



Clinical trial results:

A staged Phase I/II observer-blind, randomised, controlled, multi-country study to evaluate the safety, reactogenicity, and immune responses to the GVGH altSonflex1-2-3 vaccine against *S. sonnei* and *S. flexneri*, serotypes 1b, 2a, and 3a, in adults in Europe (Stage 1) followed by age de-escalation from adults to children and infants, and dose-finding in infants in Africa (Stage 2)

Summary

EudraCT number	2021-000891-12
Trial protocol	BE
Global end of trial date	24 June 2025

Results information

Result version number	v1 (current)
This version publication date	07 January 2026
First version publication date	07 January 2026

Trial information

Trial identification

Sponsor protocol code	212149
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05073003
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	79 New Oxford Street, London, WC1A 1DG, United Kingdom, TW8 9GS
Public contact	GSK Response Center, GlaxoSmithKline, 44 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 44 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	
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	24 July 2025
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	24 June 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim of the current clinical study is to evaluate, for the first time in humans (FTIH), the safety and immunogenicity of the altSonflex1-2-3 candidate vaccine against *S. sonnei* and *S. flexneri* serotypes 1b, 2a, and 3a.

Protection of trial subjects:

Participants will be closely monitored for any symptoms of anaphylaxis. Medical treatment will be readily available in case of anaphylactic reactions following vaccine/control/placebo administration. Safe blood sampling procedures will be applied by appropriately trained and qualified staff to minimise distress and sampling errors

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 October 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	Kenya: 449
Country: Number of subjects enrolled	Belgium: 102
Worldwide total number of subjects	551
EEA total number of subjects	102

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)	389
Children (2-11 years)	40
Adolescents (12-17 years)	0
Adults (18-64 years)	122
From 65 to 84 years	0

85 years and over	0
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Subject disposition

Recruitment

Recruitment details:

Out of 551 participants enrolled, 550 started the study and were included in the Exposed set.

Pre-assignment

Screening details:

As pre-specified in the Statistical Analysis Plan (SAP), the participants that received placebo in Stage 1 were pooled for all analyses (demography, immunogenicity and safety).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Stage 1 Adults: altSonflex1-2-3 High Dose Group 1

Arm description:

European participants 18-50 years of age were randomized to receive a high dose of altSonflex1-2-3 on Day 1 and Day 85.

Arm type	Experimental
Investigational medicinal product name	AltSonflex1-2-3 High Dose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 doses in adults 18-50 years of age and children 24-59 months of age, 3 doses in infants 9 months of age

Arm title	Stage 1 Adults: altSonflex1-2-3 High Dose Group 2
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Arm description:

European participants 18-50 years of age were randomized to receive a high dose of altSonflex1-2-3 on Day 1 and Day 169.

Arm type	Experimental
Investigational medicinal product name	AltSonflex1-2-3 High Dose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 doses in adults 18-50 years of age and children 24-59 months of age, 3 doses in infants 9 months of age

Arm title	Stage 1 Adults: Placebo Group
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Arm description:

European participants 18-50 years of age were randomized to receive 1 dose of Placebo on Day 1 and on Day 85 or 169. All participants in Step 1 that received placebo were pooled, as pre-specified in Statistical Analysis Plan.

Arm type	Placebo
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Investigational medicinal product name	altSonflex Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
2 doses in adults 18-50 years of age (stage 1)	
Arm title	Stage 2 Adults: altSonflex1-2-3 High Dose
Arm description:	
African participants 18-50 years of age were randomized to receive a high dose of altSonflex1-2-3 on Day 1 and Day 85.	
Arm type	Experimental
Investigational medicinal product name	AltSonflex1-2-3 High Dose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
2 doses in adults 18-50 years of age and children 24-59 months of age, 3 doses in infants 9 months of age	
Arm title	Stage 2 Adults: Control
Arm description:	
African participants 18-50 years of age were randomized to receive 1 dose of MENVEO as comparator on Day 1 and 1 dose of BOOSTRIX as comparator Day 85.	
Arm type	Active comparator
Investigational medicinal product name	Boostrix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
1 dose in adults 18-50 years of age (stage 2)	
Investigational medicinal product name	Menveo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
1 dose in adults 18-50 years of age (stage 2) and children 24-59 months of age and 2 doses in infants 9 months of age	
Arm title	Stage 2 Children: altSonflex1-2-3 Medium Dose
Arm description:	
African participants 24-59 months of age were randomized to receive a medium dose of altSonflex1-2-3 on Day 1 and Day 85.	
Arm type	Experimental
Investigational medicinal product name	AltSonflex1-2-3 Medium Dose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
2 doses in children 24-59 months of age, 3 doses in infants 9 months of age	

Arm title	Stage 2 Children: altSonflex1-2-3 High Dose
Arm description: African participants 24-59 months of age were randomized to receive a high dose of altSonflex1-2-3 on Day 1 and Day 85.	
Arm type	Experimental
Investigational medicinal product name	AltSonflex1-2-3 High Dose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: 2 doses in adults 18-50 years of age and children 24-59 months of age, 3 doses in infants 9 months of age	
Arm title	Stage 2 Children: Control
Arm description: African participants 24-59 months of age were randomized to receive 1 dose of MENVEO as comparator on Day 1 and 1 dose of TYPHIM VI as comparator on Day 85.	
Arm type	Active comparator
Investigational medicinal product name	Typhim-Vi
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: 1 dose in children 24-59 months of age	
Investigational medicinal product name	Menveo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: 1 dose in adults 18-50 years of age (stage 2) and children 24-59 months of age and 2 doses in infants 9 months of age	
Arm title	Stage 2 Infants safety cohort: altSonflex1-2-3 Low Dose
Arm description: African participants 9 months of age were randomized to receive a low dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. The measles-rubella vaccine (MR-VAC) was administered on Day 29 and Day 281.	
Arm type	Experimental
Investigational medicinal product name	MR-Vac
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: 2 doses in children 24-59 months of age	
Investigational medicinal product name	AltSonflex1-2-3 Low Dose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: 3 doses in infants 9 months of age	

Arm title	Stage 2 Infants safety cohort: altSonflex1-2-3 Medium Dose
Arm description: African participants 9 months of age were randomized to receive a medium dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. MR-VAC was administered on Day 29 and Day 281.	
Arm type	Experimental
Investigational medicinal product name	MR-Vac
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: 2 doses in infants 9 months of age	
Investigational medicinal product name	AltSonflex1-2-3 Medium Dose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: 2 doses in children 24-59 months of age, 3 doses in infants 9 months of age	
Arm title	Stage 2 Infants safety cohort: altSonflex1-2-3 High Dose
Arm description: African participants 9 months of age were randomized to receive a high dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. MR-VAC was administered on Day 29 and Day 281.	
Arm type	Experimental
Investigational medicinal product name	AltSonflex1-2-3 High Dose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: 2 doses in adults 18-50 years of age and children 24-59 months of age, 3 doses in infants 9 months of age	
Investigational medicinal product name	MR-Vac
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: 2 doses in infants 9 months of age	
Arm title	Stage 2 Infants safety cohort: Control
Arm description: African participants 9 months of age were randomized to receive a dose of MENVEO as comparator on Day 1 and Day 85 and INFRANRIX HEXA as comparator on Day 253. MR-VAC was administered on Day 29 and Day 281.	
Arm type	Active comparator
Investigational medicinal product name	Menveo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: 1 dose in adults 18-50 years of age (stage 2) and children 24-59 months of age and 2 doses in infants 9 months of age	

Investigational medicinal product name	MR-Vac
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: 2 doses in infants 9 months of age	
Investigational medicinal product name	INFANRIX HEXA
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: 1 dose in infants 9 months of age	
Arm title	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose
Arm description: African participants 9 months of age were randomized to receive a low dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. MR-VAC was co-administered on Day 1 and Day 253. This cohort was created to identify the preferred dose among low, medium and high doses.	
Arm type	Experimental
Investigational medicinal product name	MR-Vac
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: 2 doses in infants 9 months of age	
Investigational medicinal product name	AltSonflex1-2-3 Low Dose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: 3 doses in infants 9 months of age	
Arm title	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Med Dose
Arm description: African participants 9 months of age were randomized to receive a medium (Med) dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. MR-VAC was co-administered on Day 1 and Day 253. This cohort was created to identify the preferred dose among low, medium and high doses.	
Arm type	Experimental
Investigational medicinal product name	MR-Vac
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: 2 doses in infants 9 months of age	
Investigational medicinal product name	AltSonflex1-2-3 Medium Dose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 doses in children 24-59 months of age, 3 doses in infants 9 months of age

Arm title	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose
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Arm description:

African participants 9 months of age were randomized to receive a high dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. MR-VAC was co-administered on Day 1 and Day 253. This cohort was created to identify the preferred dose among low, medium and high doses.

Arm type	Experimental
Investigational medicinal product name	MR-Vac
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

2 doses in infants 9 months of age

Investigational medicinal product name	AltSonflex1-2-3 High Dose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 doses in adults 18-50 years of age and children 24-59 months of age, 3 doses in infants 9 months of age

Arm title	Stage 2 Infants dose-finding cohort: Control
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Arm description:

African participants 9 months of age were randomized to receive a dose of MENVEO as comparator on Day 1 and Day 85 and INFRANRIX HEXA as comparator on Day 253. MR-VAC was co-administered on Day 1 and Day 253. This cohort was created to identify the preferred dose among low, medium and high doses.

Arm type	Active comparator
Investigational medicinal product name	Menveo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose in adults 18-50 years of age (stage 2) and children 24-59 months of age and 2 doses in infants 9 months of age

Investigational medicinal product name	INFANRIX HEXA
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose in infants 9 months of age

Investigational medicinal product name	MR-Vac
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:
2 doses in infants 9 months of age

Number of subjects in period 1 ^[1]	Stage 1 Adults: altSonflex1-2-3 High Dose Group 1	Stage 1 Adults: altSonflex1-2-3 High Dose Group 2	Stage 1 Adults: Placebo Group
Started	34	34	34
Completed	29	34	28
Not completed	5	0	6
Migrated / moved from the study area	-	-	-
Not Specified	2	-	4
Consent withdrawal, not due to an (S)AE	1	-	-
Lost to follow-up	-	-	-
Adverse Events (including death)	2	-	2

Number of subjects in period 1 ^[1]	Stage 2 Adults: altSonflex1-2-3 High Dose	Stage 2 Adults: Control	Stage 2 Children: altSonflex1-2-3 Medium Dose
Started	10	10	10
Completed	10	10	10
Not completed	0	0	0
Migrated / moved from the study area	-	-	-
Not Specified	-	-	-
Consent withdrawal, not due to an (S)AE	-	-	-
Lost to follow-up	-	-	-
Adverse Events (including death)	-	-	-

Number of subjects in period 1 ^[1]	Stage 2 Children: altSonflex1-2-3 High Dose	Stage 2 Children: Control	Stage 2 Infants safety cohort: altSonflex1-2-3 Low Dose
Started	10	20	10
Completed	10	20	9
Not completed	0	0	1
Migrated / moved from the study area	-	-	-
Not Specified	-	-	1
Consent withdrawal, not due to an (S)AE	-	-	-
Lost to follow-up	-	-	-
Adverse Events (including death)	-	-	-

Number of subjects in period 1^[1]	Stage 2 Infants safety cohort: altSonflex1-2-3 Medium Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 High Dose	Stage 2 Infants safety cohort: Control
Started	10	10	30
Completed	8	10	27
Not completed	2	0	3
Migrated / moved from the study area	1	-	1
Not Specified	-	-	-
Consent withdrawal, not due to an (S)AE	1	-	2
Lost to follow-up	-	-	-
Adverse Events (including death)	-	-	-

Number of subjects in period 1^[1]	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Med Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose
Started	82	81	83
Completed	69	71	73
Not completed	13	10	10
Migrated / moved from the study area	2	2	2
Not Specified	1	-	1
Consent withdrawal, not due to an (S)AE	9	4	5
Lost to follow-up	1	3	2
Adverse Events (including death)	-	1	-

Number of subjects in period 1^[1]	Stage 2 Infants dose-finding cohort: Control
Started	82
Completed	71
Not completed	11
Migrated / moved from the study area	-
Not Specified	1
Consent withdrawal, not due to an (S)AE	5
Lost to follow-up	5
Adverse Events (including death)	-

Notes:

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

Justification: Out of 551 participants enrolled, 550 started the study and were included in the Exposed set.

Baseline characteristics

Reporting groups

Reporting group title	Stage 1 Adults: altSonflex1-2-3 High Dose Group 1
Reporting group description: European participants 18-50 years of age were randomized to receive a high dose of altSonflex1-2-3 on Day 1 and Day 85.	
Reporting group title	Stage 1 Adults: altSonflex1-2-3 High Dose Group 2
Reporting group description: European participants 18-50 years of age were randomized to receive a high dose of altSonflex1-2-3 on Day 1 and Day 169.	
Reporting group title	Stage 1 Adults: Placebo Group
Reporting group description: European participants 18-50 years of age were randomized to receive 1 dose of Placebo on Day 1 and on Day 85 or 169. All participants in Step 1 that received placebo were pooled, as pre-specified in Statistical Analysis Plan.	
Reporting group title	Stage 2 Adults: altSonflex1-2-3 High Dose
Reporting group description: African participants 18-50 years of age were randomized to receive a high dose of altSonflex1-2-3 on Day 1 and Day 85.	
Reporting group title	Stage 2 Adults: Control
Reporting group description: African participants 18-50 years of age were randomized to receive 1 dose of MENVEO as comparator on Day 1 and 1 dose of BOOSTRIX as comparator Day 85.	
Reporting group title	Stage 2 Children: altSonflex1-2-3 Medium Dose
Reporting group description: African participants 24-59 months of age were randomized to receive a medium dose of altSonflex1-2-3 on Day 1 and Day 85.	
Reporting group title	Stage 2 Children: altSonflex1-2-3 High Dose
Reporting group description: African participants 24-59 months of age were randomized to receive a high dose of altSonflex1-2-3 on Day 1 and Day 85.	
Reporting group title	Stage 2 Children: Control
Reporting group description: African participants 24-59 months of age were randomized to receive 1 dose of MENVEO as comparator on Day 1 and 1 dose of TYPHIM VI as comparator on Day 85.	
Reporting group title	Stage 2 Infants safety cohort: altSonflex1-2-3 Low Dose
Reporting group description: African participants 9 months of age were randomized to receive a low dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. The measles-rubella vaccine (MR-VAC) was administered on Day 29 and Day 281.	
Reporting group title	Stage 2 Infants safety cohort: altSonflex1-2-3 Medium Dose
Reporting group description: African participants 9 months of age were randomized to receive a medium dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. MR-VAC was administered on Day 29 and Day 281.	
Reporting group title	Stage 2 Infants safety cohort: altSonflex1-2-3 High Dose
Reporting group description: African participants 9 months of age were randomized to receive a high dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. MR-VAC was administered on Day 29 and Day 281.	
Reporting group title	Stage 2 Infants safety cohort: Control
Reporting group description: African participants 9 months of age were randomized to receive a dose of MENVEO as comparator on Day 1 and Day 85 and INFRANRIX HEXA as comparator on Day 253. MR-VAC was administered on Day 29 and Day 281.	
Reporting group title	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose

Reporting group description:

African participants 9 months of age were randomized to receive a low dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. MR-VAC was co-administered on Day 1 and Day 253. This cohort was created to identify the preferred dose among low, medium and high doses.

Reporting group title	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Med Dose
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Reporting group description:

African participants 9 months of age were randomized to receive a medium (Med) dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. MR-VAC was co-administered on Day 1 and Day 253. This cohort was created to identify the preferred dose among low, medium and high doses.

Reporting group title	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose
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Reporting group description:

African participants 9 months of age were randomized to receive a high dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. MR-VAC was co-administered on Day 1 and Day 253. This cohort was created to identify the preferred dose among low, medium and high doses.

Reporting group title	Stage 2 Infants dose-finding cohort: Control
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Reporting group description:

African participants 9 months of age were randomized to receive a dose of MENVEO as comparator on Day 1 and Day 85 and INFRANRIX HEXA as comparator on Day 253. MR-VAC was co-administered on Day 1 and Day 253. This cohort was created to identify the preferred dose among low, medium and high doses.

Reporting group values	Stage 1 Adults: altSonflex1-2-3 High Dose Group 1	Stage 1 Adults: altSonflex1-2-3 High Dose Group 2	Stage 1 Adults: Placebo Group
Number of subjects	34	34	34
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	34	34	34
>=65 years	0	0	0
Sex: Female, Male Units: Participants			
Male	6	7	7
Female	28	27	27
Race/Ethnicity, Customized Units: Subjects			
BLACK OR AFRICAN AMERICAN	0	0	0
WHITE	34	34	34

Reporting group values	Stage 2 Adults: altSonflex1-2-3 High Dose	Stage 2 Adults: Control	Stage 2 Children: altSonflex1-2-3 Medium Dose
Number of subjects	10	10	10
Age Categorical Units: Participants			
<=18 years	0	0	10
Between 18 and 65 years	10	10	0
>=65 years	0	0	0
Sex: Female, Male Units: Participants			
Male	4	4	6
Female	6	6	4

Race/Ethnicity, Customized Units: Subjects			
BLACK OR AFRICAN AMERICAN	10	10	10
WHITE	0	0	0

Reporting group values	Stage 2 Children: altSonflex1-2-3 High Dose	Stage 2 Children: Control	Stage 2 Infants safety cohort: altSonflex1-2-3 Low Dose
Number of subjects	10	20	10
Age Categorical Units: Participants			
<=18 years	10	20	10
Between 18 and 65 years	0	0	0
>=65 years	0	0	0
Sex: Female, Male Units: Participants			
Male	6	9	3
Female	4	11	7
Race/Ethnicity, Customized Units: Subjects			
BLACK OR AFRICAN AMERICAN	10	20	10
WHITE	0	0	0

Reporting group values	Stage 2 Infants safety cohort: altSonflex1-2-3 Medium Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 High Dose	Stage 2 Infants safety cohort: Control
Number of subjects	10	10	30
Age Categorical Units: Participants			
<=18 years	10	10	30
Between 18 and 65 years	0	0	0
>=65 years	0	0	0
Sex: Female, Male Units: Participants			
Male	5	6	14
Female	5	4	16
Race/Ethnicity, Customized Units: Subjects			
BLACK OR AFRICAN AMERICAN	10	10	30
WHITE	0	0	0

Reporting group values	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Med Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose
Number of subjects	82	81	83
Age Categorical Units: Participants			
<=18 years	82	81	83
Between 18 and 65 years	0	0	0
>=65 years	0	0	0

Sex: Female, Male			
Units: Participants			
Male	50	38	42
Female	32	43	41
Race/Ethnicity, Customized			
Units: Subjects			
BLACK OR AFRICAN AMERICAN	82	81	83
WHITE	0	0	0

Reporting group values	Stage 2 Infants dose-finding cohort: Control	Total	
Number of subjects	82	550	
Age Categorical			
Units: Participants			
<=18 years	82	428	
Between 18 and 65 years	0	122	
>=65 years	0	0	
Sex: Female, Male			
Units: Participants			
Male	33	240	
Female	49	310	
Race/Ethnicity, Customized			
Units: Subjects			
BLACK OR AFRICAN AMERICAN	82	448	
WHITE	0	102	

End points

End points reporting groups

Reporting group title	Stage 1 Adults: altSonflex1-2-3 High Dose Group 1
Reporting group description: European participants 18-50 years of age were randomized to receive a high dose of altSonflex1-2-3 on Day 1 and Day 85.	
Reporting group title	Stage 1 Adults: altSonflex1-2-3 High Dose Group 2
Reporting group description: European participants 18-50 years of age were randomized to receive a high dose of altSonflex1-2-3 on Day 1 and Day 169.	
Reporting group title	Stage 1 Adults: Placebo Group
Reporting group description: European participants 18-50 years of age were randomized to receive 1 dose of Placebo on Day 1 and on Day 85 or 169. All participants in Step 1 that received placebo were pooled, as pre-specified in Statistical Analysis Plan.	
Reporting group title	Stage 2 Adults: altSonflex1-2-3 High Dose
Reporting group description: African participants 18-50 years of age were randomized to receive a high dose of altSonflex1-2-3 on Day 1 and Day 85.	
Reporting group title	Stage 2 Adults: Control
Reporting group description: African participants 18-50 years of age were randomized to receive 1 dose of MENVEO as comparator on Day 1 and 1 dose of BOOSTRIX as comparator Day 85.	
Reporting group title	Stage 2 Children: altSonflex1-2-3 Medium Dose
Reporting group description: African participants 24-59 months of age were randomized to receive a medium dose of altSonflex1-2-3 on Day 1 and Day 85.	
Reporting group title	Stage 2 Children: altSonflex1-2-3 High Dose
Reporting group description: African participants 24-59 months of age were randomized to receive a high dose of altSonflex1-2-3 on Day 1 and Day 85.	
Reporting group title	Stage 2 Children: Control
Reporting group description: African participants 24-59 months of age were randomized to receive 1 dose of MENVEO as comparator on Day 1 and 1 dose of TYPHIM VI as comparator on Day 85.	
Reporting group title	Stage 2 Infants safety cohort: altSonflex1-2-3 Low Dose
Reporting group description: African participants 9 months of age were randomized to receive a low dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. The measles-rubella vaccine (MR-VAC) was administered on Day 29 and Day 281.	
Reporting group title	Stage 2 Infants safety cohort: altSonflex1-2-3 Medium Dose
Reporting group description: African participants 9 months of age were randomized to receive a medium dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. MR-VAC was administered on Day 29 and Day 281.	
Reporting group title	Stage 2 Infants safety cohort: altSonflex1-2-3 High Dose
Reporting group description: African participants 9 months of age were randomized to receive a high dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. MR-VAC was administered on Day 29 and Day 281.	
Reporting group title	Stage 2 Infants safety cohort: Control
Reporting group description: African participants 9 months of age were randomized to receive a dose of MENVEO as comparator on Day 1 and Day 85 and INFRANRIX HEXA as comparator on Day 253. MR-VAC was administered on Day 29 and Day 281.	
Reporting group title	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose

Reporting group description:

African participants 9 months of age were randomized to receive a low dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. MR-VAC was co-administered on Day 1 and Day 253. This cohort was created to identify the preferred dose among low, medium and high doses.

Reporting group title	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Med Dose
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Reporting group description:

African participants 9 months of age were randomized to receive a medium (Med) dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. MR-VAC was co-administered on Day 1 and Day 253. This cohort was created to identify the preferred dose among low, medium and high doses.

Reporting group title	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose
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Reporting group description:

African participants 9 months of age were randomized to receive a high dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. MR-VAC was co-administered on Day 1 and Day 253. This cohort was created to identify the preferred dose among low, medium and high doses.

Reporting group title	Stage 2 Infants dose-finding cohort: Control
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Reporting group description:

African participants 9 months of age were randomized to receive a dose of MENVEO as comparator on Day 1 and Day 85 and INFRANRIX HEXA as comparator on Day 253. MR-VAC was co-administered on Day 1 and Day 253. This cohort was created to identify the preferred dose among low, medium and high doses.

Subject analysis set title	Stage 2 Infants: altSonflex1-2-3 Low Dose Pooled
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Subject analysis set type	Per protocol
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Subject analysis set description:

African participants 9 months of age were randomized to receive a low dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. MR-VAC was administered either on Day 1 and Day 253 or on Day 29 and Day 281. This group was obtained by pooling the Stage 2 Infants safety cohort: altSonflex1-2-3 Low Dose group and the Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose group.

Subject analysis set title	Stage 2 Infants: altSonflex1-2-3 Medium Dose Pooled
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Subject analysis set type	Per protocol
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Subject analysis set description:

African participants 9 months of age were randomized to receive a medium dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. MR-VAC was administered either on Day 1 and Day 253 or on Day 29 and Day 281. This group was obtained by pooling the Stage 2 Infants safety cohort: altSonflex1-2-3 Medium Dose group and the Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Medium Dose group.

Subject analysis set title	Stage 2 Infants: altSonflex1-2-3 High Dose Pooled
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Subject analysis set type	Per protocol
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Subject analysis set description:

African participants 9 months of age were randomized to receive a high dose of altSonflex1-2-3 on Day 1, Day 85 and Day 253. MR-VAC was administered either on Day 1 and Day 253 or on Day 29 and Day 281. This group was obtained by pooling the Stage 2 Infants safety cohort: altSonflex1-2-3 High Dose group and the Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose group.

Primary: Stage 2: Geometric mean concentrations (GMCs) of Anti-serotype specific Shigella lipopolysaccharide (LPS)/O-Antigen (OAg) serum immunoglobulin G (IgG) in participants 9 months of age in Africa

End point title	Stage 2: Geometric mean concentrations (GMCs) of Anti-serotype specific Shigella lipopolysaccharide (LPS)/O-Antigen (OAg) serum immunoglobulin G (IgG) in participants 9 months of age in Africa
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End point description:

Anti-serotype specific Shigella LPS/OAg serum IgG GMCs were measured by enzyme-linked immunosorbent assay (ELISA) and expressed in ELISA units per milliliter (EU/mL) of serum. *S. sonnei*, *S. flexneri* 1b, *S. flexneri* 2a, and *S. flexneri* 3a serotypes were tested. The analysis was performed on the Per protocol set (PPS) for Stage 2 Infants which included all eligible participants who received all doses as per protocol, had immunogenicity results post-dose, complied with dosing/blood draw intervals, without intercurrent conditions that may interfere with immunogenicity & without prohibited concomitant medication/vaccination. The PPS for immunogenicity was defined by time point. Due to the PPS for Stage 2 Infants – dose finding cohort having less than the planned 72 participants per group, the Stage 2 Infants safety cohort and dose-finding cohort were pooled for this analysis. As per protocol, statistical analysis was performed only for the *S. sonnei* serotype, comparing medium vs low dose.

End point type	Primary
End point timeframe:	
At Day 281 (28 days after the third study intervention)	

End point values	Stage 2 Infants: altSonflex1-2-3 Low Dose Pooled	Stage 2 Infants: altSonflex1-2-3 Medium Dose Pooled	Stage 2 Infants: altSonflex1-2-3 High Dose Pooled	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	75	72	80	
Units: ELISA units per milliliter (EU/mL)				
geometric mean (confidence interval 95%)				
S. sonnei Ab IgG	379.3 (81.4 to 1766.5)	463.5 (95.0 to 2261.3)	457.6 (94.7 to 2211.3)	
S. flexneri 1b Ab IgG	51.1 (39.3 to 66.4)	32.1 (25.6 to 40.4)	35.6 (28.3 to 44.8)	
S. flexneri 2a Ab IgG	177.8 (57.4 to 550.6)	135.3 (34.0 to 537.9)	173.8 (62.4 to 484.0)	
S. flexneri 3a Ab IgG	32.6 (6.1 to 173.2)	24.4 (4.8 to 125.4)	27.5 (5.0 to 152.2)	

Statistical analyses

Statistical analysis title	Ratio of Geometric mean concentrations (GMR)
Statistical analysis description:	
To identify the preferred dose of S. sonnei component of the vaccine (medium vs. low) for infants 9 months of age in Africa. The statistical tests to identify the preferred dose among the 3 different dose levels (Dose A, Dose B, and Dose C) in infants were defined according to GMCs dose-response shapes of each of the 4 components as measured by GVGH ELISA. The selection strategy had been predefined for each of the possible scenarios of the dose-response shapes.	
Comparison groups	Stage 2 Infants: altSonflex1-2-3 Low Dose Pooled v Stage 2 Infants: altSonflex1-2-3 Medium Dose Pooled
Number of subjects included in analysis	147
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.273
Method	t-test, 2-sided
Parameter estimate	Geometric Mean Concentration Ratio
Point estimate	1.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.75

Primary: Stage 1: Number of participants 18 to 50 years of age in Europe with

solicited administration site events

End point title	Stage 1: Number of participants 18 to 50 years of age in Europe with solicited administration site events ^{[1][2]}
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End point description:

The solicited administration site events assessed were erythema, pain and swelling. 9999 = data not available. The analysis was performed on the Solicited Safety Set for Stage 1 Adults which included all participants who received at least 1 dose of the study intervention, who have solicited safety data. As the participants in Stage 1 Adults: Placebo Group received the second placebo intervention at Day 85 or at Day 169, the analysis being performed on the pooled participants as per the SAP, no differentiation was made by timepoint of administration for the second dose for this group.

End point type	Primary
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End point timeframe:

Within 7 days after each study intervention (administered at Day 1, Day 85 and Day 169 [depending on the vaccination schedule])

Notes:

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

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

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

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

End point values	Stage 1 Adults: altSonflex1-2-3 High Dose Group 1	Stage 1 Adults: altSonflex1-2-3 High Dose Group 2	Stage 1 Adults: Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	34	34	34	
Units: Participants				
Erythema, Vaccination at Day 1	4	6	1	
Erythema, Vaccination at Day 85	2	9999	9999	
Erythema, Vaccination at 169	9999	4	9999	
Erythema, Vaccination at Day 85/169	9999	9999	0	
Pain, Vaccination at Day 1	32	33	16	
Pain, Vaccination at Day 85	22	9999	9999	
Pain, Vaccination at Day 169	9999	31	9999	
Pain, Vaccination at Day 85/169	9999	9999	8	
Swelling, Vaccination at Day 1	2	7	0	
Swelling, Vaccination at Day 85	5	9999	9999	
Swelling, Vaccination at 169	9999	5	9999	
Swelling, Vaccination at Day 85/169	9999	9999	0	

Statistical analyses

No statistical analyses for this end point

Primary: Stage 1: Number of adults 18 to 50 years of age in Europe with solicited systemic events

End point title	Stage 1: Number of adults 18 to 50 years of age in Europe with solicited systemic events ^{[3][4]}
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End point description:

The solicited systemic event assessed was fever. Fever is defined as temperature equal to or above

(=>) 38.0°C. N = number of participants analyzed in the specific time frame. 9999 = data not available. The analysis was performed on the Solicited Safety Set for Stage 1 Adults. As the participants in Stage 1 Adults: Placebo Group received the second placebo intervention at Day 85 or at Day 169, the analysis being performed on the pooled participants as per the SAP, no differentiation was made by timepoint of administration for the second dose for this group.

End point type	Primary
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End point timeframe:

Within 7 days after each study intervention (administered at Day 1, Day 85 and Day 169 [depending on the vaccination schedule])

Notes:

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

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

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 1 Adults: altSonflex1-2-3 High Dose Group 1	Stage 1 Adults: altSonflex1-2-3 High Dose Group 2	Stage 1 Adults: Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	34	34	34	
Units: Participants				
Within 7 days after vaccination at Day 1	0	1	0	
Within 7 days after vaccination at Day 85	2	9999	9999	
Within 7 days after vaccination at Day 169	9999	1	9999	
Within 7 days after vaccination at Day 85/169	9999	9999	1	

Statistical analyses

No statistical analyses for this end point

Primary: Stage 1: Number of participants 18 to 50 years of age in Europe with Serious adverse events (SAEs)

End point title	Stage 1: Number of participants 18 to 50 years of age in Europe with Serious adverse events (SAEs) ^{[5][6]}
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End point description:

An SAE is defined as any untoward medical occurrence that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect in the offspring of a study participant, results in abnormal pregnancy outcomes or any other situation based on appropriate medical or scientific judgement. 9999 = data not available. The analysis was performed on the Exposed Set for Stage 1 Adults which included all participants who received at least 1 dose of the study intervention. As the participants in Stage 1 Adults: Placebo Group received the second placebo intervention at Day 85 or at Day 169, the analysis being performed on the pooled participants as per the SAP, no differentiation was made by timepoint of administration for the second dose for this group.

End point type	Primary
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End point timeframe:

From Day 1 to Day 113 and/or Day 197

Notes:

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

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

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 1 Adults: altSonflex1-2-3 High Dose Group 1	Stage 1 Adults: altSonflex1-2-3 High Dose Group 2	Stage 1 Adults: Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	34	34	34	
Units: Participants				
From Day 1 to Day 113	0	9999	9999	
From Day 1 to Day 197	9999	1	9999	
From Day 1 to Day 113/197	9999	9999	0	

Statistical analyses

No statistical analyses for this end point

Primary: Stage 1: Number of participants 18 to 50 years of age in Europe with unsolicited adverse events (AEs)

End point title	Stage 1: Number of participants 18 to 50 years of age in Europe with unsolicited adverse events (AEs) ^{[7][8]}
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End point description:

An unsolicited AE is defined as an AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms is reported as an unsolicited adverse event. 9999 = data not available. The analysis was performed on the Unsolicited Safety Set for Stage 1 Adults which included all participants who received at least 1 dose of the study intervention that reported having/not having unsolicited AEs. As the participants in Stage 1 Adults: Placebo Group received the second placebo intervention at Day 85 or at Day 169, the analysis being performed on the pooled participants as per the SAP, no differentiation was made by timepoint of administration for the second dose for this group.

End point type	Primary
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End point timeframe:

Within 28 days after each study intervention (administered at at Day 1, Day 85 and Day 169 [depending on the vaccination schedule])

Notes:

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

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

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 1 Adults: altSonflex1-2-3 High Dose Group 1	Stage 1 Adults: altSonflex1-2-3 High Dose Group 2	Stage 1 Adults: Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	34	34	34	
Units: Participants				
Within 28 days after vaccination at Day 1	25	21	25	
Within 28 days after vaccination at Day 85	14	9999	9999	
Within 28 days after vaccination at Day 169	9999	14	9999	
Within 28 days after vaccination at Day 85/169	9999	9999	12	

Statistical analyses

No statistical analyses for this end point

Primary: Stage 1: Number of participants 18 to 50 years of age in Europe with deviations from normal values of haematological, renal, and hepatic panel test results after first study intervention

End point title	Stage 1: Number of participants 18 to 50 years of age in Europe with deviations from normal values of haematological, renal, and hepatic panel test results after first study intervention ^{[9][10]}
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End point description:

Panel tests include measures of alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine, basophils, eosinophils, erythrocytes, haematocrit, haemoglobin, lymphocytes, monocytes, neutrophils, platelets and white blood cells (WBC). Categories reported when comparing Day 1 (baseline) and normal range hematological, renal and hepatic laboratory results are defined as follows: <parameter>,<range at baseline>,<range at timing>, where range is being classified as Below = value below; Within = value within; and Above = value above the laboratory reference range defined for the specified visit and laboratory parameter. The analysis was performed on the Exposed Set for Stage 1 Adults.

End point type	Primary
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End point timeframe:

At Day 8

Notes:

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

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

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 1 Adults: altSonflex1-2-3 High Dose Group 1	Stage 1 Adults: altSonflex1-2-3 High Dose Group 2	Stage 1 Adults: Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	34	34	34	
Units: Participants				

ALT, Within, Within	32	33	30
ALT, Within, Above	1	0	1
ALT, Above, Within	1	0	1
ALT, Above, Above	0	1	2
AST, Within, Within	31	33	31
AST, Within, Above	0	0	3
AST, Above, Within	3	0	0
AST, Above, Above	0	1	0
Creatinine, Within, Within	33	34	34
Creatinine, Above, Above	1	0	0
Basophils, Below, Below	0	0	1
Basophils, Below, Within	3	0	1
Basophils, Within, Below	0	0	1
Basophils, Within, Within	31	33	31
Basophils, Above, Within	0	1	0
Eosinophils, Below, Within	1	1	1
Eosinophils, Within, Below	0	2	0
Eosinophils, Within, Within	32	30	31
Eosinophils, Within, Above	0	0	1
Eosinophils, Above, Within	1	0	0
Eosinophils, Above, Above	0	1	1
Erythrocytes, Below, Below	1	0	0
Erythrocytes, Below, Within	1	0	0
Erythrocytes, Within, Below	0	1	0
Erythrocytes, Within, Within	32	32	33
Erythrocytes, Above, Within	0	1	1
Haematocrit, Below, Below	0	1	0
Haematocrit, Below, Within	1	0	1
Haematocrit, Within, Within	32	32	33
Haematocrit, Above, Within	1	0	0
Haematocrit, Above, Above	0	1	0
Haemoglobin, Below, Below	1	1	0
Haemoglobin, Below, Within	2	1	0
Haemoglobin, Within, Below	0	1	0
Haemoglobin, Within, Within	30	28	33
Haemoglobin, Within, Above	0	1	0
Haemoglobin, Above, Within	1	1	1
Haemoglobin, Above, Above	0	1	0
Lymphocytes, Below, Below	2	2	0
Lymphocytes, Below, Within	1	0	1
Lymphocytes, Within, Within	31	32	31
Lymphocytes, Within, Above	0	0	2
Monocytes, Below, Within	0	1	1
Monocytes, Within, Below	1	0	0
Monocytes, Within, Within	33	33	31
Monocytes, Above, Within	0	0	1
Monocytes, Above, Above	0	0	1
Neutrophils, Below, Within	1	0	1
Neutrophils, Below, Above	1	0	0
Neutrophils, Within, Below	0	2	1
Neutrophils, Within, Within	28	28	32
Neutrophils, Within, Above	1	3	0

Neutrophils, Above, Within	3	1	0	
Platelets, Below, Within	0	1	2	
Platelets, Within, Within	29	28	29	
Platelets, Within, Above	0	3	1	
Platelets, Above, Within	1	0	1	
Platelets, Above, Above	4	2	1	
WBC, Below, Within	2	1	2	
WBC, Within, Below	1	4	0	
WBC, Within, Within	30	29	32	
WBC, Within, Above	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Stage 1: Number of participants 18 to 50 years of age in Europe with deviations from normal values of haematological, renal, and hepatic panel test results after second study intervention

End point title	Stage 1: Number of participants 18 to 50 years of age in Europe with deviations from normal values of haematological, renal, and hepatic panel test results after second study intervention ^{[11][12]}
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End point description:

Panel tests include measures of ALT, AST, creatinine, basophils, eosinophils, erythrocytes, haematocrit, haemoglobin, lymphocytes, monocytes, neutrophils, platelets and WBC. Categories reported when comparing Day 85/Day 169 (baseline) and normal range hematological, renal and hepatic laboratory results are defined as follows: <parameter>, <range at baseline>, <range at timing>, where range is being classified as Below = value below; Within = value within; and Above = value above the laboratory reference range defined for the specified visit and laboratory parameter. The analysis was performed on the Exposed Set for Stage 1 Adults.

End point type	Primary
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End point timeframe:

At Day 92 (Stage 1 Adults: altSonflex1-2-3 High Dose Group 1), at Day 176 (Stage 1 Adults: altSonflex1-2-3 High Dose Group 2) and at Day 92/Day 176 (Stage 1 Adults: Placebo Group)

Notes:

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

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

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 1 Adults: altSonflex1-2-3 High Dose Group 1	Stage 1 Adults: altSonflex1-2-3 High Dose Group 2	Stage 1 Adults: Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	29	34	28	
Units: Participants				
ALT, Within, Within	26	32	26	
ALT, Within, Above	1	0	0	
ALT, Above, Within	1	1	1	

ALT, Above, Above	1	1	1	
AST, Within, Within	27	32	27	
AST, Within, Above	1	0	0	
AST, Above, Within	1	1	1	
AST, Above, Above	0	1	0	
Creatinine, Within, Within	28	34	27	
Creatinine, Within, Above	0	0	1	
Creatinine, Above, Above	1	0	0	
Basophils, Below, Below	0	0	1	
Basophils, Below, Within	1	1	1	
Basophils, Within, Below	2	0	0	
Basophils, Within, Within	26	33	25	
Basophils, Within, Above	0	0	1	
Eosinophils, Below, Below	0	2	0	
Eosinophils, Within, Below	1	0	1	
Eosinophils, Within, Within	25	30	24	
Eosinophils, Within, Above	1	1	1	
Eosinophils, Above, Within	0	0	1	
Eosinophils, Above, Above	2	1	1	
Erythrocytes, Within, Below	0	0	1	
Erythrocytes, Within, Within	29	32	27	
Erythrocytes, Above, Within	0	1	0	
Erythrocytes, Above, Above	0	1	0	
Haematocrit, Below, Below	0	1	0	
Haematocrit, Within, Below	0	1	0	
Haematocrit, Within, Within	29	31	28	
Haematocrit, Above, Within	0	1	0	
Haemoglobin, Below, Below	0	1	0	
Haemoglobin, Below, Within	1	0	0	
Haemoglobin, Within, Below	0	1	0	
Haemoglobin, Within, Within	27	30	28	
Haemoglobin, Within, Above	1	0	0	
Haemoglobin, Above, Within	0	2	0	
Lymphocytes, Below, Below	1	1	1	
Lymphocytes, Below, Within	2	2	0	
Lymphocytes, Within, Below	0	3	0	
Lymphocytes, Within, Within	25	28	27	
Lymphocytes, Within, Above	1	0	0	
Monocytes, Below, Below	0	0	1	
Monocytes, Below, Within	1	1	1	
Monocytes, Within, Within	28	30	23	
Monocytes, Within, Above	0	2	0	
Monocytes, Above, Within	0	1	3	
Neutrophils, Below, Below	0	0	1	
Neutrophils, Below, Within	2	3	0	
Neutrophils, Within, Below	1	0	1	
Neutrophils, Within, Within	26	26	22	
Neutrophils, Within, Above	0	2	1	
Neutrophils, Above, Within	0	2	2	
Neutrophils, Above, Above	0	1	1	
Platelets, Below, Within	1	0	1	
Platelets, Within, Below	1	0	1	

Platelets, Within, Within	23	29	23	
Platelets, Within, Above	1	2	3	
Platelets, Above, Within	3	0	0	
Platelets, Above, Above	0	3	0	
WBC, Below, Below	1	3	1	
WBC, Below, Within	2	2	0	
WBC, Within, Below	1	0	1	
WBC, Within, Within	25	26	24	
WBC, Within, Above	0	3	0	
WBC, Above, Within	0	0	1	
WBC, Above, Above	0	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 18 to 50 years of age in Africa with solicited systemic events

End point title	Stage 2: Number of participants 18 to 50 years of age in Africa with solicited systemic events ^{[13][14]}
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End point description:

The solicited systemic event assessed was fever. Fever is defined as temperature equal to or above (\geq) 38.0°C. The analysis was performed on the Solicited Safety Set for Stage 2 Adults.

End point type	Primary
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End point timeframe:

Within 7 days after each study intervention (administered at Day 1 and Day 85)

Notes:

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

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

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Adults: altSonflex1-2-3 High Dose	Stage 2 Adults: Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: Participants				
Vaccination at Day 1	0	0		
Vaccination at Day 85	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 18 to 50 years of age in Africa with solicited administration site events

End point title	Stage 2: Number of participants 18 to 50 years of age in Africa with solicited administration site events ^{[15][16]}
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End point description:

The solicited administration site events assessed were pain, erythema, and swelling. The analysis was performed on the Solicited Safety Set for Stage 2 Adults.

End point type	Primary
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End point timeframe:

Within 7 days after each study intervention (administered at Day 1 and Day 85)

Notes:

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

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

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Adults: altSonflex1-2-3 High Dose	Stage 2 Adults: Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: Participants				
Pain, Vaccination at Day 1	5	2		
Pain, Vaccination at Day 85	4	3		
Erythema, Vaccination at Day 1	0	0		
Erythema, Vaccination at Day 85	0	0		
Swelling, Vaccination at Day 1	0	0		
Swelling, Vaccination at Day 85	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 18 to 50 years of age in Africa with unsolicited adverse events (AEs)

End point title	Stage 2: Number of participants 18 to 50 years of age in Africa with unsolicited adverse events (AEs) ^{[17][18]}
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End point description:

An unsolicited AE is defined as an AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms is reported as an unsolicited adverse event. The analysis was performed on the Unsolicited Safety Set for Stage 2 Adults.

End point type	Primary
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End point timeframe:

Within 28 days after each study intervention (administered at Day 1 and Day 85)

Notes:

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

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

performed.

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Adults: altSonflex1-2-3 High Dose	Stage 2 Adults: Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: Participants				
Vaccination at Day 1	2	1		
Vaccination at Day 85	2	2		

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 18 to 50 years of age in Africa with Serious adverse events (SAEs)

End point title	Stage 2: Number of participants 18 to 50 years of age in Africa with Serious adverse events (SAEs) ^{[19][20]}
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End point description:

An SAE is defined as any untoward medical occurrence that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect in the offspring of a study participant, results in abnormal pregnancy outcomes or any other situation based on appropriate medical or scientific judgement. The analysis was performed on the Exposed Set for Stage 2 Adults.

End point type	Primary
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End point timeframe:

From Day 1 to Day 113

Notes:

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

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

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Adults: altSonflex1-2-3 High Dose	Stage 2 Adults: Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: Participants	0	0		

Statistical analyses

Primary: Stage 2: Number of participants 18 to 50 years of age in Africa with deviations from normal values of haematological, renal, and hepatic panel test results after first study intervention

End point title	Stage 2: Number of participants 18 to 50 years of age in Africa with deviations from normal values of haematological, renal, and hepatic panel test results after first study intervention ^{[21][22]}
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End point description:

Panel tests include measures of ALT, AST, creatinine, basophils, eosinophils, erythrocytes, haematocrit, haemoglobin, lymphocytes, monocytes, neutrophils, platelets and WBC. Categories reported when comparing Day 1 (baseline) and normal range hematological, renal and hepatic laboratory results are defined as follows: <parameter>,<range at baseline>,<range at timing>, where range is being classified as Below = value below; Within = value within; and Above = value above the laboratory reference range defined for the specified visit and laboratory parameter. The analysis was performed on the Exposed Set for Stage 2 Adults.

End point type	Primary
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End point timeframe:

At Day 8

Notes:

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

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Adults: altSonflex1-2-3 High Dose	Stage 2 Adults: Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: Participants				
ALT, Within, Below	0	1		
ALT, Within, Within	10	9		
AST, Within, Within	10	10		
Creatinine, Below, Below	6	6		
Creatinine, Below, Within	1	0		
Creatinine, Within, Below	0	1		
Creatinine, Within, Within	3	3		
Basophils, Within, Within	10	10		
Eosinophils, Within, Below	0	1		
Eosinophils, Within, Within	10	9		
Erythrocytes, Within, Within	10	10		
Haematocrit, Within, Within	10	10		
Haemoglobin, Within, Within	10	10		
Lymphocytes, Below, Within	0	2		
Lymphocytes, Within, Within	9	8		
Lymphocytes, Above, Above	1	0		
Monocytes, Within, Within	9	7		
Monocytes, Within, Above	0	1		
Monocytes, Above, Above	1	2		
Neutrophils, Within, Within	9	9		

Neutrophils, Within, Above	1	1		
Platelets, Within, Within	10	10		
WBC, Below, Within	0	1		
WBC, Within, Within	8	8		
WBC, Within, Above	1	1		
WBC, Above, Above	1	0		

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 18 to 50 years of age in Africa with deviations from normal values of haematological, renal, and hepatic panel test results after second study intervention

End point title	Stage 2: Number of participants 18 to 50 years of age in Africa with deviations from normal values of haematological, renal, and hepatic panel test results after second study intervention ^{[23][24]}
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End point description:

Panel tests include measures of ALT, AST, creatinine, basophils, eosinophils, erythrocytes, haematocrit, haemoglobin, lymphocytes, monocytes, neutrophils, platelets and WBC. Categories reported when comparing Day 85 (baseline) and normal range hematological, renal and hepatic laboratory results are defined as follows: <parameter>,<range at baseline>,<range at timing>, where range is being classified as Below = value below; Within = value within; and Above = value above the laboratory reference range defined for the specified visit and laboratory parameter. The analysis was performed on the Exposed Set for Stage 2 Adults.

End point type	Primary
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End point timeframe:

At Day 92

Notes:

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

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

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Adults: altSonflex1-2-3 High Dose	Stage 2 Adults: Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: Participants				
ALT, Within, Within	9	10		
ALT, Within, Above	1	0		
AST, Below, Within	1	0		
AST, Within, Within	8	10		
AST, Within, Above	1	0		
Creatinine, Below, Below	6	4		
Creatinine, Within, Below	1	2		
Creatinine, Within, Within	3	4		
Basophils, Within, Within	10	10		

Eosinophils, Below, Within	0	1		
Eosinophils, Within, Within	10	9		
Erythrocytes, Within, Within	10	10		
Haematocrit, Within, Within	10	10		
Haemoglobin, Within, Within	10	10		
Lymphocytes, Below, Within	0	1		
Lymphocytes, Within, Within	9	9		
Lymphocytes, Above, Above	1	0		
Monocytes, Within, Within	7	9		
Monocytes, Within, Above	2	1		
Monocytes, Above, Within	1	0		
Neutrophils, Within, Within	8	10		
Neutrophils, Within, Above	1	0		
Neutrophils, Above, Within	1	0		
Platelets, Within, Within	9	10		
Platelets, Within, Above	1	0		
WBC, Within, Within	8	10		
WBC, Within, Above	1	0		
WBC, Above, Within	1	0		

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 24 to 59 months of age in Africa with solicited administration site events

End point title	Stage 2: Number of participants 24 to 59 months of age in Africa with solicited administration site events ^[25] ^[26]
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End point description:

The solicited administration site events assessed were erythema, pain, and swelling. The analysis was performed on the Solicited Safety Set for Stage Children. The analysis was performed on the Solicited Safety Set for Stage 2 Children.

End point type	Primary
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End point timeframe:

Within 7 days after each study intervention (administered at Day 1 and Day 85)

Notes:

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

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

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Children: altSonflex1-2-3 Medium Dose	Stage 2 Children: altSonflex1-2-3 High Dose	Stage 2 Children: Control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	20	
Units: Participants				

Erythema, Vaccination at Day 1	1	1	0	
Erythema, Vaccination at Day 85	1	0	0	
Pain, Vaccination at Day 1	6	2	3	
Pain, Vaccination at Day 85	7	2	3	
Swelling, Vaccination at Day 1	1	1	0	
Swelling, Vaccination at Day 85	1	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 24 to 59 months of age in Africa with solicited systemic events

End point title	Stage 2: Number of participants 24 to 59 months of age in Africa with solicited systemic events ^{[27][28]}
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End point description:

The solicited systemic event assessed was fever. Fever is defined as temperature equal to or above (\geq) 38.0°C. The analysis was performed on the Solicited Safety Set for Stage 2: Children.

End point type	Primary
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End point timeframe:

Within 7 days after each study intervention (administered at Day 1 and Day 85)

Notes:

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

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

[28] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Children: altSonflex1-2-3 Medium Dose	Stage 2 Children: altSonflex1-2-3 High Dose	Stage 2 Children: Control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	20	
Units: Participants				
Vaccination at Day 1	1	1	0	
Vaccination at Day 85	1	2	3	

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 24 to 59 months of age in Africa with unsolicited adverse events (AEs)

End point title	Stage 2: Number of participants 24 to 59 months of age in Africa with unsolicited adverse events (AEs) ^{[29][30]}
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End point description:

An unsolicited AE is defined as an AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms is reported as an unsolicited adverse event. The analysis was performed on the Unsolicited Safety Set for Stage 2: Children.

End point type	Primary
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End point timeframe:

Within 28 days after each study intervention (administered at Day 1 and Day 85)

Notes:

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

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

[30] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Children: altSonflex1-2-3 Medium Dose	Stage 2 Children: altSonflex1-2-3 High Dose	Stage 2 Children: Control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	20	
Units: Participants				
Vaccination at Day 1	4	3	8	
Vaccination at Day 85	2	0	3	

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 24 to 59 months of age in Africa with Serious adverse events (SAEs)

End point title	Stage 2: Number of participants 24 to 59 months of age in Africa with Serious adverse events (SAEs) ^{[31][32]}
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End point description:

An SAE is defined as any untoward medical occurrence that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect in the offspring of a study participant, results in abnormal pregnancy outcomes or any other situation based on appropriate medical or scientific judgement. The analysis was performed on the Exposed Set for Stage 2 Children.

End point type	Primary
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End point timeframe:

From Day 1 to Day 113

Notes:

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

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

[32] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Children: altSonflex1-2-3 Medium Dose	Stage 2 Children: altSonflex1-2-3 High Dose	Stage 2 Children: Control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	20	
Units: Participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 24 to 59 months of age in Africa with deviations from normal values of haematological, renal, and hepatic panel test results after first study intervention

End point title	Stage 2: Number of participants 24 to 59 months of age in Africa with deviations from normal values of haematological, renal, and hepatic panel test results after first study intervention ^{[33][34]}
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End point description:

Panel tests include measures of ALT, AST, creatinine, basophils, eosinophils, erythrocytes, haematocrit, haemoglobin, lymphocytes, monocytes, neutrophils, platelets and WBC. Categories reported when comparing Day 1 (baseline) and normal range hematological, renal and hepatic laboratory results are defined as follows: <parameter>,<range at baseline>,<range at timing>, where range is being classified as Below = value below; Within = value within; and Above = value above the laboratory reference range defined for the specified visit and laboratory parameter. The analysis was performed on the Exposed Set for Stage 2 Children.

End point type	Primary
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End point timeframe:

At Day 8

Notes:

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

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

[34] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Children: altSonflex1-2-3 Medium Dose	Stage 2 Children: altSonflex1-2-3 High Dose	Stage 2 Children: Control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	20	
Units: Participants				
ALT, Within, Within	8	9	16	
ALT, Within, Above	0	1	1	
ALT, Above, Within	0	0	2	
ALT, Above, Above	2	0	1	
AST, Within, Within	8	10	20	
AST, Above, Within	2	0	0	
Creatinine, Below, Below	8	9	17	
Creatinine, Below, Within	1	0	0	

Creatinine, Within, Below	1	1	1	
Creatinine, Within, Within	0	0	1	
Creatinine, Above, Within	0	0	1	
Basophils, Within, Below	0	0	1	
Basophils, Within, Within	9	10	16	
Basophils, Within, Above	1	0	2	
Basophils, Above, Within	0	0	1	
Eosinophils, Below, Within	1	0	0	
Eosinophils, Within, Below	0	0	1	
Eosinophils, Within, Within	5	6	12	
Eosinophils, Within, Above	0	0	1	
Eosinophils, Above, Within	0	1	1	
Eosinophils, Above, Above	4	3	5	
Erythrocytes, Within, Within	8	9	12	
Erythrocytes, Within, Above	1	0	0	
Erythrocytes, Above, Within	0	1	5	
Erythrocytes, Above, Above	1	0	3	
Haematocrit, Below, Below	0	1	0	
Haematocrit, Within, Within	8	7	14	
Haematocrit, Within, Above	0	0	1	
Haematocrit, Above, Within	2	2	5	
Haemoglobin, Below, Below	0	1	0	
Haemoglobin, Below, Within	1	0	0	
Haemoglobin, Within, Below	0	0	1	
Haemoglobin, Within, Within	7	7	18	
Haemoglobin, Above, Within	1	2	0	
Haemoglobin, Above, Above	1	0	1	
Lymphocytes, Within, Within	7	7	8	
Lymphocytes, Within, Above	1	0	2	
Lymphocytes, Above, Within	2	1	7	
Lymphocytes, Above, Above	0	2	3	
Monocytes, Within, Within	9	8	13	
Monocytes, Within, Above	1	2	3	
Monocytes, Above, Within	0	0	1	
Monocytes, Above, Above	0	0	3	
Neutrophils, Below, Below	0	0	1	
Neutrophils, Below, Within	2	0	2	
Neutrophils, Within, Below	2	0	1	
Neutrophils, Within, Within	6	10	16	
Platelets, Within, Within	1	3	4	
Platelets, Within, Above	5	4	2	
Platelets, Above, Within	0	0	4	
Platelets, Above, Above	4	3	10	
WBC, Below, Within	1	0	0	
WBC, Within, Within	9	10	19	
WBC, Above, Above	0	0	1	

Statistical analyses

Primary: Stage 2: Number of participants 24 to 59 months of age in Africa with deviations from normal values of haematological, renal, and hepatic panel test results after second study intervention

End point title	Stage 2: Number of participants 24 to 59 months of age in Africa with deviations from normal values of haematological, renal, and hepatic panel test results after second study intervention ^[35] ^[36]
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End point description:

Panel tests include measures of ALT, AST, creatinine, basophils, eosinophils, erythrocytes, haematocrit, haemoglobin, lymphocytes, monocytes, neutrophils, platelets and WBC. Categories reported when comparing Day 85 (baseline) and normal range hematological, renal and hepatic laboratory results are defined as follows: <parameter>, <range at baseline>, <range at timing>, where range is being classified as Below = value below; Within = value within; and Above = value above the laboratory reference range defined for the specified visit and laboratory parameter. The analysis was performed on the Exposed Set for Stage 2 Children.

End point type	Primary
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End point timeframe:

At Day 92

Notes:

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

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

[36] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Children: altSonflex1-2-3 Medium Dose	Stage 2 Children: altSonflex1-2-3 High Dose	Stage 2 Children: Control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	20	
Units: Participants				
ALT, Within, Within	9	5	15	
ALT, Within, Above	0	0	2	
ALT, Above, Within	0	2	1	
ALT, Above, Above	1	3	2	
AST, Within, Within	10	10	19	
AST, Within, Above	0	0	1	
Creatinine, Below, Below	10	8	18	
Creatinine, Within, Below	0	2	2	
Basophils, Within, Within	9	9	20	
Basophils, Above, Within	1	0	0	
Basophils, Above, Above	0	1	0	
Eosinophils, Within, Below	1	0	0	
Eosinophils, Within, Within	6	8	16	
Eosinophils, Within, Above	1	0	1	
Eosinophils, Above, Above	2	2	3	
Erythrocytes, Below, Within	1	0	0	
Erythrocytes, Within, Within	7	8	17	
Erythrocytes, Within, Above	1	0	1	
Erythrocytes, Above, Within	0	1	0	

Erythrocytes, Above, Above	1	1	2	
Haematocrit, Below, Below	1	0	0	
Haematocrit, Below, Within	0	0	1	
Haematocrit, Within, Within	9	10	19	
Haemoglobin, Below, Below	1	0	1	
Haemoglobin, Within, Below	0	0	1	
Haemoglobin, Within, Within	9	8	18	
Haemoglobin, Above, Within	0	2	0	
Lymphocytes, Within, Within	7	6	14	
Lymphocytes, Within, Above	0	0	2	
Lymphocytes, Above, Within	3	2	3	
Lymphocytes, Above, Above	0	2	1	
Monocytes, Below, Within	0	1	0	
Monocytes, Within, Within	9	7	13	
Monocytes, Within, Above	1	0	2	
Monocytes, Above, Within	0	0	4	
Monocytes, Above, Above	0	2	1	
Neutrophils, Below, Below	2	0	0	
Neutrophils, Below, Within	1	0	1	
Neutrophils, Within, Below	0	0	1	
Neutrophils, Within, Within	5	10	18	
Neutrophils, Within, Above	2	0	0	
Platelets, Within, Within	3	3	7	
Platelets, Within, Above	1	1	5	
Platelets, Above, Within	2	1	2	
Platelets, Above, Above	4	5	6	
WBC, Below, Within	2	0	0	
WBC, Within, Within	7	10	19	
WBC, Above, Above	1	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 9 months of age in Africa with solicited administration site events - Infants safety cohort

End point title	Stage 2: Number of participants 9 months of age in Africa with solicited administration site events - Infants safety cohort ^[37] ^[38]
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End point description:

The solicited administration site events assessed were erythema, pain, and swelling. N = number of participants analyzed in the specific time frame. The analysis was performed on the Solicited Safety Set for Stage 2 Infants, safety cohort.

End point type	Primary
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End point timeframe:

Within 7 days after each study intervention (administered at Day 1 and Day 85)

Notes:

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

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

[38] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants safety cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 Medium Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 High Dose	Stage 2 Infants safety cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	10	10	30
Units: Participants				
Erythema, Vaccination at Day 1	0	0	3	1
Erythema, Vaccination at Day 85	0	1	2	0
Erythema, Vaccination at Day 253	0	0	4	0
Pain, Vaccination at Day 1	2	3	7	3
Pain, Vaccination at Day 85	2	3	6	3
Pain, Vaccination at Day 253	2	4	7	6
Swelling, Vaccination at Day 1	0	1	4	2
Swelling, Vaccination at Day 85	0	1	2	1
Swelling, Vaccination at Day 253	1	0	5	3

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 9 months of age in Africa with solicited administration site events - Infants dose-finding cohort

End point title	Stage 2: Number of participants 9 months of age in Africa with solicited administration site events - Infants dose-finding cohort ^[39] ^[40]
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End point description:

The solicited administration site events assessed were erythema, pain, and swelling. N = number of participants analyzed in the specific time frame. The analysis was performed on the Solicited Safety Set for Stage 2 Infants, dose-finding cohort.

End point type	Primary
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End point timeframe:

Within 7 days after each study intervention (administered at Day 1, Day 85 and Day 253)

Notes:

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

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

[40] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Med Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose	Stage 2 Infants dose-finding cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	81	83	82
Units: Participants				
Erythema, Vaccination at Day 1	16	9	21	9
Erythema, Vaccination at Day 85	11	12	11	4
Erythema, Vaccination at Day 253	6	7	11	8
Pain, Vaccination at Day 1	40	42	43	14
Pain, Vaccination at Day 85	34	36	43	20
Pain, Vaccination at Day 253	27	39	41	26
Swelling, Vaccination at Day 1	21	21	21	9
Swelling, Vaccination at Day 85	19	20	22	2
Swelling, Vaccination at Day 253	15	12	17	14

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 9 months of age in Africa with solicited systemic events - Infants safety cohort

End point title	Stage 2: Number of participants 9 months of age in Africa with solicited systemic events - Infants safety cohort ^{[41][42]}
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End point description:

The solicited systemic event is fever. Fever is defined as temperature equal to or above (\geq) 38.0°C. The analysis was performed on the Solicited Safety Set for Stage 2 Infants, safety cohort.

End point type	Primary
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End point timeframe:

Within 7 days after each study intervention (administered at Day 1, Day 85 and Day 253)

Notes:

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

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

[42] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants safety cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 Medium Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 High Dose	Stage 2 Infants safety cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	10	10	30
Units: Participants				
Vaccination at Day 1	3	1	4	5
Vaccination at Day 85	2	1	1	2
Vaccination at Day 253	1	2	2	4

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 9 months of age in Africa with solicited systemic events - Infants dose-finding cohort

End point title	Stage 2: Number of participants 9 months of age in Africa with solicited systemic events - Infants dose-finding cohort ^[43] ^[44]
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End point description:

The solicited systemic event is fever. Fever is defined as temperature equal to or above (\geq) 38.0°C. The analysis was performed on the Solicited Safety Set for Stage 2 Infants, dose finding cohort.

End point type	Primary
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End point timeframe:

Within 7 days after each study intervention (administered at Day 1, Day 85 and Day 253)

Notes:

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

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

[44] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Med Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose	Stage 2 Infants dose-finding cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	80	79	82	81
Units: Participants				
Vaccination at Day 1	27	18	23	7
Vaccination at Day 85	17	13	10	17
Vaccination at Day 253	21	16	22	9

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 9 months of age in Africa with unsolicited adverse events (AEs) - Infants dose-finding cohort

End point title	Stage 2: Number of participants 9 months of age in Africa with unsolicited adverse events (AEs) - Infants dose-finding cohort ^[45] ^[46]
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End point description:

An unsolicited AE is defined as an AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms is reported as an unsolicited adverse event. The analysis was performed on the Unsolicited Safety Set for Stage 2 Infants, dose-finding cohort.

End point type	Primary
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End point timeframe:

Within 28 days after each study intervention (administered at Day 1, Day 85 and Day 253)

Notes:

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

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

[46] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Med Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose	Stage 2 Infants dose-finding cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	81	83	82
Units: Participants				
Vaccination at Day 1	35	37	34	41
Vaccination at Day 85	23	25	31	28
Vaccination at Day 253	21	29	31	26

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 9 months of age in Africa with unsolicited adverse events (AEs) - Infants safety cohort

End point title	Stage 2: Number of participants 9 months of age in Africa with unsolicited adverse events (AEs) - Infants safety cohort ^[47] ^[48]
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End point description:

An unsolicited AE is defined as an AE reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms is reported as an unsolicited adverse event. The analysis was performed on the Unsolicited Safety Set for Stage 2 Infants, safety cohort.

End point type	Primary
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End point timeframe:

Within 28 days after each study intervention (administered at Day 1, Day 85 and Day 253)

Notes:

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

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

[48] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants safety cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 Medium Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 High Dose	Stage 2 Infants safety cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	10	10	30
Units: Participants				
Vaccination at Day 1	2	3	4	17
Vaccination at Day 85	1	4	6	10
Vaccination at Day 253	4	2	4	4

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 9 months of age in Africa with deviations from normal values of haematological, renal, and hepatic panel test results after first study intervention - Infants safety cohort

End point title	Stage 2: Number of participants 9 months of age in Africa with deviations from normal values of haematological, renal, and hepatic panel test results after first study intervention - Infants safety cohort ^{[49][50]}
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End point description:

Panel tests include measures of alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine, potassium, sodium, urea, basophils, eosinophils, erythrocytes, haematocrit, haemoglobin, lymphocytes, monocytes, neutrophils, platelets and white blood cells (WBC). Categories reported when comparing Day 1 (baseline) and normal range hematological, renal and hepatic laboratory results are defined as follows: <parameter>,<range at baseline>,<range at timing>, where range is being classified as Below = value below; Within = value within; and Above = value above the laboratory reference range defined for the specified visit and laboratory parameter. The analysis was performed on the Exposed Set for Stage 2 Infants, safety cohort.

End point type	Primary
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End point timeframe:

At Day 8

Notes:

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

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

[50] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants safety cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 Medium Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 High Dose	Stage 2 Infants safety cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	10	10	30
Units: Participants				
ALT, Below, Within	0	0	1	0
ALT, Within, Within	10	9	9	29
ALT, Within, Above	0	0	0	1
AST, Within, Within	10	9	10	30

Creatinine, Below, Below	10	9	10	30
Basophils, Within, Within	8	0	10	18
Basophils, Within, Above	1	0	0	2
Basophils, Above, Within	1	1	0	1
Basophils, Above, Above	0	8	0	9
Eosinophils, Within, Within	10	8	10	28
Eosinophils, Above, Above	0	1	0	2
Erythrocytes, Within, Within	8	9	9	24
Erythrocytes, Within, Above	0	0	1	1
Erythrocytes, Above, Within	2	0	0	1
Erythrocytes, Above, Above	0	0	0	4
Haematocrit, Below, Below	1	0	0	1
Haematocrit, Below, Within	1	0	1	1
Haematocrit, Within, Below	1	1	0	0
Haematocrit, Within, Within	7	8	8	25
Haematocrit, Within, Above	0	0	1	0
Haematocrit, Above, Within	0	0	0	1
Haematocrit, Above, Above	0	0	0	2
Haemoglobin, Below, Below	2	0	0	1
Haemoglobin, Below, Within	1	0	1	1
Haemoglobin, Within, Below	1	3	1	4
Haemoglobin, Within, Within	6	6	6	23
Haemoglobin, Within, Above	0	0	1	1
Haemoglobin, Above, Within	0	0	1	0
Lymphocytes, Within, Within	8	5	9	15
Lymphocytes, Within, Above	1	1	1	5
Lymphocytes, Above, Within	1	1	0	3
Lymphocytes, Above, Above	0	2	0	7
Monocytes, Below, Below	0	1	0	0
Monocytes, Below, Within	0	0	1	1
Monocytes, Within, Within	7	7	6	23
Monocytes, Within, Above	0	0	1	3
Monocytes, Above, Within	0	1	2	2
Monocytes, Above, Above	3	0	0	1
Neutrophils, Below, Below	0	0	0	1
Neutrophils, Below, Within	2	0	2	2
Neutrophils, Within, Below	1	0	0	3
Neutrophils, Within, Within	6	9	8	24
Neutrophils, Above, Within	1	0	0	0
Platelets, Within, Below	0	0	0	1
Platelets, Within, Within	1	1	2	2
Platelets, Within, Above	2	0	4	8
Platelets, Above, Within	3	0	0	3
Platelets, Above, Above	4	8	4	16
WBC, Below, Within	0	0	1	1
WBC, Within, Below	0	0	0	1
WBC, Within, Within	8	7	9	22
WBC, Within, Above	1	0	0	4
WBC, Above, Within	0	1	0	0
WBC, Above, Above	1	1	0	2

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 9 months of age in Africa with Serious adverse events (SAEs) - Infants dose-finding cohort

End point title	Stage 2: Number of participants 9 months of age in Africa with Serious adverse events (SAEs) - Infants dose-finding cohort ^[51] ^[52]
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End point description:

An SAE is defined as any untoward medical occurrence that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect in the offspring of a study participant, results in abnormal pregnancy outcomes or any other situation based on appropriate medical or scientific judgement. Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

The analysis was performed on the Exposed Set for Stage 2 Infants, dose-finding cohort.

End point type	Primary
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End point timeframe:

From Day 1 to Day 281

Notes:

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

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

[52] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Med Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose	Stage 2 Infants dose-finding cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	81	83	82
Units: Participants	2	1	4	1

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 9 months of age in Africa with Serious adverse events (SAEs) - Infants safety cohort

End point title	Stage 2: Number of participants 9 months of age in Africa with Serious adverse events (SAEs) - Infants safety cohort ^[53] ^[54]
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End point description:

An SAE is defined as any untoward medical occurrence that results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect in the offspring of a study participant, results in abnormal pregnancy outcomes or any other situation based on appropriate medical or scientific judgement. The analysis was performed on the Exposed Set for Stage 2 Infants, safety cohort.

End point type	Primary
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End point timeframe:

From Day 1 to Day 281

Notes:

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

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

[54] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants safety cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 Medium Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 High Dose	Stage 2 Infants safety cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	10	10	30
Units: Participants	0	0	0	1

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 9 months of age in Africa with deviations from normal values of haematological, renal, and hepatic panel test results after first study intervention - Infants dose-finding cohort

End point title	Stage 2: Number of participants 9 months of age in Africa with deviations from normal values of haematological, renal, and hepatic panel test results after first study intervention - Infants dose-finding cohort ^{[55][56]}
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End point description:

Panel tests include measures of ALT, AST, creatinine, basophils, eosinophils, erythrocytes, haematocrit, haemoglobin, lymphocytes, monocytes, neutrophils, platelets and WBC. Categories reported when comparing Day 1 (baseline) and normal range hematological, renal and hepatic laboratory results are defined as follows: <parameter>, <range at baseline>, <range at timing>, where range is being classified as Below = value below; Within = value within; and Above = value above the laboratory reference range defined for the specified visit and laboratory parameter. The analysis was performed on the Exposed Set for Stage 2 Infants.

End point type	Primary
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End point timeframe:

At Day 8

Notes:

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

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

[56] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all

the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Med Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose	Stage 2 Infants dose-finding cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	81	83	82
Units: Participants				
ALT, Within, Within	77	75	79	80
ALT, Within, Above	1	1	2	1
ALT, Above, Within	1	0	1	0
AST, Within, Within	76	76	78	81
AST, Within, Above	3	0	2	0
AST, Above, Within	0	0	2	0
Creatinine, Below, Below	79	76	81	81
Creatinine, Within, Below	0	0	1	0
Potassium, Below, Within	0	0	0	1
Potassium, Within, Below	0	0	1	0
Potassium, Within, Within	79	76	81	78
Potassium, Within, Above	0	0	0	1
Potassium, Above, Within	0	0	0	1
Sodium, Within, Within	40	35	39	37
Sodium, Within, Above	14	20	19	19
Sodium, Above, Within	8	11	14	14
Sodium, Above, Above	17	10	10	11
Urea, Below, Below	31	29	36	25
Urea, Below, Within	13	13	16	14
Urea, Within, Below	10	14	11	15
Urea, Within, Within	25	20	19	27
Basophils, Within, Within	69	70	73	68
Basophils, Within, Above	2	2	2	5
Basophils, Above, Within	5	4	7	6
Basophils, Above, Above	3	0	0	2
Eosinophils, Below, Within	0	2	3	1
Eosinophils, Within, Below	4	3	1	3
Eosinophils, Within, Within	70	65	73	66
Eosinophils, Within, Above	2	1	0	3
Eosinophils, Above, Within	2	3	2	4
Eosinophils, Above, Above	1	2	3	4
Erythrocytes, Below, Below	1	2	1	0
Erythrocytes, Below, Within	0	1	3	0
Erythrocytes, Within, Below	1	1	1	1
Erythrocytes, Within, Within	57	45	52	53
Erythrocytes, Within, Above	4	7	7	5
Erythrocytes, Above, Within	8	5	5	5
Erythrocytes, Above, Above	8	15	13	17
Haematocrit, Below, Below	4	0	0	1
Haematocrit, Below, Within	1	3	2	1
Haematocrit, Within, Below	2	2	2	4

Haematocrit, Within, Within	62	64	73	66
Haematocrit, Within, Above	0	1	1	2
Haematocrit, Above, Within	9	4	2	5
Haematocrit, Above, Above	1	2	2	2
Haemoglobin, Below, Below	7	3	4	3
Haemoglobin, Below, Within	5	3	4	2
Haemoglobin, Within, Below	4	9	2	5
Haemoglobin, Within, Within	58	58	68	67
Haemoglobin, Within, Above	0	1	2	0
Haemoglobin, Above, Within	4	1	0	3
Haemoglobin, Above, Above	1	1	2	1
Lymphocytes, Below, Within	0	0	0	1
Lymphocytes, Within, Within	51	54	58	51
Lymphocytes, Within, Above	2	3	6	3
Lymphocytes, Above, Within	7	9	8	14
Lymphocytes, Above, Above	19	10	10	12
Monocytes, Within, Below	0	0	0	1
Monocytes, Within, Within	50	53	51	50
Monocytes, Within, Above	23	16	19	18
Monocytes, Above, Within	2	1	4	5
Monocytes, Above, Above	4	6	8	7
Neutrophils, Below, Below	7	4	7	7
Neutrophils, Below, Within	7	6	6	6
Neutrophils, Within, Below	12	16	12	11
Neutrophils, Within, Within	52	49	56	56
Neutrophils, Within, Above	0	1	1	0
Neutrophils, Above, Within	1	0	0	1
Platelets, Below, Above	1	0	0	0
Platelets, Within, Within	12	19	14	18
Platelets, Within, Above	11	14	12	6
Platelets, Above, Within	14	10	15	16
Platelets, Above, Above	41	33	41	41
WBC, Below, Below	2	1	1	1
WBC, Below, Within	0	4	4	2
WBC, Within, Below	4	6	5	3
WBC, Within, Within	54	51	55	60
WBC, Within, Above	2	5	3	2
WBC, Above, Within	9	6	10	7
WBC, Above, Above	8	3	4	6

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 9 months of age in Africa with deviations from normal values of haematological, renal, and hepatic panel test results after second study intervention - Infants safety cohort

End point title	Stage 2: Number of participants 9 months of age in Africa with deviations from normal values of haematological, renal, and hepatic panel test results after second study intervention -
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End point description:

Panel tests include measures of ALT, AST, creatinine, basophils, eosinophils, erythrocytes, haematocrit, haemoglobin, lymphocytes, monocytes, neutrophils, platelets and WBC. Categories reported when comparing Day 1 (baseline) and normal range hematological, renal and hepatic laboratory results are defined as follows: <parameter>, <range at baseline>, <range at timing>, where range is being classified as Below = value below; Within = value within; and Above = value above the laboratory reference range defined for the specified visit and laboratory parameter. 9999 = data not available. The analysis was performed on the Exposed Set for Stage 2 Infants, safety cohort.

End point type Primary

End point timeframe:

At Day 92

Notes:

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

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

[58] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants safety cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 Medium Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 High Dose	Stage 2 Infants safety cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	10	10	30
Units: Participants				
ALT, Below, Below	0	0	1	0
ALT, Within, Within	8	8	9	28
ALT, Above, Within	1	0	0	0
AST, Within, Within	8	8	9	28
AST, Within, Above	0	0	1	0
AST, Above, Above	1	0	0	0
Creatinine, Below, Below	9	8	10	28
Potassium, Within, Within	9999	9999	2	6
Potassium, Within, Above	9999	9999	4	3
Potassium, Above, Within	9999	9999	2	0
Potassium, Above, Above	9999	9999	2	1
Sodium, Within, Within	9999	9999	5	9
Sodium, Within, Above	9999	9999	2	1
Sodium, Above, Within	9999	9999	3	0
Urea, Below, Below	9999	9999	7	3
Urea, Below, Within	9999	9999	0	3
Urea, Within, Below	9999	9999	1	1
Urea, Within, Within	9999	9999	2	3
Basophils, Within, Within	1	3	6	12
Basophils, Within, Above	1	3	2	5
Basophils, Above, Within	0	1	1	1
Basophils, Above, Above	7	1	1	10
Eosinophils, Within, Below	0	0	0	1
Eosinophils, Within, Within	8	6	10	24
Eosinophils, Within, Above	1	0	0	1
Eosinophils, Above, Within	0	1	0	1

Eosinophils, Above, Above	0	1	0	1
Erythrocytes, Below, Below	0	0	0	1
Erythrocytes, Within, Below	0	0	0	1
Erythrocytes, Within, Within	6	5	7	19
Erythrocytes, Within, Above	1	1	0	1
Erythrocytes, Above, Within	0	0	1	2
Erythrocytes, Above, Above	2	2	2	4
Haematocrit, Below, Below	0	0	1	0
Haematocrit, Below, Within	1	0	0	0
Haematocrit, Within, Below	3	0	0	1
Haematocrit, Within, Within	5	5	8	21
Haematocrit, Within, Above	0	0	0	3
Haematocrit, Above, Within	0	3	0	2
Haematocrit, Above, Above	0	0	1	1
Haemoglobin, Below, Below	4	1	2	1
Haemoglobin, Below, Within	1	0	0	0
Haemoglobin, Within, Below	0	0	0	1
Haemoglobin, Within, Within	4	7	7	26
Haemoglobin, Above, Above	0	0	1	0
Lymphocytes, Within, Within	8	5	7	14
Lymphocytes, Within, Above	0	0	1	3
Lymphocytes, Above, Within	0	1	0	1
Lymphocytes, Above, Above	1	2	2	10
Monocytes, Below, Within	0	0	0	1
Monocytes, Within, Below	0	0	1	2
Monocytes, Within, Within	9	6	8	24
Monocytes, Within, Above	0	2	1	0
Monocytes, Above, Above	0	0	0	1
Neutrophils, Below, Below	1	0	1	1
Neutrophils, Below, Within	1	1	1	2
Neutrophils, Below, Above	0	1	0	0
Neutrophils, Within, Below	0	1	0	2
Neutrophils, Within, Within	7	5	8	22
Neutrophils, Within, Above	0	0	0	1
Platelets, Within, Within	1	2	2	7
Platelets, Within, Above	1	0	0	2
Platelets, Above, Within	0	0	0	4
Platelets, Above, Above	7	6	8	15
WBC, Below, Below	0	0	1	1
WBC, Below, Within	0	0	0	1
WBC, Within, Within	8	4	6	18
WBC, Within, Above	1	3	2	2
WBC, Above, Within	0	0	0	5
WBC, Above, Above	0	1	1	1

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 9 months of age in Africa with deviations from normal values of haematological, renal, and hepatic panel test results after second study intervention - Infants dose-finding cohort

End point title	Stage 2: Number of participants 9 months of age in Africa with deviations from normal values of haematological, renal, and hepatic panel test results after second study intervention - Infants dose-finding cohort ^{[59][60]}
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End point description:

Panel tests include measures of alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine, potassium, sodium, urea, basophils, eosinophils, erythrocytes, haematocrit, haemoglobin, lymphocytes, monocytes, neutrophils, platelets and white blood cells (WBC). Categories reported when comparing Day 1 (baseline) and normal range hematological, renal and hepatic laboratory results are defined as follows: <parameter>,<range at baseline>,<range at timing>, where range is being classified as Below = value below; Within = value within; and Above = value above the laboratory reference range defined for the specified visit and laboratory parameter. The analysis was performed on the Exposed Set for Stage 2 Infants, dose-finding cohort.

End point type	Primary
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End point timeframe:

At Day 92

Notes:

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

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

[60] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Med Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose	Stage 2 Infants dose-finding cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	81	83	82
Units: Participants				
ALT, Below, Below	0	1	0	0
ALT, Below, Within	0	0	1	0
ALT, Within, Below	0	0	0	2
ALT, Within, Within	70	68	71	68
ALT, Within, Above	2	2	0	3
ALT, Above, Within	0	1	2	0
AST, Within, Within	69	71	73	72
AST, Within, Above	2	1	0	0
AST, Above, Within	1	0	0	0
AST, Above, Above	0	0	1	1
Creatinine, Below, Below	72	71	74	72
Creatinine, Below, Within	0	1	0	1
Potassium, Within, Within	18	16	18	19
Potassium, Within, Above	24	26	34	28
Potassium, Above, Within	9	8	2	10
Potassium, Above, Above	21	22	20	16
Sodium, Within, Within	48	53	54	52
Sodium, Within, Above	7	5	8	8
Sodium, Above, Within	17	11	10	13
Sodium, Above, Above	0	3	2	0

Urea, Below, Below	27	24	32	24
Urea, Below, Within	9	12	7	11
Urea, Below, Above	0	1	0	0
Urea, Within, Below	13	15	13	13
Urea, Within, Within	23	20	22	25
Basophils, Below, Within	0	1	0	0
Basophils, Within, Below	0	0	0	2
Basophils, Within, Within	58	58	64	54
Basophils, Within, Above	8	3	7	8
Basophils, Above, Within	5	5	2	5
Basophils, Above, Above	1	5	1	4
Eosinophils, Below, Within	0	0	1	0
Eosinophils, Within, Below	1	2	1	1
Eosinophils, Within, Within	61	60	62	61
Eosinophils, Within, Above	2	1	2	4
Eosinophils, Above, Within	6	0	1	2
Eosinophils, Above, Above	2	9	7	5
Erythrocytes, Below, Within	1	1	0	0
Erythrocytes, Within, Below	0	0	2	0
Erythrocytes, Within, Within	48	45	44	50
Erythrocytes, Within, Above	5	2	5	3
Erythrocytes, Above, Within	5	3	4	7
Erythrocytes, Above, Above	13	21	19	13
Haematocrit, Below, Below	1	0	1	2
Haematocrit, Below, Within	1	2	0	0
Haematocrit, Within, Below	3	2	2	3
Haematocrit, Within, Within	60	60	57	62
Haematocrit, Within, Above	4	0	5	1
Haematocrit, Above, Within	0	5	3	2
Haematocrit, Above, Above	3	3	6	3
Haemoglobin, Below, Below	7	7	5	4
Haemoglobin, Below, Within	2	3	1	1
Haemoglobin, Within, Below	5	2	4	7
Haemoglobin, Within, Within	54	56	59	57
Haemoglobin, Within, Above	1	1	1	1
Haemoglobin, Above, Within	2	2	1	2
Haemoglobin, Above, Above	1	1	3	1
Lymphocytes, Within, Below	0	0	0	1
Lymphocytes, Within, Within	38	43	44	36
Lymphocytes, Within, Above	13	11	11	9
Lymphocytes, Above, Within	6	5	10	11
Lymphocytes, Above, Above	15	13	9	16
Monocytes, Below, Within	1	0	0	0
Monocytes, Within, Below	0	0	0	2
Monocytes, Within, Within	52	47	60	62
Monocytes, Within, Above	7	15	8	2
Monocytes, Above, Within	9	7	3	4
Monocytes, Above, Above	3	3	3	3
Neutrophils, Below, Below	1	1	3	5
Neutrophils, Below, Within	6	7	11	6
Neutrophils, Within, Below	5	7	3	2
Neutrophils, Within, Within	57	53	54	60

Neutrophils, Within, Above	2	2	1	0
Neutrophils, Above, Within	1	2	1	0
Neutrophils, Above, Above	0	0	1	0
Platelets, Within, Within	9	15	11	15
Platelets, Within, Above	10	14	16	5
Platelets, Above, Below	1	0	0	0
Platelets, Above, Within	8	6	7	7
Platelets, Above, Above	44	37	40	46
WBC, Below, Within	3	1	2	2
WBC, Within, Below	3	1	1	3
WBC, Within, Within	47	48	56	53
WBC, Within, Above	6	9	5	7
WBC, Above, Within	5	6	3	2
WBC, Above, Above	8	7	7	6

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 9 months of age in Africa with deviations from normal values of haematological, renal, and hepatic panel test results after third study intervention - Infants safety cohort

End point title	Stage 2: Number of participants 9 months of age in Africa with deviations from normal values of haematological, renal, and hepatic panel test results after third study intervention - Infants safety cohort ^[61] ^[62]
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End point description:

Panel tests include measures of ALT, AST, creatinine, basophils, eosinophils, erythrocytes, haematocrit, haemoglobin, lymphocytes, monocytes, neutrophils, platelets and WBC. Categories reported when comparing Day 1 (baseline) and normal range hematological, renal and hepatic laboratory results are defined as follows: <parameter>,<range at baseline>,<range at timing>, where range is being classified as Below = value below; Within = value within; and Above = value above the laboratory reference range defined for the specified visit and laboratory parameter. The analysis was performed on the Exposed Set for Stage 2 Infants, safety cohort.

End point type	Primary
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End point timeframe:

At Day 260

Notes:

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

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

[62] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants safety cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 Medium Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 High Dose	Stage 2 Infants safety cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	10	10	30
Units: Participants				
ALT, Within, Within	9	8	9	27
ALT, Above, Above	0	0	0	1
AST, Within, Within	9	8	9	28
Creatinine, Below, Below	8	8	9	28
Creatinine, Within, Below	1	0	0	0
Potassium, Within, Within	1	3	3	11
Potassium, Within, Above	3	1	0	5
Potassium, Above, Within	1	1	3	7
Potassium, Above, Above	4	3	3	5
Sodium, Within, Within	4	8	6	18
Sodium, Within, Above	2	0	0	2
Sodium, Above, Within	1	0	3	5
Sodium, Above, Above	2	0	0	3
Urea, Below, Below	3	2	5	9
Urea, Below, Within	3	1	1	2
Urea, Within, Below	1	1	1	4
Urea, Within, Within	2	4	2	13
Basophils, Within, Within	5	7	8	23
Basophils, Within, Above	2	0	0	3
Basophils, Above, Within	2	0	1	2
Basophils, Above, Above	0	1	0	0
Eosinophils, Below, Within	0	0	0	2
Eosinophils, Within, Within	8	7	9	22
Eosinophils, Within, Above	1	0	0	1
Eosinophils, Above, Above	0	1	0	3
Erythrocytes, Below, Below	0	0	0	1
Erythrocytes, Within, Within	6	4	7	20
Erythrocytes, Within, Above	1	1	0	0
Erythrocytes, Above, Within	1	2	2	3
Erythrocytes, Above, Above	1	1	0	4
Haematocrit, Below, Below	0	0	0	2
Haematocrit, Below, Within	0	0	0	1
Haematocrit, Within, Within	7	6	8	16
Haematocrit, Within, Above	1	1	0	2
Haematocrit, Above, Within	1	1	0	2
Haematocrit, Above, Above	0	0	1	5
Haemoglobin, Below, Below	0	0	2	3
Haemoglobin, Below, Within	0	0	0	2
Haemoglobin, Within, Below	1	0	0	1
Haemoglobin, Within, Within	8	8	6	17
Haemoglobin, Within, Above	0	0	0	2
Haemoglobin, Above, Within	0	0	0	2
Haemoglobin, Above, Above	0	0	1	1
Lymphocytes, Within, Within	6	6	6	21
Lymphocytes, Within, Above	2	1	0	2
Lymphocytes, Above, Within	1	1	1	2

Lymphocytes, Above, Above	0	0	2	3
Monocytes, Below, Within	1	0	0	2
Monocytes, Within, Below	0	0	1	0
Monocytes, Within, Within	7	8	6	22
Monocytes, Within, Above	1	0	2	2
Monocytes, Above, Within	0	0	0	1
Monocytes, Above, Above	0	0	0	1
Neutrophils, Below, Below	0	0	0	1
Neutrophils, Below, Within	0	1	2	1
Neutrophils, Within, Below	1	0	1	2
Neutrophils, Within, Within	8	5	6	24
Neutrophils, Within, Above	0	2	0	0
Platelets, Below, Within	0	1	0	0
Platelets, Within, Within	2	2	2	6
Platelets, Within, Above	0	0	3	5
Platelets, Above, Within	2	1	2	5
Platelets, Above, Above	5	4	2	12
WBC, Below, Below	0	0	1	0
WBC, Below, Within	1	2	2	0
WBC, Within, Below	0	0	0	3
WBC, Within, Within	7	4	3	18
WBC, Within, Above	1	1	2	3
WBC, Above, Within	0	1	0	3
WBC, Above, Above	0	0	1	1

Statistical analyses

No statistical analyses for this end point

Primary: Stage 2: Number of participants 9 months of age in Africa with deviations from normal values of haematological, renal, and hepatic panel test results after third study intervention - Infants dose-finding cohort

End point title	Stage 2: Number of participants 9 months of age in Africa with deviations from normal values of haematological, renal, and hepatic panel test results after third study intervention - Infants dose-finding cohort ^{[63][64]}
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End point description:

Panel tests include measures of alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine, potassium, sodium, urea, basophils, eosinophils, erythrocytes, haematocrit, haemoglobin, lymphocytes, monocytes, neutrophils, platelets and white blood cells (WBC). Categories reported when comparing Day 1 (baseline) and normal range hematological, renal and hepatic laboratory results are defined as follows: <parameter>,<range at baseline>,<range at timing>, where range is being classified as Below = value below; Within = value within; and Above = value above the laboratory reference range defined for the specified visit and laboratory parameter. The analysis was performed on the Exposed Set for Stage 2 Infants, dose-finding cohort.

End point type	Primary
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End point timeframe:

At Day 260

Notes:

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

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

[64] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Med Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose	Stage 2 Infants dose-finding cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	81	83	82
Units: Participants				
ALT, Below, Within	1	2	1	2
ALT, Within, Below	2	1	0	0
ALT, Within, Within	64	67	69	65
ALT, Within, Above	1	0	3	0
ALT, Above, Within	1	1	0	0
ALT, Above, Above	0	0	0	4
AST, Within, Within	68	71	71	70
AST, Within, Above	1	0	1	0
AST, Above, Within	0	0	1	0
AST, Above, Above	0	0	0	1
Creatinine, Below, Below	68	70	73	71
Creatinine, Below, Within	0	1	0	0
Creatinine, Within, Below	1	0	0	0
Potassium, Within, Within	26	28	25	21
Potassium, Within, Above	12	18	23	23
Potassium, Above, Within	11	8	7	10
Potassium, Above, Above	20	17	18	17
Sodium, Below, Within	1	2	4	2
Sodium, Within, Below	0	0	1	0
Sodium, Within, Within	55	61	55	63
Sodium, Within, Above	4	4	7	2
Sodium, Above, Within	8	3	6	4
Sodium, Above, Above	1	1	0	0
Urea, Below, Below	18	15	16	13
Urea, Below, Within	12	6	11	12
Urea, Within, Below	10	14	14	5
Urea, Within, Within	29	36	32	41
Basophils, Below, Within	0	0	0	1
Basophils, Within, Within	53	54	62	53
Basophils, Within, Above	7	8	4	8
Basophils, Above, Within	6	6	6	3
Basophils, Above, Above	3	3	1	6
Eosinophils, Below, Within	1	1	0	3
Eosinophils, Within, Below	0	2	2	0
Eosinophils, Within, Within	59	58	59	56
Eosinophils, Within, Above	2	4	2	2
Eosinophils, Above, Within	2	1	3	3
Eosinophils, Above, Above	5	5	7	7
Erythrocytes, Below, Below	0	1	0	0
Erythrocytes, Within, Within	44	39	46	44

Erythrocytes, Within, Above	4	5	5	5
Erythrocytes, Above, Within	8	2	4	5
Erythrocytes, Above, Above	13	24	18	17
Haematocrit, Below, Below	2	2	0	0
Haematocrit, Below, Within	1	1	0	1
Haematocrit, Within, Below	0	1	0	0
Haematocrit, Within, Within	55	55	56	57
Haematocrit, Within, Above	1	7	9	1
Haematocrit, Above, Within	5	2	2	7
Haematocrit, Above, Above	5	3	6	5
Haemoglobin, Below, Below	6	4	4	4
Haemoglobin, Below, Within	3	3	0	3
Haemoglobin, Within, Below	2	5	2	1
Haemoglobin, Within, Within	53	52	57	59
Haemoglobin, Within, Above	1	2	4	1
Haemoglobin, Above, Within	2	1	4	2
Haemoglobin, Above, Above	2	4	2	1
Lymphocytes, Within, Within	43	57	58	48
Lymphocytes, Within, Above	13	6	5	8
Lymphocytes, Above, Within	4	3	8	8
Lymphocytes, Above, Above	9	5	2	7
Monocytes, Below, Below	1	0	0	0
Monocytes, Below, Within	1	0	2	1
Monocytes, Within, Below	1	1	0	2
Monocytes, Within, Within	54	61	63	62
Monocytes, Within, Above	7	3	5	3
Monocytes, Above, Within	4	4	2	2
Monocytes, Above, Above	1	2	1	1
Neutrophils, Below, Below	5	1	0	1
Neutrophils, Below, Within	4	5	9	6
Neutrophils, Within, Below	3	3	5	5
Neutrophils, Within, Within	55	60	58	58
Neutrophils, Within, Above	1	0	0	1
Neutrophils, Above, Within	1	2	1	0
Platelets, Below, Below	0	0	1	0
Platelets, Below, Within	0	0	1	0
Platelets, Within, Within	17	21	19	16
Platelets, Within, Above	10	18	17	11
Platelets, Above, Within	8	7	8	6
Platelets, Above, Above	34	25	27	38
WBC, Below, Below	1	0	2	0
WBC, Below, Within	4	3	6	2
WBC, Within, Below	1	2	1	0
WBC, Within, Within	44	51	53	53
WBC, Within, Above	6	6	2	6
WBC, Above, Within	4	7	6	6
WBC, Above, Above	9	2	3	4

Statistical analyses

Secondary: Stage 1: Anti-serotype specific Shigella LPS/OAg serum IgG GMCs in participants 18 to 50 years of age in Europe

End point title	Stage 1: Anti-serotype specific Shigella LPS/OAg serum IgG GMCs in participants 18 to 50 years of age in Europe ^[65]
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End point description:

Anti-serotype specific Shigella LPS/OAg serum IgG GMCs were measured by ELISA and expressed in EU/mL of serum. *S. sonnei*, *S. flexneri* 1b, *S. flexneri* 2a, and *S. flexneri* 3a serotypes were tested. 9999 = data not available. The analysis was performed on the PPS for Stage 1 Adults. As the participants in Stage 1 Adults: Placebo Group received the second placebo intervention at Day 85 or at Day 169, the analysis being performed on the pooled participants as per the SAP, no differentiation was made by timepoint of administration for the second dose for this group.

End point type	Secondary
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End point timeframe:

At Day 1 and Day 85/Day 169(before each study intervention); at Day 15 (14 days after the first study intervention); at Day 29 and Day 113/Day 197 (28 days after each study intervention)

Notes:

[65] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 1 Adults: altSonflex1-2-3 High Dose Group 1	Stage 1 Adults: altSonflex1-2-3 High Dose Group 2	Stage 1 Adults: Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	34	34	34	
Units: EU/mL				
geometric mean (confidence interval 95%)				
S sonnei Ab IgG, Day 1	15.3 (10.8 to 21.8)	8.9 (6.9 to 11.5)	21.0 (13.2 to 33.6)	
S sonnei Ab IgG, Day 15	307.5 (167.3 to 565.2)	170.7 (98.2 to 296.5)	18.4 (11.6 to 29.3)	
S sonnei Ab IgG, Day 29	325.3 (181.6 to 582.8)	172.1 (96.7 to 306.4)	18.1 (11.5 to 28.6)	
S sonnei Ab IgG, Day 85	287.6 (144.1 to 574.1)	9999 (9999 to 9999)	9999 (9999 to 9999)	
S sonnei Ab IgG, Day 169	9999 (9999 to 9999)	94.8 (55.2 to 162.9)	9999 (9999 to 9999)	
S sonnei Ab IgG, Day 85/169	9999 (9999 to 9999)	9999 (9999 to 9999)	19.0 (11.1 to 32.3)	
S sonnei Ab IgG, Day 113	387.8 (206.6 to 727.8)	9999 (9999 to 9999)	9999 (9999 to 9999)	
S sonnei Ab IgG, Day 197	9999 (9999 to 9999)	167.2 (104.3 to 267.9)	9999 (9999 to 9999)	
S sonnei Ab IgG, Day 113/197	9999 (9999 to 9999)	9999 (9999 to 9999)	19.9 (11.8 to 33.7)	
S flexneri 1b Ab IgG, Day 1	23.5 (13.6 to 40.5)	22.9 (13.9 to 37.8)	26.9 (15.3 to 47.3)	
S flexneri 1b Ab IgG, Day 15	123.1 (71.8 to 211.1)	102.1 (63.8 to 163.5)	27.4 (16.1 to 46.7)	
S flexneri 1b Ab IgG, Day 29	118.3 (70.5 to 198.5)	90.2 (55.9 to 145.5)	27.0 (15.8 to 46.3)	
S flexneri 1b Ab IgG, Day 85	79.1 (45.3 to 138.1)	9999 (9999 to 9999)	9999 (9999 to 9999)	

S flexneri 1b Ab IgG, Day 169	9999 (9999 to 9999)	48.5 (30.1 to 78.0)	9999 (9999 to 9999)
S flexneri 1b Ab IgG, Day 85/169	9999 (9999 to 9999)	9999 (9999 to 9999)	27.2 (15.5 to 47.7)
S flexneri 1b Ab IgG, Day 113	129.7 (79.6 to 211.5)	9999 (9999 to 9999)	9999 (9999 to 9999)
S flexneri 1b Ab IgG, Day 197	9999 (9999 to 9999)	73.0 (48.6 to 109.7)	9999 (9999 to 9999)
S flexneri 1b Ab IgG, Day 113/197	9999 (9999 to 9999)	9999 (9999 to 9999)	26.1 (14.6 to 46.9)
S flexneri 2a Ab IgG, Day 1	33.3 (23.1 to 47.9)	32.7 (22.2 to 48.2)	44.5 (27.3 to 72.6)
S flexneri 2a Ab IgG, Day 15	608.0 (432.4 to 854.9)	635.2 (459.5 to 878.1)	44.3 (27.4 to 71.6)
S flexneri 2a Ab IgG, Day 29	545.8 (393.1 to 757.6)	582.6 (424.1 to 800.4)	42.8 (26.3 to 69.5)
S flexneri 2a Ab IgG, Day 85	411.8 (300.4 to 564.6)	9999 (9999 to 9999)	9999 (9999 to 9999)
S flexneri 2a Ab IgG, Day 169	9999 (9999 to 9999)	364.9 (259.9 to 512.5)	9999 (9999 to 9999)
S flexneri 2a Ab IgG, Day 85/169	9999 (9999 to 9999)	9999 (9999 to 9999)	41.4 (23.3 to 73.6)
S flexneri 2a Ab IgG, Day 113	473.6 (351.1 to 638.8)	9999 (9999 to 9999)	9999 (9999 to 9999)
S flexneri 2a Ab IgG, Day 197	9999 (9999 to 9999)	451.0 (327.8 to 620.6)	9999 (9999 to 9999)
S flexneri 2a Ab IgG, Day 113/197	9999 (9999 to 9999)	9999 (9999 to 9999)	43.8 (25.1 to 76.3)
S flexneri 3a Ab IgG, Day 1	17.3 (11.1 to 27.0)	14.2 (8.4 to 23.9)	19.9 (13.1 to 30.2)
S flexneri 3a Ab IgG, Day 15	59.1 (40.5 to 86.1)	63.8 (36.2 to 112.4)	18.4 (12.2 to 27.8)
S flexneri 3a Ab IgG, Day 29	56.7 (37.6 to 85.4)	60.6 (34.8 to 105.5)	19.3 (12.7 to 29.4)
S flexneri 3a Ab IgG, Day 85	26.9 (16.7 to 43.4)	9999 (9999 to 9999)	9999 (9999 to 9999)
S flexneri 3a Ab IgG, Day 169	9999 (9999 to 9999)	24.7 (14.1 to 43.2)	9999 (9999 to 9999)
S flexneri 3a Ab IgG, Day 85/169	9999 (9999 to 9999)	9999 (9999 to 9999)	10.1 (6.4 to 15.9)
S flexneri 3a Ab IgG, Day 113	43.1 (26.9 to 69.2)	9999 (9999 to 9999)	9999 (9999 to 9999)
S flexneri 3a Ab IgG, Day 197	9999 (9999 to 9999)	37.2 (22.4 to 61.7)	9999 (9999 to 9999)
S flexneri 3a Ab IgG, Day 113/197	9999 (9999 to 9999)	9999 (9999 to 9999)	9.2 (5.6 to 15.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Stage 2: Anti-serotype specific Shigella LPS/OAg serum IgG GMCs in participants 18 to 50 years of age in Africa

End point title	Stage 2: Anti-serotype specific Shigella LPS/OAg serum IgG GMCs in participants 18 to 50 years of age in Africa ^[66]
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End point description:

The analysis was performed on the PPS for Stage 2 Adults.

End point type	Secondary
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End point timeframe:

At Day 1 and Day 85 (before each study intervention administration) and Day 29 and Day 113 (28 days after each study intervention administration)

Notes:

[66] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Adults: altSonflex1-2-3 High Dose	Stage 2 Adults: Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: EU/mL				
geometric mean (confidence interval 95%)				
S sonnei Ab IgG, Day 1	166.4 (82.8 to 334.2)	171.2 (65.0 to 450.6)		
S sonnei Ab IgG, Day 29	3112.0 (2181.6 to 4439.2)	172.0 (66.7 to 443.6)		
S sonnei Ab IgG, Day 85	2046.5 (1372.1 to 3052.5)	182.1 (73.2 to 453.1)		
S sonnei Ab IgG, Day 113	1974.4 (1288.5 to 3025.6)	172.3 (68.8 to 431.6)		
S flexneri 1b Ab IgG, Day 1	194.7 (44.0 to 862.2)	106.4 (41.0 to 276.2)		
S flexneri 1b Ab IgG, Day 29	388.5 (98.6 to 1531.3)	103.3 (40.2 to 265.8)		
S flexneri 1b Ab IgG, Day 85	328.0 (84.8 to 1268.8)	110.8 (38.9 to 315.5)		
S flexneri 1b Ab IgG, Day 113	358.3 (98.6 to 1301.7)	107.2 (37.5 to 306.1)		
S flexneri 2a Ab IgG, Day 1	192.3 (93.7 to 394.6)	155.8 (70.7 to 343.6)		
S flexneri 2a Ab IgG, Day 29	563.0 (269.1 to 1177.7)	146.1 (68.7 to 311.0)		
S flexneri 2a Ab IgG, Day 85	463.0 (220.3 to 973.4)	158.1 (67.7 to 369.3)		
S flexneri 2a Ab IgG, Day 113	538.6 (269.9 to 1074.7)	154.0 (68.5 to 346.2)		
S flexneri 3a Ab IgG, Day 1	84.8 (34.5 to 208.8)	61.3 (19.6 to 192.0)		
S flexneri 3a Ab IgG, Day 29	212.8 (89.9 to 503.6)	57.4 (18.2 to 181.5)		
S flexneri 3a Ab IgG, Day 85	174.4 (75.1 to 405.3)	62.3 (16.7 to 233.3)		
S flexneri 3a Ab IgG, Day 113	225.4 (103.2 to 492.7)	61.6 (16.7 to 226.8)		

Statistical analyses

Secondary: Stage 2: Anti-serotype specific Shigella LPS/OAg serum IgG GMCs in participants 24 to 59 months of age in Africa

End point title	Stage 2: Anti-serotype specific Shigella LPS/OAg serum IgG GMCs in participants 24 to 59 months of age in Africa ^[67]
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End point description:

The analysis was performed on the PPS for Stage 2 Children.

End point type	Secondary
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End point timeframe:

At Day 1 and Day 85 (before each study intervention) and Day 29 and Day 113 (28 days after each study intervention)

Notes:

[67] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Children: altSonflex1-2-3 Medium Dose	Stage 2 Children: altSonflex1-2-3 High Dose	Stage 2 Children: Control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	20	
Units: EU/mL				
geometric mean (confidence interval 95%)				
S sonnei Ab IgG, Day 1	22.7 (8.5 to 61.0)	39.1 (9.5 to 160.1)	20.7 (10.5 to 41.0)	
S sonnei Ab IgG, Day 29	899.0 (122.7 to 6588.6)	746.9 (93.9 to 5940.9)	19.3 (10.4 to 35.8)	
S sonnei Ab IgG, Day 85)	702.7 (125.7 to 3927.4)	388.2 (56.6 to 2663.4)	24.7 (11.1 to 54.7)	
S sonnei Ab IgG, Day 113	1163.2 (289.8 to 4668.7)	560.2 (86.0 to 3651.0)	40.2 (15.9 to 101.6)	
S flexneri 1b Ab IgG, Day 1	28.6 (6.6 to 123.1)	38.4 (7.0 to 211.4)	37.0 (16.4 to 83.3)	
S flexneri 1b Ab IgG, Day 29	74.0 (23.3 to 234.8)	119.4 (27.2 to 525.1)	33.4 (13.6 to 81.7)	
S flexneri 1b Ab IgG, Day 85	39.3 (10.7 to 144.5)	65.4 (13.1 to 326.7)	34.5 (15.0 to 79.6)	
S flexneri 1b Ab IgG, Day 113	66.7 (20.5 to 217.0)	100.3 (21.6 to 466.4)	31.9 (14.0 to 72.4)	
S flexneri 2a Ab IgG, Day 1	24.5 (5.1 to 117.9)	21.0 (4.7 to 93.0)	30.9 (12.4 to 77.3)	
S flexneri 2a Ab IgG, Day 29	219.2 (65.6 to 732.9)	193.5 (76.2 to 491.6)	30.6 (12.7 to 74.2)	
S flexneri 2a Ab IgG, Day 85	101.2 (28.7 to 356.9)	103.8 (36.3 to 297.0)	32.1 (14.2 to 72.5)	
S flexneri 2a Ab IgG, Day 113	267.3 (101.0 to 707.4)	290.0 (115.0 to 731.3)	29.5 (13.8 to 63.2)	
S flexneri 3a Ab IgG, Day 1	14.2 (4.5 to 44.7)	8.5 (3.5 to 20.6)	7.6 (3.0 to 19.8)	
S flexneri 3a Ab IgG, Day 29	30.7 (10.7 to 87.9)	22.0 (7.6 to 63.7)	6.2 (2.5 to 15.2)	
S flexneri 3a Ab IgG, Day 85	17.8 (5.9 to 53.4)	14.1 (4.9 to 40.3)	6.2 (2.7 to 14.2)	
S flexneri 3a Ab IgG, Day 113	32.1 (12.3 to 84.2)	26.1 (10.2 to 66.7)	7.0 (3.2 to 15.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Stage 2: Anti-serotype specific Shigella LPS/OAg serum IgG GMCs in participants 9 months of age in Africa - Infants safety cohort

End point title	Stage 2: Anti-serotype specific Shigella LPS/OAg serum IgG GMCs in participants 9 months of age in Africa - Infants safety cohort ^[68]
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End point description:

The analysis was performed on the PPS for Stage 2 Infants, safety cohort.

End point type	Secondary
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End point timeframe:

At Day 1, Day 85 and Day 253 (before each study intervention administration) and Day 29, Day 113 and Day 281 (28 days after each study intervention administration)

Notes:

[68] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants safety cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 Medium Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 High Dose	Stage 2 Infants safety cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	10	10	30
Units: EU/mL				
geometric mean (confidence interval 95%)				
S sonnei Ab IgG, Day 1	6.4 (6.4 to 6.4)	6.9 (5.8 to 8.1)	6.4 (6.4 to 6.4)	6.6 (6.2 to 6.9)
S sonnei Ab IgG, Day 29	16.9 (7.8 to 36.6)	17.5 (9.5 to 32.4)	17.3 (9.1 to 33.0)	6.4 (6.4 to 6.4)
S sonnei Ab IgG, Day 85	27.2 (12.6 to 58.3)	32.7 (16.1 to 66.6)	23.3 (11.1 to 48.9)	6.4 (6.4 to 6.4)
S sonnei Ab IgG, Day 113	240.4 (60.3 to 958.3)	264.7 (105.1 to 666.9)	171.0 (67.7 to 431.6)	6.4 (6.4 to 6.4)
S sonnei Ab IgG, Day 253	128.5 (60.1 to 274.9)	99.5 (50.4 to 196.3)	63.4 (24.4 to 165.1)	6.4 (6.4 to 6.4)
S sonnei Ab IgG, Day 281	429.9 (155.7 to 1186.8)	275.8 (90.1 to 844.3)	185.2 (111.2 to 308.4)	6.4 (6.4 to 6.4)
S flexneri 1b Ab IgG, Day 1	6.0 (2.5 to 14.8)	6.4 (3.9 to 10.6)	4.2 (2.4 to 7.4)	5.9 (4.1 to 8.5)
S flexneri 1b Ab IgG, Day 29	24.2 (8.2 to 71.2)	18.5 (10.6 to 32.3)	7.0 (3.1 to 16.0)	6.3 (4.6 to 8.6)
S flexneri 1b Ab IgG, Day 85	16.3 (6.7 to 40.0)	9.4 (4.9 to 17.8)	6.3 (3.1 to 12.7)	7.4 (5.0 to 10.9)
S flexneri 1b Ab IgG, Day 113	30.5 (8.6 to 108.0)	18.2 (12.1 to 27.5)	14.2 (5.0 to 40.2)	7.4 (5.0 to 10.9)
S flexneri 1b Ab IgG, Day 253	9.0 (3.5 to 23.2)	7.2 (3.2 to 16.1)	8.9 (4.5 to 17.3)	7.4 (5.0 to 10.9)

S flexneri 1b Ab IgG, Day 281	23.3 (9.5 to 57.0)	20.4 (8.1 to 51.2)	29.4 (15.3 to 56.6)	8.0 (5.3 to 12.0)
S flexneri 2a Ab IgG, Day 1	3.6 (1.5 to 9.0)	4.4 (2.3 to 8.3)	3.9 (1.8 to 8.4)	4.1 (2.2 to 7.4)
S flexneri 2a Ab IgG, Day 29	34.6 (11.0 to 109.1)	40.5 (16.3 to 100.6)	17.1 (6.0 to 49.0)	4.6 (2.5 to 8.4)
S flexneri 2a Ab IgG, Day 85	29.6 (11.5 to 76.6)	16.4 (7.4 to 36.3)	9.7 (3.8 to 24.7)	5.8 (3.2 to 10.6)
S flexneri 2a Ab IgG, Day 113	81.6 (38.9 to 171.1)	77.4 (31.1 to 192.5)	65.5 (33.0 to 130.0)	7.2 (3.6 to 14.2)
S flexneri 2a Ab IgG, Day 253	9.9 (2.5 to 38.8)	11.2 (2.7 to 47.6)	14.4 (5.2 to 40.1)	7.7 (3.9 to 15.2)
S flexneri 2a Ab IgG, Day 281	135.0 (81.6 to 223.1)	72.5 (24.6 to 213.7)	110.7 (60.4 to 203.0)	8.2 (4.4 to 15.2)
S flexneri 3a Ab IgG, Day 1	2.7 (1.3 to 5.6)	5.1 (2.7 to 9.7)	2.6 (1.4 to 4.7)	3.3 (2.2 to 5.0)
S flexneri 3a Ab IgG, Day 29	9.6 (3.4 to 26.9)	8.9 (3.1 to 25.2)	3.5 (1.7 to 7.3)	3.4 (2.2 to 5.2)
S flexneri 3a Ab IgG, Day 85	5.1 (2.2 to 12.2)	6.0 (2.4 to 15.1)	2.1 (1.1 to 4.2)	4.0 (2.5 to 6.4)
S flexneri 3a Ab IgG, Day 113	12.5 (4.0 to 38.4)	7.9 (2.5 to 25.1)	4.5 (2.3 to 8.8)	3.8 (2.4 to 5.8)
S flexneri 3a Ab IgG, Day 253	6.8 (2.4 to 19.2)	8.5 (2.0 to 35.6)	3.2 (1.6 to 6.5)	4.5 (2.8 to 7.0)
S flexneri 3a Ab IgG, Day 281	23.0 (7.0 to 75.8)	20.4 (5.2 to 79.7)	13.2 (3.5 to 49.8)	4.9 (3.1 to 7.9)

Statistical analyses

No statistical analyses for this end point

Secondary: Stage 2: Anti-serotype specific Shigella LPS/OAg serum IgG GMCs in participants 9 months of age in Africa - dose-finding cohort

End point title	Stage 2: Anti-serotype specific Shigella LPS/OAg serum IgG GMCs in participants 9 months of age in Africa - dose-finding cohort ^[69]
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End point description:

The analysis was performed on the PPS for Stage 2 Infants, dose-finding cohort.

End point type	Secondary
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End point timeframe:

At Day 1, Day 85 and Day 253 (before each study intervention administration) and Day 29, Day 113 and Day 281 (28 days after each study intervention administration)

Notes:

[69] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Med Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose	Stage 2 Infants dose-finding cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	81	83	82
Units: EU/mL				
geometric mean (confidence interval)				

95%)				
S sonnei Ab IgG, Day 1	10.9 (8.9 to 13.2)	9.5 (8.1 to 11.0)	10.7 (8.7 to 13.3)	9.8 (8.2 to 11.6)
S sonnei Ab IgG, Day 29	36.0 (27.4 to 47.4)	41.9 (33.6 to 52.4)	38.5 (29.0 to 51.3)	9.5 (8.1 to 11.1)
S sonnei Ab IgG, Day 85	41.7 (32.3 to 53.9)	46.7 (36.8 to 59.2)	41.1 (33.5 to 50.6)	8.2 (6.9 to 9.7)
S sonnei Ab IgG, Day 113	313.6 (224.5 to 438.1)	353.4 (244.7 to 510.4)	328.7 (235.4 to 459.1)	9.0 (7.2 to 11.3)
S sonnei Ab IgG, Day 253	162.1 (128.9 to 203.8)	195.3 (154.9 to 246.2)	219.0 (164.3 to 291.8)	16.9 (12.5 to 22.8)
S sonnei Ab IgG, Day 281	446.3 (342.1 to 582.3)	535.1 (416.2 to 688.0)	603.8 (461.4 to 790.2)	18.6 (13.7 to 25.2)
S flexneri 1b Ab IgG, Day 1	11.4 (8.5 to 15.4)	11.8 (8.7 to 15.9)	12.6 (9.1 to 17.3)	13.4 (9.9 to 18.0)
S flexneri 1b Ab IgG, Day 29	32.9 (23.7 to 45.6)	47.5 (34.8 to 64.9)	36.8 (26.5 to 51.0)	13.4 (10.0 to 18.0)
S flexneri 1b Ab IgG, Day 85	13.0 (9.9 to 17.0)	11.1 (8.5 to 14.4)	9.6 (7.5 to 12.3)	8.1 (6.2 to 10.7)
S flexneri 1b Ab IgG, Day 113	25.4 (18.5 to 34.8)	21.2 (17.4 to 25.8)	20.6 (16.4 to 25.8)	7.4 (5.7 to 9.5)
S flexneri 1b Ab IgG, Day 253	15.7 (11.6 to 21.3)	9.3 (7.4 to 11.7)	10.3 (7.8 to 13.5)	16.9 (11.7 to 24.2)
S flexneri 1b Ab IgG, Day 281	57.3 (43.2 to 76.0)	34.4 (26.6 to 44.3)	36.7 (28.1 to 47.9)	16.6 (11.5 to 23.9)
S flexneri 2a Ab IgG, Day 1	6.1 (4.6 to 8.2)	5.2 (4.0 to 6.6)	6.2 (4.7 to 8.2)	5.7 (4.4 to 7.5)
S flexneri 2a Ab IgG, Day 29	51.6 (38.1 to 69.9)	58.2 (42.6 to 79.5)	59.4 (42.2 to 83.7)	6.2 (4.7 to 8.2)
S flexneri 2a Ab IgG, Day 85	20.0 (14.0 to 28.6)	12.7 (9.2 to 17.7)	14.4 (10.1 to 20.6)	4.7 (3.2 to 6.7)
S flexneri 2a Ab IgG, Day 113	95.4 (72.4 to 125.5)	69.9 (52.2 to 93.7)	84.4 (62.4 to 114.2)	4.5 (3.2 to 6.4)
S flexneri 2a Ab IgG, Day 253	27.5 (19.9 to 38.1)	19.5 (15.3 to 25.0)	23.2 (18.0 to 30.0)	11.8 (8.2 to 17.1)
S flexneri 2a Ab IgG, Day 281	189.2 (139.2 to 257.2)	142.3 (112.6 to 179.7)	177.9 (134.7 to 234.9)	12.1 (8.3 to 17.4)
S flexneri 3a Ab IgG, Day 1	8.1 (5.3 to 12.5)	5.4 (3.7 to 7.9)	6.3 (4.1 to 9.6)	10.2 (6.6 to 15.8)
S flexneri 3a Ab IgG, Day 29	22.4 (15.2 to 33.0)	19.1 (12.8 to 28.5)	14.8 (9.7 to 22.6)	10.0 (6.3 to 15.8)
S flexneri 3a Ab IgG, Day 85	11.1 (7.3 to 16.6)	11.4 (7.7 to 16.8)	6.6 (4.5 to 9.8)	8.5 (5.5 to 13.2)
S flexneri 3a Ab IgG, Day 113	25.7 (17.3 to 38.3)	18.4 (12.2 to 27.7)	16.0 (11.2 to 22.9)	7.7 (5.2 to 11.5)
S flexneri 3a Ab IgG, Day 253	13.5 (9.8 to 18.7)	8.8 (6.6 to 11.8)	9.6 (6.9 to 13.2)	10.7 (7.4 to 15.5)
S flexneri 3a Ab IgG, Day 281	45.7 (34.0 to 61.5)	28.1 (21.1 to 37.4)	36.3 (27.0 to 48.8)	10.9 (7.4 to 16.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Stage 1: Number of participants 18 to 50 years of age achieving a GVGH ELISA level equivalent to $\geq 1:800$ titer against S. sonnei LPS/OAg

End point title	Stage 1: Number of participants 18 to 50 years of age achieving a GVGH ELISA level equivalent to $\geq 1:800$ titer against S. sonnei LPS/OAg ^[70]
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End point description:

The analysis was performed on the PPS for Stage 1 Adults. As the participants in Stage 1 Adults: Placebo Group received the second placebo intervention at Day 85 or at Day 169, the analysis being performed on the pooled participants as per the SAP, no differentiation was made by timepoint of administration for the second dose for this group. 9999 = data not available.

End point type	Secondary
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End point timeframe:

At Day 1 and Day 85/Day 169 (before each study intervention); at Day 15 (14 days after the first study intervention); at Day 29 and Day 113/Day 197 (28 days after each study intervention)

Notes:

[70] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 1 Adults: altSonflex1-2-3 High Dose Group 1	Stage 1 Adults: altSonflex1-2-3 High Dose Group 2	Stage 1 Adults: Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	34	34	34	
Units: Participants				
Day 1	1	0	5	
Day 15	22	19	4	
Day 29	22	18	4	
Day 85	17	9999	9999	
Day 169	9999	14	9999	
Day 85/169	9999	9999	3	
Day 113	21	9999	9999	
Day 197	9999	22	9999	
Day 113/197	9999	9999	3	

Statistical analyses

No statistical analyses for this end point

Secondary: Stage 2: Number of participants 18 to 50 years of age achieving a GVGH ELISA level equivalent to $\geq 1:800$ titer against S. sonnei LPS/OAg

End point title	Stage 2: Number of participants 18 to 50 years of age achieving a GVGH ELISA level equivalent to $\geq 1:800$ titer against S. sonnei LPS/OAg ^[71]
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End point description:

The analysis was performed on the PPS for Stage 2 Adults.

End point type	Secondary
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End point timeframe:

At Day 1 and Day 85 (before each study intervention) and Day 29 and Day 113 (28 days after each study intervention)

Notes:

[71] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Adults: altSonflex1-2-3 High Dose	Stage 2 Adults: Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: Participants				
Day 1	7	5		
Day 29	10	5		
Day 85	10	6		
Day 113	10	5		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage 2: Number of participants 24 to 59 months of age achieving a GVGH ELISA level equivalent to $\geq 1:800$ titer against S. sonnei LPS/OAg

End point title	Stage 2: Number of participants 24 to 59 months of age achieving a GVGH ELISA level equivalent to $\geq 1:800$ titer against S. sonnei LPS/OAg ^[72]
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End point description:

The analysis was performed on the PPS for Stage 2 Children.

End point type	Secondary
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End point timeframe:

At Day 1 and Day 85 (before each study intervention) and Day 29 and Day 113 (28 days after each study intervention)

Notes:

[72] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

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

End point values	Stage 2 Children: altSonflex1-2-3 Medium Dose	Stage 2 Children: altSonflex1-2-3 High Dose	Stage 2 Children: Control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	20	
Units: Participants				
Day 1	2	4	3	
Day 29	7	6	2	
Day 85	7	6	3	
Day 113	7	6	5	

Statistical analyses

No statistical analyses for this end point

Secondary: Stage 2: Number of participants 9 months of age achieving a GVGH

ELISA level equivalent to $\geq 1:800$ titer against S. sonnei LPS/Oag - safety cohort

End point title	Stage 2: Number of participants 9 months of age achieving a GVGH ELISA level equivalent to $\geq 1:800$ titer against S. sonnei LPS/Oag - safety cohort ^[73]
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End point description:

The analysis was performed on the PPS for Stage 2 Infants, safety cohort.

End point type	Secondary
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End point timeframe:

At Day 1, Day 85 and Day 253 (before each study intervention) and Day 29, Day 113 and Day 281 (28 days after each study intervention)

Notes:

[73] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants safety cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 Medium Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 High Dose	Stage 2 Infants safety cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	10	10	30
Units: Participants				
Day 1	0	0	0	0
Day 29	0	0	0	0
Day 85	0	1	0	0
Day 113	6	6	5	0
Day 253	4	2	3	0
Day 281	6	6	6	0

Statistical analyses

No statistical analyses for this end point

Secondary: Stage 2: Number of participants 9 months of age achieving a GVGH ELISA level equivalent to $\geq 1:800$ titer against S. sonnei LPS/Oag - dose-finding cohort

End point title	Stage 2: Number of participants 9 months of age achieving a GVGH ELISA level equivalent to $\geq 1:800$ titer against S. sonnei LPS/Oag - dose-finding cohort ^[74]
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End point description:

The analysis was performed on the PPS for Stage 2 Infants, dose-finding cohort.

End point type	Secondary
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End point timeframe:

At Day 1, Day 85 and Day 253 (before each study intervention) and Day 29, Day 113 and Day 281 (28 days after each study intervention)

Notes:

[74] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Med Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose	Stage 2 Infants dose-finding cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	81	83	82
Units: Participants				
Day 1	1	0	2	1
Day 29	10	11	12	0
Day 85	9	9	6	1
Day 113	51	52	57	2
Day 253	42	48	49	8
Day 281	61	61	67	8

Statistical analyses

No statistical analyses for this end point

Secondary: Stage 1: Number of participants 18 to 50 years of age achieving a GVGH ELISA level equivalent to $\geq 1:1600$ titer against S. sonnei LPS/OAg

End point title	Stage 1: Number of participants 18 to 50 years of age achieving a GVGH ELISA level equivalent to $\geq 1:1600$ titer against S. sonnei LPS/OAg ^[75]
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End point description:

The analysis was performed on the PPS for Stage 1 Adults. As the participants in Stage 1 Adults: Placebo Group received the second placebo intervention at Day 85 or at Day 169, the analysis being performed on the pooled participants as per the SAP, no differentiation was made by timepoint of administration for the second dose for this group. 9999 = data not available.

End point type	Secondary
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End point timeframe:

At Day 1 and Day 85/Day 169 (before each study intervention); at Day 15 (14 days after the first study intervention); at Day 29 and Day 113/Day 197 (28 days after each study intervention)

Notes:

[75] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 1 Adults: altSonflex1-2-3 High Dose Group 1	Stage 1 Adults: altSonflex1-2-3 High Dose Group 2	Stage 1 Adults: Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	34	34	34	
Units: Participants				
Day 1	1	0	2	
Day 15	13	11	2	
Day 29	12	11	2	
Day 85	12	9999	9999	
Day 169	9999	9	9999	
Day 85/169	9999	9999	2	
Day 113	11	9999	9999	

Day 197	9999	10	9999	
Day 113/197	9999	9999	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Stage 2: Number of participants 18 to 50 years of age achieving a GVGH ELISA level equivalent to $\geq 1:1600$ titer against *S. sonnei* LPS/OAg

End point title	Stage 2: Number of participants 18 to 50 years of age achieving a GVGH ELISA level equivalent to $\geq 1:1600$ titer against <i>S. sonnei</i> LPS/OAg ^[76]
End point description:	The analysis was performed on the PPS for Stage 2 Adults.
End point type	Secondary
End point timeframe:	At Day 1 and Day 85 (before each study intervention) and Day 29 and Day 113 (28 days after each study intervention)

Notes:

[76] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Adults: altSonflex1-2-3 High Dose	Stage 2 Adults: Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: Participants				
Day 1	2	3		
Day 29	10	3		
Day 85	10	3		
Day 113	10	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage 2: Number of participants 9 months of age achieving a GVGH ELISA level equivalent to $\geq 1:1600$ titer against *S. sonnei* LPS/OAg - safety cohort

End point title	Stage 2: Number of participants 9 months of age achieving a GVGH ELISA level equivalent to $\geq 1:1600$ titer against <i>S. sonnei</i> LPS/OAg - safety cohort ^[77]
End point description:	The analysis was performed on the PPS for Stage 2 Infants, safety cohort.
End point type	Secondary

End point timeframe:

At Day 1, Day 85 and Day 253 (before each study intervention) and Day 29, Day 113 and Day 281 (28 days after each study intervention)

Notes:

[77] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants safety cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 Medium Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 High Dose	Stage 2 Infants safety cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	10	10	30
Units: Participants				
Day 1	0	0	0	0
Day 29	0	0	0	0
Day 85	0	0	0	0
Day 113	5	3	3	0
Day 253	3	0	0	0
Day 281	5	3	2	0

Statistical analyses

No statistical analyses for this end point

Secondary: Stage 2: Number of participants 24 to 59 months of age achieving a GVGH ELISA level equivalent to $\geq 1:1600$ titer against S. sonnei LPS/OAg

End point title	Stage 2: Number of participants 24 to 59 months of age achieving a GVGH ELISA level equivalent to $\geq 1:1600$ titer against S. sonnei LPS/OAg ^[78]
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End point description:

The analysis was performed on the PPS for Stage 2 Children.

End point type	Secondary
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End point timeframe:

At Day 1 and Day 85 (before each study intervention) and Day 29 and Day 113 (28 days after each study intervention)

Notes:

[78] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Children: altSonflex1-2-3 Medium Dose	Stage 2 Children: altSonflex1-2-3 High Dose	Stage 2 Children: Control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	20	
Units: Participants				
Day 1	0	1	1	
Day 29	7	6	0	

Day 85	7	6	1	
Day 113	7	6	3	

Statistical analyses

No statistical analyses for this end point

Secondary: Stage 2: Number of participants 9 months of age achieving a GVGH ELISA level equivalent to $\geq 1:1600$ titer against *S. sonnei* LPS/OAg - dose-finding cohort

End point title	Stage 2: Number of participants 9 months of age achieving a GVGH ELISA level equivalent to $\geq 1:1600$ titer against <i>S. sonnei</i> LPS/OAg - dose-finding cohort ^[79]
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End point description:

The analysis was performed on the PPS for Stage 2 Infants, dose-finding cohort.

End point type	Secondary
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End point timeframe:

At Day 1, Day 85 and Day 253 (before each study intervention) and Day 29, Day 113 and Day 281 (28 days after each study intervention)

Notes:

[79] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Med Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose	Stage 2 Infants dose-finding cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	81	83	82
Units: Participants				
Day 1	1	0	2	0
Day 29	2	0	2	0
Day 85	2	2	1	1
Day 113	38	36	36	1
Day 253	18	20	28	2
Day 281	40	45	47	2

Statistical analyses

No statistical analyses for this end point

Secondary: Stage 1: Number of participants 18 to 50 years of age showing at least a 4-fold increase in anti-serotype specific *Shigella* LPS/OAg serum IgG concentrations, as measured by GVGH ELISA

End point title	Stage 1: Number of participants 18 to 50 years of age showing at least a 4-fold increase in anti-serotype specific <i>Shigella</i>
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End point description:

S. sonnei (S.s), S. flexneri 1b (S.f1b), S. flexneri 2a (S.f2a), and S. flexneri 3a (S.f3a) serotypes were tested. 9999 = data not available. The analysis was performed on the PPS for Stage 1 Adults. As the participants in Stage 1 Adults: Placebo Group received the second placebo intervention at Day 85 or at Day 169, the analysis being performed on the pooled participants as per the SAP, no differentiation was made by timepoint of administration for the second dose for this group.

End point type	Secondary
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End point timeframe:

At Day 15 (14 days after the first study intervention) and at Day 29 and Day 113/Day 197 (28 days after each study intervention) compared to baseline (Day 1 and Day 85/Day 169)

Notes:

[80] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 1 Adults: altSonflex1-2-3 High Dose Group 1	Stage 1 Adults: altSonflex1-2-3 High Dose Group 2	Stage 1 Adults: Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	34	34	32	
Units: Participants				
S.s Ab IgG, Day15 compared to Day1	25	27	0	
S.s Ab IgG, Day29 compared to Day1	26	26	0	
S.s Ab IgG, Day113 compared to Day85	0	9999	9999	
S.s Ab IgG, Day197 compared to Day169	9999	4	9999	
S.s Ab IgG, Day113/197 compared to Day85/169	9999	9999	0	
S.f1b Ab IgG, Day15 compared to Day1	17	16	0	
S.f1b Ab IgG, Day29 compared to Day1	15	14	0	
S.f1b Ab IgG, Day113 compared to Day85	2	9999	9999	
S.f1b Ab IgG, Day197 compared to Day169	9999	1	9999	
S.f1b Ab IgG, Day113/197 compared to Day85/169	9999	9999	0	
S.f2a Ab IgG, Day15 compared to Day 1	32	31	0	
S.f2a Ab IgG, Day29 compared to Day1	30	31	0	
S.f2a Ab IgG, Day113 compared to Day85	1	9999	9999	
S.f2a Ab IgG, Day197 compared to Day169	9999	0	9999	
S.f2a Ab IgG, Day113/197 compared to Day85/169	9999	9999	1	
S.f3a Ab IgG, Day15 compared to Day1	12	17	0	
S.f3a Ab IgG, Day29 compared to Day1	12	17	0	
S.f3a Ab IgG, Day113 compared to Day85	3	9999	9999	
S.f3a Ab IgG, Day197 compared to Day169	9999	1	9999	
S.f3a Ab IgG, Day113/197 compared to Day85/169	9999	9999	0	
S.s Ab IgG, Day 85 compared to Day 1	22	9999	9999	
S.s Ab IgG, Day 169 compared to Day 1	9999	21	9999	

S.s Ab IgG, Day 85/169 compared to Day 1	9999	9999	0	
S.s Ab IgG, Day 113 compared to Day 1	22	9999	9999	
S.s Ab IgG, Day 197 compared to Day 85	9999	26	9999	
S.s Ab IgG, Day 113/197 compared to Day 1	9999	9999	0	
S.f1b Ab IgG, Day 85 compared to Day 1	7	9999	9999	
S.f1b Ab IgG, Day 85/169 compared to Day 1	9999	9999	0	
S.f1b Ab IgG, Day 113 compared to Day 1	11	9999	9999	
S.f1b Ab IgG, Day 197 compared to Day 1	9999	10	9999	
S.f1b Ab IgG, Day 113/197 compared to Day 1	9999	9999	0	
S.f2a Ab IgG, Day 85 compared to Day 1	27	9999	9999	
S.f2a Ab IgG, Day 169 compared to Day 1	9999	31	9999	
S.f2a Ab IgG, Day 85/169 compared to Day 1	9999	9999	0	
S.f2a Ab IgG, Day 113 compared to Day 1	26	9999	9999	
S.f2a Ab IgG, Day 197 compared to Day 1	9999	32	9999	
S.f2a Ab IgG, Day 113/197 compared to Day 1	9999	9999	0	
S.f3a Ab IgG, Day 85 compared to Day 1	2	9999	9999	
S.f3a Ab IgG, Day 169 compared to Day 1	9999	4	9999	
S.f3a Ab IgG, Day 85/169 compared to Day 1	9999	9999	0	
S.f3a Ab IgG, Day 113 compared to Day 1	6	9999	9999	
S.f3a Ab IgG, Day 197 compared to Day 1	9999	9	9999	
S.f3a Ab IgG, Day 113/197 compared to Day 1	9999	9999	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Stage 2: Number of participants 18 to 50 years of age showing at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG concentrations, as measured by GVGH ELISA

End point title	Stage 2: Number of participants 18 to 50 years of age showing at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG concentrations, as measured by GVGH ELISA ^[81]
End point description:	The analysis was performed on the PPS for Stage 2 Adults.
End point type	Secondary

End point timeframe:

At Day 29 and Day 113 (28 days after each study intervention) compared to baseline (Day 1 and Day 85)

Notes:

[81] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Adults: altSonflex1-2-3 High Dose	Stage 2 Adults: Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: Participants				
S sonnei Ab IgG, Day 29 compared to Day 1	10	0		
S sonnei Ab IgG, Day 85 compared to Day 1	10	0		
S sonnei Ab IgG, Day 113 compared to Day 1	10	0		
S Sonnei Ab IgG, Day 113 compared to Day 85	0	0		
S flexneri 1b Ab IgG, Day 29 compared to Day 1	2	0		
S flexneri 1b Ab IgG, Day 85 compared to Day 1	1	0		
S flexneri 1b Ab IgG, Day 113 compared to Day 1	1	0		
S flexneri 1b Ab IgG, Day 113 compared to Day 85	0	0		
S flexneri 2a Ab IgG, Day 29 compared to Day 1	3	0		
S flexneri 2a Ab IgG, Day 85 compared to Day 1	2	0		
S flexneri 2a Ab IgG, Day 113 compared to Day 1	3	0		
S flexneri 2a Ab IgG, Day 113 compared to Day 85	0	0		
S flexneri 3a Ab IgG, Day 29 compared to Day 1	4	0		
S flexneri 3a Ab IgG, Day 85 compared to Day 1	2	0		
S flexneri 3a Ab IgG, Day 113 compared to Day 1	3	0		
S flexneri 3a Ab IgG, Day 113 compared to Day 85	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage 2: Number of participants 24 to 59 months of age showing at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG concentrations, as measured by GVGH ELISA

End point title	Stage 2: Number of participants 24 to 59 months of age
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showing at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG concentrations, as measured by GVGH ELISA^[82]

End point description:

The analysis was performed on the PPS for Stage 2 Children.

End point type Secondary

End point timeframe:

At Day 29 and Day 113 (28 days after each study intervention) compared to baseline (Day 1 and Day 85)

Notes:

[82] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Children: altSonflex1-2-3 Medium Dose	Stage 2 Children: altSonflex1-2-3 High Dose	Stage 2 Children: Control	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10	10	20	
Units: Participants				
S sonnei Ab IgG, Day 29 compared to Day 1	7	5	1	
S sonnei Ab IgG, Day 85 compared to Day 1	7	5	3	
S sonnei Ab IgG, Day 113 compared to Day 1	10	6	5	
S sonnei Ab IgG, Day 113 compared to Day 85	1	1	3	
S flexneri 1b Ab IgG, Day 29 compared to Day 1	2	4	1	
S flexneri 1b Ab IgG, Day 85 compared to Day 1	0	1	1	
S flexneri 1b Ab IgG, Day 113 compared to Day 1	2	3	1	
S flexneri 1b Ab IgG, Day 113 compared to Day 85	0	0	1	
S flexneri 2a Ab IgG, Day 29 compared to Day 1	6	6	0	
S flexneri 2a Ab IgG, Day 85 compared to Day 1	3	5	1	
S flexneri 2a Ab IgG, Day 113 compared to Day 1	7	10	0	
S flexneri 2a Ab IgG, Day 113 compared to Day 85	3	2	0	
S flexneri 3a Ab IgG, Day 29 compared to Day 1	0	3	0	
S flexneri 3a Ab IgG, Day 85 compared to Day 1	0	1	0	
S flexneri 3a Ab IgG, Day 113 compared to Day 1	1	3	1	
S flexneri 3a Ab IgG, Day 113 compared to Day 85	0	0	1	

Statistical analyses

Secondary: Stage 2: Number of participants 9 months of age showing at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG concentrations, as measured by GVGH ELISA - safety cohort

End point title	Stage 2: Number of participants 9 months of age showing at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG concentrations, as measured by GVGH ELISA - safety cohort ^[83]
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End point description:

The analysis was performed on the PPS for Stage 2 Infants, safety cohort.

End point type	Secondary
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End point timeframe:

At Day 29, Day 113 and Day 281 (28 days after each study intervention) compared to baseline (Day 1, Day 85 and Day 253)

Notes:

[83] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants safety cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 Medium Dose	Stage 2 Infants safety cohort: altSonflex1-2-3 High Dose	Stage 2 Infants safety cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	9	10	30
Units: Participants				
S sonnei Ab IgG, Day 29 compared to Day 1	2	0	1	0
S sonnei Ab IgG, Day 85 compared to Day 1	2	1	3	0
S sonnei Ab IgG, Day 113 compared to Day 1	8	8	9	0
S sonnei Ab IgG, Day 113 compared to Day 85	7	6	7	0
S sonnei Ab IgG, Day 253 compared to Day 1	8	6	6	0
S sonnei Ab IgG, Day 281 compared to Day 1	9	7	9	0
S sonnei Ab IgG, Day 281 compared to Day 253	3	2	2	0
S flexneri 1b Ab IgG, Day 29 compared to Day 1	3	1	1	0
S flexneri 1b Ab IgG, Day 85 compared to Day 1	1	0	0	3
S flexneri 1b Ab IgG, Day 113 compared to Day 1	3	0	2	3
S flexneri 1b Ab IgG, Day 113 compared to Day 85	2	0	2	1
S flexneri 1b Ab IgG, Day 253 compared to Day 1	1	0	1	5
S flexneri 1b Ab IgG, Day 281 compared to Day 1	3	2	4	3
S flexneri 1b Ab IgG, Day 281 compared to Day 253	1	1	2	0
S flexneri 2a Ab IgG, Day 29 compared to Day 1	6	5	5	3

S flexneri 2a Ab IgG, Day 85 compared to Day 1	4	3	3	3
S flexneri 2a Ab IgG, Day 113 compared to Day 1	8	6	9	6
S flexneri 2a Ab IgG, Day 113 compared to Day 85	1	4	5	3
S flexneri 2a Ab IgG, Day 253 compared to Day 1	2	2	4	8
S flexneri 2a Ab IgG, Day 281 compared to Day 1	8	7	7	7
S flexneri 2a Ab IgG, Day 281 compared to Day 253	6	5	7	0
S flexneri 3a Ab IgG, Day 29 compared to Day 1	4	2	0	2
S flexneri 3a Ab IgG, Day 85 compared to Day 1	0	0	0	2
S flexneri 3a Ab IgG, Day 113 compared to Day 1	3	1	0	1
S flexneri 3a Ab IgG, Day 113 compared to Day 85	2	0	0	0
S flexneri 3a Ab IgG, Day 253 compared to Day 1	2	2	0	3
S flexneri 3a Ab IgG, Day 281 compared to Day 1	4	4	3	2
S flexneri 3a Ab IgG, Day 281 compared to Day 253	3	1	3	1

Statistical analyses

No statistical analyses for this end point

Secondary: Stage 2: Number of participants 9 months of age showing at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG concentrations, as measured by GVGH ELISA - dose-finding cohort

End point title	Stage 2: Number of participants 9 months of age showing at least a 4-fold increase in anti-serotype specific Shigella LPS/OAg serum IgG concentrations, as measured by GVGH ELISA - dose-finding cohort ^[84]
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End point description:

The analysis was performed on the PPS for Stage 2 Infants, dose-finding cohort.

End point type	Secondary
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End point timeframe:

At Day 29, Day 113 and Day 281 (28 days after each study intervention) compared to baseline (Day 1, Day 85 and Day 253)

Notes:

[84] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Med Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose	Stage 2 Infants dose-finding cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	81	83	82
Units: Participants				
S sonnei Ab IgG, Day 29 compared to Day 1	20	30	24	0
S sonnei Ab IgG, Day 85 compared to Day 1	28	29	20	3
S sonnei Ab IgG, Day 113 compared to Day 1	57	61	64	2
S sonnei Ab IgG, Day 113 compared to Day 85	19	15	15	0
S sonnei Ab IgG, Day 253 compared to Day 1	53	60	58	11
S sonnei Ab IgG, Day 281 compared to Day 1	62	62	69	12
S sonnei Ab IgG, Day 281 compared to Day 253	7	4	8	1
S flexneri 1b Ab IgG, Day 29 compared to Day 1	22	24	18	3
S flexneri 1b Ab IgG, Day 85 compared to Day 1	7	9	5	3
S flexneri 1b Ab IgG, Day 113 compared to Day 1	17	13	11	1
S flexneri 1b Ab IgG, Day 113 compared to Day 85	5	2	4	1
S flexneri 1b Ab IgG, Day 253 compared to Day 1	10	3	4	12
S flexneri 1b Ab IgG, Day 281 compared to Day 1	31	29	25	13
S flexneri 1b Ab IgG, Day 281 compared to Day 253	19	15	13	1
S flexneri 2a Ab IgG, Day 29 compared to Day 1	50	52	49	3
S flexneri 2a Ab IgG, Day 85 compared to Day 1	22	24	24	8
S flexneri 2a Ab IgG, Day 113 compared to Day 1	54	52	58	7
S flexneri 2a Ab IgG, Day 113 compared to Day 85	39	36	42	3
S flexneri 2a Ab IgG, Day 253 compared to Day 1	30	27	29	18
S flexneri 2a Ab IgG, Day 281 compared to Day 1	59	59	65	16
S flexneri 2a Ab IgG, Day 281 compared to Day 253	41	48	52	3
S flexneri 3a Ab IgG, Day 29 compared to Day 1	15	25	14	3
S flexneri 3a Ab IgG, Day 85 compared to Day 1	13	20	9	10
S flexneri 3a Ab IgG, Day 113 compared to Day 1	26	25	22	9
S flexneri 3a Ab IgG, Day 113 compared to Day 85	16	8	14	2
S flexneri 3a Ab IgG, Day 253 compared to Day 1	17	15	16	18
S flexneri 3a Ab IgG, Day 281 compared to Day 1	36	36	41	17

S flexneri 3a Ab IgG, Day 281 compared to Day 253	22	18	30	2
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Statistical analyses

No statistical analyses for this end point

Secondary: Stage 2: Anti-measles IgG concentrations in participants 9 months of age in the dose-finding cohort

End point title	Stage 2: Anti-measles IgG concentrations in participants 9 months of age in the dose-finding cohort ^[85]
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End point description:

The analysis was performed on the PPS for Stage 2 Infants, dose-finding cohort.

End point type	Secondary
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End point timeframe:

At Day 1 (before first measles and rubella vaccine (MR-VAC)) and at Day 281 (28 days after the second MR-VAC administration)

Notes:

[85] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Med Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose	Stage 2 Infants dose-finding cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	81	83	82
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Day 1	26.2 (23.8 to 28.9)	25.4 (24.6 to 26.1)	25 (25 to 25)	26.2 (24.5 to 28.1)
Day 281	1204.4 (1043.2 to 1390.6)	1099.7 (957.2 to 1263.4)	1142.5 (983 to 1327.9)	971.4 (793.2 to 1189.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Stage 2: Anti-rubella IgG concentrations in participants 9 months of age in the dose-finding groups

End point title	Stage 2: Anti-rubella IgG concentrations in participants 9 months of age in the dose-finding groups ^[86]
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End point description:

The analysis was performed on the PPS for Stage 2 Infants, dose-finding cohort.

End point type	Secondary
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End point timeframe:

At Day 1 (before first measles and rubella vaccine (MR-VAC)) and at Day 281 (28 days after the second MR-VAC administration)

Notes:

[86] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Med Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose	Stage 2 Infants dose-finding cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	81	83	82
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Day 1	1.2 (1 to 1.4)	1 (1 to 1)	1.1 (1 to 1.3)	1.1 (1 to 1.1)
Day 281	138.2 (124.7 to 153.1)	110.3 (99.6 to 122.1)	116.4 (105.1 to 129)	107.1 (89.9 to 127.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Stage 2: Number of participants 9 months of age in the dose-finding groups achieving anti-measles IgG concentrations of ≥ 150 milli international units per milliliter (mIU/mL) and ≥ 200 mIU/mL

End point title	Stage 2: Number of participants 9 months of age in the dose-finding groups achieving anti-measles IgG concentrations of ≥ 150 milli international units per milliliter (mIU/mL) and ≥ 200 mIU/mL ^[87]
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End point description:

The analysis was performed on the PPS for Stage 2 Infants, dose-finding cohort.

End point type	Secondary
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End point timeframe:

Day 281 (28 days after the second MR-VAC administration)

Notes:

[87] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Med Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose	Stage 2 Infants dose-finding cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	81	83	82
Units: Participants				

>= 150 mIU/mL, Day 281	66	64	71	68
>= 200 mIU/mL, Day 281	66	64	71	67

Statistical analyses

No statistical analyses for this end point

Secondary: Stage 2: Number of participants 9 months of age in the dose-finding groups achieving anti-rubella IgG concentrations of ≥ 4 mIU/mL and ≥ 10 mIU/mL

End point title	Stage 2: Number of participants 9 months of age in the dose-finding groups achieving anti-rubella IgG concentrations of ≥ 4 mIU/mL and ≥ 10 mIU/mL ^[88]
End point description:	The analysis was performed on the PPS for Stage 2 Infants, dose-finding cohort.
End point type	Secondary
End point timeframe:	Day 281 (28 days after the second MR-VAC administration)

Notes:

[88] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As per study design, this endpoint presents analysis of a specific set of participants, hence only the arms included in the specified stage and cohorts are included in the analysis.

End point values	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 Med Dose	Stage 2 Infants dose-finding cohort: altSonflex1-2-3 High Dose	Stage 2 Infants dose-finding cohort: Control
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	82	81	83	82
Units: Participants				
>= 4 IU/mL Day 281	66	64	71	68
>= 10 IU/mL Day 281	66	64	71	68

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited AEs were collected within 7 days and unsolicited AEs within 28 days after any intervention (administered on Day (D) 1 and D85 for Stage 1 adults, Stage 2 adults and children and D1, D85 and D253 for Stage 2 infants).

Adverse event reporting additional description:

SAEs and all-cause mortality: from Day (D) 1 to D113/D197 for Stage 1, from D1 to D113 for Stage 2 adults & children, from D1 to D281 for Stage 2 infants.

Assessment type	Systematic
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Dictionary used

Dictionary name	v28.0
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Dictionary version	28.0
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Reporting groups

Reporting group title	Stage 1 Adults: altSonflex1-2-3 High Dose Group 1
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Reporting group description:

European participants 18-50 years of age were randomized to receive 1 dose of altSonflex1-2-3 High Dose on Day 1 and Day 85

Reporting group title	Stage 1 Adults: altSonflex1-2-3 High Dose Group 2
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Reporting group description:

European participants 18-50 years of age were randomized to receive 1 dose of altSonflex1-2-3 High Dose on Day 1 and Day 169

Reporting group title	Stage 2 Infants: altSonflex1-2-3 High Dose
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Reporting group description:

African participants 9 months of age were randomized to receive a dose of altSonflex1-2-3 high dose on Day 1, Day 85 and Day 253. MR-VAC was administered on Day 29 and Day 281.

Reporting group title	Stage 2 Infants: altSonflex1-2-3 Medium Dose
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Reporting group description:

African participants 9 months of age were randomized to receive a dose of altSonflex1-2-3 medium dose on Day 1, Day 85 and Day 253. MR-VAC was administered on Day 29 and Day 281.

Reporting group title	Stage 2 Infants: altSonflex1-2-3 Low Dose
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Reporting group description:

African participants 9 months of age were randomized to receive a dose of altSonflex1-2-3 low dose on Day 1, Day 85 and Day 253. The measles-rubella vaccine (MR-VAC) was administered on Day 29 and Day 281.

Reporting group title	Stage 2 Children: Control
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Reporting group description:

African participants 24-59 months of age were randomized to receive 1 dose of MENVEO as comparator on Day 1 and 1 dose of TYPHIM VI as comparator on Day 85.

Reporting group title	Stage 1 Adults: Placebo Group
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Reporting group description:

European participants 18-50 years of age were randomized to receive 1 dose of Placebo on Day 1 and on Day 85 or 169. All participants that received placebo were pooled, as per SAP.

Reporting group title	Stage 2 Adults: altSonflex1-2-3 High Dose
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Reporting group description:

African participants 18-50 years of age were randomized to receive 1 dose of altSonflex1-2-3 high dose on Day 1 and Day 85

Reporting group title	Stage 2 Adults: Control
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Reporting group description:

African participants 18-50 years of age were randomized to receive 1 dose of MENVEO as comparator on Day 1 and 1 dose of BOOSTRIX as comparator Day 85

Reporting group title	Stage 2 Children: altSonflex1-2-3 Medium Dose
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Reporting group description:

African participants 24-59 months of age were randomized to receive a dose of altSonflex1-2-3 medium dose on Day 1 and Day 85.

Reporting group title	Stage 2 Children: altSonflex1-2-3 High Dose
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Reporting group description:

African participants 24-59 months of age were randomized to receive a dose of altSonflex1-2-3 high dose on Day 1 and Day 85.

Reporting group title	Stage 2 dose-finding cohort: altSonflex1-2-3 Medium Dose
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Reporting group description:

African participants 9 months of age were randomized to receive a dose of altSonflex1-2-3 medium dose on Day 1, Day 85 and Day 253. MR-VAC was co-administered on Day 1 and Day 253. This cohort was evaluated to identify the preferred dose among low, medium and high doses.

Reporting group title	Stage 2 dose-finding cohort: altSonflex1-2-3 Low Dose
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Reporting group description:

African participants 9 months of age were randomized to receive a dose of altSonflex1-2-3 low dose on Day 1, Day 85 and Day 253. MR-VAC was co-administered on Day 1 and Day 253. This cohort was evaluated to identify the preferred dose among low, medium and high doses.

Reporting group title	Stage 2 Infants: Control
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Reporting group description:

African participants 9 months of age were randomized to receive a dose of MENVEO as comparator on Day 1 and Day 85 and INFRANRIX HEXA as comparator on Day 253. MR-VAC was administered on Day 29 and Day 281.

Reporting group title	Stage 2 dose-finding cohort: altSonflex1-2-3 High Dose
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Reporting group description:

African participants 9 months of age were randomized to receive a dose of altSonflex1-2-3 high dose on Day 1, Day 85 and Day 253. MR-VAC was co-administered on Day 1 and Day 253. This cohort was evaluated to identify the preferred dose among low, medium and high doses.

Reporting group title	Stage 2 dose-finding cohort: Control
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Reporting group description:

African participants 9 months of age were randomized to receive a dose of MENVEO as comparator on Day 1 and Day 85 and INFRANRIX HEXA as comparator on Day 253. MR-VAC was co-administered on Day 1 and Day 253. This cohort was evaluated to identify the preferred dose among low, medium and high doses.

Serious adverse events	Stage 1 Adults: altSonflex1-2-3 High Dose Group 1	Stage 1 Adults: altSonflex1-2-3 High Dose Group 2	Stage 2 Infants: altSonflex1-2-3 High Dose
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 10 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (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			
Infantile spasms			

subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Stomatitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (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
Faecaloma			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 10 (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
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (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
Oral candidiasis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (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	Stage 2 Infants: altSonflex1-2-3 Medium Dose	Stage 2 Infants: altSonflex1-2-3 Low Dose	Stage 2 Children: Control
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
number of deaths (all causes)	0	0	0

number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (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			
Infantile spasms			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Stomatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (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
Faecaloma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (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			
Pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (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
Oral candidiasis			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (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	Stage 1 Adults: Placebo Group	Stage 2 Adults: altSonflex1-2-3 High Dose	Stage 2 Adults: Control
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (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			
Infantile spasms			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Stomatitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (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
Faecaloma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (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			
Pneumonia			

subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (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
Oral candidiasis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (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	Stage 2 Children: altSonflex1-2-3 Medium Dose	Stage 2 Children: altSonflex1-2-3 High Dose	Stage 2 dose-finding cohort: altSonflex1- 2-3 Medium Dose
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	1
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (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			
Infantile spasms			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Stomatitis			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (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
Faecaloma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (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			
Pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Oral candidiasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (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	Stage 2 dose-finding cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants: Control	Stage 2 dose-finding cohort: altSonflex1-2-3 High Dose
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 82 (2.44%)	1 / 30 (3.33%)	4 / 83 (4.82%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Infantile spasms			

subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	1 / 82 (1.22%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Stomatitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (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			
Pneumonia			
subjects affected / exposed	1 / 82 (1.22%)	1 / 30 (3.33%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Stage 2 dose-finding cohort: Control		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 82 (1.22%)		
number of deaths (all causes)	0		
number of deaths resulting from	0		

adverse events			
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Infantile spasms			
subjects affected / exposed	1 / 82 (1.22%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Epilepsy			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Stomatitis			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Faecaloma			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Oral candidiasis			

subjects affected / exposed	0 / 82 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Stage 1 Adults: altSonflex1-2-3 High Dose Group 1	Stage 1 Adults: altSonflex1-2-3 High Dose Group 2	Stage 2 Infants: altSonflex1-2-3 High Dose
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 34 (97.06%)	33 / 34 (97.06%)	10 / 10 (100.00%)
General disorders and administration site conditions			
Administration site erythema			
subjects affected / exposed	5 / 34 (14.71%)	8 / 34 (23.53%)	6 / 10 (60.00%)
occurrences (all)	6	10	9
Axillary pain			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Administration site swelling			
subjects affected / exposed	5 / 34 (14.71%)	9 / 34 (26.47%)	5 / 10 (50.00%)
occurrences (all)	7	12	11
Application site hypersensitivity			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Administration site pain			
subjects affected / exposed	33 / 34 (97.06%)	33 / 34 (97.06%)	7 / 10 (70.00%)
occurrences (all)	54	64	20
Chills			
subjects affected / exposed	2 / 34 (5.88%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	2	2	0
Fatigue			
subjects affected / exposed	4 / 34 (11.76%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	5	1	0
Injection site eczema			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	0	1	0

Influenza like illness			
subjects affected / exposed	3 / 34 (8.82%)	5 / 34 (14.71%)	0 / 10 (0.00%)
occurrences (all)	4	5	0
Injection site discolouration			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Feeling hot			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Injection site erythema			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Injection site haematoma			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Injection site induration			
subjects affected / exposed	2 / 34 (5.88%)	2 / 34 (5.88%)	0 / 10 (0.00%)
occurrences (all)	2	2	0
Injection site reaction			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	1 / 34 (2.94%)	3 / 34 (8.82%)	0 / 10 (0.00%)
occurrences (all)	1	3	0
Injection site rash			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Injection site nodule			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Injection site warmth			
subjects affected / exposed	0 / 34 (0.00%)	3 / 34 (8.82%)	0 / 10 (0.00%)
occurrences (all)	0	4	0
Malaise			
subjects affected / exposed	2 / 34 (5.88%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0

Vaccination site pain subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	1 / 34 (2.94%) 1	0 / 10 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	2 / 34 (5.88%) 2	1 / 34 (2.94%) 1	5 / 10 (50.00%) 6
Swelling face subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0
Peripheral swelling subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0
Immune system disorders Food allergy subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 34 (0.00%) 0	1 / 10 (10.00%) 1
Reproductive system and breast disorders Vaginal discharge subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0
Dysmenorrhoea subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Nasal congestion subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	1 / 34 (2.94%) 1	1 / 10 (10.00%) 1
Bronchospasm subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 34 (0.00%) 0	1 / 10 (10.00%) 1
Allergic cough subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0

Rhinitis allergic			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 34 (0.00%)	2 / 34 (5.88%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Sneezing			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pulmonary congestion			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	2 / 34 (5.88%)	2 / 34 (5.88%)	0 / 10 (0.00%)
occurrences (all)	2	2	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood sodium increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Eosinophil count increased			

subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Lymphocyte count increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
White blood cell count increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Respiratory rate increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Bone contusion			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Face injury			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			

subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Immunisation reaction			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Hand fracture			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Greenstick fracture			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Soft tissue injury			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	2 / 34 (5.88%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Syncope			

subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Partial seizures			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Migraine			
subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Hypotonia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	12 / 34 (35.29%)	10 / 34 (29.41%)	0 / 10 (0.00%)
occurrences (all)	16	13	0
Tension headache			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Lymph node pain			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0
Thrombocytosis subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0
Ear and labyrinth disorders Hypoacusis subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0
Eye disorders Conjunctivitis allergic subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0
Eye irritation subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0
Lacrimation increased subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0
Eye pruritus subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0
Cheilitis subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	1 / 34 (2.94%) 1	0 / 10 (0.00%) 0
Flatulence			

subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Enteritis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Faeces hard			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	2
Gastritis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Mucous stools			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Mouth ulceration			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1

Blister			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Autoimmune hypothyroidism			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Groin pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Back pain			

subjects affected / exposed	1 / 34 (2.94%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Neck pain			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Myalgia intercostal			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Muscle tightness			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Amoebic dysentery			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Amoebiasis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Bronchitis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
COVID-19			
subjects affected / exposed	4 / 34 (11.76%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	4	1	0
Dermatitis infected			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Genital abscess			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	2 / 10 (20.00%)
occurrences (all)	0	1	2
Furuncle			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Helminthic infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Infectious mononucleosis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0

Labyrinthitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Malaria			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	2 / 34 (5.88%)	1 / 34 (2.94%)	1 / 10 (10.00%)
occurrences (all)	2	1	1
Oral candidiasis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Otitis media acute			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Plasmodium falciparum infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 34 (0.00%)	2 / 34 (5.88%)	4 / 10 (40.00%)
occurrences (all)	0	2	5
Upper respiratory tract infection			
subjects affected / exposed	2 / 34 (5.88%)	0 / 34 (0.00%)	2 / 10 (20.00%)
occurrences (all)	2	0	2

Scabies			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	2 / 34 (5.88%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	2	2	0
Tonsillitis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Varicella			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Stage 2 Infants: altSonflex1-2-3 Medium Dose	Stage 2 Infants: altSonflex1-2-3 Low Dose	Stage 2 Children: Control
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 10 (80.00%)	6 / 10 (60.00%)	12 / 20 (60.00%)
General disorders and administration site conditions			
Administration site erythema			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Axillary pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Administration site swelling			
subjects affected / exposed	2 / 10 (20.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	2	1	0
Application site hypersensitivity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Administration site pain			
subjects affected / exposed	5 / 10 (50.00%)	4 / 10 (40.00%)	3 / 20 (15.00%)
occurrences (all)	10	6	6

Chills			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injection site eczema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injection site discolouration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injection site rash			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Injection site nodule subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Injection site warmth subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Malaise subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Vaccination site pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	3 / 10 (30.00%) 3	1 / 10 (10.00%) 2	3 / 20 (15.00%) 3
Swelling face subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Peripheral swelling subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Immune system disorders Food allergy subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Reproductive system and breast disorders Vaginal discharge subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Nasal congestion subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0

Cough			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Bronchospasm			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Allergic cough			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pulmonary congestion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood sodium increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Eosinophil count increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Haemoglobin decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Respiratory rate increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			

Arthropod bite			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Immunisation reaction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Greenstick fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Soft tissue injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Partial seizures			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	2 / 10 (20.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Neutropenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Thrombocytopenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	2 / 10 (20.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	2	0	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis allergic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Eye irritation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cheilitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Faeces hard			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Mucous stools			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0

Nausea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Blister			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			

Autoimmune hypothyroidism subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Limb discomfort subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Groin pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Neck pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Myalgia intercostal subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Muscle tightness subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Muscle spasms subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Infections and infestations			
Abscess limb subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Body tinea			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Amoebic dysentery			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Amoebiasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 20 (10.00%)
occurrences (all)	0	0	2
Bronchiolitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Dermatitis infected			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Cystitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Genital abscess			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	1	0	0
Furuncle			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Helminthic infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Infectious mononucleosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Labyrinthitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Malaria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 20 (5.00%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	1	0
Otitis media acute			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			

subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Plasmodium falciparum infection subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Pneumonia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Rhinitis subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2	2 / 10 (20.00%) 3	2 / 20 (10.00%) 2
Upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 2	2 / 10 (20.00%) 2	1 / 20 (5.00%) 1
Scabies subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Sinusitis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Tonsillitis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Varicella subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 20 (0.00%) 0

Non-serious adverse events	Stage 1 Adults: Placebo Group	Stage 2 Adults: altSonflex1-2-3 High Dose	Stage 2 Adults: Control
Total subjects affected by non-serious adverse events subjects affected / exposed	32 / 34 (94.12%)	7 / 10 (70.00%)	5 / 10 (50.00%)
General disorders and administration site conditions			

Administration site erythema subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Axillary pain subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Administration site swelling subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Application site hypersensitivity subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Administration site pain subjects affected / exposed occurrences (all)	20 / 34 (58.82%) 24	7 / 10 (70.00%) 9	4 / 10 (40.00%) 5
Chills subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Fatigue subjects affected / exposed occurrences (all)	2 / 34 (5.88%) 2	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Injection site eczema subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Influenza like illness subjects affected / exposed occurrences (all)	4 / 34 (11.76%) 4	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Injection site discolouration subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Feeling hot subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Injection site erythema subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0

Injection site haematoma			
subjects affected / exposed	1 / 34 (2.94%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Injection site induration			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	2 / 34 (5.88%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Injection site pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Injection site rash			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Injection site nodule			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Injection site warmth			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vaccination site pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Swelling face			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Immune system disorders Food allergy subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Reproductive system and breast disorders Vaginal discharge subjects affected / exposed occurrences (all) Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0 0 / 34 (0.00%) 0	0 / 10 (0.00%) 0 0 / 10 (0.00%) 0	1 / 10 (10.00%) 1 0 / 10 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Nasal congestion subjects affected / exposed occurrences (all) Cough subjects affected / exposed occurrences (all) Bronchospasm subjects affected / exposed occurrences (all) Allergic cough subjects affected / exposed occurrences (all) Rhinitis allergic subjects affected / exposed occurrences (all) Rhinorrhoea subjects affected / exposed occurrences (all) Sneezing subjects affected / exposed occurrences (all) Pulmonary congestion subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0 0 / 34 (0.00%) 0 0 / 34 (0.00%) 0 0 / 34 (0.00%) 0 0 / 34 (0.00%) 0 0 / 34 (0.00%) 0 0 / 34 (0.00%) 0 0 / 34 (0.00%) 0	0 / 10 (0.00%) 0 0 / 10 (0.00%) 0 0 / 10 (0.00%) 0 0 / 10 (0.00%) 0 0 / 10 (0.00%) 0 0 / 10 (0.00%) 0 0 / 10 (0.00%) 0 0 / 10 (0.00%) 0	0 / 10 (0.00%) 0 0 / 10 (0.00%) 0 0 / 10 (0.00%) 0 0 / 10 (0.00%) 0 0 / 10 (0.00%) 0 0 / 10 (0.00%) 0 0 / 10 (0.00%) 0

Oropharyngeal pain subjects affected / exposed occurrences (all)	3 / 34 (8.82%) 3	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Upper-airway cough syndrome subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Nasal discomfort subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Blood potassium increased subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Blood sodium increased subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Blood thyroid stimulating hormone increased subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Eosinophil count increased subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Haemoglobin decreased subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Hepatic enzyme increased subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Lymphocyte count increased subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Neutrophil count decreased			

subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Platelet count increased subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
White blood cell count increased subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Respiratory rate increased subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Injury, poisoning and procedural complications			
Arthropod bite subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Bone contusion subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Face injury subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Ligament sprain subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Immunisation reaction subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Hand fracture subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Greenstick fracture subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Limb injury			

subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Muscle strain subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Soft tissue injury subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Thermal burn subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Cardiac disorders Palpitations subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Syncope subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Partial seizures subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Migraine subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Hypotonia subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Hypoaesthesia			

subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	8 / 34 (23.53%)	3 / 10 (30.00%)	1 / 10 (10.00%)
occurrences (all)	13	3	1
Tension headache			
subjects affected / exposed	0 / 34 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Thrombocytosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eye disorders			

Conjunctivitis allergic subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Eye irritation subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Lacrimation increased subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Eye pruritus subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	1 / 34 (2.94%) 1	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Cheilitis subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Flatulence subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Enteritis subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Faeces hard subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Diarrhoea			

subjects affected / exposed	2 / 34 (5.88%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Gastritis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			
subjects affected / exposed	1 / 34 (2.94%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Mucous stools			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 34 (2.94%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Mouth ulceration			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 34 (2.94%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Blister			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Eczema			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Autoimmune hypothyroidism			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	1 / 34 (2.94%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Myalgia intercostal			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Myalgia			

subjects affected / exposed	2 / 34 (5.88%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Muscle tightness			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Amoebic dysentery			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Amoebiasis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	6 / 34 (17.65%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	6	0	0
Dermatitis infected			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Conjunctivitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Genital abscess			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Furuncle			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Helminthic infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Infectious mononucleosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Labyrinthitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Malaria			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Nasopharyngitis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Oral candidiasis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Otitis media acute			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Plasmodium falciparum infection			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 34 (5.88%)	0 / 10 (0.00%)	1 / 10 (10.00%)
occurrences (all)	2	0	1
Scabies			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 10 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 34 (0.00%)	1 / 10 (10.00%)	0 / 10 (0.00%)
occurrences (all)	0	1	0

Varicella subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	0 / 34 (0.00%) 0	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0

Non-serious adverse events	Stage 2 Children: altSonflex1-2-3 Medium Dose	Stage 2 Children: altSonflex1-2-3 High Dose	Stage 2 dose-finding cohort: altSonflex1- 2-3 Medium Dose
Total subjects affected by non-serious adverse events subjects affected / exposed	9 / 10 (90.00%)	5 / 10 (50.00%)	74 / 81 (91.36%)
General disorders and administration site conditions			
Administration site erythema subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 2	1 / 10 (10.00%) 1	21 / 81 (25.93%) 28
Axillary pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0
Administration site swelling subjects affected / exposed occurrences (all)	1 / 10 (10.00%) 2	1 / 10 (10.00%) 1	32 / 81 (39.51%) 53
Application site hypersensitivity subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0
Administration site pain subjects affected / exposed occurrences (all)	7 / 10 (70.00%) 13	3 / 10 (30.00%) 4	57 / 81 (70.37%) 117
Chills subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0
Fatigue subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0
Injection site eczema subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0

Influenza like illness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Injection site discolouration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Injection site rash			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Injection site nodule			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Injection site warmth			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0

Vaccination site pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	2 / 10 (20.00%) 2	2 / 10 (20.00%) 2	28 / 81 (34.57%) 35
Swelling face subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0
Peripheral swelling subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0
Immune system disorders Food allergy subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0
Reproductive system and breast disorders Vaginal discharge subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0
Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Nasal congestion subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	2 / 81 (2.47%) 2
Bronchospasm subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	1 / 81 (1.23%) 1
Allergic cough subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0

Rhinitis allergic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	5 / 81 (6.17%)
occurrences (all)	0	0	5
Sneezing			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Pulmonary congestion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Blood sodium increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Eosinophil count increased			

subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	1	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	3 / 81 (3.70%)
occurrences (all)	0	1	3
Hepatic enzyme increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Neutrophil count decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Platelet count increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	2
Respiratory rate increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Ligament sprain			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Immunisation reaction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Greenstick fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Limb injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Muscle strain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Soft tissue injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Thermal burn			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Syncope			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Partial seizures			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1

Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0
Thrombocytosis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0
Ear and labyrinth disorders Hypoacusis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0
Eye disorders Conjunctivitis allergic subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0
Eye irritation subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	1 / 81 (1.23%) 1
Lacrimation increased subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0
Eye pruritus subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	1 / 81 (1.23%) 1
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0
Abdominal distension subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0
Cheilitis subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	0 / 81 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	0 / 10 (0.00%) 0	0 / 10 (0.00%) 0	1 / 81 (1.23%) 1
Flatulence			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Faeces hard			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	15 / 81 (18.52%)
occurrences (all)	0	1	15
Gastritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 81 (2.47%)
occurrences (all)	0	0	2
Irritable bowel syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Mucous stools			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 81 (2.47%)
occurrences (all)	0	0	2
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	3 / 81 (3.70%)
occurrences (all)	0	0	3

Blister			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Rash pruritic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Autoimmune hypothyroidism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Limb discomfort			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Back pain			

subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Myalgia intercostal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Muscle tightness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Body tinea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Amoebic dysentery			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Bacterial infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Amoebiasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Bronchiolitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1

Bronchitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Dermatitis infected			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 81 (2.47%)
occurrences (all)	0	0	2
Conjunctivitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	3 / 81 (3.70%)
occurrences (all)	0	0	3
Cystitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Genital abscess			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	8 / 81 (9.88%)
occurrences (all)	0	0	9
Furuncle			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Helminthic infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Infectious mononucleosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0

Labyrinthitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Lower respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Malaria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	6 / 81 (7.41%)
occurrences (all)	0	0	6
Oral candidiasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 81 (2.47%)
occurrences (all)	0	0	2
Otitis media			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	0 / 81 (0.00%)
occurrences (all)	0	1	0
Otitis media acute			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	1 / 81 (1.23%)
occurrences (all)	0	0	1
Pharyngitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 81 (2.47%)
occurrences (all)	0	0	2
Plasmodium falciparum infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 10 (10.00%)	1 / 81 (1.23%)
occurrences (all)	0	1	1
Rhinitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	9 / 81 (11.11%)
occurrences (all)	1	0	11
Upper respiratory tract infection			
subjects affected / exposed	2 / 10 (20.00%)	0 / 10 (0.00%)	19 / 81 (23.46%)
occurrences (all)	2	0	21

Scabies			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 10 (0.00%)	3 / 81 (3.70%)
occurrences (all)	1	0	3
Varicella			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	2 / 81 (2.47%)
occurrences (all)	0	0	2
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 10 (0.00%)	0 / 10 (0.00%)	0 / 81 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Stage 2 dose-finding cohort: altSonflex1-2-3 Low Dose	Stage 2 Infants: Control	Stage 2 dose-finding cohort: altSonflex1-2-3 High Dose
Total subjects affected by non-serious adverse events			
subjects affected / exposed	77 / 82 (93.90%)	26 / 30 (86.67%)	80 / 83 (96.39%)
General disorders and administration site conditions			
Administration site erythema			
subjects affected / exposed	20 / 82 (24.39%)	1 / 30 (3.33%)	32 / 83 (38.55%)
occurrences (all)	33	1	43
Axillary pain			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Administration site swelling			
subjects affected / exposed	30 / 82 (36.59%)	5 / 30 (16.67%)	34 / 83 (40.96%)
occurrences (all)	55	6	60
Application site hypersensitivity			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Administration site pain			
subjects affected / exposed	49 / 82 (59.76%)	7 / 30 (23.33%)	58 / 83 (69.88%)
occurrences (all)	101	12	127

Chills			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Injection site eczema			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Injection site discolouration			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 82 (0.00%)	1 / 30 (3.33%)	1 / 83 (1.20%)
occurrences (all)	0	1	1
Injection site erythema			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Injection site haematoma			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Injection site rash			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0

Injection site nodule subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 30 (0.00%) 0	0 / 83 (0.00%) 0
Injection site warmth subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 30 (0.00%) 0	0 / 83 (0.00%) 0
Malaise subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 30 (0.00%) 0	0 / 83 (0.00%) 0
Vaccination site pain subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 30 (0.00%) 0	0 / 83 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	38 / 82 (46.34%) 48	9 / 30 (30.00%) 10	37 / 83 (44.58%) 44
Swelling face subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 30 (0.00%) 0	0 / 83 (0.00%) 0
Peripheral swelling subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 30 (0.00%) 0	0 / 83 (0.00%) 0
Immune system disorders Food allergy subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 30 (0.00%) 0	0 / 83 (0.00%) 0
Reproductive system and breast disorders Vaginal discharge subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 30 (0.00%) 0	0 / 83 (0.00%) 0
Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 30 (0.00%) 0	0 / 83 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Nasal congestion subjects affected / exposed occurrences (all)	1 / 82 (1.22%) 1	0 / 30 (0.00%) 0	0 / 83 (0.00%) 0

Cough			
subjects affected / exposed	6 / 82 (7.32%)	2 / 30 (6.67%)	9 / 83 (10.84%)
occurrences (all)	6	2	9
Bronchospasm			
subjects affected / exposed	0 / 82 (0.00%)	1 / 30 (3.33%)	1 / 83 (1.20%)
occurrences (all)	0	1	1
Allergic cough			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	1 / 83 (1.20%)
occurrences (all)	0	0	1
Rhinitis allergic			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	3 / 82 (3.66%)	0 / 30 (0.00%)	6 / 83 (7.23%)
occurrences (all)	3	0	6
Sneezing			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Pulmonary congestion			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Nasal discomfort			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 82 (2.44%)	0 / 30 (0.00%)	1 / 83 (1.20%)
occurrences (all)	2	0	1
Blood potassium increased			

subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Blood sodium increased			
subjects affected / exposed	1 / 82 (1.22%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Eosinophil count increased			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	8 / 82 (9.76%)	0 / 30 (0.00%)	5 / 83 (6.02%)
occurrences (all)	8	0	5
Hepatic enzyme increased			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count increased			
subjects affected / exposed	3 / 82 (3.66%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	3	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	4 / 82 (4.88%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	4	0	0
Respiratory rate increased			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	1 / 83 (1.20%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			

Arthropod bite			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Bone contusion			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Immunisation reaction			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Greenstick fracture			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	1 / 83 (1.20%)
occurrences (all)	0	0	1
Limb injury			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Muscle strain			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Soft tissue injury			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	1 / 83 (1.20%)
occurrences (all)	0	0	1
Thermal burn			
subjects affected / exposed	1 / 82 (1.22%)	0 / 30 (0.00%)	1 / 83 (1.20%)
occurrences (all)	1	0	1
Cardiac disorders			
Palpitations			

subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Partial seizures			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Tension headache			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 82 (1.22%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			

subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Lymph node pain			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	8 / 82 (9.76%)	0 / 30 (0.00%)	6 / 83 (7.23%)
occurrences (all)	9	0	7
Thrombocytopenia			
subjects affected / exposed	1 / 82 (1.22%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0
Thrombocytosis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	1 / 82 (1.22%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Conjunctivitis allergic			
subjects affected / exposed	1 / 82 (1.22%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0
Eye irritation			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 82 (0.00%)	1 / 30 (3.33%)	0 / 83 (0.00%)
occurrences (all)	0	1	0
Cheilitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	1 / 83 (1.20%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Enteritis			
subjects affected / exposed	2 / 82 (2.44%)	0 / 30 (0.00%)	2 / 83 (2.41%)
occurrences (all)	2	0	2
Faeces hard			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	1 / 83 (1.20%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	4 / 82 (4.88%)	3 / 30 (10.00%)	5 / 83 (6.02%)
occurrences (all)	4	3	5
Gastritis			
subjects affected / exposed	1 / 82 (1.22%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0
Irritable bowel syndrome			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Mucous stools			
subjects affected / exposed	1 / 82 (1.22%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0

Nausea			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 82 (1.22%)	1 / 30 (3.33%)	3 / 83 (3.61%)
occurrences (all)	1	1	3
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	2 / 82 (2.44%)	0 / 30 (0.00%)	5 / 83 (6.02%)
occurrences (all)	2	0	5
Blister			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	1 / 83 (1.20%)
occurrences (all)	0	0	1
Dermatitis allergic			
subjects affected / exposed	1 / 82 (1.22%)	0 / 30 (0.00%)	2 / 83 (2.41%)
occurrences (all)	1	0	2
Eczema			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	1 / 82 (1.22%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0
Rash pruritic			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			

Autoimmune hypothyroidism subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 30 (0.00%) 0	0 / 83 (0.00%) 0
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 30 (0.00%) 0	0 / 83 (0.00%) 0
Limb discomfort subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 30 (0.00%) 0	0 / 83 (0.00%) 0
Groin pain subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 30 (0.00%) 0	0 / 83 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 30 (0.00%) 0	0 / 83 (0.00%) 0
Neck pain subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 30 (0.00%) 0	0 / 83 (0.00%) 0
Myalgia intercostal subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 30 (0.00%) 0	0 / 83 (0.00%) 0
Myalgia subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 30 (0.00%) 0	0 / 83 (0.00%) 0
Muscle tightness subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 30 (0.00%) 0	0 / 83 (0.00%) 0
Muscle spasms subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 30 (0.00%) 0	0 / 83 (0.00%) 0
Infections and infestations			
Abscess limb subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0	0 / 30 (0.00%) 0	1 / 83 (1.20%) 1
Body tinea			

subjects affected / exposed	0 / 82 (0.00%)	1 / 30 (3.33%)	1 / 83 (1.20%)
occurrences (all)	0	1	1
Amoebic dysentery			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Bacterial infection			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	1 / 83 (1.20%)
occurrences (all)	0	0	1
Amoebiasis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Bronchiolitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Dermatitis infected			
subjects affected / exposed	0 / 82 (0.00%)	1 / 30 (3.33%)	2 / 83 (2.41%)
occurrences (all)	0	1	2
Conjunctivitis			
subjects affected / exposed	2 / 82 (2.44%)	4 / 30 (13.33%)	1 / 83 (1.20%)
occurrences (all)	2	4	1
Cystitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	1 / 83 (1.20%)
occurrences (all)	0	0	1
Ear infection			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Genital abscess			

subjects affected / exposed	1 / 82 (1.22%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	3 / 82 (3.66%)	0 / 30 (0.00%)	11 / 83 (13.25%)
occurrences (all)	4	0	12
Furuncle			
subjects affected / exposed	1 / 82 (1.22%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0
Helminthic infection			
subjects affected / exposed	0 / 82 (0.00%)	1 / 30 (3.33%)	0 / 83 (0.00%)
occurrences (all)	0	1	0
Infectious mononucleosis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Labyrinthitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	1 / 82 (1.22%)	0 / 30 (0.00%)	1 / 83 (1.20%)
occurrences (all)	1	0	1
Malaria			
subjects affected / exposed	1 / 82 (1.22%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	6 / 82 (7.32%)	2 / 30 (6.67%)	5 / 83 (6.02%)
occurrences (all)	6	2	5
Oral candidiasis			
subjects affected / exposed	3 / 82 (3.66%)	0 / 30 (0.00%)	5 / 83 (6.02%)
occurrences (all)	3	0	6
Otitis media			
subjects affected / exposed	0 / 82 (0.00%)	1 / 30 (3.33%)	0 / 83 (0.00%)
occurrences (all)	0	1	0
Otitis media acute			
subjects affected / exposed	1 / 82 (1.22%)	0 / 30 (0.00%)	1 / 83 (1.20%)
occurrences (all)	1	0	1
Pharyngitis			

subjects affected / exposed	1 / 82 (1.22%)	1 / 30 (3.33%)	0 / 83 (0.00%)
occurrences (all)	1	1	0
Plasmodium falciparum infection			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	1 / 83 (1.20%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	1 / 83 (1.20%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	7 / 82 (8.54%)	6 / 30 (20.00%)	6 / 83 (7.23%)
occurrences (all)	7	7	8
Upper respiratory tract infection			
subjects affected / exposed	17 / 82 (20.73%)	8 / 30 (26.67%)	18 / 83 (21.69%)
occurrences (all)	21	8	21
Scabies			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	3 / 82 (3.66%)	1 / 30 (3.33%)	3 / 83 (3.61%)
occurrences (all)	3	1	3
Varicella			
subjects affected / exposed	1 / 82 (1.22%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 82 (0.00%)	0 / 30 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Stage 2 dose-finding cohort: Control		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	69 / 82 (84.15%)		
General disorders and administration site conditions			

Administration site erythema subjects affected / exposed occurrences (all)	14 / 82 (17.07%) 21		
Axillary pain subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Administration site swelling subjects affected / exposed occurrences (all)	20 / 82 (24.39%) 25		
Application site hypersensitivity subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Administration site pain subjects affected / exposed occurrences (all)	35 / 82 (42.68%) 60		
Chills subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Fatigue subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Injection site eczema subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Influenza like illness subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Injection site discolouration subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Feeling hot subjects affected / exposed occurrences (all)	1 / 82 (1.22%) 1		
Injection site erythema subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		

Injection site haematoma			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Injection site induration			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Injection site reaction			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Injection site pain			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Injection site rash			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Injection site nodule			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Injection site warmth			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Malaise			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Vaccination site pain			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	18 / 82 (21.95%)		
occurrences (all)	22		
Swelling face			
subjects affected / exposed	1 / 82 (1.22%)		
occurrences (all)	1		
Peripheral swelling			
subjects affected / exposed	1 / 82 (1.22%)		
occurrences (all)	1		

Immune system disorders Food allergy subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Reproductive system and breast disorders Vaginal discharge subjects affected / exposed occurrences (all) Dysmenorrhoea subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0 0 / 82 (0.00%) 0		
Respiratory, thoracic and mediastinal disorders Nasal congestion subjects affected / exposed occurrences (all) Cough subjects affected / exposed occurrences (all) Bronchospasm subjects affected / exposed occurrences (all) Allergic cough subjects affected / exposed occurrences (all) Rhinitis allergic subjects affected / exposed occurrences (all) Rhinorrhoea subjects affected / exposed occurrences (all) Sneezing subjects affected / exposed occurrences (all) Pulmonary congestion subjects affected / exposed occurrences (all)	1 / 82 (1.22%) 1 10 / 82 (12.20%) 10 2 / 82 (2.44%) 2 1 / 82 (1.22%) 1 1 / 82 (1.22%) 1 5 / 82 (6.10%) 5 0 / 82 (0.00%) 0 1 / 82 (1.22%) 1		

Oropharyngeal pain subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Upper-airway cough syndrome subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Nasal discomfort subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	1 / 82 (1.22%) 1		
Blood potassium increased subjects affected / exposed occurrences (all)	1 / 82 (1.22%) 1		
Blood sodium increased subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Blood thyroid stimulating hormone increased subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Eosinophil count increased subjects affected / exposed occurrences (all)	1 / 82 (1.22%) 1		
Haemoglobin decreased subjects affected / exposed occurrences (all)	3 / 82 (3.66%) 3		
Hepatic enzyme increased subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Lymphocyte count increased subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Neutrophil count decreased			

subjects affected / exposed	2 / 82 (2.44%)		
occurrences (all)	2		
Platelet count increased			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
White blood cell count increased			
subjects affected / exposed	1 / 82 (1.22%)		
occurrences (all)	1		
Respiratory rate increased			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Bone contusion			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Face injury			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Ligament sprain			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Immunisation reaction			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Hand fracture			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Greenstick fracture			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Limb injury			

subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Muscle strain			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Soft tissue injury			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Thermal burn			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Tachycardia			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Syncope			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Partial seizures			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Migraine			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Hypotonia			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Hypoaesthesia			

subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Tension headache			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Lymphadenopathy			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Lymph node pain			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Iron deficiency anaemia			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Neutropenia			
subjects affected / exposed	3 / 82 (3.66%)		
occurrences (all)	3		
Thrombocytopenia			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Thrombocytosis			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Eye disorders			

Conjunctivitis allergic subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Eye irritation subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Lacrimation increased subjects affected / exposed occurrences (all)	1 / 82 (1.22%) 1		
Eye pruritus subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Gastrointestinal disorders			
Abdominal pain subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Abdominal distension subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Cheilitis subjects affected / exposed occurrences (all)	1 / 82 (1.22%) 1		
Constipation subjects affected / exposed occurrences (all)	1 / 82 (1.22%) 1		
Flatulence subjects affected / exposed occurrences (all)	0 / 82 (0.00%) 0		
Enteritis subjects affected / exposed occurrences (all)	1 / 82 (1.22%) 1		
Faeces hard subjects affected / exposed occurrences (all)	2 / 82 (2.44%) 2		
Diarrhoea			

subjects affected / exposed	14 / 82 (17.07%)		
occurrences (all)	15		
Gastritis			
subjects affected / exposed	1 / 82 (1.22%)		
occurrences (all)	1		
Irritable bowel syndrome			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Toothache			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Mucous stools			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Mouth ulceration			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	4 / 82 (4.88%)		
occurrences (all)	5		
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	3 / 82 (3.66%)		
occurrences (all)	4		
Blister			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Dermatitis			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Dermatitis allergic			
subjects affected / exposed	1 / 82 (1.22%)		
occurrences (all)	1		

Eczema			
subjects affected / exposed	1 / 82 (1.22%)		
occurrences (all)	1		
Pruritus			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Urticaria			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Rash pruritic			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Autoimmune hypothyroidism			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 82 (1.22%)		
occurrences (all)	1		
Limb discomfort			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Groin pain			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Back pain			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Neck pain			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Myalgia intercostal			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Myalgia			

subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Muscle tightness			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Muscle spasms			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Body tinea			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Amoebic dysentery			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Bacterial infection			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Amoebiasis			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Bronchiolitis			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Bronchitis			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
COVID-19			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Dermatitis infected			
subjects affected / exposed	1 / 82 (1.22%)		
occurrences (all)	1		

Conjunctivitis			
subjects affected / exposed	1 / 82 (1.22%)		
occurrences (all)	1		
Cystitis			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Cellulitis			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Ear infection			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Genital abscess			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Gastroenteritis			
subjects affected / exposed	8 / 82 (9.76%)		
occurrences (all)	8		
Furuncle			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Helminthic infection			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Infectious mononucleosis			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Labyrinthitis			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Lower respiratory tract infection			
subjects affected / exposed	1 / 82 (1.22%)		
occurrences (all)	1		
Malaria			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		

Nasopharyngitis			
subjects affected / exposed	1 / 82 (1.22%)		
occurrences (all)	1		
Oral candidiasis			
subjects affected / exposed	1 / 82 (1.22%)		
occurrences (all)	1		
Otitis media			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Otitis media acute			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	2 / 82 (2.44%)		
occurrences (all)	2		
Plasmodium falciparum infection			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Pneumonia			
subjects affected / exposed	2 / 82 (2.44%)		
occurrences (all)	2		
Rhinitis			
subjects affected / exposed	13 / 82 (15.85%)		
occurrences (all)	13		
Upper respiratory tract infection			
subjects affected / exposed	21 / 82 (25.61%)		
occurrences (all)	23		
Scabies			
subjects affected / exposed	1 / 82 (1.22%)		
occurrences (all)	1		
Sinusitis			
subjects affected / exposed	0 / 82 (0.00%)		
occurrences (all)	0		
Tonsillitis			
subjects affected / exposed	3 / 82 (3.66%)		
occurrences (all)	3		

Varicella subjects affected / exposed occurrences (all)	1 / 82 (1.22%) 1		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	1 / 82 (1.22%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 September 2021	This amendment has been prepared based on feedback received from the clinical trial application to the Belgian health authority. The word "booster vaccination" has been replaced by "third vaccination" or "primary" vaccination. The screening period has been shortened to 28 days. Additional rationale have been added for choice of schedule, choice of study population, and justification of dose. Inclusion criterion has been revised to mention that laboratory assessment is used as assessment for healthy participants. Travel and occupational exposure to Shigella have been added to the exclusion criterion on known exposure to Shigella. The criterion on reaction/hypersensitivity to any component of the study vaccine has been clarified. Exceptions for flu and COVID-19 vaccines in adults and EPI vaccines in children and infants have been added to the exclusion criteria. Bone marrow transplantation has been added to the exclusion criteria. Immediate allergic reaction to previous study vaccination has been added as contraindication. Additional clarifications on the additional blood volume collected in some participants for peripheral blood mononuclear cell (PBMC) extraction has been added. Instructions have been added for the investigator or delegate to assess the exclusion criterion of known exposure to Shigella.
14 February 2022	This amendment has been prepared to incorporate the latest company strategy on result analysis before the first interim analysis data lock point, address operational issues due to the COVID-19 pandemic, and to incorporate feedback received from the Kenyan site Institutional Review Boards (IRB). An additional benefit is added for children and infants participants who did not receive MENVEO during the study so they can receive a meningitis vaccine at the end of the study. GVGH will also play a role in supporting revaccination of non-responder with measles and rubella vaccines in Stage 2. In case the Quantitative Decision Making (QDM) success criterion is not met during Interim Analysis 1, a comprehensive review of all Stage 1 immunogenicity and safety data (Interim analysis 2) will lead to the GO-NO-GO decision to proceed to Stage 2 (instead on relying only on QDM). Changes have been made due to the COVID-19 pandemic The 3rd and 4th interim analyses have been combined into 1 interim analysis. Other minor changes have been made.
07 February 2023	This amendment has been prepared due to a change of the laboratory performing primary and secondary immunogenicity analyses, the addition of endpoints for serum bactericidal assay, and the inclusion of an additional interim analysis for the infant safety cohort.
31 October 2023	The amendment has been prepared to improve safety monitoring of participants by modifying the creatinine grading scale using a range that better represents the population being evaluated and by introducing blood urea, sodium, and potassium testing to ensure further monitoring of renal function. Serology sampling has been optimised to obtain more representative results with reference ELISA testing and focus on immune response characterization. Due to supply constraints, the trivalent INFANRIX vaccine is also being substituted with the hexavalent INFANRIX HEXA vaccine providing additional potential benefit to the participants.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Limitations of the trial were small numbers of participants analyzed for the adults and children cohorts. Short study follow-up (1 month after last vaccination) did not allow for the assessment of the persistence of immune responses.

Notes: