Salmonella Vaccines in Oxford (SALVO)

CLINICAL STUDY REPORT (CSR)

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Contents

Demographics

Table 1 - Summary of demography and baseline characteristics - Stage 1 - Exposed Set

	Study group			Overall
Characteristic	**Placebo, N = 12**	**Lower dose, N = 4**	**Full dose, N = 15**	**N = 31**
Age (years), median (IQR)	30 (22, 43)	38 (23, 52)	27 (24, 39)	27 (23, 46)
Weight (kg), median (IQR)	81 (73, 85)	94 (89, 95)	84 (75, 89)	84 (74, 89)
Sex				
Male	9 (75%)	3 (75%)	9 (60%)	21 (68%)
Female	3 (25%)	1 (25%)	6 (40%)	10 (32%)
Ethnicity				
White English/Welsh/Scottish/Northern Irish/British	7 (58%)	2 (50%)	12 (80%)	21 (68%)
White Irish	1 (8.3%)	0 (0%)	0 (0%)	1 (3.2%)
Any other White background	4 (33%)	0 (0%)	1 (6.7%)	5 (16%)
White and Asian	0 (0%)	0 (0%)	2 (13%)	2 (6.5%)
Any other Mixed/Multiple ethnic background	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Any other ethnic group	0 (0%)	2 (50%)	0 (0%)	2 (6.5%)

Listing 2 - Listing of Demographic Characteristics - Exposed Set

ID	Study arm	Age	Weight	Sex	Ethnicity	Other ethnicity
SAL-001	Full dose	27	70.15	Male	White and Asian	
SAL-003	Full dose	52	91	Male	White English/Welsh/Scottish/Northern Irish/British	
SAL-004	Placebo	21	59	Male	White English/Welsh/Scottish/Northern Irish/British	
SAL-009	Placebo	22	74.2	Male	Any other White background	Eastern European
SAL-013	Placebo	22	85.5	Male	White English/Welsh/Scottish/Northern Irish/British	
SAL-021	Full dose	19	87	Female	White English/Welsh/Scottish/Northern Irish/British	
SAL-023	Lower dose	53	94	Male	White English/Welsh/Scottish/Northern Irish/British	
SAL-024	Placebo	22	60.5	Female	White Irish	
SAL-026	Lower dose	24	94.3	Female	Any other ethnic group	Hispanic/White Irish
SAL-028	Full dose	27	61.8	Female	White English/Welsh/Scottish/Northern Irish/British	
SAL-029	Full dose	50	84.6	Male	White English/Welsh/Scottish/Northern Irish/British	
SAL-030	Lower dose	20	75	Male	Any other ethnic group	White other (Finland)
SAL-031	Lower dose	51	97.8	Male	White English/Welsh/Scottish/Northern Irish/British	
SAL-032	Full dose	31	56	Female	Any other White background	French / European
SAL-034	Full dose	26	95.7	Female	White English/Welsh/Scottish/Northern Irish/British	
SAL-039	Full dose	24	83.7	Female	White English/Welsh/Scottish/Northern Irish/British	
SAL-042	Placebo	48	78.7	Male	Any other White background	Spain
SAL-046	Placebo	49	87	Male	White English/Welsh/Scottish/Northern Irish/British	
SAL-048	Full dose	44	135.6	Male	White English/Welsh/Scottish/Northern Irish/British	
SAL-051	Placebo	50	82.6	Female	White English/Welsh/Scottish/Northern Irish/British	
SAL-062	Placebo	21	84	Male	White English/Welsh/Scottish/Northern Irish/British	
SAL-066	Placebo	35	74.4	Male	White English/Welsh/Scottish/Northern Irish/British	
SAL-067	Full dose	52	84	Male	White English/Welsh/Scottish/Northern Irish/British	
SAL-068	Placebo	41	110	Female	Any other White background	Polish
SAL-070	Full dose	27	81.2	Male	White English/Welsh/Scottish/Northern Irish/British	
SAL-071	Full dose	33	93.3	Male	White English/Welsh/Scottish/Northern Irish/British	
SAL-075	Full dose	23	84.5	Male	White and Asian	

ID	Study arm	Age	Weight	Sex	Ethnicity	Other ethnicity
SAL-076	Full dose	18	64	Male	White English/Welsh/Scottish/Northern Irish/British	
SAL-077	Full dose	24	79	Female	White English/Welsh/Scottish/Northern Irish/British	
SAL-078	Placebo	39	69.7	Male	White English/Welsh/Scottish/Northern Irish/British	
SAL-089	Placebo	24	85	Male	Any other White background	European - half British / Half Greek

Listing 3 - Listing of participants withdrawn from the study - Exposed Set

ID	Study arm	Reason study not completed	Other reason	Last visit conducted
SAL-001	Full dose	Consent withdrawn		11
SAL-009	Placebo	Consent withdrawn		9
SAL-031	Lower dose	Consent withdrawn		5
SAL-048	Full dose	Other	Participant uncontactable - lost to follow up	10
SAL-070	Full dose	Other	Participant uncontactable - lost to follow up	8

Listing 4 - Listing of participants withdrawn from the study due to grade 3 AE - Exposed Set

There were no withdrawals due to adverse events.

Vital signs

Listing 5 - Listing of Vital signs - Exposed Set

Vital sign	ID	Study arm	Screening	V1 pre-vaccination	V1 post-vaccination	V2	V3	V4	V5	V6 pre-vaccination	V6 post-vaccination	V7	V8	V9 pre-vaccination	V9 post-vaccination	V10	V11	V12
Oral temperature	SAL-001	Full dose	36.7	36.8	36.9	36.6	36.7	36.4	36.3	36.8	36.3	36.5	36.3	NA	NA		NA	
	SAL-003	Full dose	36.3	36.5	37.4	36.3	36.4	36.6	36.1	37.1	37.1	36.3	36.3	36.5	36.1	36.7	36.5	36.4
	SAL-004	Placebo	36.2	37.1	37.4	36.6	36.2	36.8	36.6	36.3	36.9	36.4	37	37	36.5	36.7	36.7	36.7
	SAL-009	Placebo	37.4	36.9	36.9	36.9	36.7	36.6	UNK	36.9	36.6	36.6	37.2	36.9	NA		NA	
	SAL-013	Placebo	36.6	36.3	36.6	36.4	36.6	36.8	36.6	36.2	36.4	36.4	36.8	36.7	36.7	36.5	36.5	36.3
	SAL-021	Full dose	36.6	36.4	36.4	36.9	36.6	37.2	36.2	36.9	36.9	36.9	36.3	36.4	36.9	36.5	36.5	36.7
	SAL-023	Lower dose	36.6	36.7	37.2	37	36.5	36.7	36.6	37	36.7	36.9	36.5	36.5	36.8	36.7	36.5	36.3
	SAL-024	Placebo	36.5	37	37	37	36.5	36.6	35.9	36.5	37.1	37.1	37.2	36.9	36.9	UNK	37.1	36.4
	SAL-026	Lower dose	37.3	36.9	37.1	36.7	UNK	37	37.1	37	36.9	36.6	36.8	36.9	37	UNK	36.7	36.3
	SAL-028	Full dose	37.3	37.3	37.1	36.6	36.9	36.7	36.6	36.7	36.9	UNK	37.2	36.6	36.7	36.8	36.7	36.6
	SAL-029	Full dose	36.5	36.8	36.6	36.7	36.9	36.5	36.5	36.7	36.8	36.2	36.2	36.6	36.6	36.7	36.5	36.6
	SAL-030	Lower dose	36.7	36.4	36.7	36.7	36.7	36.5	37.1	36.2	36.7	36.8	37	36.7	36.8	36.8	36.6	36
	SAL-031	Lower dose	37.1	36.7	37.2	37	37	37.2	36.9	NA				NA	NA		NA	
	SAL-032	Full dose	36.7	36.4	36.4	36.9	36.1	36.6	35.7	36.9	37.1	36.1	36.5	36.7	36.1	36.4	36.6	36.9
	SAL-034	Full dose	36.7	36.8	37	36.6	36.6	37	UNK	36.4	36.6	36.6	36.3	36.4	36.6	36.7	36.6	36.4
	SAL-039	Full dose	36.5	36.8	36.7	37.1	37.2	36.8	36.8	36.8	36.9	36.7	36.1	36.6	36.6	UNK	36.8	36.8
	SAL-042	Placebo	36.7	36.6	36.4	36.5	36.6	36.6	36.8	36.2	37.1	36.2	36.5	36.5	36.4	36.8	36.8	36.6
	SAL-046	Placebo	36.4	36.7	36.6	36.7	36.8	36.8	36.9	36.4	36.3	36.7	36.2	35.6	36.6	36.5	36.5	36.4
	SAL-048	Full dose	36.8	37.1	36.6	36.6	36.7	36.8	37	36.7	36.4	36.6	UNK	NA	NA	UNK	NA	
	SAL-051	Placebo	36.7	36.8	36.8	36.9	37.1	37.1	36.8	37	UNK	37	36.9	36.8	36.7	37.1	36.9	36.7
	SAL-062	Placebo	36.6	37.1	36.4	36.6	36.8	36.5	36.7	37	37.1	36.7	36.6	36.7	36.2	36.8	36.7	36.6
	SAL-066	Placebo	36.9	36.9	36.7	36.4	36.6	36.9	36.8	36.6	36.8	UNK	36.2	36.9	37.1	37	36.6	36.5
	SAL-067	Full dose	36.9	36.7	36.4	36.9	36.6	36.4	36.4	36.5	36.6	UNK	35.7	36.7	36.3	UNK	36.3	36.4
	SAL-068	Placebo	36.8	37.1	37	37.2	37.1	36.8	36.8	36.7	37.1	36.5	36.7	36.8	36.6	36.8	36.7	36.6
	SAL-070	Full dose	36.5	36.9	36.7	36.7	36.5	36.7	36.6	36.6	36.7	36.5	36.8	NA	NA		NA	
	SAL-071	Full dose	36.6	36.6	36.2	36.4	36.2	36.5	36.7	36.9	36.5	36.7	36.7	36.5	36.2	36.7	36.4	36.5

Vital sign	ID	Study arm	Screening	V1 pre-vaccination	V1 post-vaccination	V2	V3	V4	V5	V6 pre-vaccination	V6 post-vaccination	V7	V8	V9 pre-vaccination	V9 post-vaccination	V10	V11	V12
	SAL-075	Full dose	36.3	36.4	36.3	36.7	36.7	36.7	36.3	37	36.7	36.6	36.9	36.7	36.7	36.7	36.8	36.6
	SAL-076	Full dose	36.9	36.9	36.9	37.3	36.4	36.7	36.1	36.6	36.8	37.2	36.4	36.4	NA	36.5	36.7	36.9
	SAL-077	Full dose	36.7	36.7	36.9	36.6	36.5	UNK	36.5	37	37.2	37.3	36.7	36.9	NA	UNK	36.7	UNK
	SAL-078	Placebo	36.4	37.1	36.2	37.2	36.8	36.7	36.6	37	36.8	37.1	36.4	36.8	36.6	36.7	36.7	36.6
	SAL-089	Placebo	36.1	36.6	35.9	36.9	36.6	36.5	36.2	36.8	36.8	36	36.4	36.3	36.4	36.3	36.5	36.4
Pulse	SAL-001	Full dose	97	84	66	76	80	73	94	89	71	83	67	NA	NA		NA	
	SAL-003	Full dose	78	78	72	93	73	60	76	60	71	68	63	72	62	66	67	74
	SAL-004	Placebo	57	84	73	72	76	85	99	91	79	80	86	81	91	96	93	84
	SAL-009	Placebo	73	72	52	79	72	71	UNK	80	70	60	69	86	NA		NA	
	SAL-013	Placebo	76	86	73	77	62	68	78	95	66	60	86	87	62	77	83	88
	SAL-021	Full dose	85	80	72	82	77	80	75	87	86	99	69	75	76	73	70	67
	SAL-023	Lower dose	69	70	66	86	60	79	72	78	70	67	67	69	62	73	68	73
	SAL-024	Placebo	80	75	64	81	76	89	69	96	75	61	79	83	80	UNK	96	84
	SAL-026	Lower dose	71	74	67	81	UNK	71	84	72	72	68	69	76	75	UNK	76	77
	SAL-028	Full dose	66	62	65	67	UNK	65	65	73	64	UNK	76	71	64	79	72	56
	SAL-029	Full dose	60	71	61	74	64	73	79	83	66	86	68	76	59	61	73	84
	SAL-030	Lower dose	94	80	81	81	82	83	78	85	81	78	88	88	68	99	82	88
	SAL-031	Lower dose	77	79	71	73	81	96	79	NA				NA	NA		NA	
	SAL-032	Full dose	78	92	56	90	60	69	60	80	73	76	86	71	59	68	72	79
	SAL-034	Full dose	71	71	80	86	69	89	60	69	56	83	74	62	55	59	65	71
	SAL-039	Full dose	72	76	61	78	87	80	85	69	75	73	90	70	61	UNK	77	84
	SAL-042	Placebo	55	80	66	56	65	54	61	60	55	64	61	73	58	62	69	66
	SAL-046	Placebo	59	71	55	62	75	73	66	64	56	70	59	80	65	61	97	83
	SAL-048	Full dose	61	68	66	81	68	64	64	62	55	56	UNK	NA	NA	UNK	NA	
	SAL-051	Placebo	86	83	56	88	94	98	85	71	UNK	99	97	91	85	89	73	89
	SAL-062	Placebo	82	90	55	100	87	78	87	89	60	76	75	86	65	77	89	65
	SAL-066	Placebo	76	93	68	87	75	90	88	82	73	UNK	95	68	53	77	84	66
	SAL-067	Full dose	62	65	61	92	67	70	69	62	58	UNK	60	84	62	UNK	60	84
	SAL-068	Placebo	77	81	99	63	97	72	80	88	75	80	82	84	60	82	75	62
	SAL-070	Full dose	74	64	57	78	73	69	86	67	69	71	74	NA	NA		NA	
	SAL-071	Full dose	90	66	55	89	81	69	79	83	60	64	92	64	68	93	81	76
	SAL-075	Full dose	78	88	66	81	79	89	82	114	80	72	69	87	84	83	88	84

