time point. 2) For participants who were seropositive at screening: percentage of participants with a >= 4-fold rise in OspA IgG antibody titer from screening. PPAS consisted of the FAS population excluding those participants with at least one relevant protocol deviation (i.e., a protocol deviation with possible impact on immunogenicity). All participants reported under 'Subjects Analyzed' contributed data to the table but may not have evaluable data for every row. Here, "n" signifies participants with available results for each serotype at specified time points.

End point type	Secondary

End point timeframe:

At Months 19, 23, 26, 30, 31, 39, 42, 43 and 48

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	176	162	175	
Units: Percentage of participants				
number (confidence interval 95%)				
ST1: Month 19 (n=126, 111, 123)	96.8 (92.1 to 98.8)	94.6 (88.7 to 97.5)	0.0 (0.0 to 3.0)	
ST1: Month 23 (n=115, 109, 118)	87.8 (80.6 to 92.6)	80.7 (72.3 to 87.0)	1.7 (0.5 to 6.0)	
ST1: Month 26 (n=110, 103, 112)	75.5 (66.6 to 82.5)	62.1 (52.5 to 70.9)	3.6 (1.4 to 8.8)	
ST1: Month 30 (n=107, 97, 97)	57.9 (48.5 to 66.9)	49.5 (39.7 to 59.3)	0.0 (0.0 to 3.8)	
ST1: Month 31 (n=113, 98, 97)	97.3 (92.5 to 99.1)	98.0 (92.9 to 99.4)	1.0 (0.2 to 5.6)	
ST1: Month 39 (n=107, 83, 86)	80.4 (71.9 to 86.8)	71.1 (60.6 to 79.7)	2.3 (0.6 to 8.1)	
ST1: Month 42 (n=105, 82, 85)	77.1 (68.2 to 84.1)	67.1 (56.3 to 76.3)	2.4 (0.6 to 8.2)	
ST1: Month 43 (n=112, 91, 88)	100 (96.7 to 100)	98.9 (94.0 to 99.8)	2.3 (0.6 to 7.9)	
ST1: Month 48 (n=92, 79, 75)	92.4 (85.1 to 96.3)	93.7 (86.0 to 97.3)	0.0 (0.0 to 4.9)	

ST2: Month 19 (n=126, 111, 123)	97.6 (93.2 to 99.2)	96.4 (91.1 to 98.6)	0.0 (0.0 to 3.0)	
ST2: Month 23 (n=115, 109, 118)	96.5 (91.4 to 98.6)	92.7 (86.2 to 96.2)	0.8 (0.1 to 4.6)	
ST2: Month 26 (n=110, 103, 112)	91.8 (85.2 to 95.6)	81.6 (73.0 to 87.9)	4.5 (1.9 to 10.0)	
ST2: Month 30 (n=107, 97, 97)	78.5 (69.8 to 85.2)	74.2 (64.7 to 81.9)	1.0 (0.2 to 5.6)	
ST2: Month 31 (n=113, 98, 97)	99.1 (95.2 to 99.8)	99.0 (94.4 to 99.8)	2.1 (0.6 to 7.2)	
ST2: Month 39 (n=107, 83, 86)	90.7 (83.6 to 94.8)	84.3 (75.0 to 90.6)	2.3 (0.6 to 8.1)	
ST2: Month 42 (n=105, 82, 85)	85.7 (77.8 to 91.1)	81.7 (72.0 to 88.6)	1.2 (0.2 to 6.4)	
ST2: Month 43 (n=112, 91, 88)	100 (96.7 to 100)	98.9 (94.0 to 99.8)	1.1 (0.2 to 6.2)	
ST2: Month 48 (n=92, 79, 75)	94.6 (87.9 to 97.7)	97.5 (91.2 to 99.3)	0.0 (0.0 to 4.9)	
ST3: Month 19 (n=126, 111, 123)	97.6 (93.2 to 99.2)	96.4 (91.1 to 98.6)	2.4 (0.8 to 6.9)	
ST3: Month 23 (n=115, 109, 118)	93.0 (86.9 to 96.4)	91.7 (85.0 to 95.6)	1.7 (0.5 to 6.0)	
ST3: Month 26 (n=110, 103, 112)	90.0 (83.0 to 94.3)	85.4 (77.4 to 91.0)	5.4 (2.5 to 11.2)	
ST3: Month 30 (n=107, 97, 97)	74.8 (65.8 to 82.0)	78.4 (69.2 to 85.4)	6.2 (2.9 to 12.8)	
ST3: Month 31 (n=113, 98, 97)	99.1 (95.2 to 99.8)	99.0 (94.4 to 99.8)	4.1 (1.6 to 10.1)	
ST3: Month 39 (n=107, 83, 86)	90.7 (83.6 to 94.8)	84.3 (75.0 to 90.6)	2.3 (0.6 to 8.1)	
ST3: Month 42 (n=105, 82, 85)	88.6 (81.1 to 93.3)	86.6 (77.6 to 92.3)	2.4 (0.6 to 8.2)	
ST3: Month 43 (n=112, 91, 88)	100 (96.7 to 100)	98.9 (94.0 to 99.8)	3.4 (1.2 to 9.5)	
ST3: Month 48 (n=92, 79, 75)	95.7 (89.3 to 98.3)	96.2 (89.4 to 98.7)	2.7 (0.7 to 9.2)	
ST4: Month 19 (n=126, 111, 123)	97.6 (93.2 to 99.2)	94.6 (88.7 to 97.5)	3.3 (1.3 to 8.1)	
ST4: Month 23 (n=115, 109, 118)	91.3 (84.7 to 95.2)	88.1 (80.7 to 92.9)	2.5 (0.9 to 7.2)	
ST4: Month 26 (n=110, 103, 112)	86.4 (78.7 to 91.6)	72.8 (63.5 to 80.5)	7.1 (3.7 to 13.5)	
ST4: Month 30 (n=107, 97, 97)	72.9 (63.8 to 80.4)	60.8 (50.9 to 69.9)	1.0 (0.2 to 5.6)	
ST4: Month 31 (n=113, 98, 97)	99.1 (95.2 to 99.8)	98.0 (92.9 to 99.4)	3.1 (1.1 to 8.7)	
ST4: Month 39 (n=107, 83, 86)	85.0 (77.1 to 90.6)	80.7 (71.0 to 87.8)	2.3 (0.6 to 8.1)	
ST4: Month 42 (n=105, 82, 85)	82.9 (74.5 to 88.9)	74.4 (64.0 to 82.6)	4.7 (1.8 to 11.5)	
ST4: Month 43 (n=112, 91, 88)	100 (96.7 to 100)	98.9 (94.0 to 99.8)	4.5 (1.8 to 11.1)	
ST4: Month 48 (n=92, 79, 75)	94.6 (87.9 to 97.7)	98.7 (93.2 to 99.8)	0.0 (0.0 to 4.9)	
ST5: Month 19 (n=126, 111, 123)	96.8 (92.1 to 98.8)	94.6 (88.7 to 97.5)	0.8 (0.1 to 4.5)	
ST5: Month 23 (n=115, 109, 118)	91.3 (84.7 to 95.2)	78.0 (69.3 to 84.7)	2.5 (0.9 to 7.2)	
ST5: Month 26 (n=110, 103, 112)	85.5 (77.7 to 90.8)	68.0 (58.4 to 76.2)	5.4 (2.5 to 11.2)	
ST5: Month 30 (n=107, 97, 97)	61.7 (52.2 to 70.3)	60.8 (50.9 to 69.9)	1.0 (0.2 to 5.6)	

ST5: Month 31 (n=113, 98, 97)	99.1 (95.2 to 99.8)	99.0 (94.4 to 99.8)	4.1 (1.6 to 10.1)	
ST5: Month 39 (n=107, 83, 86)	86.0 (78.2 to 91.3)	80.7 (71.0 to 87.8)	3.5 (1.2 to 9.8)	
ST5: Month 42 (n=105, 82, 85)	80.0 (71.4 to 86.5)	79.3 (69.3 to 86.6)	1.2 (0.2 to 6.4)	
ST5: Month 43 (n=112, 91, 88)	100 (96.7 to 100)	98.9 (94.0 to 99.8)	2.3 (0.6 to 7.9)	
ST5: Month 48 (n=92, 79, 75)	92.4 (85.1 to 96.3)	87.3 (78.2 to 93.0)	1.3 (0.2 to 7.2)	
ST6: Month 19 (n=127, 111, 123)	96.9 (92.2 to 98.8)	94.6 (88.7 to 97.5)	4.1 (1.7 to 9.2)	
ST6: Month 23 (n=115, 109, 118)	90.4 (83.7 to 94.6)	83.5 (75.4 to 89.3)	2.5 (0.9 to 7.2)	
ST6: Month 26 (n=110, 103, 112)	86.4 (78.7 to 91.6)	66.0 (56.4 to 74.4)	7.1 (3.7 to 13.5)	
ST6: Month 30 (n=107, 97, 97)	59.8 (50.3 to 68.6)	59.8 (49.8 to 69.0)	4.1 (1.6 to 10.1)	
ST6 :Month 31 (n=113, 98, 97)	99.1 (95.2 to 99.8)	98.0 (92.9 to 99.4)	3.1 (1.1 to 8.7)	
ST6: Month 39 (n=107, 83, 86)	85.0 (77.1 to 90.6)	77.1 (67.0 to 84.8)	4.7 (1.8 to 11.4)	
ST6: Month 42 (n=105, 82, 85)	79.0 (70.3 to 85.7)	70.7 (60.1 to 79.5)	2.4 (0.6 to 8.2)	
ST6: Month 43 (n=112, 91, 88)	100 (96.7 to 100)	98.9 (94.0 to 99.8)	3.4 (1.2 to 9.5)	
ST6: Month 48 (n=92, 79, 75)	92.4 (85.1 to 96.3)	93.7 (86.0 to 97.3)	1.3 (0.2 to 7.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: GMFR for IgG Against Each OspA Serotype (ST1 to ST6) at Month 18 (M18)-M19, M30-M31, M42-M43 During the Booster Phase

End point title	GMFR for IgG Against Each OspA Serotype (ST1 to ST6) at Month 18 (M18)-M19, M30-M31, M42-M43 During the Booster Phase

End point description:

GMFRs for IgG were determined by IgG binding assay for each OspA serotype (ST1–ST6) at Months 19, 31, and 43 relative to the corresponding pre-booster timepoints (Months 18, 30, and 42, respectively). PPAS consisted of the FAS population excluding those participants with at least one relevant protocol deviation (i.e., a protocol deviation with possible impact on immunogenicity). All participants reported under 'Subjects Analyzed' contributed data to the table but may not have evaluable data for every row. Here, "n" signifies participants with available results for each serotype at specified time points.

End point type	Secondary

End point timeframe:

At Months 19, 31 and 43

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	176	162	175	
Units: Fold rise				
geometric mean (confidence interval 95%)				
ST1: Month 19 (n=127, 110, 123)	38.4 (31.0 to 47.7)	36.5 (27.7 to 48.1)	1.0 (1.0 to 1.0)	
ST1: Month 31 (n=113, 97, 96)	19.3 (15.0 to 25.0)	19.1 (15.0 to 24.5)	1.0 (0.9 to 1.2)	
ST1: Month 43 (n=111, 90, 87)	13.3 (11.3 to 15.7)	14.3 (11.5 to 17.7)	1.0 (0.9 to 1.2)	
ST2: Month 19 (n=126, 110, 123)	50.6 (41.7 to 61.5)	53.7 (42.3 to 68.2)	1.0 (1.0 to 1.0)	
ST2: Month 31 (n=113, 97, 96)	16.2 (12.9 to 20.3)	15.9 (12.9 to 19.5)	1.1 (1.0 to 1.2)	
ST2: Month 43 (n=111, 90, 87)	12.2 (10.3 to 14.4)	13.6 (10.8 to 17.0)	1.0 (0.9 to 1.2)	
ST3: Month 19 (n=127, 110, 123)	46.7 (38.3 to 57.1)	44.9 (35.6 to 56.6)	1.0 (1.0 to 1.1)	
ST3: Month 31 (n=113, 97, 96)	16.6 (13.2 to 21.1)	14.1 (11.5 to 17.2)	1.0 (0.9 to 1.2)	
ST3: Month 43 (n=111, 90, 87)	11.6 (10.0 to 13.5)	11.6 (9.4 to 14.3)	1.1 (0.9 to 1.2)	
ST4: Month 19 (n=127, 110, 123)	40.1 (32.6 to 49.2)	40.9 (31.5 to 53.0)	1.0 (1.0 to 1.1)	
ST4: Month 31 (n=113, 97, 96)	18.1 (14.3 to 23.0)	18.1 (14.6 to 22.5)	1.1 (1.0 to 1.2)	
ST4: Month 43 (n=111, 90, 87)	13.1 (11.1 to 15.4)	13.6 (11.0 to 17.0)	1.1 (0.9 to 1.2)	
ST5: Month 19 (n=126, 110, 123)	41.3 (33.5 to 50.9)	40.5 (31.3 to 52.4)	1.0 (1.0 to 1.0)	
ST5: Month 31 (n=113, 97, 96)	18.5 (14.6 to 23.5)	16.5 (13.4 to 20.4)	1.1 (1.0 to 1.2)	
ST5: Month 43 (n=111, 90, 87)	13.0 (11.1 to 15.2)	13.1 (10.6 to 16.1)	1.1 (1.0 to 1.2)	
ST6: Month 19 (n=127, 110, 123)	37.2 (30.2 to 45.8)	37.4 (28.9 to 48.5)	1.0 (1.0 to 1.1)	
ST6: Month 31 (n=113, 97, 96)	18.2 (14.4 to 23.1)	15.4 (12.5 to 19.0)	1.1 (0.9 to 1.2)	
ST6: Month 43 (n=111, 90, 87)	12.0 (10.3 to 14.0)	13.0 (10.5 to 16.1)	1.1 (0.9 to 1.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: GMTs for IgG Against Each OspA Serotype (ST1 to ST6) Stratified by Age Group at Months 19, 23, 26, 30, 31, 39, 42, 43 and 48 During the Booster Phase

