		0.62 (0.58 to 0.65)	0.64 (0.60 to 0.68)	0.65 (0.57 to 0.73)
Day 29	Number Analyzed	151 participants	118 participants	34 participants
		0.64 (0.62 to 0.67)	0.67 (0.65 to 0.70)	0.69 (0.62 to 0.76)
Day 57	Number Analyzed	151 participants	117 participants	34 participants
		0.63 (0.60 to 0.65)	0.64 (0.61 to 0.67)	0.67 (0.62 to 0.72)
Day 197	Number Analyzed	151 participants	118 participants	34 participants
		0.59 (0.57 to 0.62)	0.63 (0.60 to 0.66)	0.66 (0.60 to 0.71)
Day 225	Number Analyzed	150 participants	118 participants	34 participants
		0.55 (0.53 to 0.58)	0.65 (0.62 to 0.68)	0.66 (0.60 to 0.72)

8. Secondary Outcome

Title:	Geometric Mean Titer (GMT) of Anti-Hepatitis B Surface Antigen (HBsAg) Antibodies in Groups 1, 2, and 3
▼ Description:	The RTS,S vaccine antigen consists of sequences of both the P. falciparum circumsporozoite protein and hepatitis B surface antigen, hence anti-HBsAg antibodies were also measured. Anti-hepatitis B surface antigen antibodies were assessed at the International AIDS Vaccine Initiative Human Immunology Laboratory (IAVI-HIL) at Imperial College, London, UK, using a commercially available ELISA kit.
Time Frame:	Baseline, Day 29 (28 days after first vaccination) and Day 225 (28 days after third vaccination)

▼ Outcome Measure Data ✔

▼ Analysis Population Description
ATP Cohort for Immunogenicity with available data at each time point.

Arm/Group Title		Group 1: Positive Parasitemia; Anti-malarial Treatment + RTS,S/AS01E Vaccine	Group 2: No Parasitemia; Anti-malarial Prophylaxis + RTS,S/AS01E Vaccine	Group 3: Positive Parasitemia; RTS,S/AS01E Vaccine
▼ Arm/Group Description:		Participants with detectable P. falciparum parasitemia at baseline received anti-malarial treatment with DHA/Pip plus LD PQ 4 weeks prior to the first vaccination and another course of DHA/Pip plus LD PQ two weeks before the second vaccination. One week before the third vaccination, a course of A/L plus LD PQ was administered. Participants received 3 vaccinations with malarial vaccine RTS,S/AS01E by intramuscular injection given on a 0, 1, and 7 month schedule with the final dose being 1/5 of the dose of the first two immunizations.	Participants with no detectable P. falciparum parasitemia at baseline received anti-malarial prophylaxis with DHA/Pip plus LD PQ 4 weeks prior to the first vaccination and a 2nd course of DHA/Pip plus LD PQ 2 weeks before the second vaccination. One week before the third vaccination, a course of A/L plus LD PQ was administered. Participants received 3 vaccinations with malarial vaccine RTS,S/AS01E by intramuscular injection given on a 0, 1, and 7 month schedule with the final dose being 1/5 of the dose of the first two immunizations.	Participants with detectable P. falciparum parasitemia at baseline did not receive any anti-malarial medications to clear parasites. Participants received 3 vaccinations with malarial vaccine RTS,S/AS01E by intramuscular injection given on a 0, 1, and 7 month schedule with the final dose being 1/5 of the dose of the first two immunizations. This group is included only for immunological assessment and not for vaccine efficacy.
Overall Number of Participants Analyzed		151	118	34
Geometric Mean (95% Confidence Interval) Unit of Measure: titer				
Row Title				
Baseline	Number Analyzed	151 participants	118 participants	34 participants
		16.88 (12.56 to 22.69)	14.32 (10.25 to 19.99)	15.57 (8.47 to 28.63)
Day 29	Number Analyzed	151 participants	118 participants	34 participants
		61.27 (36.80 to 102.00)	60.16 (34.48 to 104.96)	87.89 (23.73 to 325.44)
Day 225	Number Analyzed	150 participants	118 participants	34 participants
		1500.56 (1014.34 to 2219.85)	1789.89 (1237.46 to 2588.91)	2321.30 (1255.51 to 4291.81)

Adverse Events

Time Frame	All-cause mortality and serious adverse events are reported through the end of the study, up to 65 weeks Non-serious adverse events were collected up to 28 days following administration of each dose of vaccine and, where applicable, course of per protocol scheduled anti-malarial treatment.
Adverse Event Reporting	All-cause mortality is reported for all randomized participants. Adverse events are reported for all participants who received at least one vaccination.

Source Vocabulary Name for Table Default	MedDRA (23.0)
Collection Approach for Table Default	Systematic Assessment

Arm/Group Title	Group 1: Positive Parasitemia; Anti-malarial Treatment + RTS,S/AS01E Vaccine	Group 2: No Parasitemia; Anti-malarial Prophylaxis + RTS,S/AS01E Vaccine	Group 3: Positive Parasitemia; RTS,S/AS01E Vaccine	Group 4: Positive Parasitemia; Anti-malarial Treatment + Rabies Vaccine	Group 5: No Parasitemia, Anti-malarial Prophylaxis + Rabies Vaccine
▼ Arm/Group Description	Participants with detectable P. falciparum parasitemia at baseline received anti-malarial treatment with DHA/Pip plus LD PQ 4 weeks prior to the first vaccination and another course of DHA/Pip plus LD PQ two weeks before the second vaccination. One week before the third vaccination, a course of A/L plus LD PQ was administered. Participants were randomized to receive 3 vaccinations with malarial vaccine RTS,S/AS01E by intramuscular injection given on a 0, 1, and 7 month schedule with the final dose being 1/5 of the dose of the first two immunizations.	Participants with no detectable P. falciparum parasitemia at baseline received anti-malarial prophylaxis with DHA/Pip plus LD PQ 4 weeks prior to the first vaccination and a 2nd course of DHA/Pip plus LD PQ 2 weeks before the second vaccination. One week before the third vaccination, a course of A/L plus LD PQ was administered. Participants were randomized to receive 3 vaccinations with malarial vaccine RTS,S/AS01E by intramuscular injection given on a 0, 1, and 7 month schedule with the final dose being 1/5 of the dose of the first two immunizations.	Participants with detectable P. falciparum parasitemia at baseline did not receive any anti-malarial medications to clear parasites. Participants were randomized to receive 3 vaccinations with malarial vaccine RTS,S/AS01E by intramuscular injection given on a 0, 1, and 7 month schedule with the final dose being 1/5 of the dose of the first two immunizations. This group is included only for immunological assessment and not for vaccine efficacy.	Participants with detectable P. falciparum parasitemia at baseline received anti-malarial treatment with DHA/Pip plus LD PQ 4 weeks prior to the first vaccination and another course of DHA/Pip plus LD PQ two weeks before the second vaccination. One week before the third vaccination, a three-day course of A/L plus LD PQ was administered. Participants were randomized to receive 3 vaccinations of Abhayrab rabies vaccine on a 0, 1, 7 month schedule.	Participants with no detectable P. falciparum parasitemia at baseline received anti-malarial prophylaxis with DHA/Pip plus LD PQ 4 weeks prior to the first vaccination and a 2nd course of DHA/Pip plus LD PQ 2 weeks before the second vaccination. One week before the third vaccination, a course of A/L plus LD PQ was administered. Participants were randomized to receive 3 vaccinations of Abhayrab rabies vaccine on a 0, 1, 7 month schedule.

All-Cause Mortality

	Group 1: Positive Parasitemia; Anti-malarial Treatment + RTS,S/AS01E Vaccine	Group 2: No Parasitemia; Anti-malarial Prophylaxis + RTS,S/AS01E Vaccine	Group 3: Positive Parasitemia; RTS,S/AS01E Vaccine	Group 4: Positive Parasitemia; Anti-malarial Treatment + Rabies Vaccine	Group 5: No Parasitemia, Anti-malarial Prophylaxis + Rabies Vaccine
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	1/164 (0.61%)	0/128 (0%)	0/36 (0%)	0/164 (0%)	0/128 (0%)

▼ **Serious Adverse Events**

	Group 1: Positive Parasitemia; Anti-malarial Treatment + RTS,S/AS01E Vaccine	Group 2: No Parasitemia; Anti-malarial Prophylaxis + RTS,S/AS01E Vaccine	Group 3: Positive Parasitemia; RTS,S/AS01E Vaccine	Group 4: Positive Parasitemia; Anti-malarial Treatment + Rabies Vaccine	Group 5: No Parasitemia, Anti-malarial Prophylaxis + Rabies Vaccine
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	3/160 (1.88%)	2/124 (1.61%)	1/35 (2.86%)	1/159 (0.63%)	3/127 (2.36%)
Gastrointestinal disorders					
Haemorrhoids †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Inguinal hernia strangulated †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Infections and infestations					
COVID-19 †A	1/160 (0.63%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Malaria †A	0/160 (0%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	0/127 (0%)

Postoperative wound infection † A	0/160 (0%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Pyomyositis † A	0/160 (0%)	0/124 (0%)	0/35 (0%)	1/159 (0.63%)	0/127 (0%)
Musculoskeletal and connective tissue disorders					
Spinal osteoarthritis † A	0/160 (0%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Nervous system disorders					
Alcoholic coma † A	1/160 (0.63%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Optic neuritis † A	1/160 (0.63%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Pregnancy, puerperium and perinatal conditions					
Abortion spontaneous † A	0/160 (0%)	0/124 (0%)	1/35 (2.86%)	0/159 (0%)	0/127 (0%)
Reproductive system and breast disorders					
Prostatic haemorrhage † A	0/160 (0%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	0/127 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (23.0)

▼ Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	0%

	Group 1: Positive Parasitemia; Anti-malarial Treatment + RTS,S/AS01E Vaccine	Group 2: No Parasitemia; Anti-malarial Prophylaxis + RTS,S/AS01E Vaccine	Group 3: Positive Parasitemia; RTS,S/AS01E Vaccine	Group 4: Positive Parasitemia; Anti-malarial Treatment + Rabies Vaccine	Group 5: No Parasitemia, Anti-malarial Prophylaxis + Rabies Vaccine
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	111/160 (69.38%)	96/124 (77.42%)	25/35 (71.43%)	110/159 (69.18%)	92/127 (72.44%)
Blood and lymphatic system disorders					
Anaemia † A	3/160 (1.88%)	1/124 (0.81%)	0/35 (0%)	1/159 (0.63%)	0/127 (0%)
Eosinophilia † A	0/160 (0%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Leukopenia † A	0/160 (0%)	0/124 (0%)	0/35 (0%)	1/159 (0.63%)	0/127 (0%)
Thrombocytopenia † A	0/160 (0%)	0/124 (0%)	0/35 (0%)	1/159 (0.63%)	0/127 (0%)
Ear and labyrinth disorders					
Ear pain † A	1/160 (0.63%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Eye disorders					
Cataract † A	0/160 (0%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Conjunctivitis allergic † A	2/160 (1.25%)	2/124 (1.61%)	0/35 (0%)	1/159 (0.63%)	2/127 (1.57%)
Myopia † A	0/160 (0%)	0/124 (0%)	0/35 (0%)	1/159 (0.63%)	0/127 (0%)
Pterygium † A	0/160 (0%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Gastrointestinal disorders					
Abdominal discomfort † A	0/160 (0%)	2/124 (1.61%)	1/35 (2.86%)	6/159 (3.77%)	1/127 (0.79%)
Abdominal pain † A	1/160 (0.63%)	0/124 (0%)	0/35 (0%)	1/159 (0.63%)	0/127 (0%)
Abdominal pain lower † A	0/160 (0%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Anal fissure † A	0/160 (0%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Dental caries † A	2/160 (1.25%)	5/124 (4.03%)	0/35 (0%)	6/159 (3.77%)	4/127 (3.15%)
Diarrhoea † A	1/160 (0.63%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Epulis † A	1/160 (0.63%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Gastritis † A	2/160 (1.25%)	0/124 (0%)	0/35 (0%)	3/159 (1.89%)	3/127 (2.36%)
Gastrointestinal disorder † A	5/160 (3.12%)	5/124 (4.03%)	1/35 (2.86%)	0/159 (0%)	0/127 (0%)
Glossitis † A	2/160 (1.25%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	0/127 (0%)

Hyperaesthesia teeth †A	1/160 (0.63%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Hyperchlorhydria †A	0/160 (0%)	5/124 (4.03%)	0/35 (0%)	1/159 (0.63%)	3/127 (2.36%)
Nausea †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Oral pain †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Peptic ulcer †A	1/160 (0.63%)	2/124 (1.61%)	0/35 (0%)	2/159 (1.26%)	1/127 (0.79%)
Stomatitis †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	1/159 (0.63%)	0/127 (0%)
Toothache †A	2/160 (1.25%)	0/124 (0%)	1/35 (2.86%)	1/159 (0.63%)	0/127 (0%)
Vomiting †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	1/159 (0.63%)	0/127 (0%)
General disorders					
Chest pain †A	0/160 (0%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Fatigue †A	10/160 (6.25%)	10/124 (8.06%)	8/35 (22.86%)	0/159 (0%)	0/127 (0%)
Feeling hot †A	0/160 (0%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Injection site pain †A	24/160 (15%)	25/124 (20.16%)	14/35 (40%)	0/159 (0%)	0/127 (0%)
Injection site swelling †A	7/160 (4.37%)	10/124 (8.06%)	5/35 (14.29%)	0/159 (0%)	0/127 (0%)
Malaise †A	1/160 (0.63%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Pyrexia †A	5/160 (3.12%)	4/124 (3.23%)	2/35 (5.71%)	3/159 (1.89%)	1/127 (0.79%)
Immune system disorders					
Conjunctivitis †A	5/160 (3.12%)	9/124 (7.26%)	1/35 (2.86%)	2/159 (1.26%)	7/127 (5.51%)
Infections and infestations					
Abscess limb †A	0/160 (0%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Bacterial infection †A	1/160 (0.63%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	2/127 (1.57%)
Bartholin's abscess †A	0/160 (0%)	0/124 (0%)	1/35 (2.86%)	0/159 (0%)	0/127 (0%)
Body tinea †A	4/160 (2.5%)	4/124 (3.23%)	2/35 (5.71%)	5/159 (3.14%)	2/127 (1.57%)
Bronchitis †A	0/160 (0%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
COVID-19 †A	2/160 (1.25%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Candida infection †A	0/160 (0%)	2/124 (1.61%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Cellulitis †A	7/160 (4.37%)	1/124 (0.81%)	0/35 (0%)	3/159 (1.89%)	2/127 (1.57%)
Dermatitis infected †A	1/160 (0.63%)	1/124 (0.81%)	0/35 (0%)	1/159 (0.63%)	0/127 (0%)
Folliculitis †A	0/160 (0%)	1/124 (0.81%)	0/35 (0%)	1/159 (0.63%)	0/127 (0%)
Furuncle †A	1/160 (0.63%)	1/124 (0.81%)	0/35 (0%)	2/159 (1.26%)	1/127 (0.79%)
Gastroenteritis †A	0/160 (0%)	2/124 (1.61%)	0/35 (0%)	2/159 (1.26%)	1/127 (0.79%)
Genital herpes †A	0/160 (0%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Impetigo †A	1/160 (0.63%)	2/124 (1.61%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Malaria †A	15/160 (9.38%)	15/124 (12.1%)	5/35 (14.29%)	19/159 (11.95%)	16/127 (12.6%)
Nasopharyngitis †A	3/160 (1.88%)	1/124 (0.81%)	1/35 (2.86%)	2/159 (1.26%)	2/127 (1.57%)
Otitis media †A	1/160 (0.63%)	0/124 (0%)	0/35 (0%)	2/159 (1.26%)	0/127 (0%)
Otitis media acute †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	1/159 (0.63%)	0/127 (0%)
Periodontitis †A	2/160 (1.25%)	1/124 (0.81%)	0/35 (0%)	3/159 (1.89%)	0/127 (0%)
Pharyngitis †A	1/160 (0.63%)	2/124 (1.61%)	0/35 (0%)	2/159 (1.26%)	4/127 (3.15%)
Rash pustular †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Respiratory tract infection †A	24/160 (15%)	10/124 (8.06%)	4/35 (11.43%)	39/159 (24.53%)	22/127 (17.32%)
Rhinitis †A	1/160 (0.63%)	0/124 (0%)	0/35 (0%)	2/159 (1.26%)	1/127 (0.79%)
Schistosomiasis †A	0/160 (0%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Sepsis †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	2/159 (1.26%)	2/127 (1.57%)
Septic rash †A	1/160 (0.63%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Sexually transmitted disease †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	1/159 (0.63%)	0/127 (0%)
Sexually transmitted disease †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	1/159 (0.63%)	0/127 (0%)
Tinea capitis †A	0/160 (0%)	2/124 (1.61%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Tinea cruris †A	0/160 (0%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Tinea pedis †A	0/160 (0%)	0/124 (0%)	1/35 (2.86%)	0/159 (0%)	0/127 (0%)
Tinea versicolour †A	2/160 (1.25%)	1/124 (0.81%)	1/35 (2.86%)	0/159 (0%)	1/127 (0.79%)

Upper respiratory tract infection †A	5/160 (3.12%)	18/124 (14.52%)	0/35 (0%)	19/159 (11.95%)	16/127 (12.6%)
Urethritis †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	1/159 (0.63%)	0/127 (0%)
Urinary tract infection †A	6/160 (3.75%)	5/124 (4.03%)	0/35 (0%)	2/159 (1.26%)	3/127 (2.36%)
Vulvovaginal candidiasis †A	1/160 (0.63%)	2/124 (1.61%)	1/35 (2.86%)	2/159 (1.26%)	4/127 (3.15%)
Injury, poisoning and procedural complications					
Animal bite †A	1/160 (0.63%)	0/124 (0%)	0/35 (0%)	1/159 (0.63%)	0/127 (0%)
Arthropod sting †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	1/159 (0.63%)	0/127 (0%)
Contusion †A	1/160 (0.63%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Joint injury †A	0/160 (0%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Ligament sprain †A	2/160 (1.25%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Muscle strain †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	1/159 (0.63%)	0/127 (0%)
Soft tissue injury †A	5/160 (3.12%)	4/124 (3.23%)	1/35 (2.86%)	4/159 (2.52%)	3/127 (2.36%)
Thermal burn †A	0/160 (0%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Ulna fracture †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	1/159 (0.63%)	0/127 (0%)
Wound †A	1/160 (0.63%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Investigations					
Alanine aminotransferase increased †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	1/159 (0.63%)	1/127 (0.79%)
Blood pressure increased †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	2/159 (1.26%)	0/127 (0%)
Metabolism and nutrition disorders					
Decreased appetite †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Musculoskeletal and connective tissue disorders					
Arthralgia †A	4/160 (2.5%)	4/124 (3.23%)	0/35 (0%)	1/159 (0.63%)	2/127 (1.57%)
Back pain †A	6/160 (3.75%)	9/124 (7.26%)	0/35 (0%)	14/159 (8.81%)	9/127 (7.09%)
Exostosis †A	1/160 (0.63%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Myalgia †A	19/160 (11.87%)	15/124 (12.1%)	7/35 (20%)	9/159 (5.66%)	8/127 (6.3%)
Tenosynovitis †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Torticollis †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	1/159 (0.63%)	2/127 (1.57%)
Nervous system disorders					
Dizziness †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	1/159 (0.63%)	0/127 (0%)
Headache †A	24/160 (15%)	18/124 (14.52%)	9/35 (25.71%)	14/159 (8.81%)	8/127 (6.3%)
Hypoaesthesia †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Migraine †A	1/160 (0.63%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Neuropathy peripheral †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Renal and urinary disorders					
Dysuria †A	0/160 (0%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Reproductive system and breast disorders					
Dysmenorrhoea †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Menorrhagia †A	0/160 (0%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	2/127 (1.57%)
Respiratory, thoracic and mediastinal disorders					
Allergic cough †A	2/160 (1.25%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Asthma †A	1/160 (0.63%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Cough †A	2/160 (1.25%)	0/124 (0%)	0/35 (0%)	2/159 (1.26%)	3/127 (2.36%)
Oropharyngeal pain †A	1/160 (0.63%)	0/124 (0%)	0/35 (0%)	1/159 (0.63%)	2/127 (1.57%)
Rhinitis allergic †A	0/160 (0%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Rhinorrhoea †A	0/160 (0%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Skin and subcutaneous tissue					

Dermatitis † A	0/160 (0%)	1/124 (0.81%)	1/35 (2.86%)	1/159 (0.63%)	0/127 (0%)
Dermatitis allergic † A	2/160 (1.25%)	3/124 (2.42%)	0/35 (0%)	1/159 (0.63%)	2/127 (1.57%)
Dermatitis contact † A	1/160 (0.63%)	0/124 (0%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Eczema † A	0/160 (0%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	0/127 (0%)
Pruritus † A	0/160 (0%)	3/124 (2.42%)	0/35 (0%)	1/159 (0.63%)	1/127 (0.79%)
Rash † A	2/160 (1.25%)	1/124 (0.81%)	0/35 (0%)	0/159 (0%)	1/127 (0.79%)
Rash pruritic † A	4/160 (2.5%)	1/124 (0.81%)	1/35 (2.86%)	3/159 (1.89%)	1/127 (0.79%)
Urticaria † A	0/160 (0%)	0/124 (0%)	1/35 (2.86%)	0/159 (0%)	0/127 (0%)
Vascular disorders					
Hypertension † A	0/160 (0%)	0/124 (0%)	0/35 (0%)	1/159 (0.63%)	1/127 (0.79%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (23.0)

Limitations and Caveats

[Not Specified]

More Information

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There is NOT an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact

Name/Official Title: Christian F. Ockenhouse, MD, PhD
Organization: PATH
Phone: 1 (206) 285-3500
Email: cockenhouse@path.org