Vital sign	ID	Study arm	Screening	V1 pre-vaccination	V1 post-vaccination	V2	V3	V4	V5	V6 pre-vaccination	V6 post-vaccination	V7	V8	V9 pre-vaccination	V9 post-vaccination	V10	V11	V12
	SAL-076	Full dose	90	100	68	98	64	60	67	80	77	92	63	66	NA	85	72	76
	SAL-077	Full dose	69	75	75	88	83	UNK	80	79	71	73	71	85	NA	UNK	71	UNK
	SAL-078	Placebo	73	89	60	85	78	86	72	99	76	83	87	76	91	73	96	67
	SAL-089	Placebo	50	57	51	47	67	69	56	72	67	57	73	54	56	62	58	78
Systolic blood pressure	SAL-001	Full dose	125	128	123	124	128	129	132	121	112	116	107	NA	NA		NA	
	SAL-003	Full dose	132	124	118	128	130	144	120	147	140	134	138	133	130	142	131	124
	SAL-004	Placebo	100	101	97	97	97	95	105	105	99	108	95	99	105	101	102	99
	SAL-009	Placebo	121	136	123	125	133	118	UNK	122	120	114	121	132	NA		NA	
	SAL-013	Placebo	119	126	115	109	103	107	110	125	102	102	130	120	107	126	107	107
	SAL-021	Full dose	120	117	106	117	101	136	116	116	109	122	102	113	124	100	114	122
	SAL-023	Lower dose	118	133	127	120	120	123	117	114	111	130	126	108	131	126	117	128
	SAL-024	Placebo	127	105	100	111	112	112	116	119	110	114	110	112	101	UNK	119	107
	SAL-026	Lower dose	120	121	117	118	UNK	120	127	114	111	124	119	127	121	UNK	123	118
	SAL-028	Full dose	122	125	113	116	UNK	115	112	113	113	UNK	116	108	115	113	100	104
	SAL-029	Full dose	116	125	123	116	116	101	109	121	126	110	114	137	111	101	102	113
	SAL-030	Lower dose	134	134	133	130	132	129	133	137	130	128	126	150	127	135	132	137
	SAL-031	Lower dose	125	126	129	120	114	123	123	NA				NA	NA		NA	
	SAL-032	Full dose	97	116	117	118	100	107	104	110	108	102	114	106	98	110	100	105
	SAL-034	Full dose	126	123	140	124	123	121	119	120	118	112	128	125	121	123	112	114
	SAL-039	Full dose	99	122	102	108	118	120	119	111	119	108	131	114	115	UNK	128	126
	SAL-042	Placebo	146	124	125	128	114	114	118	108	118	118	117	128	119	98	121	122
	SAL-046	Placebo	140	126	129	117	124	124	121	135	123	112	119	127	129	125	120	134
	SAL-048	Full dose	124	126	129	106	113	136	124	115	123	126	UNK	NA	NA	UNK	NA	
	SAL-051	Placebo	121	109	127	115	124	116	126	129	UNK	138	133	11	129	129	122	126
	SAL-062	Placebo	113	105	112	123	110	104	122	124	101	114	108	108	117	103	119	122
	SAL-066	Placebo	128	125	117	127	124	126	126	108	115	UNK	124	125	115	120	111	120
	SAL-067	Full dose	128	133	118	114	125	126	126	136	128	UNK	133	119	132	UNK	113	108
	SAL-068	Placebo	120	125	105	121	125	119	111	138	129	121	109	137	117	112	118	110
	SAL-070	Full dose	121	112	101	128	124	104	137	127	121	114	114	NA	NA		NA	
	SAL-071	Full dose	115	116	123	129	119	116	112	124	132	133	114	113	111	118	113	124
	SAL-075	Full dose	122	122	114	128	131	117	130	125	123	135	119	136	127	133	124	142
	SAL-076	Full dose	131	129	107	117	108	119	110	103	124	105	124	112	NA	130	120	110

Vital sign	ID	Study arm	Screening	V1 pre-vaccination	V1 post-vaccination	V2	V3	V4	V5	V6 pre-vaccination	V6 post-vaccination	V7	V8	V9 pre-vaccination	V9 post-vaccination	V10	V11	V12
	SAL-077	Full dose	116	122	114	107	100	UNK	105	110	121	99	97	110	NA	UNK	95	UNK
	SAL-078	Placebo	117	135	133	139	126	124	127	137	134	134	134	123	147	130	116	127
	SAL-089	Placebo	123	132	113	124	124	133	128	126	116	116	132	110	115	136	133	111
Diastolic blood pressure	SAL-001	Full dose	89	79	77	83	80	84	82	73	80	77	72	NA	NA		NA	
	SAL-003	Full dose	90	76	74	81	86	65	83	95	89	84	92	78	87	98	91	84
	SAL-004	Placebo	62	62	62	60	59	56	66	62	64	68	57	59	62	62	64	65
	SAL-009	Placebo	75	80	77	78	84	69	UNK	78	76	47	71	77	NA		NA	
	SAL-013	Placebo	70	78	61	73	64	63	66	72	60	64	69	66	63	71	70	55
	SAL-021	Full dose	75	75	60	73	70	78	76	74	70	83	64	73	75	66	79	75
	SAL-023	Lower dose	77	82	85	75	77	80	81	76	74	77	84	69	83	83	76	74
	SAL-024	Placebo	70	69	63	74	70	70	76	70	67	75	68	71	66	UNK	67	68
	SAL-026	Lower dose	83	88	80	79	UNK	78	87	80	70	81	78	88	81	UNK	78	80
	SAL-028	Full dose	80	81	72	77	UNK	79	76	73	75	UNK	85	70	83	83	67	70
	SAL-029	Full dose	82	83	84	80	77	66	73	75	84	72	79	78	76	68	68	80
	SAL-030	Lower dose	86	72	71	82	70	82	72	72	82	82	75	80	78	62	75	88
	SAL-031	Lower dose	81	74	71	76	71	78	76	NA				NA	NA		NA	
	SAL-032	Full dose	60	70	76	78	66	76	71	74	72	71	70	67	65	75	71	71
	SAL-034	Full dose	83	79	84	80	80	73	78	74	71	73	74	85	63	64	68	77
	SAL-039	Full dose	63	74	69	72	74	77	80	71	73	74	70	68	71	UNK	76	83
	SAL-042	Placebo	96	83	80	79	78	75	80	72	83	80	75	85	76	66	73	72
	SAL-046	Placebo	84	80	81	77	86	83	83	80	80	77	76	82	78	76	77	88
	SAL-048	Full dose	84	86	89	74	80	83	85	73	85	83	UNK	NA	NA	UNK	NA	
	SAL-051	Placebo	86	75	87	71	76	83	86	74	UNK	90	83	75	82	85	77	83
	SAL-062	Placebo	69	63	66	71	69	68	64	74	65	70	66	63	68	68	75	78
	SAL-066	Placebo	82	83	80	78	77	82	75	66	74	UNK	77	73	71	77	80	86
	SAL-067	Full dose	83	85	79	73	76	69	82	85	83	UNK	75	73	90	UNK	74	72
	SAL-068	Placebo	83	82	74	82	76	82	70	82	81	85	73	75	79	71	73	71
	SAL-070	Full dose	79	76	69	72	75	67	85	70	75	73	73	NA	NA		NA	
	SAL-071	Full dose	81	76	82	81	77	79	73	76	84	82	76	70	72	71	75	70
	SAL-075	Full dose	75	76	70	76	76	75	67	70	77	88	66	78	79	74	76	79
	SAL-076	Full dose	75	79	63	74	67	70	61	64	71	57	71	73	NA	70	70	68
	SAL-077	Full dose	78	79	73	71	63	UNK	68	73	75	65	63	72	NA	UNK	58	UNK

Vital sign	ID	Study arm	Screening	V1 pre-vaccination	V1 post-vaccination	V2	V3	V4	V5	V6 pre-vaccination	V6 post-vaccination	V7	V8	V9 pre-vaccination	V9 post-vaccination	V10	V11	V12
	SAL-078	Placebo	85	89	88	89	84	86	86	89	73	93	91	84	92	89	83	83
	SAL-089	Placebo	73	76	68	71	68	76	68	68	68	66	78	62	69	73	77	60

Medical history

Listing 6 - Listing of Medical History - Exposed Set

ID	Study arm	Cardiovascular	Respiratory	Gastrointestinal	Neurological	Renal	Hepatic	Endocrine/ Metabolic	ENT	Eyes	Skin	Haematological	Cancer	Severe/Recurrent Infections	Psychiatric	Musculoskeletal	Other surgical	Recent illness/ treatments	Any other medical history (including any autoimmune conditions)
SAL-001	Full dose	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No
SAL-003	Full dose	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No
SAL-004	Placebo	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes
SAL-009	Placebo	No	No	Yes	No	No	No	No	Yes	Yes	No	No	No	No	Yes	No	Yes	No	Yes
SAL-013	Placebo	No	No	No	No	No	No	No	No	No	Yes	No	No	No	Yes	No	No	No	No
SAL-021	Full dose	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No
SAL-023	Lower dose	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No
SAL-024	Placebo	No	Yes	No	No	No	No	No	No	No	Yes	No	No	No	No	No	Yes	No	No
SAL-026	Lower dose	No	No	No	Yes	No	No	No	Yes	No	No	No	No	No	Yes	No	Yes	No	Yes
SAL-028	Full dose	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	Yes	No	No
SAL-029	Full dose	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No	No	No	No	No	No	No
SAL-030	Lower dose	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No
SAL-031	Lower dose	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No
SAL-032	Full dose	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No
SAL-034	Full dose	No	Yes	No	No	No	No	No	No	No	No	No	No	No	Yes	No	Yes	No	No
SAL-039	Full dose	No	No	No	No	No	No	No	No	Yes	No	No	No	No	Yes	No	No	No	No
SAL-042	Placebo	No	No	No	No	Yes	No	No	Yes	No	No	No	No	No	Yes	No	Yes	No	No
SAL-046	Placebo	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
SAL-048	Full dose	No	No	No	No	No	No	No	No	No	Yes	No	Yes	No	No	No	Yes	No	No
SAL-051	Placebo	No	No	Yes	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No

ID	Study arm	Cardiovascular	Respiratory	Gastrointestinal	Neurological	Renal	Hepatic	Endocrine/ Metabolic	ENT	Eyes	Skin	Haematological	Cancer	Severe/Recurrent Infections	Psychiatric	Musculoskeletal	Other surgical	Recent illness/ treatments	Any other medical history (including any autoimmune conditions)
SAL-062	Placebo	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No
SAL-066	Placebo	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No
SAL-067	Full dose	No	No	No	No	No	No	No	No	No	Yes	No	No	No	No	No	No	No	No
SAL-068	Placebo	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
SAL-070	Full dose	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No
SAL-071	Full dose	Yes	No	No	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No
SAL-075	Full dose	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No
SAL-076	Full dose	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No
SAL-077	Full dose	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No
SAL-078	Placebo	No	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	No
SAL-089	Placebo	No	No	No	No	No	No	No	No	No	No	No	No	No	No	Yes	No	Yes	No

Pregnancy test

Listing 7 - Listing of Pregnancy testing - Exposed Set

ID	Study arm	Screening test done	Screening test result	V1 test done	V1 test result	V6 test done	V6 test result	V9 test done	V9 test result
SAL-021	Full dose	Yes	Negative	Yes	Negative	Yes	Negative	Yes	Negative
SAL-024	Placebo	Yes	Negative	Yes	Negative	Yes	Negative	Yes	Negative
SAL-026	Lower dose	Yes	Negative	Yes	Negative	Yes	Negative	Yes	Negative
SAL-028	Full dose	Yes	Negative	Yes	Negative	Yes	Negative	Yes	Negative
SAL-032	Full dose	Yes	Negative	Yes	Negative	Yes	Negative	Yes	Negative
SAL-034	Full dose	Yes	Negative	Yes	Negative	Yes	Negative	Yes	Negative
SAL-039	Full dose	Yes	Negative	Yes	Negative	Yes	Negative	Yes	Negative
SAL-051	Placebo	Yes	Negative	Yes	Negative	Yes	Negative	Yes	Negative
SAL-068	Placebo	Yes	Negative	Yes	Negative	Yes	Negative	Yes	Negative
SAL-077	Full dose	Yes	Negative	Yes	Negative	Yes	Negative	No	NA

Exposure

Listing 8 - Listing of participant's exposure - Exposed Set

ID	Study arm	V1 vaccination	V6 vaccination	V9 vaccination
SAL-001	Full dose	26/09/2022	22/11/2022	
SAL-003	Full dose	22/11/2022	16/01/2023	10/05/2023
SAL-004	Placebo	20/10/2022	12/12/2022	31/03/2023
SAL-009	Placebo	22/06/2022	17/08/2022	
SAL-013	Placebo	18/07/2022	14/09/2022	10/01/2023
SAL-021	Full dose	09/11/2022	06/01/2023	26/04/2023
SAL-023	Lower dose	22/06/2022	17/08/2022	08/12/2022
SAL-024	Placebo	06/07/2022	01/09/2022	16/12/2022
SAL-026	Lower dose	06/07/2022	01/09/2022	16/12/2022
SAL-028	Full dose	17/10/2022	20/12/2022	13/04/2023
SAL-029	Full dose	20/10/2022	15/12/2022	06/04/2023
SAL-030	Lower dose	03/08/2022	28/09/2022	18/01/2023
SAL-031	Lower dose	20/07/2022		
SAL-032	Full dose	23/11/2022	17/01/2023	10/05/2023
SAL-034	Full dose	17/08/2022	09/11/2022	28/02/2023
SAL-039	Full dose	20/10/2022	16/12/2022	06/04/2023
SAL-042	Placebo	08/09/2022	03/11/2022	21/02/2023
SAL-046	Placebo	14/09/2022	21/11/2022	09/03/2023
SAL-048	Full dose	14/09/2022	07/11/2022	
SAL-051	Placebo	22/09/2022	21/11/2022	10/03/2023
SAL-062	Placebo	23/11/2022	23/01/2023	10/05/2023
SAL-066	Placebo	20/10/2022	12/12/2022	06/04/2023
SAL-067	Full dose	20/10/2022	12/12/2022	31/03/2023
SAL-068	Placebo	20/10/2022	15/12/2022	06/04/2023
SAL-070	Full dose	21/11/2022	18/01/2023	
SAL-071	Full dose	21/11/2022	18/01/2023	10/05/2023
SAL-075	Full dose	24/11/2022	19/01/2023	15/05/2023
SAL-076	Full dose	21/11/2022	18/01/2023	

ID	Study arm	V1 vaccination	V6 vaccination	V9 vaccination
SAL-077	Full dose	23/11/2022	16/01/2023	
SAL-078	Placebo	22/11/2022	17/01/2023	10/05/2023
SAL-089	Placebo	22/11/2022	19/01/2023	10/05/2023

Concomitant medications

Listing 9 - Listing of Concomitant Medications - Exposed Set

ID	Study arm	Name	Indication	Dose	Dose unit	Frequency	Route	Start date	Ongoing	Stop date
SAL-001	Full dose	Salbutamol	Asthma exacerbation	2	puffs	As required	Inhaled	01/01/2000	Yes	
SAL-001	Full dose	Paracetamol	headache	500	mg	Once a day	Oral	28/09/2022	No	28/09/2022
SAL-001	Full dose	Ibuprofen	Pain, feverishness	200	mg	As required	Oral	23/11/2022	No	25/11/2022
SAL-001	Full dose	Seretide 250	Asthma	1	puffs	Once a day	Inhaled	01/06/2000	Yes	
SAL-003	Full dose	Omeprazole	Whilst taking naproxen	20	mg	As required	Oral	05/05/2022	Yes	
SAL-003	Full dose	Atorvastatin	dyslipidaemia - in relation to father's history of MI	20	mg	Once a day	Oral	01/01/2015	Yes	
SAL-003	Full dose	Naproxen	Osteoarthritis both hips	200	mg	As required	Oral	17/05/2022	Yes	
SAL-004	Placebo	Moderna COVID-19 vaccine	Prophylaxis against COVID-19	1	dose	Other	IM	29/06/2022	No	29/06/2022
SAL-009	Placebo	Paracetamol	Back pain	1	g	As required	Oral	26/06/2022	No	30/06/2022
SAL-009	Placebo	Codeine	Lower back pain	60	mg	Once a day	Oral	25/06/2022	UNK	
SAL-009	Placebo	Codeine	Back Pain	30	mg	As required	Oral	29/06/2022	No	30/06/2022
SAL-009	Placebo	Ibuprofen	Back pain	200	mg	As required	Oral	26/06/2022	No	30/06/2022
SAL-013	Placebo	Eumovate	Eczema	1	other	As required	Topical	18/07/2019	Yes	
SAL-021	Full dose	Ibuprofen	period pain	200	mg	As required	Oral	12/11/2022	Yes	
SAL-021	Full dose	Paracetamol	Pain related to period	1	g	As required	Oral	30/11/2022	Yes	
SAL-021	Full dose	Contraceptive implant	Contraception	1	unit	Other	Other	01/06/2022	Yes	
SAL-023	Lower dose	Sertraline	Depression	50	mg	Once a day	Oral	01/09/2021	Yes	
SAL-024	Placebo	Paracetamol	Pain	500	mg	As required	Oral	18/12/2022	Yes	
SAL-024	Placebo	rigevidon	Anticonceptive	150	microgram	Once a day	Oral	12/02/2023	Yes	
SAL-026	Lower dose	Acrivastine	Allergic reaction to sushi	8	mg	As required	Oral	04/09/2022	No	04/09/2022
SAL-026	Lower dose	Ibuprofen	Headache	200	mg	Four times a day	Oral	17/12/2022	No	17/12/2022

ID	Study arm	Name	Indication	Dose	Dose unit	Frequency	Route	Start date	Ongoing	Stop date
SAL-026	Lower dose	Paracetamol	COVID	1	g	Four times a day	Oral	12/07/2022	No	16/07/2022
SAL-026	Lower dose	Ibuprofen	Sunburn pain, headache	400	mg	As required	Oral	12/07/2022	Yes	
SAL-026	Lower dose	Sertraline	Depression	100	mg	Once a day	Oral	10/03/2023	Yes	
SAL-026	Lower dose	Citalopram	Anxiety Disorder	40	mg	Once a day	Oral	01/01/2021	No	10/03/2023
SAL-026	Lower dose	Ibuprofen	COVID	400	mg	Three times a day	Oral	12/07/2022	No	16/07/2022
SAL-026	Lower dose	Imodium	Diarrhoea	2	mg	As required	Oral	08/07/2022	No	09/07/2022
SAL-026	Lower dose	Moderna SARS-CoV-2 vaccine	Prophylaxis against COVID-19	1	dose	Other	IM	28/12/2022	No	28/12/2022
SAL-028	Full dose	Paracetamol	Headache	1	g	Once a day	Oral	23/12/2022	No	23/12/2022
SAL-028	Full dose	Rigevidon	Contraception	1	unit	Once a day	Oral	01/01/2020	Yes	
SAL-028	Full dose	Paracetamol	LRTI	1	g	As required	Oral	03/12/2022	No	07/12/2022
SAL-028	Full dose	Paracetamol	Cold	1	g	As required	Oral	24/10/2022	No	28/10/2022
SAL-028	Full dose	Ibuprofen	LRTI	400	mg	As required	Oral	03/12/2022	No	07/12/2022
SAL-028	Full dose	Ibuprofen	Headache	400	mg	As required	Oral	22/12/2022	No	22/12/2022
SAL-028	Full dose	Amoxicillin	LRTI	500	mg	Three times a day	Oral	05/12/2022	No	09/12/2022
SAL-028	Full dose	Sertraline	Low mood	50	mg	Once a day	Oral	01/11/2020	Yes	
SAL-029	Full dose	Paracetamol	Ache in arm / neck	1000	mg	Once a day	Oral	20/10/2022	No	20/10/2022
SAL-029	Full dose	Salbutamol	Asthma	1	puffs	As required	Inhaled	01/07/2021	Yes	
SAL-029	Full dose	Ibuprofen	Arm pain at site of injection	400	mg	As required	Oral	15/12/2022	No	15/12/2022
SAL-029	Full dose	Fostair	Asthma	1	puffs	Twice a day	Inhaled	01/07/2021	Yes	
SAL-029	Full dose	Comirnaty (Pfizer COVID vaccine)	Prophylaxis	1	dose	Other	IM	05/11/2022	No	05/11/2022
SAL-029	Full dose	Epiderm cream	Eczema	1	other	As required	Topical	10/04/2013	Yes	
SAL-029	Full dose	Influenza vaccine	Prophylaxis	1	dose	Other	IM	05/11/2022	No	05/11/2022
SAL-029	Full dose	Paracetamol	post-vaccine symptoms: headache, myalgia, fever	500	mg	As required	Oral	06/04/2023	No	07/04/2023
SAL-029	Full dose	Paracetamol	Arm pain at site of injection	1000	mg	As required	Oral	15/12/2022	No	15/12/2022

ID	Study arm	Name	Indication	Dose	Dose unit	Frequency	Route	Start date	Ongoing	Stop date
SAL-029	Full dose	ibuprofen	post-vaccine symptoms: headache, myalgia, fever	1	other	As required	Oral	06/04/2023	No	06/04/2023
SAL-029	Full dose	Ibuprofen	Aches	400	mg	Once a day	Oral	20/10/2022	No	20/10/2022
SAL-029	Full dose	Montelukast	Asthma	10	mg	Once a day	Oral	01/01/2021	Yes	
SAL-032	Full dose	Paracetamol	Pain	1000	mg	As required	Oral	11/12/2022	No	20/12/2022
SAL-032	Full dose	paracetamol	Pain	500	mg	As required	Oral	18/01/2023	No	18/01/2023
SAL-032	Full dose	Paracetamol	Headache	500	mg	As required	Oral	12/05/2023	No	12/05/2023
SAL-032	Full dose	Paracetamol	Pain	500	mg	As required	Oral	23/11/2022	No	24/11/2022
SAL-034	Full dose	Paracetamol	Headache	1	g	As required	Oral	02/03/2023	No	02/03/2023
SAL-034	Full dose	Sertraline	Anxiety/depression	50	mg	Once a day	Oral	27/02/2020	Yes	
SAL-034	Full dose	Progesterone only pill	Contraception	1	other	Once a day	Oral	01/01/2019	Yes	
SAL-039	Full dose	Paracetamol	Pain	500	mg	Four times a day	Oral	17/12/2022	No	19/12/2022
SAL-039	Full dose	Benadryl Chesty Cough syrup	Cough	UNK	UNK	As required	Oral	16/12/2022	No	17/12/2022
SAL-039	Full dose	Nexplanon	Contraceptive implant	1	other	Other	IM	01/10/2020	No	13/03/2023
SAL-039	Full dose	paracetamol	post-vaccine symptoms: myalgia, arthralgia, localised pain	1000	mg	As required	Oral	07/04/2023	No	08/04/2023
SAL-039	Full dose	Sertraline	Low mood	25	mg	Once a day	Oral	01/01/2021	No	10/04/2023
SAL-039	Full dose	Copper IUD	Contraception	1	other	Other	Other	01/08/2023	Yes	
SAL-042	Placebo	Ibuprofen	Testicular pain	400	mg	As required	Oral	03/11/2022	No	04/11/2022
SAL-046	Placebo	Paracetamol	Back pain	1000	g	As required	Oral	09/12/2022	Yes	
SAL-048	Full dose	Paracetamol	Myalgia	500	mg	As required	Oral	08/11/2022	No	10/11/2022
SAL-051	Placebo	Mirena IUD	Contraception	1	other	Other	Other	05/06/2023	Yes	
SAL-051	Placebo	Omeprazole	Acid reflux	20	mg	Once a day	Oral	10/12/2022	No	14/04/2023
SAL-051	Placebo	Gaviscon	Acid Reflux	15	mls	Four times a day	Oral	10/12/2022	No	12/12/2022
SAL-051	Placebo	Amoxicillin	Helicobacter pylori eradication	500	mg	Four times a day	Oral	18/03/2023	No	24/03/2023
SAL-051	Placebo	Mirena IUS	Contraception	1	other	Other	Other	01/01/2009	No	05/06/2023

ID	Study arm	Name	Indication	Dose	Dose unit	Frequency	Route	Start date	Ongoing	Stop date
SAL-051	Placebo	Metronidazole	Helicobacter pylori eradication	200	mg	Four times a day	Oral	18/03/2023	No	24/03/2023
SAL-051	Placebo	Levothyroxine	Hypothyroidism	125	microgram	Once a day	Oral	09/09/2018	Yes	
SAL-051	Placebo	Omeprazole	Acid reflux	20	mg	Once a day	Oral	18/01/2023	Yes	
SAL-051	Placebo	HRT	Menopause	1	other	Once a day	Topical	05/02/2023	Yes	
SAL-051	Placebo	Omeprazole	reflux	10	mg	Once a day	Oral	29/10/2022	No	27/11/2022
SAL-051	Placebo	Paracetamol	Headache	1	g	As required	Oral	12/03/2023	No	12/03/2023
SAL-062	Placebo	Vitamins C and D	Cold like symptoms	1	UNK	Once a day	Oral	16/12/2022	No	18/12/2022
SAL-062	Placebo	Paracetamol	Cold like symptoms	500	mg	Once a day	Oral	13/02/2023	No	15/02/2023
SAL-062	Placebo	Valerian extract	Sleeping	385	mg	Once a day	Oral	13/02/2023	No	15/02/2023
SAL-062	Placebo	Beconase	Hay fever	1	other	Once a day	Inhaled	14/05/2023	No	30/09/2023
SAL-062	Placebo	Omega 3	fish oils	1	dose	Once a day	Oral	21/09/2023	Yes	
SAL-062	Placebo	Cetirizine	Hay fever	10	mg	Once a day	Oral	14/05/2023	No	30/09/2023
SAL-067	Full dose	Ibuprofen	Pain and tenderness at vaccination site	400	mg	As required	Oral	20/10/2022	No	20/10/2022
SAL-067	Full dose	Ibuprofen	Pain back of the mouth left side	400	mg	As required	Oral	13/12/2022	No	17/12/2022
SAL-067	Full dose	Paracetamol	Coryzal symptoms	1000	mg	As required	Oral	17/12/2022	No	17/12/2022
SAL-068	Placebo	Clarithromycin	Sinusitis	500	mg	Twice a day	Oral	03/02/2023	No	08/02/2023
SAL-068	Placebo	Soolantra	Rosacea	10	mg	Once a day	Topical	18/04/2023	No	31/07/2023
SAL-068	Placebo	Doxycycline	Sinusitis	100	mg	Once a day	Oral	01/03/2023	No	05/03/2023
SAL-068	Placebo	Doxycycline	Root canal	250	mg	Twice a day	Oral	15/07/2023	No	20/07/2023
SAL-068	Placebo	Ciprofloxacin	Root canal	500	mg	Twice a day	Oral	25/07/2023	No	30/07/2023
SAL-068	Placebo	Paracetamol	URTI symptoms	1	g	As required	Oral	10/12/2022	No	13/12/2022
SAL-068	Placebo	Antihistamine (exact name not known)	Hay fever	1	UNK	Once a day	Oral	28/04/2023	Yes	
SAL-068	Placebo	Liraglutide	Weight Loss	0.6	mg	Once a day	Other	09/01/2023	No	16/01/2023
SAL-068	Placebo	Multivitamin	Participant choice	1	other	Once a day	Oral	01/08/2022	Yes	
SAL-068	Placebo	Ibuprofen	URTI	400	mg	As required	Oral	10/12/2022	No	13/12/2022
SAL-070	Full dose	Truvada	PReP	1	unit	Once a day	Oral	30/09/2022	Yes	
SAL-070	Full dose	Paracetamol	Headache	1000	mg	As required	Oral	23/11/2022	No	23/11/2022

ID	Study arm	Name	Indication	Dose	Dose unit	Frequency	Route	Start date	Ongoing	Stop date
SAL-071	Full dose	Paracetamol	Malaise	1000	mg	As required	Oral	21/11/2022	No	22/11/2022
SAL-071	Full dose	Paracetamol	Post-vaccine symptoms	1	g	As required	Oral	18/01/2023	No	24/01/2023
SAL-071	Full dose	Cetirizine	Hay Fever	10	mg	As required	Oral	24/04/2023	Yes	
SAL-071	Full dose	Paracetamol	Headache, malaise, myalgia	1000	mg	As required	Oral	11/05/2023	No	12/05/2023
SAL-075	Full dose	Paracetamol	Pain	1	g	As required	Oral	25/11/2022	No	26/11/2022
SAL-075	Full dose	Paracetamol	Headache	1	g	Twice a day	Oral	29/04/2023	No	30/04/2023
SAL-076	Full dose	Paracetamol	Pain, fever, malaise, headache	1	g	As required	Oral	22/11/2022	No	23/11/2022
SAL-076	Full dose	Ibuprofen	tooth pain	200	mg	As required	Oral	18/01/2023	No	18/01/2023
SAL-076	Full dose	Paracetamol	Veisalgia	1000	mg	As required	Oral	25/11/2022	No	25/11/2022
SAL-077	Full dose	Paracetamol	Cold	1	g	As required	Oral	02/12/2022	No	09/12/2022
SAL-077	Full dose	Paracetamol	Period cramps	1000	mg	As required	Oral	15/01/2023	No	16/01/2023
SAL-077	Full dose	Phenylephrine	Cold	6.1	mg	As required	Oral	02/12/2022	No	09/12/2022
SAL-078	Placebo	Salbutamol	Mild asthma	1	puffs	As required	Inhaled	01/01/2010	Yes	

Concomitant vaccinations

Listing 10 - Listing of Concomitant Vaccinations - Exposed Set

See concomitant medications listing 9

Solicited adverse events

Table 11 - Summary of participants with solicited administration site events by maximum intensity within 7 days after each and any vaccination - Exposed Set

Solicited adverse event	Severity Grade	Dose 1			Dose 2			Dose 3			Any dose		
		Full dose	Low dose	Placebo	Full dose	Low dose	Placebo	Full dose	Low dose	Placebo	Full dose	Low dose	Placebo
Hardness	None	14 (93.3%)	4 (100%)	12 (100%)	14 (93.3%)	3 (100%)	12 (100%)	10 (100%)	2 (66.7%)	11 (100%)	14 (93.3%)	3 (75%)	12 (100%)
	Mild	1 (6.7%)	NA	NA	1 (6.7%)	NA	NA	NA	1 (33.3%)	NA	1 (6.7%)	1 (25%)	NA
	Moderate	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	Severe	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pain	None	2 (13.3%)	2 (50%)	8 (66.7%)	1 (6.7%)	1 (33.3%)	12 (100%)	1 (10%)	NA	9 (81.8%)	1 (6.7%)	1 (25%)	6 (50%)
	Mild	4 (26.7%)	1 (25%)	4 (33.3%)	12 (80%)	2 (66.7%)	NA	6 (60%)	2 (66.7%)	1 (9.1%)	4 (26.7%)	2 (50%)	5 (41.7%)
	Moderate	9 (60%)	1 (25%)	NA	2 (13.3%)	NA	NA	3 (30%)	1 (33.3%)	1 (9.1%)	10 (66.7%)	1 (25%)	1 (8.3%)
	Severe	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Redness	None	11 (73.3%)	4 (100%)	12 (100%)	15 (100%)	2 (66.7%)	12 (100%)	10 (100%)	3 (100%)	11 (100%)	11 (73.3%)	3 (75%)	12 (100%)
	Mild	1 (6.7%)	NA	NA	NA	NA	NA	NA	NA	NA	1 (6.7%)	NA	NA
	Moderate	NA	NA	NA	NA	1 (33.3%)	NA	NA	NA	NA	NA	1 (25%)	NA
	Severe	3 (20%)	NA	NA	NA	NA	NA	NA	NA	NA	3 (20%)	NA	NA
Swelling	None	13 (86.7%)	4 (100%)	12 (100%)	14 (93.3%)	2 (66.7%)	12 (100%)	9 (90%)	3 (100%)	11 (100%)	13 (86.7%)	3 (75%)	12 (100%)

Solicited adverse event	Severity Grade	Dose 1			Dose 2			Dose 3			Any dose		
		Full dose	Low dose	Placebo	Full dose	Low dose	Placebo	Full dose	Low dose	Placebo	Full dose	Low dose	Placebo
	Mild	1 (6.7%)	NA	NA	1 (6.7%)	NA	NA	1 (10%)	NA	NA	1 (6.7%)	NA	NA
	Moderate	NA	NA	NA	NA	1 (33.3%)	NA	NA	NA	NA	NA	1 (25%)	NA
	Severe	1 (6.7%)	NA	NA	NA	NA	NA	NA	NA	NA	1 (6.7%)	NA	NA
Tenderness	None	NA	NA	10 (83.3%)	1 (6.7%)	NA	10 (83.3%)	NA	NA	10 (90.9%)	NA	NA	9 (75%)
	Mild	7 (46.7%)	2 (50%)	2 (16.7%)	7 (46.7%)	3 (100%)	2 (16.7%)	7 (70%)	2 (66.7%)	1 (9.1%)	5 (33.3%)	2 (50%)	3 (25%)
	Moderate	8 (53.3%)	2 (50%)	NA	7 (46.7%)	NA	NA	3 (30%)	1 (33.3%)	NA	10 (66.7%)	2 (50%)	NA
	Severe	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Redness, swelling, and hardness have been graded as: None (Grade 0): 0 to <2.5cm, Mild (Grade 1): 2.5cm to ≤5cm, Moderate (Grade 2): 5 to <10cm, Severe (Grade 3): ≥10cm

Table 12 - Summary of participants with solicited systemic events by maximum intensity within 7 days after each and any vaccination - Exposed Set

Solicited adverse event	Severity Grade	Dose 1			Dose 2			Dose 3			Any dose		
		Full dose	Low dose	Placebo	Full dose	Low dose	Placebo	Full dose	Low dose	Placebo	Full dose	Low dose	Placebo
Abdominal pain	None	15 (100%)	3 (75%)	10 (83.3%)	14 (93.3%)	2 (66.7%)	10 (83.3%)	9 (90%)	1 (33.3%)	10 (90.9%)	13 (86.7%)	2 (50%)	9 (75%)
Abdominal pain	Mild	NA	1 (25%)	2 (16.7%)	1 (6.7%)	1 (33.3%)	2 (16.7%)	NA	2 (66.7%)	1 (9.1%)	1 (6.7%)	2 (50%)	3 (25%)
Abdominal pain	Moderate	NA	NA	NA	NA	NA	NA	1 (10%)	NA	NA	1 (6.7%)	NA	NA
Abdominal pain	Severe	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Chills	None	8 (53.3%)	3 (75%)	12 (100%)	10 (66.7%)	3 (100%)	12 (100%)	9 (90%)	3 (100%)	11 (100%)	7 (46.7%)	3 (75%)	12 (100%)
Chills	Mild	5 (33.3%)	1 (25%)	NA	4 (26.7%)	NA	NA	1 (10%)	NA	NA	6 (40%)	1 (25%)	NA
Chills	Moderate	2 (13.3%)	NA	NA	1 (6.7%)	NA	NA	NA	NA	NA	2 (13.3%)	NA	NA
Chills	Severe	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Diarrhoea	None	14 (93.3%)	3 (75%)	11 (91.7%)	14 (93.3%)	2 (66.7%)	11 (91.7%)	8 (80%)	1 (33.3%)	9 (81.8%)	12 (80%)	2 (50%)	10 (83.3%)
Diarrhoea	Mild	1 (6.7%)	NA	1 (8.3%)	1 (6.7%)	1 (33.3%)	1 (8.3%)	2 (20%)	2 (66.7%)	2 (18.2%)	3 (20%)	1 (25%)	2 (16.7%)
Diarrhoea	Moderate	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Diarrhoea	Severe	NA	1 (25%)	NA	NA	NA	NA	NA	NA	NA	NA	1 (25%)	NA
Fatigue	None	3 (20%)	3 (75%)	7 (58.3%)	3 (20%)	3 (100%)	11 (91.7%)	4 (40%)	3 (100%)	6 (54.5%)	2 (13.3%)	3 (75%)	5 (41.7%)
Fatigue	Mild	7 (46.7%)	NA	4 (33.3%)	9 (60%)	NA	1 (8.3%)	2 (20%)	NA	4 (36.4%)	5 (33.3%)	NA	5 (41.7%)
Fatigue	Moderate	5 (33.3%)	1 (25%)	1 (8.3%)	3 (20%)	NA	NA	3 (30%)	NA	NA	7 (46.7%)	1 (25%)	1 (8.3%)

Solicited adverse event	Severity Grade	Dose 1			Dose 2			Dose 3			Any dose		
		Full dose	Low dose	Placebo	Full dose	Low dose	Placebo	Full dose	Low dose	Placebo	Full dose	Low dose	Placebo
Fatigue	Severe	NA	NA	NA	NA	NA	NA	1 (10%)	NA	1 (9.1%)	1 (6.7%)	NA	1 (8.3%)
Fever	None	12 (80%)	3 (75%)	12 (100%)	14 (93.3%)	3 (100%)	12 (100%)	9 (90%)	3 (100%)	11 (100%)	11 (73.3%)	3 (75%)	12 (100%)
Fever	Mild	2 (13.3%)	1 (25%)	NA	1 (6.7%)	NA	NA	1 (10%)	NA	NA	3 (20%)	1 (25%)	NA
Fever	Moderate	1 (6.7%)	NA	NA	NA	NA	NA	NA	NA	NA	1 (6.7%)	NA	NA
Fever	Severe	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Feverishness	None	10 (66.7%)	3 (75%)	12 (100%)	11 (73.3%)	3 (100%)	12 (100%)	9 (90%)	2 (66.7%)	11 (100%)	8 (53.3%)	3 (75%)	12 (100%)
Feverishness	Mild	5 (33.3%)	1 (25%)	NA	3 (20%)	NA	NA	1 (10%)	NA	NA	6 (40%)	NA	NA
Feverishness	Moderate	NA	NA	NA	1 (6.7%)	NA	NA	NA	1 (33.3%)	NA	1 (6.7%)	1 (25%)	NA
Feverishness	Severe	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Headache	None	4 (26.7%)	3 (75%)	7 (58.3%)	10 (66.7%)	1 (33.3%)	10 (83.3%)	5 (50%)	1 (33.3%)	9 (81.8%)	2 (13.3%)	2 (50%)	5 (41.7%)
Headache	Mild	9 (60%)	NA	4 (33.3%)	NA	1 (33.3%)	2 (16.7%)	3 (30%)	1 (33.3%)	NA	6 (40%)	1 (25%)	4 (33.3%)
Headache	Moderate	2 (13.3%)	1 (25%)	1 (8.3%)	4 (26.7%)	1 (33.3%)	NA	2 (20%)	NA	2 (18.2%)	6 (40%)	NA	3 (25%)
Headache	Severe	NA	NA	NA	1 (6.7%)	NA	NA	NA	1 (33.3%)	NA	1 (6.7%)	1 (25%)	NA
Joint pain	None	13 (86.7%)	3 (75%)	11 (91.7%)	11 (73.3%)	3 (100%)	12 (100%)	8 (80%)	3 (100%)	11 (100%)	11 (73.3%)	3 (75%)	11 (91.7%)
Joint pain	Mild	2 (13.3%)	1 (25%)	1 (8.3%)	2 (13.3%)	NA	NA	NA	NA	NA	1 (6.7%)	1 (25%)	1 (8.3%)
Joint pain	Moderate	NA	NA	NA	2 (13.3%)	NA	NA	2 (20%)	NA	NA	3 (20%)	NA	NA
Joint pain	Severe	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Solicited adverse event	Severity Grade	Dose 1			Dose 2			Dose 3			Any dose		
		Full dose	Low dose	Placebo	Full dose	Low dose	Placebo	Full dose	Low dose	Placebo	Full dose	Low dose	Placebo
Loss of appetite	None	13 (86.7%)	3 (75%)	11 (91.7%)	11 (73.3%)	2 (66.7%)	12 (100%)	10 (100%)	2 (66.7%)	10 (90.9%)	9 (60%)	3 (75%)	10 (83.3%)
Loss of appetite	Mild	2 (13.3%)	NA	1 (8.3%)	4 (26.7%)	1 (33.3%)	NA	NA	1 (33.3%)	1 (9.1%)	6 (40%)	NA	2 (16.7%)
Loss of appetite	Moderate	NA	1 (25%)	NA	NA	NA	NA	NA	NA	NA	NA	1 (25%)	NA
Loss of appetite	Severe	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaise	None	4 (26.7%)	3 (75%)	10 (83.3%)	6 (40%)	3 (100%)	12 (100%)	7 (70%)	3 (100%)	9 (81.8%)	3 (20%)	3 (75%)	10 (83.3%)
Malaise	Mild	7 (46.7%)	NA	2 (16.7%)	6 (40%)	NA	NA	1 (10%)	NA	NA	7 (46.7%)	NA	NA
Malaise	Moderate	3 (20%)	1 (25%)	NA	1 (6.7%)	NA	NA	2 (20%)	NA	1 (9.1%)	2 (13.3%)	1 (25%)	1 (8.3%)
Malaise	Severe	1 (6.7%)	NA	NA	2 (13.3%)	NA	NA	NA	NA	1 (9.1%)	3 (20%)	NA	1 (8.3%)
Muscle aches	None	5 (33.3%)	2 (50%)	9 (75%)	5 (33.3%)	2 (66.7%)	11 (91.7%)	5 (50%)	2 (66.7%)	11 (100%)	2 (13.3%)	2 (50%)	8 (66.7%)
Muscle aches	Mild	5 (33.3%)	2 (50%)	2 (16.7%)	7 (46.7%)	1 (33.3%)	1 (8.3%)	3 (30%)	NA	NA	7 (46.7%)	1 (25%)	3 (25%)
Muscle aches	Moderate	5 (33.3%)	NA	NA	3 (20%)	NA	NA	2 (20%)	1 (33.3%)	NA	6 (40%)	1 (25%)	NA
Muscle aches	Severe	NA	NA	1 (8.3%)	NA	NA	NA	NA	NA	NA	NA	NA	1 (8.3%)
Nausea	None	14 (93.3%)	3 (75%)	8 (66.7%)	13 (86.7%)	2 (66.7%)	12 (100%)	8 (80%)	2 (66.7%)	9 (81.8%)	11 (73.3%)	3 (75%)	7 (58.3%)
Nausea	Mild	1 (6.7%)	NA	4 (33.3%)	1 (6.7%)	1 (33.3%)	NA	1 (10%)	NA	2 (18.2%)	3 (20%)	NA	5 (41.7%)
Nausea	Moderate	NA	1 (25%)	NA	1 (6.7%)	NA	NA	NA	1 (33.3%)	NA	NA	1 (25%)	NA
Nausea	Severe	NA	NA	NA	NA	NA	NA	1 (10%)	NA	NA	1 (6.7%)	NA	NA
Vomiting	None	15 (100%)	4 (100%)	12 (100%)	14 (93.3%)	3 (100%)	12 (100%)	9 (90%)	3 (100%)	11 (100%)	13 (86.7%)	4 (100%)	12 (100%)

Solicited adverse event	Severity Grade	Dose 1			Dose 2			Dose 3			Any dose		
		Full dose	Low dose	Placebo	Full dose	Low dose	Placebo	Full dose	Low dose	Placebo	Full dose	Low dose	Placebo
Vomiting	Mild	NA	NA	NA	1 (6.7%)	NA	NA	1 (10%)	NA	NA	2 (13.3%)	NA	NA
Vomiting	Moderate	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Vomiting	Severe	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Rash	None	12 (80%)	4 (100%)	12 (100%)	11 (73.3%)	2 (66.7%)	12 (100%)	10 (100%)	3 (100%)	11 (100%)	9 (60%)	3 (75%)	12 (100%)
Rash	Mild	2 (13.3%)	NA	NA	3 (20%)	1 (33.3%)	NA	NA	NA	NA	5 (33.3%)	1 (25%)	NA
Rash	Moderate	1 (6.7%)	NA	NA	1 (6.7%)	NA	NA	NA	NA	NA	1 (6.7%)	NA	NA
Rash	Severe	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Fever was graded as: None (Grade 0): <37.6 °C, Mild (Grade 1): ≥37.6 to ≤38.0 °C, Moderate (Grade 2): >38.0 to <39.0 °C, Severe (Grade 3): ≥39.0 °C

Table 13 - Summary of participants with fever related to study intervention, by maximum intensity within 7 days after each and any vaccination - Exposed Set

Solicited adverse event	Severity Grade	Dose 1			Dose 2			Dose 3			Any dose		
		Full dose	Low dose	Placebo	Full dose	Low dose	Placebo	Full dose	Low dose	Placebo	Full dose	Low dose	Placebo
Fever	None	12 (80%)	3 (75%)	12 (100%)	14 (93.3%)	3 (100%)	12 (100%)	9 (90%)	3 (100%)	11 (100%)	11 (73.3%)	3 (75%)	12 (100%)
	Mild	2 (13.3%)	1 (25%)	NA	1 (6.7%)	NA	NA	1 (10%)	NA	NA	3 (20%)	1 (25%)	NA
	Moderate	1 (6.7%)	NA	NA	NA	NA	NA	NA	NA	NA	1 (6.7%)	NA	NA
	Severe	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Fever was graded as: None (Grade 0): <37.6 °C, Mild (Grade 1): ≥37.6 to ≤38.0 °C, Moderate (Grade 2): >38.0 to <39.0 °C, Severe (Grade 3): ≥39.0 °C

Unsolicited adverse events

Table 14 - Summary of participants with at least one unsolicited adverse event with onset within 28 days of any vaccination - Exposed Set

	Study group			Overall
	Placebo, N = 23	**Lower dose, N = 5**	**Full dose, N = 22**	**N = 50**
Number of unique participants	10	2	12	24
AE source				
Diary	6 (26%)	3 (60%)	10 (45%)	19 (38%)
Laboratory result, vital signs, other	17 (74%)	2 (40%)	12 (55%)	31 (62%)
Diary AE dose				
First	4 (67%)	3 (100%)	2 (20%)	9 (47%)
Second	1 (17%)	0 (0%)	6 (60%)	7 (37%)
Third	1 (17%)	0 (0%)	2 (20%)	3 (16%)
Other AE source	17	2	12	31
COVID				
No	21 (91%)	4 (80%)	19 (86%)	44 (88%)
Yes	0 (0%)	1 (20%)	1 (4.5%)	2 (4.0%)
Unsure	2 (8.7%)	0 (0%)	2 (9.1%)	4 (8.0%)
Severity				
Mild	17 (74%)	3 (60%)	14 (64%)	34 (68%)
Moderate	5 (22%)	1 (20%)	6 (27%)	12 (24%)
Severe	1 (4.3%)	1 (20%)	2 (9.1%)	4 (8.0%)
Causality				
No relationship	19 (83%)	4 (80%)	15 (68%)	38 (76%)
Possible	3 (13%)	1 (20%)	3 (14%)	7 (14%)
Probable	0 (0%)	0 (0%)	1 (4.5%)	1 (2.0%)
Definite	1 (4.3%)	0 (0%)	3 (14%)	4 (8.0%)
Ongoing at end of study				
No	18 (78%)	5 (100%)	19 (86%)	42 (84%)
Yes	5 (22%)	0 (0%)	1 (4.5%)	6 (12%)
Unknown	0 (0%)	0 (0%)	2 (9.1%)	2 (4.0%)

Includes adverse events occuring on days 0-27 following first, second and third dose vaccinations.

Table 15 - Summary of participants with at least one unsolicited adverse event with onset within 28 days of dose 1 - Exposed Set

	Study group			Overall
	Placebo, N = 13	**Lower dose, N = 4**	**Full dose, N = 8**	**N = 25**
AE source				
Diary	4 (31%)	3 (75%)	2 (25%)	9 (36%)
Laboratory result, vital signs, other	9 (69%)	1 (25%)	6 (75%)	16 (64%)
Diary AE dose				
First	4 (100%)	3 (100%)	2 (100%)	9 (100%)
Second	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Third	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Other AE source	9	1	6	16
COVID				
No	13 (100%)	3 (75%)	8 (100%)	24 (96%)
Yes	0 (0%)	1 (25%)	0 (0%)	1 (4.0%)
Unsure	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Severity				
Mild	9 (69%)	2 (50%)	3 (38%)	14 (56%)
Moderate	3 (23%)	1 (25%)	5 (63%)	9 (36%)
Severe	1 (7.7%)	1 (25%)	0 (0%)	2 (8.0%)
Causality				
No relationship	10 (77%)	3 (75%)	5 (63%)	18 (72%)
Possible	3 (23%)	1 (25%)	1 (13%)	5 (20%)
Probable	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Definite	0 (0%)	0 (0%)	2 (25%)	2 (8.0%)
Ongoing at end of study				
No	11 (85%)	4 (100%)	7 (88%)	22 (88%)
Yes	2 (15%)	0 (0%)	1 (13%)	3 (12%)

Includes adverse events occuring on days 0-27 following first vaccination.

Table 16 - Summary of participants with at least one unsolicited adverse event with onset within 28 days of dose 2 -- Exposed Set

	Study group			Overall
	Placebo, N = 5	**Lower dose, N = 1**	**Full dose, N = 10**	**N = 16**
AE source				
Diary	1 (20%)	0 (0%)	6 (60%)	7 (44%)
Laboratory result, vital signs, other	4 (80%)	1 (100%)	4 (40%)	9 (56%)
Diary AE dose				
First	0 (0%)	NA	0 (0%)	0 (0%)
Second	1 (100%)	NA	6 (100%)	7 (100%)
Third	0 (0%)	NA	0 (0%)	0 (0%)
Other AE source	4	1	4	9
COVID				
No	3 (60%)	1 (100%)	8 (80%)	12 (75%)
Yes	0 (0%)	0 (0%)	1 (10%)	1 (6.3%)
Unsure	2 (40%)	0 (0%)	1 (10%)	3 (19%)
Severity				
Mild	3 (60%)	1 (100%)	8 (80%)	12 (75%)
Moderate	2 (40%)	0 (0%)	0 (0%)	2 (13%)
Severe	0 (0%)	0 (0%)	2 (20%)	2 (13%)
Causality				
No relationship	5 (100%)	1 (100%)	7 (70%)	13 (81%)
Possible	0 (0%)	0 (0%)	1 (10%)	1 (6.3%)
Probable	0 (0%)	0 (0%)	1 (10%)	1 (6.3%)
Definite	0 (0%)	0 (0%)	1 (10%)	1 (6.3%)
Ongoing at end of study				
No	5 (100%)	1 (100%)	8 (80%)	14 (88%)
Unknown	0 (0%)	0 (0%)	2 (20%)	2 (13%)

Includes adverse events occuring on days 0-27 following second vaccination.

Table 17 - Summary of participants with at least one grade 3 unsolicited adverse event with onset within 28 days of any vaccination - Stage 1 - Exposed Set

ID	Study arm	Dose 1 vaccination date	Dose 2 vaccination date	Dose 3 vaccination date	Diagnosis	Severity	Causality	Ongoing at end of study	AE start date	AE resolution date
SAL-009	Placebo	22/06/2022	17/08/2022		Musculoskeletal back pain	Severe	No relationship	0	26/06/2022	30/06/2022
SAL-026	Lower dose	06/07/2022	01/09/2022	16/12/2022	Diarrhoea	Severe	Possible	0	08/07/2022	09/07/2022
SAL-071	Full dose	21/11/2022	18/01/2023	10/05/2023	Concussion	Severe	No relationship	0	20/01/2023	21/03/2023
SAL-077	Full dose	23/11/2022	16/01/2023		Injection site reaction	Severe	Definite	0	16/01/2023	13/02/2023

Includes adverse events occuring on days 0-27 following first, second and third dose vaccinations.

Table 18 - Summary of participants with at least one grade 3 unsolicited adverse event with onset within 28 days of dose 1 - Exposed Set

ID	Study arm	Dose 1 vaccination date	Dose 2 vaccination date	Dose 3 vaccination date	Diagnosis	Severity	Causality	Ongoing at end of study	AE start date	AE resolution date
SAL-009	Placebo	22/06/2022	17/08/2022		Musculoskeletal back pain	Severe	No relationship	0	26/06/2022	30/06/2022
SAL-026	Lower dose	06/07/2022	01/09/2022	16/12/2022	Diarrhoea	Severe	Possible	0	08/07/2022	09/07/2022

Includes adverse events occuring on days 0-27 following first vaccination.

Table 19 - Summary of participants with at least one grade 3 unsolicited adverse event with onset within 28 days of dose 2 - Exposed Set

ID	Study arm	Dose 1 vaccination date	Dose 2 vaccination date	Dose 3 vaccination date	Diagnosis	Severity	Causality	Ongoing at end of study	AE start date	AE resolution date
SAL-071	Full dose	21/11/2022	18/01/2023	10/05/2023	Concussion	Severe	No relationship	0	20/01/2023	21/03/2023
SAL-077	Full dose	23/11/2022	16/01/2023		Injection site reaction	Severe	Definite	0	16/01/2023	13/02/2023

Includes adverse events occuring on days 0-27 following second vaccination.

Listing 20 - Listing of grade 3 Adverse Events - Exposed Set

ID	Study arm	Dose 1 vaccination date	Dose 2 vaccination date	Dose 3 vaccination date	Diagnosis	Severity	Causality	Ongoing at end of study	AE start date	AE resolution date
SAL-009	Placebo	22/06/2022	17/08/2022		Musculoskeletal back pain	Severe	No relationship	0	26/06/2022	30/06/2022
SAL-026	Lower dose	06/07/2022	01/09/2022	16/12/2022	Diarrhoea	Severe	Possible	0	08/07/2022	09/07/2022
SAL-028	Full dose	17/10/2022	20/12/2022	13/04/2023	Lower respiratory tract infection	Severe	No relationship	0	03/12/2022	09/12/2022
SAL-051	Placebo	22/09/2022	21/11/2022	10/03/2023	Helicobacter pylori infection	Severe	No relationship	1	29/10/2022	
SAL-071	Full dose	21/11/2022	18/01/2023	10/05/2023	Concussion	Severe	No relationship	0	20/01/2023	21/03/2023
SAL-077	Full dose	23/11/2022	16/01/2023		Injection site reaction	Severe	Definite	0	16/01/2023	13/02/2023

Table 21 - Summary of participants with at least one related unsolicited adverse event with onset within 28 days of any vaccination - - Exposed Set

ID	Study arm	Dose 1 vaccination date	Dose 2 vaccination date	Dose 3 vaccination date	Diagnosis	Severity	Causality	Ongoing at end of study	AE start date	AE resolution date
SAL-013	Placebo	18/07/2022	14/09/2022	10/01/2023	Neutropenia	Mild	Possible	0	25/07/2022	10/01/2023
SAL-024	Placebo	06/07/2022	01/09/2022	16/12/2022	General Weakness	Moderate	Possible	0	06/07/2022	07/07/2022
SAL-026	Lower dose	06/07/2022	01/09/2022	16/12/2022	Diarrhoea	Severe	Possible	0	08/07/2022	09/07/2022
SAL-028	Full dose	17/10/2022	20/12/2022	13/04/2023	Neutropaenia	Mild	Possible	0	04/05/2023	19/09/2023
SAL-048	Full dose	14/09/2022	07/11/2022		Local pruritis	Mild	Possible	UNK	07/11/2022	
SAL-068	Placebo	20/10/2022	15/12/2022	06/04/2023	Fatigue	Mild	Definite	0	06/04/2023	07/04/2023
SAL-070	Full dose	21/11/2022	18/01/2023		Muscle discomfort	Mild	Probable	UNK	18/01/2023	
SAL-076	Full dose	21/11/2022	18/01/2023		Hyperergic localized reaction	Moderate	Definite	0	22/11/2022	02/12/2022
SAL-076	Full dose	21/11/2022	18/01/2023		Neutropenia	Moderate	Possible	1	28/11/2022	
SAL-077	Full dose	23/11/2022	16/01/2023		Injection site reaction	Moderate	Definite	0	27/11/2022	12/12/2022
SAL-077	Full dose	23/11/2022	16/01/2023		Injection site reaction	Severe	Definite	0	16/01/2023	13/02/2023
SAL-089	Placebo	22/11/2022	19/01/2023	10/05/2023	Transaminitis	Mild	Possible	0	28/11/2022	05/12/2022

Includes adverse events occuring on days 0-27 following first, second and third dose vaccinations.

Table 22 - Summary of participants with at least one related unsolicited adverse event with onset within 28 days of dose 1 - - Exposed Set

ID	Study arm	Dose 1 vaccination date	Dose 2 vaccination date	Dose 3 vaccination date	Diagnosis	Severity	Causality	Ongoing at end of study	AE start date	AE resolution date
SAL-013	Placebo	18/07/2022	14/09/2022	10/01/2023	Neutropenia	Mild	Possible	0	25/07/2022	10/01/2023
SAL-024	Placebo	06/07/2022	01/09/2022	16/12/2022	General Weakness	Moderate	Possible	0	06/07/2022	07/07/2022
SAL-026	Lower dose	06/07/2022	01/09/2022	16/12/2022	Diarrhoea	Severe	Possible	0	08/07/2022	09/07/2022
SAL-076	Full dose	21/11/2022	18/01/2023		Hyperergic localized reaction	Moderate	Definite	0	22/11/2022	02/12/2022
SAL-076	Full dose	21/11/2022	18/01/2023		Neutropenia	Moderate	Possible	1	28/11/2022	
SAL-077	Full dose	23/11/2022	16/01/2023		Injection site reaction	Moderate	Definite	0	27/11/2022	12/12/2022
SAL-089	Placebo	22/11/2022	19/01/2023	10/05/2023	Transaminitis	Mild	Possible	0	28/11/2022	05/12/2022

Includes adverse events occuring on days 0-27 following first vaccination.

Table 23 - Summary of participants with at least one related unsolicited adverse event with onset within 28 days of dose 2 -- Exposed Set

ID	Study arm	Dose 1 vaccination date	Dose 2 vaccination date	Dose 3 vaccination date	Diagnosis	Severity	Causality	Ongoing at end of study	AE start date	AE resolution date
SAL-048	Full dose	14/09/2022	07/11/2022		Local pruritis	Mild	Possible	UNK	07/11/2022	
SAL-070	Full dose	21/11/2022	18/01/2023		Muscle discomfort	Mild	Probable	UNK	18/01/2023	
SAL-077	Full dose	23/11/2022	16/01/2023		Injection site reaction	Severe	Definite	0	16/01/2023	13/02/2023

Includes adverse events occuring on days 0-27 following second vaccination.

Table 24 - Summary of participants with at least one grade 3 related unsolicited adverse event with onset within 28 days of any vaccination - Exposed Set

ID	Study arm	Dose 1 vaccination date	Dose 2 vaccination date	Dose 3 vaccination date	Diagnosis	Severity	Causality	Ongoing at end of study	AE start date	AE resolution date
SAL-026	Lower dose	06/07/2022	01/09/2022	16/12/2022	Diarrhoea	Severe	Possible	0	08/07/2022	09/07/2022
SAL-077	Full dose	23/11/2022	16/01/2023		Injection site reaction	Severe	Definite	0	16/01/2023	13/02/2023

Includes adverse events occuring on days 0-27 following first, second and third dose vaccinations.

Table 25 - Summary of participants with at least one grade 3 related unsolicited adverse event with onset within 28 days of dose 1 - Exposed Set

ID	Study arm	Dose 1 vaccination date	Dose 2 vaccination date	Dose 3 vaccination date	Diagnosis	Severity	Causality	Ongoing at end of study	AE start date	AE resolution date
SAL-026	Lower dose	06/07/2022	01/09/2022	16/12/2022	Diarrhoea	Severe	Possible	0	08/07/2022	09/07/2022

Includes adverse events occuring on days 0-27 following first vaccination.

Table 26 - Summary of participants with at least one grade 3 related unsolicited adverse event with onset within 28 days of dose 2 - Exposed Set

ID	Study arm	Dose 1 vaccination date	Dose 2 vaccination date	Dose 3 vaccination date	Diagnosis	Severity	Causality	Ongoing at end of study	AE start date	AE resolution date
SAL-077	Full dose	23/11/2022	16/01/2023		Injection site reaction	Severe	Definite	0	16/01/2023	13/02/2023

Includes adverse events occuring on days 0-27 following second vaccination.

Table 27 - Summary of participants with at least one serious unsolicited adverse event during the study period - Exposed Set

There were no SAEs.

Listing 28 - Listings of Serious Adverse Events - Exposed Set

There were no SAEs.

Table 29 - Summary of participants with at least one medically attended unsolicited adverse event with onset within 28 days of any vaccination - Exposed Set

Listing of all unsolicited adverse events occuring within 28 days of any vaccination.

ID	Study arm	Dose 1 vaccination date	Dose 2 vaccination date	Dose 3 vaccination date	Diagnosis	Severity	Causality	Ongoing at end of study	AE start date	AE resolution date
SAL-003	Full dose	22/11/2022	16/01/2023	10/05/2023	coryza	Mild	No relationship	0	13/12/2022	22/12/2022
SAL-003	Full dose	22/11/2022	16/01/2023	10/05/2023	ALT raised	Mild	No relationship	0	09/02/2023	21/02/2023
SAL-009	Placebo	22/06/2022	17/08/2022		Musculoskeletal back pain	Severe	No relationship	0	26/06/2022	30/06/2022
SAL-009	Placebo	22/06/2022	17/08/2022		URTI	Mild	No relationship	0	10/09/2022	16/10/2022
SAL-013	Placebo	18/07/2022	14/09/2022	10/01/2023	Neutropenia	Mild	Possible	0	25/07/2022	10/01/2023
SAL-021	Full dose	09/11/2022	06/01/2023	26/04/2023	Anaemia	Mild	No relationship	0	22/05/2023	03/10/2023
SAL-024	Placebo	06/07/2022	01/09/2022	16/12/2022	General Weakness	Moderate	Possible	0	06/07/2022	07/07/2022
SAL-024	Placebo	06/07/2022	01/09/2022	16/12/2022	Axillary lymphadenopathy	Mild	No relationship	0	28/07/2022	08/08/2022
SAL-024	Placebo	06/07/2022	01/09/2022	16/12/2022	Anaemia	Mild	No relationship	0	01/08/2022	04/10/2022
SAL-024	Placebo	06/07/2022	01/09/2022	16/12/2022	Low BP	Mild	No relationship	0	06/07/2022	07/07/2022
SAL-026	Lower dose	06/07/2022	01/09/2022	16/12/2022	Sunburn	Moderate	No relationship	0	11/07/2022	12/07/2022
SAL-026	Lower dose	06/07/2022	01/09/2022	16/12/2022	SARS-COV-2 Infection	Mild	No relationship	0	11/07/2022	20/07/2022
SAL-026	Lower dose	06/07/2022	01/09/2022	16/12/2022	Diarrhoea	Severe	Possible	0	08/07/2022	09/07/2022
SAL-028	Full dose	17/10/2022	20/12/2022	13/04/2023	Upper Respiratory Tract Infection	Mild	No relationship	0	24/10/2022	01/11/2022
SAL-028	Full dose	17/10/2022	20/12/2022	13/04/2023	Neutropaenia	Mild	Possible	0	04/05/2023	19/09/2023

SAL-030	Lower dose	03/08/2022	28/09/2022	18/01/2023	Transaminitis	Mild	No relationship	0	09/08/2022	26/10/2022
SAL-030	Lower dose	03/08/2022	28/09/2022	18/01/2023	Vasovagal episode	Mild	No relationship	0	05/10/2022	05/10/2022
SAL-032	Full dose	23/11/2022	17/01/2023	10/05/2023	Gastroenteritis	Moderate	No relationship	0	11/12/2022	20/12/2022
SAL-034	Full dose	17/08/2022	09/11/2022	28/02/2023	?Bruise	Mild	No relationship	0	21/08/2022	28/08/2022
SAL-039	Full dose	20/10/2022	16/12/2022	06/04/2023	cough	Mild	No relationship	0	16/12/2022	17/12/2022
SAL-042	Placebo	08/09/2022	03/11/2022	21/02/2023	Testicular pain	Moderate	No relationship	0	03/11/2022	04/11/2022
SAL-048	Full dose	14/09/2022	07/11/2022		Local pruritis	Mild	Possible	UNK	07/11/2022	
SAL-051	Placebo	22/09/2022	21/11/2022	10/03/2023	Viral upper respiratory tract infection	Mild	No relationship	0	24/09/2022	24/09/2022
SAL-051	Placebo	22/09/2022	21/11/2022	10/03/2023	Antibiotic-induced gastrointestinal disturbance	Mild	No relationship	0	22/03/2023	23/03/2023
SAL-062	Placebo	23/11/2022	23/01/2023	10/05/2023	Viral upper respiratory tract infection	Mild	No relationship	0	10/02/2023	16/02/2023
SAL-062	Placebo	23/11/2022	23/01/2023	10/05/2023	Uraemia	Moderate	No relationship	1	30/11/2022	
SAL-066	Placebo	20/10/2022	12/12/2022	06/04/2023	Coryza	Mild	No relationship	0	22/10/2022	23/10/2022
SAL-066	Placebo	20/10/2022	12/12/2022	06/04/2023	Raised bilrubin	Moderate	No relationship	1	20/10/2022	
SAL-066	Placebo	20/10/2022	12/12/2022	06/04/2023	Flu-like symptoms	Moderate	No relationship	0	04/01/2023	10/01/2023
SAL-067	Full dose	20/10/2022	12/12/2022	31/03/2023	COVID-19	Mild	No relationship	0	13/12/2022	09/01/2023
SAL-068	Placebo	20/10/2022	15/12/2022	06/04/2023	Subjective bilateral hand weakness	Mild	No relationship	0	31/10/2022	17/11/2022
SAL-068	Placebo	20/10/2022	15/12/2022	06/04/2023	Bloating	Mild	No relationship	0	20/10/2022	31/10/2022
SAL-068	Placebo	20/10/2022	15/12/2022	06/04/2023	Worsening of acne rosacea	Mild	No relationship	1	18/04/2023	

SAL-068	Placebo	20/10/2022	15/12/2022	06/04/2023	Seasonal allergic rhinitis	Mild	No relationship	1	28/04/2023	
SAL-068	Placebo	20/10/2022	15/12/2022	06/04/2023	Fatigue	Mild	Definite	0	06/04/2023	07/04/2023
SAL-070	Full dose	21/11/2022	18/01/2023		Muscle discomfort	Mild	Probable	UNK	18/01/2023	
SAL-071	Full dose	21/11/2022	18/01/2023	10/05/2023	Concussion	Severe	No relationship	0	20/01/2023	21/03/2023
SAL-071	Full dose	21/11/2022	18/01/2023	10/05/2023	Pharyngitis	Mild	No relationship	0	22/01/2023	29/01/2023
SAL-071	Full dose	21/11/2022	18/01/2023	10/05/2023	Vasovagal episode	Mild	No relationship	0	13/02/2023	14/02/2023
SAL-071	Full dose	21/11/2022	18/01/2023	10/05/2023	Bradycardia	Mild	No relationship	0	14/05/2023	14/05/2023
SAL-071	Full dose	21/11/2022	18/01/2023	10/05/2023	Viral illness	Moderate	No relationship	0	14/05/2023	24/05/2023
SAL-076	Full dose	21/11/2022	18/01/2023		Hyperergic localized reaction	Moderate	Definite	0	22/11/2022	02/12/2022
SAL-076	Full dose	21/11/2022	18/01/2023		Neutropenia	Moderate	Possible	1	28/11/2022	
SAL-077	Full dose	23/11/2022	16/01/2023		Injection site reaction	Moderate	Definite	0	27/11/2022	12/12/2022
SAL-077	Full dose	23/11/2022	16/01/2023		Upper respiratory tract infection	Moderate	No relationship	0	01/12/2022	16/12/2022
SAL-077	Full dose	23/11/2022	16/01/2023		Injection site reaction	Severe	Definite	0	16/01/2023	13/02/2023
SAL-077	Full dose	23/11/2022	16/01/2023		Anaemia	Mild	No relationship	0	24/01/2023	13/02/2023
SAL-078	Placebo	22/11/2022	17/01/2023	10/05/2023	Eosinophilia	Mild	No relationship	1	05/06/2023	
SAL-089	Placebo	22/11/2022	19/01/2023	10/05/2023	Transaminitis	Mild	Possible	0	28/11/2022	05/12/2022
SAL-089	Placebo	22/11/2022	19/01/2023	10/05/2023	Viral upper respiratory tract infection	Mild	No relationship	0	11/02/2023	17/02/2023

Table 30 - Summary of participants with at least one medically attended unsolicited adverse event with onset within 28 days of dose 1 Exposed Set

Listing of all unsolicited adverse events occuring within 28 days of first vaccination.

ID	Study arm	Dose 1 vaccination date	Dose 2 vaccination date	Dose 3 vaccination date	Diagnosis	Severity	Causality	Ongoing at end of study	AE start date	AE resolution date
SAL-003	Full dose	22/11/2022	16/01/2023	10/05/2023	coryza	Mild	No relationship	0	13/12/2022	22/12/2022
SAL-009	Placebo	22/06/2022	17/08/2022		Musculoskeletal back pain	Severe	No relationship	0	26/06/2022	30/06/2022
SAL-013	Placebo	18/07/2022	14/09/2022	10/01/2023	Neutropenia	Mild	Possible	0	25/07/2022	10/01/2023
SAL-024	Placebo	06/07/2022	01/09/2022	16/12/2022	General Weakness	Moderate	Possible	0	06/07/2022	07/07/2022
SAL-024	Placebo	06/07/2022	01/09/2022	16/12/2022	Axillary lymphadenopathy	Mild	No relationship	0	28/07/2022	08/08/2022
SAL-024	Placebo	06/07/2022	01/09/2022	16/12/2022	Anaemia	Mild	No relationship	0	01/08/2022	04/10/2022
SAL-024	Placebo	06/07/2022	01/09/2022	16/12/2022	Low BP	Mild	No relationship	0	06/07/2022	07/07/2022
SAL-026	Lower dose	06/07/2022	01/09/2022	16/12/2022	Sunburn	Moderate	No relationship	0	11/07/2022	12/07/2022
SAL-026	Lower dose	06/07/2022	01/09/2022	16/12/2022	SARS-COV-2 Infection	Mild	No relationship	0	11/07/2022	20/07/2022
SAL-026	Lower dose	06/07/2022	01/09/2022	16/12/2022	Diarrhoea	Severe	Possible	0	08/07/2022	09/07/2022
SAL-028	Full dose	17/10/2022	20/12/2022	13/04/2023	Upper Respiratory Tract Infection	Mild	No relationship	0	24/10/2022	01/11/2022
SAL-030	Lower dose	03/08/2022	28/09/2022	18/01/2023	Transaminitis	Mild	No relationship	0	09/08/2022	26/10/2022
SAL-032	Full dose	23/11/2022	17/01/2023	10/05/2023	Gastroenteritis	Moderate	No relationship	0	11/12/2022	20/12/2022
SAL-034	Full dose	17/08/2022	09/11/2022	28/02/2023	?Bruise	Mild	No relationship	0	21/08/2022	28/08/2022
SAL-051	Placebo	22/09/2022	21/11/2022	10/03/2023	Viral upper respiratory tract infection	Mild	No relationship	0	24/09/2022	24/09/2022

ID	Study arm	Dose 1 vaccination date	Dose 2 vaccination date	Dose 3 vaccination date	Diagnosis	Severity	Causality	Ongoing at end of study	AE start date	AE resolution date
SAL-062	Placebo	23/11/2022	23/01/2023	10/05/2023	Uraemia	Moderate	No relationship	1	30/11/2022	
SAL-066	Placebo	20/10/2022	12/12/2022	06/04/2023	Coryza	Mild	No relationship	0	22/10/2022	23/10/2022
SAL-066	Placebo	20/10/2022	12/12/2022	06/04/2023	Raised bilirubin	Moderate	No relationship	1	20/10/2022	
SAL-068	Placebo	20/10/2022	15/12/2022	06/04/2023	Subjective bilateral hand weakness	Mild	No relationship	0	31/10/2022	17/11/2022
SAL-068	Placebo	20/10/2022	15/12/2022	06/04/2023	Bloating	Mild	No relationship	0	20/10/2022	31/10/2022
SAL-076	Full dose	21/11/2022	18/01/2023		Hyperergic localized reaction	Moderate	Definite	0	22/11/2022	02/12/2022
SAL-076	Full dose	21/11/2022	18/01/2023		Neutropenia	Moderate	Possible	1	28/11/2022	
SAL-077	Full dose	23/11/2022	16/01/2023		Injection site reaction	Moderate	Definite	0	27/11/2022	12/12/2022
SAL-077	Full dose	23/11/2022	16/01/2023		Upper respiratory tract infection	Moderate	No relationship	0	01/12/2022	16/12/2022
SAL-089	Placebo	22/11/2022	19/01/2023	10/05/2023	Transaminitis	Mild	Possible	0	28/11/2022	05/12/2022

Table 31 - Summary of participants with at least one medically attended unsolicited adverse event with onset within 28 days of dose 2 - Exposed Set

Listing of all unsolicited adverse events occuring within 28 days of second vaccination.

ID	Study arm	Dose 1 vaccination date	Dose 2 vaccination date	Dose 3 vaccination date	Diagnosis	Severity	Causality	Ongoing at end of study	AE start date	AE resolution date
SAL-003	Full dose	22/11/2022	16/01/2023	10/05/2023	ALT raised	Mild	No relationship	0	09/02/2023	21/02/2023
SAL-009	Placebo	22/06/2022	17/08/2022		URTI	Mild	No relationship	0	10/09/2022	16/10/2022
SAL-030	Lower dose	03/08/2022	28/09/2022	18/01/2023	Vasovagal episode	Mild	No relationship	0	05/10/2022	05/10/2022
SAL-039	Full dose	20/10/2022	16/12/2022	06/04/2023	cough	Mild	No relationship	0	16/12/2022	17/12/2022
SAL-042	Placebo	08/09/2022	03/11/2022	21/02/2023	Testicular pain	Moderate	No relationship	0	03/11/2022	04/11/2022
SAL-048	Full dose	14/09/2022	07/11/2022		Local pruritis	Mild	Possible	UNK	07/11/2022	
SAL-062	Placebo	23/11/2022	23/01/2023	10/05/2023	Viral upper respiratory tract infection	Mild	No relationship	0	10/02/2023	16/02/2023
SAL-066	Placebo	20/10/2022	12/12/2022	06/04/2023	Flu-like symptoms	Moderate	No relationship	0	04/01/2023	10/01/2023
SAL-067	Full dose	20/10/2022	12/12/2022	31/03/2023	COVID-19	Mild	No relationship	0	13/12/2022	09/01/2023
SAL-070	Full dose	21/11/2022	18/01/2023		Muscle discomfort	Mild	Probable	UNK	18/01/2023	
SAL-071	Full dose	21/11/2022	18/01/2023	10/05/2023	Concussion	Severe	No relationship	0	20/01/2023	21/03/2023
SAL-071	Full dose	21/11/2022	18/01/2023	10/05/2023	Pharyngitis	Mild	No relationship	0	22/01/2023	29/01/2023
SAL-071	Full dose	21/11/2022	18/01/2023	10/05/2023	Vasovagal episode	Mild	No relationship	0	13/02/2023	14/02/2023
SAL-077	Full dose	23/11/2022	16/01/2023		Injection site reaction	Severe	Definite	0	16/01/2023	13/02/2023
SAL-077	Full dose	23/11/2022	16/01/2023		Anaemia	Mild	No relationship	0	24/01/2023	13/02/2023

ID	Study arm	Dose 1 vaccination date	Dose 2 vaccination date	Dose 3 vaccination date	Diagnosis	Severity	Causality	Ongoing at end of study	AE start date	AE resolution date
SAL-089	Placebo	22/11/2022	19/01/2023	10/05/2023	Viral upper respiratory tract infection	Mild	No relationship	0	11/02/2023	17/02/2023

Immunogenicity results

The Geometric Mean Concentration (GMC) of immunogenicity outcomes is calculated as the antilogarithm of the mean log10-transformed titre, where n represents the number of participants included in the analysis population. The 95% confidence interval (CI) is determined by taking the antilogarithm of the upper and lower limits of the two-sided CI for the mean log10-transformed titres.

Values lower than the detection threshold were imputed with a value equal to half of the threshold before the transformation. The lower limit of detection for Anti-OAg IgG responses was 15 EU/mL and the lower limits of detection for SBA responses were 51.5 IC50 for STm and 42.3 IC50 for SEn.

Table 32 – Geometric mean concentrations, and within-subject geometric mean ratio with 95% CI for STm ELISA, by study group, and timepoint.

Timepoint	Placebo		Lower dose		Full dose	
	GMC	Within-subject GMR	GMC	Within-subject GMR	GMC	Within-subject GMR
0 (first vaccination)	40.6 (17.6, 93.7) [n=12]	-	46.7 (4.4, 497.3) [n=4]	-	24.4 (11, 54) [n=15]	-
7	40 (17.6, 90.8) [n=12]	0.98 (95% CI: 0.34 - 2.82)	100.7 (0.2, 48132.3) [n=3]	2.16 (95% CI: 0.22 - 20.77)	186.7 (64.2, 542.8) [n=14]	7.65 (95% CI: 2.77 - 21.11)
28	41.1 (17.6, 95.5) [n=12]	1.01 (95% CI: 0.35 - 2.9)	1734.3 (283.2, 10623.1) [n=4]	37.15 (95% CI: 4.57 - 302.29)	833.2 (401.8, 1727.9) [n=15]	34.14 (95% CI: 12.59 - 92.57)
56 (second vaccination)	41.7 (17.9, 97.2) [n=12]	1.03 (95% CI: 0.36 - 2.94)	2016.3 (73.2, 55571) [n=3]	43.19 (95% CI: 4.49 - 415.7)	811.3 (394.4, 1668.7) [n=15]	33.25 (95% CI: 12.26 - 90.13)
63	45.4 (18.2, 113.4) [n=11]	1.12 (95% CI: 0.38 - 3.28)	1963.4 (66.3, 58180.2) [n=3]	42.06 (95% CI: 4.37 - 404.79)	921.4 (429.9, 1974.6) [n=13]	37.75 (95% CI: 13.41 - 106.29)
84	38.6 (16.1, 92.8) [n=12]	0.95 (95% CI: 0.33 - 2.72)	1858 (89.4, 38599.9) [n=3]	39.8 (95% CI: 4.13 - 383.07)	773.5 (394.1, 1518.1) [n=15]	31.69 (95% CI: 11.69 - 85.93)
168 (third vaccination)	29.7 (14.2, 62.3) [n=12]	0.73 (95% CI: 0.26 - 2.1)	1407.9 (92.6, 21397) [n=3]	30.16 (95% CI: 3.13 - 290.26)	458.7 (182.8, 1151.4) [n=12]	18.8 (95% CI: 6.53 - 54.14)
175	31.2 (12.4, 78.7) [n=10]	0.77 (95% CI: 0.26 - 2.32)	722.2 (60.3, 8646) [n=2]	15.47 (95% CI: 1.19 - 201.62)	592.4 (232.7, 1508.6) [n=9]	24.28 (95% CI: 7.67 - 76.8)
196	31.5 (13.3, 74.5) [n=11]	0.78 (95% CI: 0.26 - 2.28)	1073.1 (32.8, 35109.6) [n=3]	22.99 (95% CI: 2.39 - 221.25)	457.5 (190, 1101.6) [n=12]	18.75 (95% CI: 6.51 - 53.99)
350	29.7 (13, 68.1) [n=11]	0.73 (95% CI: 0.25 - 2.15)	620.1 (27.7, 13899.7) [n=3]	13.28 (95% CI: 1.38 - 127.85)	459.6 (212, 996.4) [n=11]	18.83 (95% CI: 6.37 - 55.7)

* STm: O:4,5 IgG ELISA

Table 33 – Geometric mean concentrations, and within-subject geometric mean ratio with 95% CI for SEn ELISA, by study group, and timepoint.

Timepoint	Placebo		Lower dose		Full dose	
	GMC	Within-subject GMR	GMC	Within-subject GMR	GMC	Within-subject GMR
0 (first vaccination)	73.4 (22.9, 234.9) [n=12]	-	18.9 (2.1, 171.7) [n=4]	-	32.9 (13.5, 80.4) [n=15]	-
7	70 (21.9, 224.4) [n=12]	0.95 (95% CI: 0.22 - 4.21)	91.5 (0.2, 40632.9) [n=3]	4.85 (95% CI: 0.74 - 31.82)	146.3 (42.4, 505) [n=14]	4.45 (95% CI: 1.47 - 13.49)
28	73.7 (22.4, 242.3) [n=12]	1.01 (95% CI: 0.23 - 4.44)	686 (251.2, 1873.2) [n=4]	36.34 (95% CI: 6.37 - 207.41)	865.4 (404.9, 1849.6) [n=15]	26.31 (95% CI: 8.85 - 78.28)
56 (second vaccination)	75.9 (23.3, 247.3) [n=12]	1.04 (95% CI: 0.23 - 4.57)	746.1 (115.7, 4812.5) [n=3]	39.53 (95% CI: 6.02 - 259.38)	888 (431.6, 1826.9) [n=15]	27 (95% CI: 9.08 - 80.32)
63	65.1 (19, 222.6) [n=11]	0.89 (95% CI: 0.19 - 4.05)	702.4 (92.5, 5336.5) [n=3]	37.22 (95% CI: 5.67 - 244.19)	899.4 (387.5, 2087.4) [n=13]	27.35 (95% CI: 8.82 - 84.77)
84	67.4 (19.6, 230.9) [n=12]	0.92 (95% CI: 0.21 - 4.05)	715.8 (85.1, 6021) [n=3]	37.92 (95% CI: 5.78 - 248.83)	942.1 (476, 1864.9) [n=15]	28.65 (95% CI: 9.63 - 85.22)
168 (third vaccination)	79.4 (27.5, 229.1) [n=12]	1.08 (95% CI: 0.25 - 4.77)	545.6 (36.7, 8118.7) [n=3]	28.91 (95% CI: 4.41 - 189.68)	712 (291.4, 1739.5) [n=12]	21.65 (95% CI: 6.81 - 68.81)
175	81.3 (22, 299.8) [n=10]	1.11 (95% CI: 0.23 - 5.26)	915.9 (4.9, 170582.6) [n=2]	48.53 (95% CI: 5.75 - 409.6)	582.6 (170.4, 1991.4) [n=9]	17.71 (95% CI: 5.03 - 62.38)
196	69.1 (20.3, 235.2) [n=11]	0.94 (95% CI: 0.21 - 4.3)	530.7 (90.1, 3126.9) [n=3]	28.12 (95% CI: 4.29 - 184.5)	759.3 (327.5, 1760.4) [n=12]	23.09 (95% CI: 7.26 - 73.38)
350	66.9 (19.4, 230.9) [n=11]	0.91 (95% CI: 0.2 - 4.16)	360.2 (19.1, 6792) [n=3]	19.09 (95% CI: 2.91 - 125.23)	550.5 (200, 1515.3) [n=11]	16.74 (95% CI: 5.12 - 54.76)

*SEn: O:9 IgG ELISA

Table 34 – Geometric mean concentrations, and within-subject geometric mean ratio with 95% CI for STm serum bactericidal antibody assay, by study group, and timepoint.

Timepoint	Placebo		Lower dose		Full dose	
	GMC	**Within-subject GMR**	**GMC**	**Within-subject GMR**	**GMC**	**Within-subject GMR**
0 (first vaccination)	8339.5 (3442.3, 20203.8) [n=12]	-	2812.9 (279.8, 28276.9) [n=4]	-	6073.5 (3247.8, 11357.7) [n=15]	-
28	6694.3 (2742, 16343.6) [n=12]	0.8 (95% CI: 0.3 - 2.18)	69153.2 (1555.5, 3074275.3) [n=4]	24.58 (95% CI: 2.87 - 210.53)	29989 (18528.6, 48537.9) [n=15]	4.94 (95% CI: 2.71 - 8.99)
84	6215.6 (2798.1, 13807.2) [n=12]	0.75 (95% CI: 0.27 - 2.02)	40021.7 (8370.3, 191359.5) [n=3]	14.23 (95% CI: 1.4 - 144.72)	27758.5 (18224.2, 42280.8) [n=15]	4.57 (95% CI: 2.51 - 8.32)
168 (third vaccination)	2814.9 (1594.2, 4970.2) [n=12]	0.34 (95% CI: 0.12 - 0.92)	12069.8 (2069.2, 70404.6) [n=3]	4.29 (95% CI: 0.42 - 43.65)	10758.9 (7057.6, 16401.4) [n=12]	1.77 (95% CI: 0.94 - 3.34)
196	3979.5 (1712.7, 9246.4) [n=11]	0.48 (95% CI: 0.17 - 1.32)	11478.9 (2310.8, 57022.7) [n=3]	4.08 (95% CI: 0.4 - 41.51)	18598.3 (12368.6, 27965.8) [n=12]	3.06 (95% CI: 1.62 - 5.78)
350	10712.1 (5325, 21548.8) [n=11]	1.28 (95% CI: 0.46 - 3.56)	24967.5 (1997.2, 312123.2) [n=3]	8.88 (95% CI: 0.87 - 90.28)	25333.7 (16403.3, 39126.1) [n=11]	4.17 (95% CI: 2.18 - 8)

Table 35 – Geometric mean concentrations, and within-subject geometric mean ratio with 95% CI for SEn serum bactericidal antibody assay, by study group, and timepoint.

Timepoint	Placebo		Lower dose		Full dose	
	GMC	**Within-subject GMR**	**GMC**	**Within-subject GMR**	**GMC**	**Within-subject GMR**
0 (first vaccination)	5922.7 (3068.9, 11430.1) [n=12]	-	9001.7 (2244.3, 36104.8) [n=4]	-	9001.8 (4181.6, 19378.2) [n=15]	-
28	9976 (4261.1, 23355.5) [n=12]	1.68 (95% CI: 0.66 - 4.28)	86436.3 (9214.8, 810783.2) [n=4]	9.6 (95% CI: 2.09 - 44.03)	38722.7 (14209, 105528.1) [n=15]	4.3 (95% CI: 1.61 - 11.52)
84	9422.5 (5007.1, 17731.3) [n=12]	1.59 (95% CI: 0.63 - 4.05)	34508.6 (1419.7, 838781.7) [n=3]	3.83 (95% CI: 0.74 - 19.86)	52435.5 (30816.7, 89220.4) [n=15]	5.83 (95% CI: 2.18 - 15.6)
168 (third vaccination)	8196.7 (3750.6, 17913.7) [n=12]	1.38 (95% CI: 0.54 - 3.52)	28093.6 (2622.3, 300982.3) [n=3]	3.12 (95% CI: 0.6 - 16.17)	28375.9 (10530.9, 76460.1) [n=12]	3.15 (95% CI: 1.11 - 8.96)
196	10504.7 (5598, 19712.1) [n=11]	1.77 (95% CI: 0.68 - 4.61)	49986.7 (17641.9, 141632.8) [n=3]	5.55 (95% CI: 1.07 - 28.76)	57245.7 (27100.6, 120922.5) [n=12]	6.36 (95% CI: 2.24 - 18.08)
350	13583.9 (5809.1, 31764.4) [n=11]	2.29 (95% CI: 0.88 - 5.96)	107338 (34539.4, 333574.4) [n=3]	11.92 (95% CI: 2.3 - 61.77)	23000.8 (12625.5, 41902.3) [n=11]	2.56 (95% CI: 0.88 - 7.45)