End point title	GMTs for IgG Against Each OspA Serotype (ST1 to ST6) Stratified by Age Group at Months 19, 23, 26, 30, 31, 39, 42, 43 and 48 During the Booster Phase

End point description:

GMTs for IgG against each OspA serotype ST1 to ST6, determined by an IgG binding assay stratified by age group (5-11, 12-17 & 18-65 yrs) were evaluated. PPAS consisted of the FAS population excluding

those participants with at least one relevant protocol deviation (i.e., a protocol deviation with possible impact on immunogenicity). All participants reported under 'Subjects Analyzed' contributed data to the table but may not have evaluable data for every row. Here, "n" signifies participants with available results for each serotype at specified time points.

End point type	Secondary

End point timeframe:

At Months 19, 23, 26, 30, 31, 39, 42, 43 and 48

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	176	162	175	
Units: Titers				
geometric mean (confidence interval 95%)				
18-65 yrs, ST1: Month 19 (n=72, 65, 67)	768.3 (565.5 to 1043.9)	499.6 (356.4 to 700.4)	21.3 (19.7 to 23.1)	
18-65 yrs, ST1: Month 23 (n=62, 60, 69:)	130.8 (95.7 to 178.8)	97.8 (71.2 to 134.1)	22.1 (19.9 to 24.5)	
18-65 yrs, ST1: Month 26 (n=63, 61, 67)	72.9 (55.5 to 95.8)	56.4 (42.6 to 74.8)	22.8 (20.5 to 25.2)	
18-65 yrs, ST1: Month 30 (n=60, 55, 54)	41.1 (33.0 to 51.3)	41.3 (31.8 to 53.6)	20.0 (20.0 to 20.0)	
18-65 yrs, ST1: Month 31 (n=66, 55, 53)	818.5 (635.6 to 1054.0)	606.0 (456.3 to 804.7)	20.0 (20.0 to 20.0)	
18-65 yrs, ST1: Month 39 (n=61, 49, 53)	79.9 (63.6 to 100.4)	59.9 (44.3 to 80.8)	20.7 (19.7 to 21.7)	
18-65 yrs, ST1: Month 42 (n=61, 49, 53)	62.7 (50.4 to 77.9)	54.7 (40.6 to 73.6)	20.0 (20.0 to 20.0)	
18-65 yrs, ST1: Month 43 (n=63, 53, 54)	791.7 (651.3 to 962.3)	589.1 (450.7 to 770.0)	22.0 (18.2 to 26.5)	
18-65 yrs, ST1: Month 48 (n=52, 46, 43)	169.2 (126.6 to 226.1)	138.4 (103.5 to 185.2)	20.0 (20.0 to 20.0)	
18-65 yrs, ST2: Month 19 (n=72, 65, 67)	1441.7 (1128.9 to 1841.1)	1144.1 (856.8 to 1527.8)	20.9 (19.6 to 22.2)	
18-65 yrs, ST2: Month 23 (n=62, 60, 69)	277.1 (219.6 to 349.7)	219.3 (166.8 to 288.4)	21.6 (19.7 to 23.6)	
18-65 yrs, ST2: Month 26 (n=63, 61, 67)	134.3 (105.3 to 171.3)	101.1 (75.9 to 134.6)	22.2 (20.2 to 24.4)	
18-65 yrs, ST2: Month 30 (n=60, 55, 54)	72.7 (56.5 to 93.5)	70.3 (53.4 to 92.4)	20.0 (20.0 to 20.0)	
18-65 yrs, ST2: Month 31 (n=66, 55, 53)	1322.1 (1109.9 to 1575.0)	1028.1 (818.4 to 1291.5)	20.0 (20.0 to 20.0)	
18-65 yrs, ST2: Month 39 (n=61, 49, 53)	143.2 (114.4 to 179.2)	100.0 (72.9 to 137.0)	20.3 (19.7 to 20.9)	
18-65 yrs, ST2: Month 42 (n=61, 49, 53)	111.6 (88.3 to 141.0)	88.8 (66.6 to 118.4)	20.0 (20.0 to 20.0)	
18-65 yrs, ST2: Month 43 (n=63, 53, 54)	1331.8 (1146.3 to 1547.4)	975.7 (759.7 to 1253.2)	22.0 (18.2 to 26.7)	
18-65 yrs, ST2: Month 48 (n=52, 46, 43)	297.4 (231.2 to 382.5)	234.3 (188.6 to 291.0)	20.0 (20.0 to 20.0)	
18-65 yrs, ST3: Month 19 (n=72, 65, 67)	1237.2 (963.1 to 1589.4)	948.9 (710.6 to 1267.1)	20.0 (20.0 to 20.0)	

18-65 yrs, ST3: Month 23 (n=62, 60, 69)	237.3 (178.4 to 315.6)	200.7 (148.8 to 270.7)	21.7 (19.5 to 24.2)	
18-65 yrs, ST3: Month 26 (n=63, 61, 67)	124.6 (97.2 to 159.6)	101.3 (75.5 to 135.9)	22.1 (20.1 to 24.3)	
18-65 yrs, ST3: Month 30 (n=60, 55, 54)	66.8 (51.9 to 86.0)	72.6 (54.9 to 96.1)	20.8 (19.6 to 22.1)	
18-65 yrs, ST3: Month 31 (n=66, 55, 53)	1157.5 (956.5 to 1400.7)	912.8 (702.6 to 1186.0)	20.6 (19.5 to 21.7)	
18-65 yrs, ST3: Month 39 (n=61, 49, 53)	133.1 (106.1 to 166.9)	97.6 (71.3 to 133.5)	20.7 (19.3 to 22.3)	
18-65 yrs, ST3: Month 42 (n=61, 49, 53)	96.0 (75.9 to 121.4)	88.9 (66.6 to 118.5)	20.6 (19.4 to 22.0)	
18-65 yrs, ST3: Month 43 (n=63, 53, 54)	1104.0 (925.1 to 1317.4)	820.3 (627.5 to 1072.4)	22.0 (18.2 to 26.6)	
18-65 yrs, ST3: Month 48 (n=52, 46, 43)	279.3 (212.3 to 367.3)	232.1 (178.2 to 302.3)	20.0 (20.0 to 20.0)	
18-65 yrs, ST4: Month 19 (n=72, 65, 67)	994.2 (762.2 to 1296.8)	668.9 (487.6 to 917.5)	21.2 (19.6 to 23.0)	
18-65 yrs, ST4: Month 23 (n=62, 60, 69)	159.1 (118.9 to 212.9)	121.5 (90.0 to 164.1)	22.5 (19.9 to 25.5)	
18-65 yrs, ST4: Month 26 (n=63, 61, 67)	95.6 (75.3 to 121.4)	67.8 (51.0 to 90.1)	23.6 (20.9 to 26.6)	
18-65 yrs, ST4: Month 30 (n=60, 55, 54)	55.5 (44.4 to 69.3)	47.1 (36.4 to 60.9)	21.5 (19.4 to 23.9)	
18-65 yrs, ST4: Month 31 (n=66, 55, 53)	1058.7 (866.2 to 1294.1)	747.9 (570.9 to 979.8)	22.3 (19.7 to 25.4)	
18-65 yrs, ST4: Month 39 (n=61, 49, 53)	106.0 (84.3 to 133.1)	79.3 (59.3 to 106.0)	21.6 (19.4 to 24.1)	
18-65 yrs, ST4: Month 42 (n=61, 49, 53)	82.3 (65.6 to 103.4)	72.3 (53.6 to 97.5)	22.0 (19.6 to 24.7)	
18-65 yrs, ST4: Month 43 (n=63, 53, 54)	1051.5 (882.2 to 1253.2)	754.6 (585.5 to 972.5)	23.2 (18.9 to 28.4)	
18-65 yrs, ST4: Month 48 (n=52, 46, 43)	223.0 (169.9 to 292.7)	176.3 (139.2 to 223.3)	21.0 (19.0 to 23.1)	
18-65 yrs, ST5: Month 19 (n=72, 65, 67)	930.5 (702.6 to 1232.3)	637.0 (460.8 to 880.6)	20.0 (20.0 to 20.0)	
18-65 yrs, ST5: Month 23 (n=62, 60, 69)	164.9 (126.3 to 215.4)	105.8 (76.3 to 146.8)	21.3 (19.5 to 23.3)	
18-65 yrs, ST5: Month 26 (n=63, 61, 67)	95.1 (75.0 to 120.6)	62.6 (46.9 to 83.6)	22.4 (20.3 to 24.7)	
18-65 yrs, ST5: Month 30 (n=60, 55, 54)	47.7 (37.4 to 60.8)	48.3 (37.1 to 63.0)	20.5 (19.5 to 21.6)	
18-65 yrs, ST5: Month 31 (n=66, 55, 53)	974.1 (797.9 to 1189.3)	696.3 (546.3 to 887.5)	20.6 (19.4 to 22.0)	
18-65 yrs, ST5: Month 39 (n=61, 49, 53)	102.2 (82.5 to 126.7)	70.9 (53.0 to 95.0)	20.9 (19.6 to 22.3)	
18-65 yrs, ST5: Month 42 (n=61, 49, 53)	72.3 (57.6 to 90.9)	69.9 (53.3 to 91.8)	20.5 (19.5 to 21.4)	
18-65 yrs, ST5: Month 43 (n=63, 53, 54)	937.6 (789.8 to 1113.1)	688.1 (540.9 to 875.3)	22.0 (18.2 to 26.7)	
18-65 yrs, ST5: Month 48 (n=52, 46, 43)	194.9 (146.5 to 259.3)	142.0 (104.3 to 193.4)	20.0 (20.0 to 20.0)	
18-65 yrs, ST6: Month 19 (n=72, 65, 67)	913.7 (700.2 to 1192.2)	621.8 (447.7 to 863.8)	21.3 (20.0 to 22.7)	
18-65 yrs, ST6: Month 23 (n=62, 60, 69)	166.9 (126.6 to 220.0)	123.7 (92.5 to 165.4)	21.5 (19.6 to 23.6)	
18-65 yrs, ST6: Month 26 (n=63, 61, 67)	99.8 (77.7 to 128.2)	65.9 (49.9 to 87.2)	23.2 (20.9 to 25.7)	
18-65 yrs, ST6: Month 30 (n=60, 55, 54)	52.0 (40.3 to 67.0)	50.2 (38.9 to 64.7)	21.0 (19.6 to 22.4)	
18-65 yrs, ST6: Month 31 (n=66, 55, 53)	962.8 (791.1 to 1171.8)	679.3 (531.4 to 868.5)	21.1 (19.5 to 22.9)	

18-65 yrs, ST6: Month 39 (n=61, 49, 53)	100.9 (79.2 to 128.6)	71.2 (52.9 to 95.9)	21.6 (19.6 to 23.7)	
18-65 yrs, ST6: Month 42 (n=61, 49, 53)	80.2 (62.8 to 102.4)	68.3 (51.1 to 91.4)	20.8 (19.3 to 22.4)	
18-65 yrs, ST6: Month 43 (n=63, 53, 54)	939.6 (785.9 to 1123.3)	676.9 (526.3 to 870.5)	22.7 (18.7 to 27.5)	
18-65 yrs, ST6: Month 48 (n=52, 46, 43)	210.1 (155.5 to 283.8)	161.2 (124.7 to 208.5)	20.4 (19.6 to 21.3)	
12-17 yrs, ST1: Month 19 (n=27, 26, 26)	1442.0 (899.5 to 2311.5)	1958.4 (1111.1 to 3451.7)	20.8 (19.1 to 22.7)	
12-17 yrs, ST1: Month 23 (n=25, 27, 21)	288.3 (189.7 to 438.2)	220.0 (131.9 to 367.1)	21.3 (18.7 to 24.3)	
12-17 yrs, ST1: Month 26 (n=24, 25, 21)	122.1 (77.2 to 193.1)	109.8 (61.4 to 196.4)	21.4 (18.6 to 24.7)	
12-17 yrs, ST1: Month 30 (n=21, 21, 19)	86.8 (47.9 to 157.4)	84.4 (47.2 to 150.9)	21.5 (18.4 to 25.1)	
12-17 yrs, ST1: Month 31 (n=20, 21, 21)	2125.7 (1487.7 to 3037.3)	2040.7 (1326.0 to 3140.8)	20.0 (20.0 to 20.0)	
12-17 yrs, ST1: Month 39 (n=21, 23, 13)	135.2 (92.8 to 196.8)	143.0 (87.4 to 234.1)	20.0 (20.0 to 20.0)	
12-17 yrs, ST1: Month 42 (n=23, 20, 15)	100.2 (69.4 to 144.5)	89.2 (53.6 to 148.7)	20.0 (20.0 to 20.0)	
12-17 yrs, ST1: Month 43 (n=23, 21, 16)	1244.9 (839.2 to 1846.9)	1638.9 (1037.2 to 2589.6)	21.8 (18.2 to 26.0)	
12-17 yrs, ST1: Month 48 (n=20, 19, 17)	185.1 (109.9 to 311.7)	207.4 (120.3 to 357.6)	20.0 (20.0 to 20.0)	
12-17 yrs, ST2: Month 19 (n=27, 26, 26)	1963.1 (1226.3 to 3142.5)	3149.2 (1904.3 to 5207.9)	20.0 (20.0 to 20.0)	
12-17 yrs, ST2: Month 23 (n=25, 27, 21)	468.8 (316.7 to 694.1)	412.2 (277.3 to 612.7)	20.0 (20.0 to 20.0)	
12-17 yrs, ST2: Month 26 (n=24, 25, 21)	241.4 (164.1 to 355.1)	278.2 (203.5 to 380.2)	21.1 (18.8 to 23.7)	
12-17 yrs, ST2: Month 30 (n=21, 21, 19)	135.3 (73.2 to 250.1)	169.7 (113.0 to 254.6)	21.4 (18.6 to 24.6)	
12-17 yrs, ST2: Month 31 (n=20, 21, 21)	2644.4 (1812.2 to 3858.8)	2678.0 (1924.1 to 3727.3)	21.6 (18.4 to 25.4)	
12-17 yrs, ST2: Month 39 (n=21, 23, 13)	225.1 (151.3 to 335.1)	265.7 (194.0 to 363.7)	20.0 (20.0 to 20.0)	
12-17 yrs, ST2: Month 42 (n=23, 20, 15)	155.8 (102.5 to 236.8)	160.6 (102.2 to 252.4)	20.0 (20.0 to 20.0)	
12-17 yrs, ST2: Month 43 (n=23, 21, 16)	1611.9 (1055.2 to 2462.4)	2400.5 (1558.0 to 3698.8)	20.0 (20.0 to 20.0)	
12-17 yrs, ST2: Month 48 (n=20, 19, 17)	231.7 (135.2 to 397.0)	366.6 (227.4 to 591.1)	20.0 (20.0 to 20.0)	
12-17 yrs, ST3: Month 19 (n=27, 26, 26)	2052.5 (1312.9 to 3208.6)	2919.2 (1746.8 to 4878.4)	21.9 (19.2 to 24.9)	
12-17 yrs, ST3: Month 23 (n=25, 27, 21)	496.9 (345.7 to 714.4)	447.1 (282.0 to 708.9)	20.0 (20.0 to 20.0)	
12-17 yrs, ST3: Month 26 (n=24, 25, 21)	237.1 (164.5 to 341.7)	283.1 (194.3 to 412.5)	21.3 (18.7 to 24.3)	
12-17 yrs, ST3: Month 30 (n=21, 21, 19)	143.5 (77.9 to 264.5)	167.0 (103.1 to 270.7)	23.0 (19.6 to 26.9)	
12-17 yrs, ST3: Month 31 (n=20, 21, 21)	2483.0 (1787.8 to 3448.5)	2690.2 (1785.0 to 4054.4)	22.5 (18.9 to 26.9)	

12-17 yrs, ST3: Month 39 (n=21, 23, 13)	207.7 (142.7 to 302.3)	253.9 (162.3 to 397.1)	20.0 (20.0 to 20.0)	
12-17 yrs, ST3: Month 42 (n=23, 20, 15)	142.1 (99.1 to 203.8)	182.2 (115.6 to 287.1)	20.0 (20.0 to 20.0)	
12-17 yrs, ST3: Month 43 (n=23, 21, 16)	1530.5 (1046.5 to 2238.4)	2339.8 (1523.4 to 3593.8)	21.1 (18.8 to 23.7)	
12-17 yrs, ST3: Month 48 (n=20, 19, 17)	264.8 (156.3 to 448.6)	392.2 (237.5 to 647.7)	21.3 (18.6 to 24.5)	
12-17 yrs, ST4: Month 19 (n=27, 26, 26)	1738.3 (1100.8 to 2745.2)	2295.9 (1323.2 to 3983.7)	22.8 (19.5 to 26.7)	
12-17 yrs, ST4: Month 23 (n=25, 27, 21)	377.6 (255.6 to 557.9)	285.3 (175.9 to 462.5)	23.2 (19.5 to 27.6)	
12-17 yrs, ST4: Month 26 (n=24, 25, 21)	169.2 (109.9 to 260.5)	178.1 (114.5 to 277.0)	23.4 (19.5 to 28.0)	
12-17 yrs, ST4: Month 30 (n=21, 21, 19)	113.4 (64.3 to 200.0)	112.7 (66.7 to 190.5)	21.5 (18.4 to 25.1)	
12-17 yrs, ST4: Month 31 (n=20, 21, 21)	2527.9 (1857.0 to 3441.0)	2274.1 (1492.7 to 3464.6)	22.6 (18.9 to 26.9)	
12-17 yrs, ST4: Month 39 (n=21, 23, 13)	166.1 (108.9 to 253.3)	180.2 (109.8 to 295.7)	20.0 (20.0 to 20.0)	
12-17 yrs, ST4: Month 42 (n=23, 20, 15)	119.4 (80.9 to 176.2)	121.5 (75.9 to 194.4)	20.0 (20.0 to 20.0)	
12-17 yrs, ST4: Month 43 (n=23, 21, 16)	1583.8 (1088.2 to 2305.2)	1895.2 (1210.3 to 2967.8)	23.2 (18.5 to 29.0)	
12-17 yrs, ST4: Month 48 (n=20, 19, 17)	227.3 (135.2 to 382.1)	269.4 (164.3 to 442.0)	20.0 (20.0 to 20.0)	
12-17 yrs, ST5: Month 19 (n=27, 26, 26)	1549.7 (988.0 to 2430.9)	2065.7 (1230.6 to 3467.7)	21.2 (18.8 to 23.7)	
12-17 yrs, ST5: Month 23 (n=25, 27, 21)	334.5 (226.5 to 493.9)	244.7 (153.9 to 389.0)	21.3 (18.7 to 24.2)	
12-17 yrs, ST5: Month 26 (n=24, 25, 21)	145.4 (89.0 to 237.5)	160.9 (107.5 to 240.6)	21.2 (18.8 to 23.9)	
12-17 yrs, ST5: Month 30 (n=21, 21, 19)	100.5 (53.8 to 187.6)	106.8 (63.4 to 179.8)	20.0 (20.0 to 20.0)	
12-17 yrs, ST5: Month 31 (n=20, 21, 21)	2084.9 (1527.0 to 2846.7)	2062.9 (1375.2 to 3094.5)	23.0 (18.8 to 28.3)	
12-17 yrs, ST5: Month 39 (n=21, 23, 13)	160.1 (108.7 to 236.0)	181.6 (124.5 to 264.8)	20.0 (20.0 to 20.0)	
12-17 yrs, ST5: Month 42 (n=23, 20, 15)	114.4 (77.0 to 169.8)	106.1 (66.1 to 170.2)	20.0 (20.0 to 20.0)	
12-17 yrs, ST5: Month 43 (n=23, 21, 16)	1285.8 (891.4 to 1854.6)	1802.3 (1124.4 to 2889.0)	21.5 (18.4 to 25.2)	
12-17 yrs, ST5: Month 48 (n=20, 19, 17)	191.5 (117.1 to 313.2)	228.7 (130.2 to 401.9)	21.5 (18.5 to 25.0)	
12-17 yrs, ST6: Month 19 (n=27, 26, 26)	1588.3 (1008.8 to 2500.9)	1975.8 (1187.5 to 3287.4)	24.4 (20.0 to 29.8)	
12-17 yrs, ST6: Month 23 (n=25, 27, 21)	336.9 (215.1 to 527.7)	237.4 (148.0 to 380.7)	25.8 (20.1 to 33.1)	
12-17 yrs, ST6: Month 26 (n=24, 25, 21)	176.2 (113.7 to 273.2)	150.7 (97.9 to 232.0)	22.6 (18.9 to 27.0)	
12-17 yrs, ST6: Month 30 (n=21, 21, 19)	110.6 (60.2 to 203.2)	97.2 (55.3 to 170.6)	27.7 (20.9 to 36.8)	
12-17 yrs, ST6: Month 31 (n=20, 21, 21)	2242.3 (1627.7 to 3089.0)	1987.0 (1371.5 to 2878.8)	25.1 (19.3 to 32.6)	

12-17 yrs, ST6: Month 39 (n=21, 23, 13)	174.9 (111.7 to 273.8)	161.4 (108.0 to 241.4)	21.7 (18.2 to 25.9)	
12-17 yrs, ST6: Month 42 (n=23, 20, 15)	131.2 (87.4 to 197.2)	106.1 (66.3 to 169.7)	20.0 (20.0 to 20.0)	
12-17 yrs, ST6: Month 43 (n=23, 21, 16)	1318.7 (907.0 to 1917.3)	1613.1 (1014.0 to 2566.2)	23.3 (18.6 to 29.2)	
12-17 yrs, ST6: Month 48 (n=20, 19, 17)	209.1 (125.3 to 349.0)	235.2 (141.3 to 391.5)	23.8 (18.5 to 30.5)	
5-11 yrs, ST1: Month 19 (n=28, 20, 30)	1778.9 (1154.1 to 2742.0)	1415.6 (657.0 to 3049.9)	20.0 (20.0 to 20.0)	
5-11 yrs, ST1: Month 23 (n=28, 22, 28)	230.2 (151.2 to 350.4)	191.4 (112.3 to 326.4)	20.0 (20.0 to 20.0)	
5-11 yrs, ST1: Month 26 (n=23, 17, 24)	123.0 (83.8 to 180.4)	85.9 (50.1 to 147.2)	20.0 (20.0 to 20.0)	
5-11 yrs, ST1: Month 30 (n=26, 21, 24)	115.0 (68.6 to 192.7)	61.6 (36.5 to 103.9)	20.0 (20.0 to 20.0)	
5-11 yrs, ST1: Month 31 (n=27, 22, 23)	1954.0 (1198.9 to 3184.7)	1353.1 (669.2 to 2736.0)	24.8 (15.9 to 38.5)	
5-11 yrs, ST1: Month 39 (n=25, 11, 20)	119.6 (79.5 to 179.7)	200.9 (119.8 to 336.9)	23.6 (16.7 to 33.6)	
5-11 yrs, ST1: Month 42 (n=21, 13, 17)	113.8 (79.6 to 162.7)	107.3 (67.7 to 170.0)	23.5 (18.5 to 29.7)	
5-11 yrs, ST1: Month 43 (n=26, 17, 18)	1752.4 (1280.9 to 2397.4)	2399.3 (1610.6 to 3574.2)	20.0 (20.0 to 20.0)	
5-11 yrs, ST1: Month 48 (n=20, 14, 15)	342.2 (200.1 to 585.1)	289.2 (151.4 to 552.7)	20.0 (20.0 to 20.0)	
5-11 yrs, ST2: Month 19 (n=28, 20, 30)	2988.8 (1955.7 to 4567.7)	1994.9 (872.8 to 4559.5)	20.0 (20.0 to 20.0)	
5-11 yrs, ST2: Month 23 (n=28, 22, 28)	455.0 (318.2 to 650.6)	354.9 (199.4 to 631.7)	20.0 (20.0 to 20.0)	
5-11 yrs, ST2: Month 26 (n=23, 17, 24)	273.5 (220.7 to 338.9)	168.7 (90.0 to 316.2)	20.0 (20.0 to 20.0)	
5-11 yrs, ST2: Month 30 (n=26, 21, 24)	215.5 (145.6 to 319.0)	118.3 (68.2 to 205.2)	20.0 (20.0 to 20.0)	
5-11 yrs, ST2: Month 31 (n=27, 22, 23)	2802.1 (1724.3 to 4553.5)	2151.1 (1095.7 to 4223.3)	25.0 (15.7 to 39.6)	
5-11 yrs, ST2: Month 39 (n=25, 11, 20)	217.0 (142.5 to 330.4)	280.2 (162.7 to 482.6)	22.9 (17.2 to 30.5)	
5-11 yrs, ST2: Month 42 (n=21, 13, 17)	185.8 (124.5 to 277.4)	187.7 (120.3 to 292.8)	22.8 (17.3 to 30.0)	
5-11 yrs, ST2: Month 43 (n=26, 17, 18)	2631.6 (1989.6 to 3480.7)	3900.7 (2855.5 to 5328.4)	20.0 (20.0 to 20.0)	
5-11 yrs, ST2: Month 48 (n=20, 14, 15)	570.7 (384.9 to 846.1)	575.7 (337.1 to 983.2)	20.0 (20.0 to 20.0)	
5-11 yrs, ST3: Month 19 (n=28, 20, 30)	2637.1 (1667.7 to 4170.0)	2046.5 (927.0 to 4518.1)	21.8 (19.7 to 24.1)	
5-11 yrs, ST3: Month 23 (n=28, 22, 28)	416.4 (281.1 to 616.8)	417.0 (248.2 to 700.7)	20.0 (20.0 to 20.0)	
5-11 yrs, ST3: Month 26 (n=23, 17, 24)	216.1 (147.4 to 316.8)	187.6 (107.3 to 327.7)	20.6 (19.4 to 21.9)	
5-11 yrs, ST3: Month 30 (n=26, 21, 24)	173.9 (102.0 to 296.4)	155.4 (96.4 to 250.5)	20.6 (19.3 to 22.1)	
5-11 yrs, ST3: Month 31 (n=27, 22, 23)	2496.3 (1509.5 to 4128.2)	2158.8 (1109.1 to 4201.9)	24.9 (15.8 to 39.0)	

5-11 yrs, ST3: Month 39 (n=25, 11, 20)	178.4 (111.2 to 286.2)	372.4 (215.1 to 644.8)	24.7 (15.9 to 38.5)	
5-11 yrs, ST3: Month 42 (n=21, 13, 17)	179.7 (117.3 to 275.2)	186.8 (121.1 to 288.2)	21.6 (18.4 to 25.3)	
5-11 yrs, ST3: Month 43 (n=26, 17, 18)	2217.9 (1600.7 to 3073.0)	3824.8 (2719.1 to 5380.1)	21.8 (19.2 to 24.6)	
5-11 yrs, ST3: Month 48 (n=20, 14, 15)	552.8 (350.8 to 871.1)	665.8 (396.9 to 1117.0)	22.1 (17.8 to 27.5)	
5-11 yrs, ST4: Month 19 (n=28, 20, 30)	2201.9 (1439.7 to 3367.7)	1501.4 (705.0 to 3197.4)	21.9 (19.7 to 24.4)	
5-11 yrs, ST4: Month 23 (n=28, 22, 28)	319.4 (221.9 to 459.8)	227.8 (137.3 to 378.2)	20.0 (20.0 to 20.0)	
5-11 yrs, ST4: Month 26 (n=23, 17, 24)	174.9 (130.3 to 234.8)	95.1 (55.5 to 163.0)	20.0 (20.0 to 20.0)	
5-11 yrs, ST4: Month 30 (n=26, 21, 24)	148.7 (89.6 to 246.7)	80.5 (49.1 to 132.0)	21.1 (18.9 to 23.6)	
5-11 yrs, ST4: Month 31 (n=27, 22, 23)	2343.1 (1449.4 to 3787.7)	1583.6 (780.5 to 3212.9)	26.0 (16.7 to 40.5)	
5-11 yrs, ST4: Month 39 (n=25, 11, 20)	147.8 (97.9 to 223.2)	215.1 (117.8 to 392.5)	24.0 (16.4 to 35.1)	
5-11 yrs, ST4: Month 42 (n=21, 13, 17)	158.6 (114.1 to 220.5)	112.3 (63.5 to 198.4)	23.5 (18.6 to 29.6)	
5-11 yrs, ST4: Month 43 (n=26, 17, 18)	1998.3 (1458.7 to 2737.5)	2890.2 (2074.0 to 4027.5)	20.0 (20.0 to 20.0)	
5-11 yrs, ST4: Month 48 (n=20, 14, 15)	443.6 (273.2 to 720.3)	410.0 (240.3 to 699.5)	20.0 (20.0 to 20.0)	
5-11 yrs, ST5: Month 19 (n=28, 20, 30)	2300.8 (1523.2 to 3475.4)	1508.5 (689.1 to 3302.0)	20.0 (20.0 to 20.0)	
5-11 yrs, ST5: Month 23 (n=28, 22, 28)	323.0 (219.7 to 474.7)	217.6 (121.4 to 390.0)	20.0 (20.0 to 20.0)	
5-11 yrs, ST5: Month 26 (n=23, 17, 24)	197.2 (152.7 to 254.5)	111.2 (63.8 to 193.6)	20.0 (20.0 to 20.0)	
5-11 yrs, ST5: Month 30 (n=26, 21, 24)	147.1 (91.6 to 236.2)	90.5 (56.1 to 146.0)	20.0 (20.0 to 20.0)	
5-11 yrs, ST5: Month 31 (n=27, 22, 23)	2203.7 (1378.3 to 3523.3)	1503.5 (776.7 to 2910.5)	25.1 (15.7 to 40.0)	
5-11 yrs, ST5: Month 39 (n=25, 11, 20)	138.4 (89.1 to 215.1)	216.9 (120.3 to 391.3)	23.8 (16.5 to 34.3)	
5-11 yrs, ST5: Month 42 (n=21, 13, 17)	144.2 (104.5 to 198.8)	114.4 (67.2 to 194.7)	20.0 (20.0 to 20.0)	
5-11 yrs, ST5: Month 43 (n=26, 17, 18)	2019.2 (1494.0 to 2729.1)	2548.2 (1845.4 to 3518.6)	20.0 (20.0 to 20.0)	
5-11 yrs, ST5: Month 48 (n=20, 14, 15)	391.6 (243.3 to 630.3)	293.9 (149.8 to 576.8)	20.0 (20.0 to 20.0)	
5-11 yrs, ST6: Month 19 (n=28, 20, 30)	2260.9 (1496.1 to 3416.6)	1515.5 (691.7 to 3320.4)	22.8 (20.0 to 25.9)	
5-11 yrs, ST6: Month 23 (n=28, 22, 28)	311.2 (210.4 to 460.5)	236.5 (129.7 to 431.4)	21.6 (19.4 to 24.0)	
5-11 yrs, ST6: Month 26 (n=23, 17, 24)	181.3 (139.3 to 236.1)	117.0 (64.7 to 211.5)	20.9 (19.1 to 22.8)	
5-11 yrs, ST6: Month 30 (n=26, 21, 24)	137.4 (84.0 to 224.6)	100.6 (63.5 to 159.5)	20.9 (19.1 to 22.8)	
5-11 yrs, ST6: Month 31 (n=27, 22, 23)	2172.0 (1355.4 to 3480.6)	1535.5 (773.0 to 3049.8)	28.3 (17.7 to 45.3)	

5-11 yrs, ST6: Month 39 (n=25, 11, 20)	153.7 (109.6 to 215.5)	219.1 (119.2 to 402.6)	23.9 (16.5 to 34.7)	
5-11 yrs, ST6: Month 42 (n=21, 13, 17)	129.0 (89.0 to 186.9)	116.4 (65.2 to 207.9)	21.6 (18.3 to 25.5)	
5-11 yrs, ST6: Month 43 (n=26, 17, 18)	1967.4 (1448.4 to 2672.4)	2723.5 (2059.6 to 3601.6)	20.9 (19.1 to 22.9)	
5-11 yrs, ST6: Month 48 (n=20, 14, 15)	396.3 (249.0 to 630.9)	361.5 (220.5 to 592.5)	20.0 (20.0 to 20.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Seroconversion Stratified by Age Group at Months 19, 23, 26, 30, 31, 39, 42, 43 and 48 After Vaccination During the Booster Phase

End point title	Percentage of Participants With Seroconversion Stratified by Age Group at Months 19, 23, 26, 30, 31, 39, 42, 43 and 48 After Vaccination During the Booster Phase

End point description:

SCR for each OspA serotype specific IgG ST1 to ST6, determined by ELISA stratified by age group (5-11, 12-17 & 18-65 yrs) were evaluated. Seroconversion for ELISA: 1) For participants who were seronegative at screening: percentage of participants with a change from seronegative at screening to seropositive (i.e. antibody titer of >=40 U/mL) at a certain time point. 2) For participants who were seropositive at screening: percentage of participants with a >= 4-fold rise in OspA IgG antibody titer from screening. PPAS consisted of the FAS population excluding those participants with at least one relevant protocol deviation (i.e., a protocol deviation with possible impact on immunogenicity). All participants reported under 'Subjects Analyzed' contributed data to the table but may not have evaluable data for every row. Here, "n" signifies participants with available results for each serotype at specified time points.

End point type	Secondary

End point timeframe:

At Months 19, 23, 26, 30, 31, 39, 42, 43 and 48

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	176	162	175	
Units: Percentage of participants				
number (confidence interval 95%)				
18-65 yrs, ST1: Month 19 (n=72, 65, 67)	97.2 (90.4 to 99.2)	95.4 (87.3 to 98.4)	0.0 (0.0 to 5.4)	
18-65 yrs, ST1: Month 23 (n=62, 60, 69)	82.3 (71.0 to 89.8)	75.0 (62.8 to 84.2)	2.9 (0.8 to 10.0)	
18-65 yrs, ST1: Month 26 (n=63, 61, 67)	68.3 (56.0 to 78.4)	57.4 (44.9 to 69.0)	6.0 (2.3 to 14.4)	
18-65 yrs, ST1: Month 30 (n=60, 55, 54)	45.0 (33.1 to 57.5)	41.8 (29.7 to 55.0)	0.0 (0.0 to 6.6)	
18-65 yrs, ST1: Month 31 (n=66, 55, 53)	97.0 (89.6 to 99.2)	100 (93.5 to 100)	0.0 (0.0 to 6.8)	
18-65 yrs, ST1: Month 39 (n=61, 49, 53)	73.8 (61.6 to 83.2)	59.2 (45.2 to 71.8)	1.9 (0.3 to 9.9)	

18-65 yrs, ST1: Month 42 (n=61, 49, 53)	70.5 (58.1 to 80.4)	57.1 (43.3 to 70.0)	0.0 (0.0 to 6.8)	
18-65 yrs, ST1: Month 43 (n=63, 53, 54)	100 (94.3 to 100)	98.1 (90.1 to 99.7)	1.9 (0.3 to 9.8)	
18-65 yrs, ST1: Month 48 (n=52, 46, 43)	90.4 (79.4 to 95.8)	93.5 (82.5 to 97.8)	0.0 (0.0 to 8.2)	
18-65 yrs, ST2: Month 19 (n=72, 65, 67)	98.6 (92.5 to 99.8)	98.5 (91.8 to 99.7)	0.0 (0.0 to 5.4)	
18-65 yrs, ST2: Month 23 (n=62, 60, 69)	95.2 (86.7 to 98.3)	91.7 (81.9 to 96.4)	1.4 (0.3 to 7.8)	
18-65 yrs, ST2: Month 26 (n=63, 61, 67)	85.7 (75.0 to 92.3)	73.8 (61.6 to 83.2)	6.0 (2.3 to 14.4)	
18-65 yrs, ST2: Month 30 (n=60, 55, 54)	68.3 (55.8 to 78.7)	65.5 (52.3 to 76.6)	0.0 (0.0 to 6.6)	
18-65 yrs, ST2: Month 31 (n=66, 55, 53)	100 (94.5 to 100)	100 (93.5 to 100)	0.0 (0.0 to 6.8)	
18-65 yrs, ST2: Month 39 (n=61, 49, 53)	86.9 (76.2 to 93.2)	73.5 (59.7 to 83.8)	1.9 (0.3 to 9.9)	
18-65 yrs, ST2: Month 42 (n=61, 49, 53)	82.0 (70.5 to 89.6)	73.5 (59.7 to 83.8)	0.0 (0.0 to 6.8)	
18-65 yrs, ST2: Month 43 (n=63, 53, 54)	100 (94.3 to 100)	98.1 (90.1 to 99.7)	1.9 (0.3 to 9.8)	
18-65 yrs, ST2: Month 48 (n=52, 46, 43)	94.2 (84.4 to 98.0)	97.8 (88.7 to 99.6)	0.0 (0.0 to 8.2)	
18-65 yrs, ST3: Month 19 (n=72, 65, 67)	98.6 (92.5 to 99.8)	98.5 (91.8 to 99.7)	0.0 (0.0 to 5.4)	
18-65 yrs, ST3: Month 23 (n=62, 60, 69)	88.7 (78.5 to 94.4)	88.3 (77.8 to 94.2)	2.9 (0.8 to 10.0)	
18-65 yrs, ST3: Month 26 (n=63, 61, 67)	84.1 (73.2 to 91.1)	77.0 (65.1 to 85.8)	7.5 (3.2 to 16.3)	
18-65 yrs, ST3: Month 30 (n=60, 55, 54)	66.7 (54.1 to 77.3)	69.1 (56.0 to 79.7)	3.7 (1.0 to 12.5)	
18-65 yrs, ST3: Month 31 (n=66, 55, 53)	100 (94.5 to 100)	100 (93.5 to 100)	1.9 (0.3 to 9.9)	
18-65 yrs, ST3: Month 39 (n=61, 49, 53)	88.5 (78.2 to 94.3)	75.5 (61.9 to 85.4)	1.9 (0.3 to 9.9)	
18-65 yrs, ST3: Month 42 (n=61, 49, 53)	83.6 (72.4 to 90.8)	79.6 (66.4 to 88.5)	1.9 (0.3 to 9.9)	
18-65 yrs, ST3: Month 43 (n=63, 53, 54)	100 (94.3 to 100)	98.1 (90.1 to 99.7)	1.9 (0.3 to 9.8)	
18-65 yrs, ST3: Month 48 (n=52, 46, 43)	96.2 (87.0 to 98.9)	95.7 (85.5 to 98.8)	0.0 (0.0 to 8.2)	
18-65 yrs, ST4: Month 19 (n=72, 65, 67)	98.6 (92.5 to 99.8)	95.4 (87.3 to 98.4)	3.0 (0.8 to 10.2)	
18-65 yrs, ST4: Month 23 (n=62, 60, 69)	85.5 (74.7 to 92.2)	83.3 (72.0 to 90.7)	2.9 (0.8 to 10.0)	
18-65 yrs, ST4: Month 26 (n=63, 61, 67)	81.0 (69.6 to 88.8)	63.9 (51.4 to 74.8)	10.4 (5.2 to 20.0)	
18-65 yrs, ST4: Month 30 (n=60, 55, 54)	65.0 (52.4 to 75.8)	52.7 (39.8 to 65.3)	1.9 (0.3 to 9.8)	
18-65 yrs, ST4: Month 31 (n=66, 55, 53)	100 (94.5 to 100)	100 (93.5 to 100)	3.8 (1.0 to 12.8)	
18-65 yrs, ST4: Month 39 (n=61, 49, 53)	83.6 (72.4 to 90.8)	73.5 (59.7 to 83.8)	1.9 (0.3 to 9.9)	
18-65 yrs, ST4: Month 42 (n=61, 49, 53)	77.0 (65.1 to 85.8)	69.4 (55.5 to 80.5)	3.8 (1.0 to 12.8)	
18-65 yrs, ST4: Month 43 (n=63, 53, 54)	100 (94.3 to 100)	98.1 (90.1 to 99.7)	3.7 (1.0 to 12.5)	
18-65 yrs, ST4: Month 48 (n=52, 46, 43)	94.2 (84.4 to 98.0)	100 (92.3 to 100)	0.0 (0.0 to 8.2)	
18-65 yrs, ST5: Month 19 (n=72, 65, 67)	97.2 (90.4 to 99.2)	95.4 (87.3 to 98.4)	0.0 (0.0 to 5.4)	

18-65 yrs, ST5: Month 23 (n=62, 60, 69)	87.1 (76.6 to 93.3)	70.0 (57.5 to 80.1)	2.9 (0.8 to 10.0)	
18-65 yrs, ST5: Month 26 (n=63, 61, 67)	81.0 (69.6 to 88.8)	55.7 (43.3 to 67.5)	7.5 (3.2 to 16.3)	
18-65 yrs, ST5: Month 30 (n=60, 55, 54)	48.3 (36.2 to 60.7)	49.1 (36.4 to 61.9)	1.9 (0.3 to 9.8)	
18-65 yrs, ST5: Month 31 (n=66, 55, 53)	100 (94.5 to 100)	100 (93.5 to 100)	1.9 (0.3 to 9.9)	
18-65 yrs, ST5: Month 39 (n=61, 49, 53)	83.6 (72.4 to 90.8)	67.3 (53.4 to 78.8)	3.8 (1.0 to 12.8)	
18-65 yrs, ST5: Month 42 (n=61, 49, 53)	72.1 (59.8 to 81.8)	75.5 (61.9 to 85.4)	1.9 (0.3 to 9.9)	
18-65 yrs, ST5: Month 43 (n=63, 53, 54)	100 (94.3 to 100)	98.1 (90.1 to 99.7)	1.9 (0.3 to 9.8)	
18-65 yrs, ST5: Month 48 (n=52, 46, 43)	90.4 (79.4 to 95.8)	84.8 (71.8 to 92.4)	0.0 (0.0 to 8.2)	
18-65 yrs, ST6: Month 19 (n=72, 65, 67)	98.6 (92.5 to 99.8)	95.4 (87.3 to 98.4)	4.5 (1.5 to 12.4)	
18-65 yrs, ST6: Month 23 (n=62, 60, 69)	87.1 (76.6 to 93.3)	81.7 (70.1 to 89.4)	4.3 (1.5 to 12.0)	
18-65 yrs, ST6: Month 26 (n=63, 61, 67)	79.4 (67.8 to 87.5)	57.4 (44.9 to 69.0)	11.9 (6.2 to 21.8)	
18-65 yrs, ST6: Month 30 (n=60, 55, 54)	50.0 (37.7 to 62.3)	50.9 (38.1 to 63.6)	3.7 (1.0 to 12.5)	
18-65 yrs, ST6: Month 31 (n=66, 55, 53)	100 (94.5 to 100)	100 (93.5 to 100)	3.8 (1.0 to 12.8)	
18-65 yrs, ST6: Month 39 (n=61, 49, 53)	78.7 (66.9 to 87.1)	65.3 (51.3 to 77.1)	5.7 (1.9 to 15.4)	
18-65 yrs, ST6: Month 42 (n=61, 49, 53)	72.1 (59.8 to 81.8)	65.3 (51.3 to 77.1)	1.9 (0.3 to 9.9)	
18-65 yrs, ST6: Month 43 (n=63, 53, 54)	100 (94.3 to 100)	98.1 (90.1 to 99.7)	3.7 (1.0 to 12.5)	
18-65 yrs, ST6: Month 48 (n=52, 46, 43)	92.3 (81.8 to 97.0)	95.7 (85.5 to 98.8)	2.3 (0.4 to 12.1)	
12-17 yrs, ST1: Month 19 (n=27, 26, 26)	96.3 (81.7 to 99.3)	96.2 (81.1 to 99.3)	0.0 (0.0 to 12.9)	
12-17 yrs, ST1: Month 23 (n=25, 27, 21)	100 (86.7 to 100)	92.6 (76.6 to 97.9)	0.0 (0.0 to 15.5)	
12-17 yrs, ST1: Month 26 (n=24, 25, 21)	83.3 (64.1 to 93.3)	68.0 (48.4 to 82.8)	0.0 (0.0 to 15.5)	
12-17 yrs, ST1: Month 30 (n=21, 21, 19)	71.4 (50.0 to 86.2)	66.7 (45.4 to 82.8)	0.0 (0.0 to 16.8)	
12-17 yrs, ST1: Month 31 (n=20, 21, 21)	100 (83.9 to 100)	100 (84.5 to 100)	0.0 (0.0 to 15.5)	
12-17 yrs, ST1: Month 39 (n=21, 23, 13)	95.2 (77.3 to 99.2)	87.0 (67.9 to 95.5)	0.0 (0.0 to 22.8)	
12-17 yrs, ST1: Month 42 (n=23, 20, 15)	87.0 (67.9 to 95.5)	75.0 (53.1 to 88.8)	0.0 (0.0 to 20.4)	
12-17 yrs, ST1: Month 43 (n=23, 21, 16)	100 (85.7 to 100)	100 (84.5 to 100)	6.3 (1.1 to 28.3)	
12-17 yrs, ST1: Month 48 (n=20, 19, 17)	90.0 (69.9 to 97.2)	94.7 (75.4 to 99.1)	0.0 (0.0 to 18.4)	
12-17 yrs, ST2: Month 19 (n=27, 26, 26)	96.3 (81.7 to 99.3)	96.2 (81.1 to 99.3)	0.0 (0.0 to 12.9)	
12-17 yrs, ST2: Month 23 (n=25, 27, 21)	100 (86.7 to 100)	96.3 (81.7 to 99.3)	0.0 (0.0 to 15.5)	
12-17 yrs, ST2: Month 26 (n=24, 25, 21)	100 (86.2 to 100)	100 (86.7 to 100)	4.8 (0.8 to 22.7)	
12-17 yrs, ST2: Month 30 (n=21, 21, 19)	81.0 (60.0 to 92.3)	95.2 (77.3 to 99.2)	5.3 (0.9 to 24.6)	
12-17 yrs, ST2: Month 31 (n=20, 21, 21)	100 (83.9 to 100)	100 (84.5 to 100)	4.8 (0.8 to 22.7)	

12-17 yrs, ST2: Month 39 (n=21, 23, 13)	100 (84.5 to 100)	100 (85.7 to 100)	0.0 (0.0 to 22.8)	
12-17 yrs, ST2: Month 42 (n=23, 20, 15)	91.3 (73.2 to 97.6)	90.0 (69.9 to 97.2)	0.0 (0.0 to 20.4)	
12-17 yrs, ST2: Month 43 (n=23, 21, 16)	100 (85.7 to 100)	100 (84.5 to 100)	0.0 (0.0 to 19.4)	
12-17 yrs, ST2: Month 48 (n=20, 19, 17)	90.0 (69.9 to 97.2)	94.7 (75.4 to 99.1)	0.0 (0.0 to 18.4)	
12-17 yrs, ST3: Month 19 (n=27, 26, 26)	96.3 (81.7 to 99.3)	96.2 (81.1 to 99.3)	3.8 (0.7 to 18.9)	
12-17 yrs, ST3: Month 23 (n=25, 27, 21)	100 (86.7 to 100)	96.3 (81.7 to 99.3)	0.0 (0.0 to 15.5)	
12-17 yrs, ST3: Month 26 (n=24, 25, 21)	100 (86.2 to 100)	100 (86.7 to 100)	4.8 (0.8 to 22.7)	
12-17 yrs, ST3: Month 30 (n=21, 21, 19)	85.7 (65.4 to 95.0)	95.2 (77.3 to 99.2)	15.8 (5.5 to 37.6)	
12-17 yrs, ST3: Month 31 (n=20, 21, 21)	100 (83.9 to 100)	100 (84.5 to 100)	9.5 (2.7 to 28.9)	
12-17 yrs, ST3: Month 39 (n=21, 23, 13)	100 (84.5 to 100)	95.7 (79.0 to 99.2)	0.0 (0.0 to 22.8)	
12-17 yrs, ST3: Month 42 (n=23, 20, 15)	95.7 (79.0 to 99.2)	95.0 (76.4 to 99.1)	0.0 (0.0 to 20.4)	
12-17 yrs, ST3: Month 43 (n=23, 21, 16)	100 (85.7 to 100)	100 (84.5 to 100)	6.3 (1.1 to 28.3)	
12-17 yrs, ST3: Month 48 (n=20, 19, 17)	90.0 (69.9 to 97.2)	94.7 (75.4 to 99.1)	5.9 (1.0 to 27.0)	
12-17 yrs, ST4: Month 19 (n=27, 26, 26)	96.3 (81.7 to 99.3)	96.2 (81.1 to 99.3)	3.8 (0.7 to 18.9)	
12-17 yrs, ST4: Month 23 (n=25, 27, 21)	100 (86.7 to 100)	96.3 (81.7 to 99.3)	4.8 (0.8 to 22.7)	
12-17 yrs, ST4: Month 26 (n=24, 25, 21)	91.7 (74.2 to 97.7)	92.0 (75.0 to 97.8)	4.8 (0.8 to 22.7)	
12-17 yrs, ST4: Month 30 (n=21, 21, 19)	81.0 (60.0 to 92.3)	71.4 (50.0 to 86.2)	0.0 (0.0 to 16.8)	
12-17 yrs, ST4: Month 31 (n=20, 21, 21)	100 (83.9 to 100)	100 (84.5 to 100)	0.0 (0.0 to 15.5)	
12-17 yrs, ST4: Month 39 (n=21, 23, 13)	90.5 (71.1 to 97.3)	87.0 (67.9 to 95.5)	0.0 (0.0 to 22.8)	
12-17 yrs, ST4: Month 42 (n=23, 20, 15)	87.0 (67.9 to 95.5)	80.0 (58.4 to 91.9)	0.0 (0.0 to 20.4)	
12-17 yrs, ST4: Month 43 (n=23, 21, 16)	100 (85.7 to 100)	100 (84.5 to 100)	12.5 (3.5 to 36.0)	
12-17 yrs, ST4: Month 48 (n=20, 19, 17)	90.0 (69.9 to 97.2)	94.7 (75.4 to 99.1)	0.0 (0.0 to 18.4)	
12-17 yrs, ST5: Month 19 (n=27, 26, 26)	96.3 (81.7 to 99.3)	96.2 (81.1 to 99.3)	3.8 (0.7 to 18.9)	
12-17 yrs, ST5: Month 23 (n=25, 27, 21)	100 (86.7 to 100)	92.6 (76.6 to 97.9)	4.8 (0.8 to 22.7)	
12-17 yrs, ST5: Month 26 (n=24, 25, 21)	83.3 (64.1 to 93.3)	92.0 (75.0 to 97.8)	4.8 (0.8 to 22.7)	
12-17 yrs, ST5: Month 30 (n=21, 21, 19)	66.7 (45.4 to 82.8)	76.2 (54.9 to 89.4)	0.0 (0.0 to 16.8)	
12-17 yrs, ST5: Month 31 (n=20, 21, 21)	100 (83.9 to 100)	100 (84.5 to 100)	9.5 (2.7 to 28.9)	
12-17 yrs, ST5: Month 39 (n=21, 23, 13)	95.2 (77.3 to 99.2)	100 (85.7 to 100)	0.0 (0.0 to 22.8)	
12-17 yrs, ST5: Month 42 (n=23, 20, 15)	87.0 (67.9 to 95.5)	80.0 (58.4 to 91.9)	0.0 (0.0 to 20.4)	
12-17 yrs, ST5: Month 43 (n=23, 21, 16)	100 (85.7 to 100)	100 (84.5 to 100)	6.3 (1.1 to 28.3)	
12-17 yrs, ST5: Month 48 (n=20, 19, 17)	90.0 (69.9 to 97.2)	89.5 (68.6 to 97.1)	5.9 (1.0 to 27.0)	

12-17 yrs, ST6: Month 19 (n=27, 26, 26)	96.3 (81.7 to 99.3)	96.2 (81.1 to 99.3)	0.0 (0.0 to 12.9)	
12-17 yrs, ST6: Month 23 (n=25, 27, 21)	96.0 (80.5 to 99.3)	88.9 (71.9 to 96.1)	0.0 (0.0 to 15.5)	
12-17 yrs, ST6: Month 26 (n=24, 25, 21)	95.8 (79.8 to 99.3)	80.0 (60.9 to 91.1)	0.0 (0.0 to 15.5)	
12-17 yrs, ST6: Month 30 (n=21, 21, 19)	66.7 (45.4 to 82.8)	61.9 (40.9 to 79.2)	10.5 (2.9 to 31.4)	
12-17 yrs, ST6: Month 31 (n=20, 21, 21)	100 (83.9 to 100)	100 (84.5 to 100)	0.0 (0.0 to 15.5)	
12-17 yrs, ST6: Month 39 (n=21, 23, 13)	95.2 (77.3 to 99.2)	91.3 (73.2 to 97.6)	0.0 (0.0 to 22.8)	
12-17 yrs, ST6: Month 42 (n=23, 20, 15)	87.0 (67.9 to 95.5)	80.0 (58.4 to 91.9)	0.0 (0.0 to 20.4)	
12-17 yrs, ST6: Month 43 (n=23, 21, 16)	100 (85.7 to 100)	100 (84.5 to 100)	0.0 (0.0 to 19.4)	
12-17 yrs, ST6: Month 48 (n=20, 19, 17)	85.0 (64.0 to 94.8)	89.5 (68.6 to 97.1)	0.0 (0.0 to 18.4)	
5-11 yrs, ST1: Month 19 (n=27, 20, 30)	96.3 (81.7 to 99.3)	90.0 (69.9 to 97.2)	0.0 (0.0 to 11.4)	
5-11 yrs, ST1: Month 23 (n=28, 22, 28)	89.3 (72.8 to 96.3)	81.8 (61.5 to 92.7)	0.0 (0.0 to 12.1)	
5-11 yrs, ST1: Month 26 (n=23, 17, 24)	87.0 (67.9 to 95.5)	70.6 (46.9 to 86.7)	0.0 (0.0 to 13.8)	
5-11 yrs, ST1: Month 30 (n=26, 21, 24)	76.9 (57.9 to 89.0)	52.4 (32.4 to 71.7)	0.0 (0.0 to 13.8)	
5-11 yrs, ST1: Month 31 (n=27, 22, 23)	96.3 (81.7 to 99.3)	90.9 (72.2 to 97.5)	4.3 (0.8 to 21.0)	
5-11 yrs, ST1: Month 39 (n=25, 11, 20)	84.0 (65.3 to 93.6)	90.9 (62.3 to 98.4)	5.0 (0.9 to 23.6)	
5-11 yrs, ST1: Month 42 (n=21, 13, 17)	85.7 (65.4 to 95.0)	92.3 (66.7 to 98.6)	11.8 (3.3 to 34.3)	
5-11 yrs, ST1: Month 43 (n=26, 17, 18)	100 (87.1 to 100)	100 (81.6 to 100)	0.0 (0.0 to 17.6)	
5-11 yrs, ST1: Month 48 (n=20, 14, 15)	100 (83.9 to 100)	92.9 (68.5 to 98.7)	0.0 (0.0 to 20.4)	
5-11 yrs, ST2: Month 19 (n=27, 20, 30)	96.3 (81.7 to 99.3)	90.0 (69.9 to 97.2)	0.0 (0.0 to 11.4)	
5-11 yrs, ST2: Month 23 (n=28, 22, 28)	96.4 (82.3 to 99.4)	90.9 (72.2 to 97.5)	0.0 (0.0 to 12.1)	
5-11 yrs, ST2: Month 26 (n=23, 17, 24)	100 (85.7 to 100)	82.4 (59.0 to 93.8)	0.0 (0.0 to 13.8)	
5-11 yrs, ST2: Month 30 (n=26, 21, 24)	100 (87.1 to 100)	76.2 (54.9 to 89.4)	0.0 (0.0 to 13.8)	
5-11 yrs, ST2: Month 31 (n=27, 22, 23)	96.3 (81.7 to 99.3)	95.5 (78.2 to 99.2)	4.3 (0.8 to 21.0)	
5-11 yrs, ST2: Month 39 (n=25, 11, 20)	92.0 (75.0 to 97.8)	100 (74.1 to 100)	1 (0.9 to 23.6)	
5-11 yrs, ST2: Month 42 (n=21, 13, 17)	90.5 (71.1 to 97.3)	100 (77.2 to 100)	5.9 (1.0 to 27.0)	
5-11 yrs, ST2: Month 43 (n=26, 17, 18)	100 (87.1 to 100)	100 (81.6 to 100)	0.0 (0.0 to 17.6)	
5-11 yrs, ST2: Month 48 (n=20, 14, 15)	100 (83.9 to 100)	100 (78.5 to 100)	0.0 (0.0 to 20.4)	
5-11 yrs, ST3: Month 19 (n=27, 20, 30)	96.3 (81.7 to 99.3)	90.0 (69.9 to 97.2)	6.7 (1.8 to 21.3)	
5-11 yrs, ST3: Month 23 (n=28, 22, 28)	96.4 (82.3 to 99.4)	95.5 (78.2 to 99.2)	0.0 (0.0 to 12.1)	
5-11 yrs, ST3: Month 26 (n=23, 17, 24)	95.7 (79.0 to 99.2)	94.1 (73.0 to 99.0)	0.0 (0.0 to 13.8)	
5-11 yrs, ST3: Month 30 (n=26, 21, 24)	84.6 (66.5 to 93.8)	85.7 (65.4 to 95.0)	4.2 (0.7 to 20.2)	

5-11 yrs, ST3: Month 31 (n=27, 22, 23)	96.3 (81.7 to 99.3)	95.5 (78.2 to 99.2)	4.3 (0.8 to 21.0)	
5-11 yrs, ST3: Month 39 (n=25, 11, 20)	88.0 (70.0 to 95.8)	100 (74.1 to 100)	5.0 (0.9 to 23.6)	
5-11 yrs, ST3: Month 42 (n=21, 13, 17)	95.2 (77.3 to 99.2)	100 (77.2 to 100)	5.9 (1.0 to 27.0)	
5-11 yrs, ST3: Month 43 (n=26, 17, 18)	100 (87.1 to 100)	100 (81.6 to 100)	5.6 (1.0 to 25.8)	
5-11 yrs, ST3: Month 48 (n=20, 14, 15)	100 (83.9 to 100)	100 (78.5 to 100)	6.7 (1.2 to 29.8)	
5-11 yrs, ST4: Month 19 (n=27, 20, 30)	96.3 (81.7 to 99.3)	90.0 (69.9 to 97.2)	3.3 (0.6 to 16.7)	
5-11 yrs, ST4: Month 23 (n=28, 22, 28)	96.4 (82.3 to 99.4)	90.9 (72.2 to 97.5)	0.0 (0.0 to 12.1)	
5-11 yrs, ST4: Month 26 (n=23, 17, 24)	95.7 (79.0 to 99.2)	76.5 (52.7 to 90.4)	0.0 (0.0 to 13.8)	
5-11 yrs, ST4: Month 30 (n=26, 21, 24)	84.6 (66.5 to 93.8)	71.4 (50.0 to 86.2)	0.0 (0.0 to 13.8)	
5-11 yrs, ST4: Month 31 (n=27, 22, 23)	96.3 (81.7 to 99.3)	90.9 (72.2 to 97.5)	4.3 (0.8 to 21.0)	
5-11 yrs, ST4: Month 39 (n=25, 11, 20)	84.0 (65.3 to 93.6)	100 (74.1 to 100)	5.0 (0.9 to 23.6)	
5-11 yrs, ST4: Month 42 (n=21, 13, 17)	95.2 (77.3 to 99.2)	84.6 (57.8 to 95.7)	11.8 (3.3 to 34.3)	
5-11 yrs, ST4: Month 43 (n=26, 17, 18)	100 (87.1 to 100)	100 (81.6 to 100)	0.0 (0.0 to 17.6)	
5-11 yrs, ST4: Month 48 (n=20, 14, 15)	100 (83.9 to 100)	100 (78.5 to 100)	0.0 (0.0 to 20.4)	
5-11 yrs, ST5: Month 19 (n=27, 20, 30)	96.3 (81.7 to 99.3)	90.0 (69.9 to 97.2)	0.0 (0.0 to 11.4)	
5-11 yrs, ST5: Month 23 (n=28, 22, 28)	92.9 (77.4 to 98)	81.8 (61.5 to 92.7)	0.0 (0.0 to 12.1)	
5-11 yrs, ST5: Month 26 (n=23, 17, 24)	100 (85.7 to 100)	76.5 (52.7 to 90.4)	0.0 (0.0 to 13.8)	
5-11 yrs, ST15: Month 30 (n=26, 21, 24)	88.5 (71.0 to 96.0)	76.2 (54.9 to 89.4)	0.0 (0.0 to 13.8)	
5-11 yrs, ST5: Month 31 (n=27, 22, 23)	96.3 (81.7 to 99.3)	95.5 (78.2 to 99.2)	4.3 (0.8 to 21.0)	
5-11 yrs, ST5: Month 39 (n=25, 11, 20)	84.0 (65.3 to 93.6)	100 (74.1 to 100)	5.0 (0.9 to 23.6)	
5-11 yrs, ST5: Month 42 (n=21, 13, 17)	95.2 (77.3 to 99.2)	92.3 (66.7 to 98.6)	0.0 (0.0 to 18.4)	
5-11 yrs, ST5: Month 43 (n=26, 17, 18)	100 (87.1 to 100)	100 (81.6 to 100)	0.0 (0.0 to 17.6)	
5-11 yrs, ST5: Month 48 (n=20, 14, 15)	100 (83.9 to 100)	92.9 (68.5 to 98.7)	0.0 (0.0 to 20.4)	
5-11 yrs, ST6: Month 19 (n=28, 20, 30)	92.9 (77.4 to 98.0)	90.0 (69.9 to 97.2)	6.7 (1.8 to 21.3)	
5-11 yrs, ST6: Month 23 (n=28, 22, 28)	92.9 (77.4 to 98.0)	81.8 (61.5 to 92.7)	0.0 (0.0 to 12.1)	
5-11 yrs, ST6: Month 26 (n=23, 17, 24)	95.7 (79.0 to 99.2)	76.5 (52.7 to 90.4)	0.0 (0.0 to 13.8)	
5-11 yrs, ST6: Month 30 (n=26, 21, 24)	76.9 (57.9 to 89.0)	81.0 (60.0 to 92.3)	0.0 (0.0 to 13.8)	
5-11 yrs, ST6: Month 31 (n=27, 22, 23)	96.3 (81.7 to 99.3)	90.9 (72.2 to 97.5)	4.3 (0.8 to 21.0)	
5-11 yrs, ST6: Month 39 (n=25, 11, 20)	92.0 (75.0 to 97.8)	100 (74.1 to 100)	5.0 (0.9 to 23.6)	
5-11 yrs, ST6: Month 42 (n=21, 13, 17)	90.5 (71.1 to 97.3)	76.9 (49.7 to 91.8)	5.9 (1.0 to 27.0)	
5-11 yrs, ST6: Month 43 (n=26, 17, 18)	100 (87.1 to 100)	100 (81.6 to 100)	5.6 (1.0 to 25.8)	

5-11 yrs, ST6: Month 48 (n=20, 14, 15)	100 (83.9 to 100)	92.9 (68.5 to 98.7)	0.0 (0.0 to 20.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: GMFR for IgG Against Each OspA Serotype (ST1 to ST6) Stratified by Age Group at M18-M19, M30-M31, M42-M43 During the Booster Phase

End point title	GMFR for IgG Against Each OspA Serotype (ST1 to ST6) Stratified by Age Group at M18-M19, M30-M31, M42-M43 During the Booster Phase

End point description:

GMFRs for IgG were determined by IgG binding assay for each OspA serotype (ST1–ST6), stratified by age group (5-11, 12-17 & 18-65 yrs) at Months 19, 31, and 43 relative to the corresponding pre-booster timepoints (Months 18, 30, and 42, respectively). PPAS consisted of the FAS population excluding those participants with at least one relevant protocol deviation (i.e., a protocol deviation with possible impact on immunogenicity). All participants reported under 'Subjects Analyzed' contributed data to the table but may not have evaluable data for every row. Here, "n" signifies participants with available results for each serotype at specified time points.

End point type	Secondary

End point timeframe:

At Months 19, 31 and 43

End point values	Group 1: VLA15	Group 2: VLA15 + Placebo	Group 3: Placebo	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	176	162	175	
Units: Fold rise				
geometric mean (confidence interval 95%)				
18-65 yrs, ST1: Month 19 (n=72, 65, 67)	32.2 (24.1 to 42.9)	23.4 (16.8 to 32.5)	1.0 (1.0 to 1.0)	
18-65 yrs, ST1: Month 31 (n=66, 55, 53)	18.5 (14.1 to 24.4)	15.1 (11.6 to 19.5)	1.0 (1.0 to 1.0)	
18-65 yrs, ST1: Month 43 (n=63, 53, 54)	12.6 (10.2 to 15.4)	11.1 (8.5 to 14.5)	1.1 (0.9 to 1.3)	
18-65 yrs, ST2: Month 19 (n=72, 65, 67)	48.3 (38.1 to 61.2)	48.5 (36.6 to 64.3)	1.0 (1.0 to 1.0)	
18-65 yrs, ST2: Month 31 (n=66, 55, 53)	16.4 (13.1 to 20.6)	14.5 (11.7 to 18.0)	1.0 (1.0 to 1.0)	
18-65 yrs, ST2: Month 43 (n=63, 53, 54)	12.1 (9.8 to 14.9)	11.7 (8.6 to 15.8)	1.1 (0.9 to 1.3)	
18-65 yrs, ST3: Month 19 (n=72, 65, 67)	44.9 (34.8 to 57.9)	39.5 (30.4 to 51.5)	1.0 (1.0 to 1.0)	
18-65 yrs, ST3: Month 31 (n=66, 55, 53)	17.0 (13.4 to 21.5)	13.1 (10.7 to 15.9)	1.0 (1.0 to 1.0)	
18-65 yrs, ST3: Month 43 (n=63, 53, 54)	11.5 (9.6 to 13.8)	9.5 (7.3 to 12.2)	1.1 (0.9 to 1.3)	
18-65 yrs, ST4: Month 19 (n=72, 65, 67)	36.0 (27.7 to 46.9)	29.8 (21.8 to 40.9)	1.0 (1.0 to 1.0)	

18-65 yrs, ST4: Month 31 (n=66, 55, 53)	17.9 (14.0 to 22.8)	15.7 (12.4 to 19.9)	1.0 (1.0 to 1.1)	
18-65 yrs, ST4: Month 43 (n=63, 53, 54)	13.0 (10.5 to 16.1)	10.8 (8.3 to 14.0)	1.1 (0.9 to 1.3)	
18-65 yrs, ST5: Month 19 (n=72, 65, 67)	37.0 (28.0 to 48.8)	29.6 (21.6 to 40.5)	1.0 (1.0 to 1.0)	
18-65 yrs, ST5: Month 31 (n=66, 55, 53)	19.2 (15.0 to 24.6)	14.2 (11.4 to 17.7)	1.0 (1.0 to 1.0)	
18-65 yrs, ST5: Month 43 (n=63, 53, 54)	13.4 (10.9 to 16.4)	10.3 (8.0 to 13.4)	1.1 (0.9 to 1.3)	
18-65 yrs, ST6: Month 19 (n=72, 65, 67)	32.6 (25.3 to 42.1)	28.3 (20.3 to 39.5)	1.0 (1.0 to 1.1)	
18-65 yrs, ST6: Month 31 (n=66, 55, 53)	18.2 (14.3 to 23.2)	12.9 (10.3 to 16.0)	1.0 (1.0 to 1.1)	
18-65 yrs, ST6: Month 43 (n=63, 53, 54)	11.8 (9.7 to 14.4)	10.4 (8.0 to 13.5)	1.1 (0.9 to 1.3)	
12-17 yrs, ST1: Month 19 (n=27, 26, 26)	43.4 (25.8 to 73.0)	78.4 (46.7 to 131.5)	1.0 (1.0 to 1.0)	
12-17 yrs, ST1: Month 31 (n=20, 21, 21)	25.7 (14.3 to 46.0)	29.8 (18.2 to 49.0)	0.9 (0.8 to 1.1)	
12-17 yrs, ST1: Month 43 (n=23, 21, 16)	12.4 (8.0 to 19.2)	18.1 (11.2 to 29.1)	1.1 (0.9 to 1.3)	
12-17 yrs, ST2: Month 19 (n=27, 26, 26)	46.2 (27.8 to 76.7)	73.9 (47.0 to 116.3)	1.0 (1.0 to 1.0)	
12-17 yrs, ST2: Month 31 (n=20, 21, 21)	19.8 (11.0 to 35.5)	16.8 (12.0 to 23.6)	1.0 (1.0 to 1.1)	
12-17 yrs, ST2: Month 43 (n=23, 21, 16)	10.3 (6.8 to 15.8)	14.4 (8.8 to 23.4)	1.0 (1.0 to 1.0)	
12-17 yrs, ST3: Month 19 (n=27, 26, 26)	45.0 (27.3 to 74.2)	70.6 (43.7 to 113.9)	1.1 (1.0 to 1.2)	
12-17 yrs, ST3: Month 31 (n=20, 21, 21)	18.5 (10.2 to 33.4)	16.7 (12.6 to 22.3)	1.0 (0.8 to 1.2)	
12-17 yrs, ST3: Month 43 (n=23, 21, 16)	10.8 (7.3 to 15.9)	12.8 (8.1 to 20.0)	1.1 (0.9 to 1.2)	
12-17 yrs, ST4: Month 19 (n=27, 26, 26)	42.4 (26.0 to 69.0)	68.1 (41.8 to 110.9)	1.1 (1.0 to 1.2)	
12-17 yrs, ST4: Month 31 (n=20, 21, 21)	22.2 (12.7 to 38.6)	22.7 (14.8 to 34.9)	1.1 (0.9 to 1.2)	
12-17 yrs, ST4: Month 43 (n=23, 21, 16)	13.3 (8.8 to 19.9)	15.1 (9.3 to 24.8)	1.2 (0.9 to 1.5)	
12-17 yrs, ST5: Month 19 (n=27, 26, 26)	40.0 (24.5 to 65.3)	71.8 (43.9 to 117.4)	1.0 (1.0 to 1.1)	
12-17 yrs, ST5: Month 31 (n=20, 21, 21)	21.1 (11.8 to 37.9)	23.5 (15.1 to 36.5)	1.2 (0.9 to 1.4)	
12-17 yrs, ST5: Month 43 (n=23, 21, 16)	11.2 (7.4 to 17.1)	16.3 (10.4 to 25.6)	1.1 (0.9 to 1.3)	
12-17 yrs, ST6: Month 19 (n=27, 26, 26)	39.1 (24.0 to 63.9)	59.1 (37.0 to 94.3)	1.1 (0.9 to 1.2)	
12-17 yrs, ST6: Month 31 (n=20, 21, 21)	21.8 (12.5 to 38.0)	23.9 (15.6 to 36.5)	0.9 (0.8 to 1.1)	
12-17 yrs, ST6: Month 43 (n=23, 21, 16)	10.0 (6.7 to 15.1)	14.4 (8.8 to 23.6)	1.1 (0.9 to 1.2)	
5-11 yrs, ST1: Month 19 (n=28, 19, 30)	54.0 (35.4 to 82.5)	58.7 (27.2 to 126.5)	1.0 (1.0 to 1.0)	
5-11 yrs, ST1: Month 31 (n=27, 21, 22)	17.4 (8.1 to 37.4)	23.0 (10.3 to 51.3)	1.2 (0.8 to 2.0)	
5-11 yrs, ST1: Month 43 (n=25, 16, 17)	16.5 (11.6 to 23.3)	24.3 (14.6 to 40.7)	0.9 (0.7 to 1.1)	
5-11 yrs, ST2: Month 19 (n=27, 19, 30)	63.1 (39.7 to 100.3)	49.0 (20.7 to 115.7)	1.0 (1.0 to 1.0)	
5-11 yrs, ST2: Month 31 (n=27, 21, 22)	13.4 (6.7 to 27.1)	18.9 (9.2 to 39.2)	1.3 (0.8 to 2.0)	

5-11 yrs, ST2: Month 43 (n=25, 16, 17)	14.3 (9.8 to 20.8)	20.4 (11.6 to 35.8)	0.9 (0.7 to 1.2)	
5-11 yrs, ST3: Month 19 (n=28, 19, 30)	53.8 (33.9 to 85.4)	37.4 (17.0 to 82.7)	1.1 (1.0 to 1.2)	
5-11 yrs, ST3: Month 31 (n=27, 21, 22)	14.6 (7.1 to 30.4)	14.4 (6.7 to 30.9)	1.2 (0.7 to 2.0)	
5-11 yrs, ST3: Month 43 (n=25, 16, 17)	12.6 (8.6 to 18.4)	20.1 (11.3 to 35.8)	1.0 (0.8 to 1.3)	
5-11 yrs, ST4: Month 19 (n=28, 19, 30)	49.8 (30.6 to 81.1)	59.6 (26.6 to 133.7)	1.1 (1.0 to 1.2)	
5-11 yrs, ST4: Month 31 (n=27, 21, 22)	16.2 (7.8 to 33.7)	21.0 (10.2 to 43.1)	1.2 (0.8 to 2.0)	
5-11 yrs, ST4: Month 43 (n=25, 16, 17)	13.2 (9.2 to 19.0)	26.0 (15.0 to 45.3)	0.9 (0.7 to 1.1)	
5-11 yrs, ST5: Month 19 (n=27, 19, 30)	57.1 (36.2 to 90.3)	54.0 (24.9 to 117.3)	1.0 (1.0 to 1.0)	
5-11 yrs, ST5: Month 31 (n=27, 21, 22)	15.3 (7.4 to 31.7)	17.4 (8.6 to 35.0)	1.3 (0.8 to 2.1)	
5-11 yrs, ST5: Month 43 (n=25, 16, 17)	13.8 (10.1 to 18.9)	21.5 (12.7 to 36.6)	1.0 (1.0 to 1.0)	
5-11 yrs, ST6: Month 19 (n=28, 19, 30)	49.8 (29.4 to 84.6)	52.0 (24.6 to 110.0)	1.1 (1.0 to 1.3)	
5-11 yrs, ST6: Month 31 (n=27, 21, 22)	16.1 (7.8 to 33.0)	16.1 (8.1 to 31.9)	1.4 (0.8 to 2.2)	
5-11 yrs, ST6: Month 43 (n=25, 16, 17)	14.9 (10.8 to 20.5)	23.4 (14.1 to 39.0)	1.0 (0.8 to 1.2)	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Systematic assessment(SA): solicited AEs were assessed for up to 7 Days after each vaccination;non-SA: unsolicited AEs were assessed for up to 28 Days after each vaccination,all-cause mortality,SAEs and AESIs were assessed up to Month 48 after vaccination

Adverse event reporting additional description:

Same event may appear as both non-SAE and SAE but are distinct events. An event may be categorized as serious in 1 participant and non-serious in another, or a participant may have experienced both SAE and non-SAE. SAS include all participants who entered into the study and received at least one vaccination.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	28.1

Reporting groups

Reporting group title	Group 2: VLA15 + Placebo

Reporting group description:

Participants aged 5 to 65 years received two IM vaccinations of 180 mcg VLA15 at Months 0 and 6 and a placebo injection at Month 2 during the Main Study Phase and received three IM vaccinations of 180 mcg VLA15 at Months 18, 30 and 42 during the Booster Phase.

Reporting group title	Group 3: Placebo

Reporting group description:

Participants aged 5 to 65 years received three IM injections of placebo at Months 0, 2 and 6 during the Main Study Phase and received three IM injections of placebo at Months 18, 30 and 42 during the Booster Phase.

Reporting group title	Group 1: VLA15

Reporting group description:

Participants aged 5 to 65 years received three IM vaccinations of 180 mcg VLA15 at Months 0, 2 and 6 during the Main Study Phase and received three intramuscular vaccinations of 180 mcg VLA15 at Months 18, 30 and 42 during the Booster Phase.

Reporting group title	All Participants

Reporting group description:

Participants aged 5 to 65 years who received either IM vaccination of 180 mcg VLA15 or placebo injections during the Main Study Phase were included. This arm also included participants who received wrong vaccination or missed a vaccination.

Reporting group title	Received any VLA15

Reporting group description:

Participants aged 5 to 65 years who received IM vaccination of 180 mcg VLA15 or placebo injections, but could not be assigned to Group 1, 2 or 3 as participants received wrong vaccination or missed a vaccination.

Serious adverse events	Group 2: VLA15 + Placebo	Group 3: Placebo	Group 1: VLA15
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 112 (3.57%)	14 / 206 (6.80%)	0 / 127 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Prostate cancer			
subjects affected / exposed	0 / 112 (0.00%)	2 / 206 (0.97%)	0 / 127 (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
Papillary thyroid cancer			
subjects affected / exposed	0 / 112 (0.00%)	0 / 206 (0.00%)	0 / 127 (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
Breast cancer stage II			
subjects affected / exposed	0 / 112 (0.00%)	1 / 206 (0.49%)	0 / 127 (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
Prostate cancer recurrent			
subjects affected / exposed	0 / 112 (0.00%)	1 / 206 (0.49%)	0 / 127 (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
Breast cancer			
subjects affected / exposed	0 / 112 (0.00%)	0 / 206 (0.00%)	0 / 127 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	0 / 112 (0.00%)	1 / 206 (0.49%)	0 / 127 (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
Concussion			
subjects affected / exposed	1 / 112 (0.89%)	0 / 206 (0.00%)	0 / 127 (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
Jaw fracture			
subjects affected / exposed	0 / 112 (0.00%)	0 / 206 (0.00%)	0 / 127 (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

Wrist fracture			
subjects affected / exposed	0 / 112 (0.00%)	1 / 206 (0.49%)	0 / 127 (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
Tibia fracture			
subjects affected / exposed	0 / 112 (0.00%)	1 / 206 (0.49%)	0 / 127 (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
Road traffic accident			
subjects affected / exposed	0 / 112 (0.00%)	1 / 206 (0.49%)	0 / 127 (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
Procedural pain			
subjects affected / exposed	1 / 112 (0.89%)	0 / 206 (0.00%)	0 / 127 (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
Congenital, familial and genetic disorders			
Klinefelter's syndrome			
subjects affected / exposed	0 / 112 (0.00%)	0 / 206 (0.00%)	0 / 127 (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			
Pericarditis			
subjects affected / exposed	0 / 112 (0.00%)	0 / 206 (0.00%)	0 / 127 (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
Acute coronary syndrome			
subjects affected / exposed	0 / 112 (0.00%)	1 / 206 (0.49%)	0 / 127 (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
Ventricular fibrillation			
subjects affected / exposed	0 / 112 (0.00%)	0 / 206 (0.00%)	0 / 127 (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			
Lumbar radiculopathy			
subjects affected / exposed	1 / 112 (0.89%)	0 / 206 (0.00%)	0 / 127 (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
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 112 (0.00%)	1 / 206 (0.49%)	0 / 127 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Tooth loss			
subjects affected / exposed	0 / 112 (0.00%)	0 / 206 (0.00%)	0 / 127 (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			
Suicidal ideation			
subjects affected / exposed	0 / 112 (0.00%)	1 / 206 (0.49%)	0 / 127 (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
Major depression			
subjects affected / exposed	1 / 112 (0.89%)	0 / 206 (0.00%)	0 / 127 (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
Reactive attachment disorder			
subjects affected / exposed	0 / 112 (0.00%)	1 / 206 (0.49%)	0 / 127 (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
Emotional distress			
subjects affected / exposed	0 / 112 (0.00%)	0 / 206 (0.00%)	0 / 127 (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			
Cellulitis			

subjects affected / exposed	0 / 112 (0.00%)	1 / 206 (0.49%)	0 / 127 (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
Appendicitis			
subjects affected / exposed	0 / 112 (0.00%)	1 / 206 (0.49%)	0 / 127 (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
Groin abscess			
subjects affected / exposed	0 / 112 (0.00%)	1 / 206 (0.49%)	0 / 127 (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
Metabolism and nutrition disorders			
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 112 (0.00%)	0 / 206 (0.00%)	0 / 127 (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	All Participants	Received any VLA15	
Total subjects affected by serious adverse events			
subjects affected / exposed	28 / 625 (4.48%)	14 / 419 (3.34%)	
number of deaths (all causes)	1	1	
number of deaths resulting from adverse events	1	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate cancer			
subjects affected / exposed	2 / 625 (0.32%)	0 / 419 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papillary thyroid cancer			
subjects affected / exposed	1 / 625 (0.16%)	1 / 419 (0.24%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer stage II			

subjects affected / exposed	1 / 625 (0.16%)	0 / 419 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer recurrent			
subjects affected / exposed	1 / 625 (0.16%)	0 / 419 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	1 / 625 (0.16%)	1 / 419 (0.24%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	2 / 625 (0.32%)	1 / 419 (0.24%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 1	
Concussion			
subjects affected / exposed	1 / 625 (0.16%)	1 / 419 (0.24%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaw fracture			
subjects affected / exposed	1 / 625 (0.16%)	1 / 419 (0.24%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist fracture			
subjects affected / exposed	1 / 625 (0.16%)	0 / 419 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	1 / 625 (0.16%)	0 / 419 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			

subjects affected / exposed	1 / 625 (0.16%)	0 / 419 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Procedural pain			
subjects affected / exposed	1 / 625 (0.16%)	1 / 419 (0.24%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Klinefelter's syndrome			
subjects affected / exposed	1 / 625 (0.16%)	1 / 419 (0.24%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Pericarditis			
subjects affected / exposed	1 / 625 (0.16%)	1 / 419 (0.24%)	
occurrences causally related to treatment / all	0 / 4	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute coronary syndrome			
subjects affected / exposed	1 / 625 (0.16%)	0 / 419 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	1 / 625 (0.16%)	1 / 419 (0.24%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Lumbar radiculopathy			
subjects affected / exposed	1 / 625 (0.16%)	1 / 419 (0.24%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic reaction			

subjects affected / exposed	1 / 625 (0.16%)	0 / 419 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Tooth loss			
subjects affected / exposed	1 / 625 (0.16%)	1 / 419 (0.24%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Suicidal ideation			
subjects affected / exposed	2 / 625 (0.32%)	1 / 419 (0.24%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			
subjects affected / exposed	1 / 625 (0.16%)	1 / 419 (0.24%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reactive attachment disorder			
subjects affected / exposed	1 / 625 (0.16%)	0 / 419 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Emotional distress			
subjects affected / exposed	1 / 625 (0.16%)	1 / 419 (0.24%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Cellulitis			
subjects affected / exposed	1 / 625 (0.16%)	0 / 419 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	1 / 625 (0.16%)	0 / 419 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Groin abscess			
subjects affected / exposed	1 / 625 (0.16%)	0 / 419 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Type 1 diabetes mellitus			
subjects affected / exposed	2 / 625 (0.32%)	2 / 419 (0.48%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Group 2: VLA15 + Placebo	Group 3: Placebo	Group 1: VLA15
Total subjects affected by non-serious adverse events			
subjects affected / exposed	111 / 112 (99.11%)	145 / 206 (70.39%)	124 / 127 (97.64%)
Nervous system disorders			
Headache			
subjects affected / exposed	51 / 112 (45.54%)	81 / 206 (39.32%)	75 / 127 (59.06%)
occurrences (all)	103	139	151
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	110 / 112 (98.21%)	80 / 206 (38.83%)	122 / 127 (96.06%)
occurrences (all)	741	213	999
Injection site swelling			
subjects affected / exposed	46 / 112 (41.07%)	18 / 206 (8.74%)	70 / 127 (55.12%)
occurrences (all)	81	27	147
Injection site induration			
subjects affected / exposed	46 / 112 (41.07%)	16 / 206 (7.77%)	62 / 127 (48.82%)
occurrences (all)	80	21	126
Pyrexia			
subjects affected / exposed	4 / 112 (3.57%)	7 / 206 (3.40%)	11 / 127 (8.66%)
occurrences (all)	4	8	11
Fatigue			
subjects affected / exposed	53 / 112 (47.32%)	64 / 206 (31.07%)	59 / 127 (46.46%)
occurrences (all)	100	104	116
Injection site erythema			

subjects affected / exposed	45 / 112 (40.18%)	23 / 206 (11.17%)	73 / 127 (57.48%)
occurrences (all)	90	34	162
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	23 / 112 (20.54%)	28 / 206 (13.59%)	21 / 127 (16.54%)
occurrences (all)	26	38	25
Vomiting			
subjects affected / exposed	6 / 112 (5.36%)	3 / 206 (1.46%)	4 / 127 (3.15%)
occurrences (all)	6	3	5
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	71 / 112 (63.39%)	50 / 206 (24.27%)	81 / 127 (63.78%)
occurrences (all)	166	68	197
Arthralgia			
subjects affected / exposed	12 / 112 (10.71%)	22 / 206 (10.68%)	36 / 127 (28.35%)
occurrences (all)	18	30	55
Infections and infestations			
COVID-19			
subjects affected / exposed	7 / 112 (6.25%)	2 / 206 (0.97%)	3 / 127 (2.36%)
occurrences (all)	7	2	3

Non-serious adverse events	All Participants	Received any VLA15	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	548 / 625 (87.68%)	403 / 419 (96.18%)	
Nervous system disorders			
Headache			
subjects affected / exposed	277 / 625 (44.32%)	196 / 419 (46.78%)	
occurrences (all)	499	360	
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	476 / 625 (76.16%)	396 / 419 (94.51%)	
occurrences (all)	2660	2447	
Injection site swelling			
subjects affected / exposed	199 / 625 (31.84%)	181 / 419 (43.20%)	
occurrences (all)	350	323	
Injection site induration			

subjects affected / exposed	190 / 625 (30.40%)	174 / 419 (41.53%)	
occurrences (all)	330	309	
Pyrexia			
subjects affected / exposed	27 / 625 (4.32%)	20 / 419 (4.77%)	
occurrences (all)	28	20	
Fatigue			
subjects affected / exposed	236 / 625 (37.76%)	172 / 419 (41.05%)	
occurrences (all)	417	313	
Injection site erythema			
subjects affected / exposed	215 / 625 (34.40%)	192 / 419 (45.82%)	
occurrences (all)	408	374	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	99 / 625 (15.84%)	71 / 419 (16.95%)	
occurrences (all)	125	87	
Vomiting			
subjects affected / exposed	23 / 625 (3.68%)	20 / 419 (4.77%)	
occurrences (all)	24	21	
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	288 / 625 (46.08%)	238 / 419 (56.80%)	
occurrences (all)	588	520	
Arthralgia			
subjects affected / exposed	100 / 625 (16.00%)	78 / 419 (18.62%)	
occurrences (all)	142	112	
Infections and infestations			
COVID-19			
subjects affected / exposed	15 / 625 (2.40%)	13 / 419 (3.10%)	
occurrences (all)	15	13	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported