Table 14.3.1.2
TEAEs by Primary System Organ Class and Preferred Term
Safety Analysis Set

MedDRA Primary System Organ Class Preferred Term	ACI-24 1000ug (N=14)		Placebo (N=7)		Overall (N=21)	
	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events
ANY	14 (100.0)	147	7 (100.0)	47	21 (100.0)	194
CARDIAC DISORDERS	1 (7.1)	1	1 (14.3)	2	2 (9.5)	3
Atrioventricular block	0	0	1 (14.3)	1	1 (4.8)	1
Atrioventricular block second degree	0	0	1 (14.3)	1	1 (4.8)	1
Pericardial effusion	1 (7.1)	1	0	0	1 (4.8)	1
EAR AND LABYRINTH DISORDERS	1 (7.1)	1	0	0	1 (4.8)	1
Ear pain	1 (7.1)	1	0	0	1 (4.8)	1
ENDOCRINE DISORDERS	0	0	1 (14.3)	1	1 (4.8)	1
Hypothyroidism	0	0	1 (14.3)	1	1 (4.8)	1
EYE DISORDERS	1 (7.1)	4	0	0	1 (4.8)	4
Dry eye	1 (7.1)	2	0	0	1 (4.8)	2
Eye pain	1 (7.1)	2	0	0	1 (4.8)	2

Coded using MedDRA version 23.0.
Source: Listing 16.2.7.1

Table 14.3.1.2
TEAEs by Primary System Organ Class and Preferred Term
Safety Analysis Set

MedDRA Primary System Organ Class Preferred Term	ACI-24 1000ug (N=14)		Placebo (N=7)		Overall (N=21)	
	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events
GASTROINTESTINAL DISORDERS	4 (28.6)	15	5 (71.4)	8	9 (42.9)	23
Abdominal discomfort	1 (7.1)	6	0	0	1 (4.8)	6
Abdominal pain	1 (7.1)	1	0	0	1 (4.8)	1
Abdominal pain upper	1 (7.1)	2	0	0	1 (4.8)	2
Colitis microscopic	1 (7.1)	1	0	0	1 (4.8)	1
Diarrhoea	1 (7.1)	2	2 (28.6)	2	3 (14.3)	4
Dyspepsia	0	0	1 (14.3)	1	1 (4.8)	1
Mouth ulceration	0	0	1 (14.3)	2	1 (4.8)	2
Nausea	0	0	1 (14.3)	1	1 (4.8)	1
Periodontal disease	0	0	1 (14.3)	1	1 (4.8)	1
Toothache	1 (7.1)	1	0	0	1 (4.8)	1
Vomiting	2 (14.3)	2	1 (14.3)	1	3 (14.3)	3

Coded using MedDRA version 23.0.
Source: Listing 16.2.7.1

Table 14.3.1.2
TEAEs by Primary System Organ Class and Preferred Term
Safety Analysis Set

MedDRA Primary System Organ Class Preferred Term	ACI-24 1000ug (N=14)		Placebo (N=7)		Overall (N=21)	
	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	5 (35.7)	6	2 (28.6)	2	7 (33.3)	8
Chills	1 (7.1)	1	0	0	1 (4.8)	1
Fatigue	1 (7.1)	1	1 (14.3)	1	2 (9.5)	2
Feeling abnormal	0	0	1 (14.3)	1	1 (4.8)	1
Gait disturbance	1 (7.1)	1	0	0	1 (4.8)	1
Hernia	1 (7.1)	1	0	0	1 (4.8)	1
Injection site pain	1 (7.1)	1	0	0	1 (4.8)	1
Non-cardiac chest pain	1 (7.1)	1	0	0	1 (4.8)	1
HEPATOBILIARY DISORDERS	1 (7.1)	1	0	0	1 (4.8)	1
Gallbladder polyp	1 (7.1)	1	0	0	1 (4.8)	1

Coded using MedDRA version 23.0.
Source: Listing 16.2.7.1

Table 14.3.1.2
TEAEs by Primary System Organ Class and Preferred Term
Safety Analysis Set

MedDRA Primary System Organ Class Preferred Term	ACI-24 1000ug (N=14)		Placebo (N=7)		Overall (N=21)	
	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events
INFECTIONS AND INFESTATIONS	13 (92.9)	24	4 (57.1)	6	17 (81.0)	30
COVID-19	1 (7.1)	1	1 (14.3)	1	2 (9.5)	2
Conjunctivitis	1 (7.1)	1	1 (14.3)	1	2 (9.5)	2
Gastroenteritis	1 (7.1)	1	0	0	1 (4.8)	1
Nasopharyngitis	3 (21.4)	3	1 (14.3)	1	4 (19.0)	4
Oral herpes	3 (21.4)	5	0	0	3 (14.3)	5
Pneumonia	1 (7.1)	1	1 (14.3)	1	2 (9.5)	2
Rhinitis	2 (14.3)	4	0	0	2 (9.5)	4
Sinusitis	1 (7.1)	1	0	0	1 (4.8)	1
Tooth infection	1 (7.1)	1	0	0	1 (4.8)	1
Upper respiratory tract infection	4 (28.6)	5	0	0	4 (19.0)	5
Urinary tract infection	1 (7.1)	1	1 (14.3)	2	2 (9.5)	3

Coded using MedDRA version 23.0.
Source: Listing 16.2.7.1

Table 14.3.1.2
TEAEs by Primary System Organ Class and Preferred Term
Safety Analysis Set

MedDRA Primary System Organ Class Preferred Term	ACI-24 1000ug (N=14)		Placebo (N=7)		Overall (N=21)	
	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	4 (28.6)	11	2 (28.6)	6	6 (28.6)	17
Concussion	0	0	1 (14.3)	1	1 (4.8)	1
Contusion	0	0	1 (14.3)	1	1 (4.8)	1
Face injury	1 (7.1)	1	0	0	1 (4.8)	1
Fall	2 (14.3)	6	1 (14.3)	1	3 (14.3)	7
Hand fracture	0	0	1 (14.3)	1	1 (4.8)	1
Head injury	0	0	1 (14.3)	1	1 (4.8)	1
Joint dislocation	0	0	1 (14.3)	1	1 (4.8)	1
Joint injury	1 (7.1)	2	0	0	1 (4.8)	2
Procedural pain	2 (14.3)	2	0	0	2 (9.5)	2
INVESTIGATIONS	2 (14.3)	5	2 (28.6)	2	4 (19.0)	7
Blood creatine phosphokinase increased	0	0	1 (14.3)	1	1 (4.8)	1
Blood creatinine increased	1 (7.1)	2	0	0	1 (4.8)	2
C-reactive protein increased	1 (7.1)	1	0	0	1 (4.8)	1
Gamma-glutamyltransferase increased	0	0	1 (14.3)	1	1 (4.8)	1
Mean cell volume increased	1 (7.1)	1	0	0	1 (4.8)	1
Platelet count increased	1 (7.1)	1	0	0	1 (4.8)	1

Coded using MedDRA version 23.0.
Source: Listing 16.2.7.1

Table 14.3.1.2
TEAEs by Primary System Organ Class and Preferred Term
Safety Analysis Set

MedDRA Primary System Organ Class Preferred Term	ACI-24 1000ug (N=14)		Placebo (N=7)		Overall (N=21)	
	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events
METABOLISM AND NUTRITION DISORDERS	2 (14.3)	3	1 (14.3)	1	3 (14.3)	4
Dehydration	1 (7.1)	1	0	0	1 (4.8)	1
Folate deficiency	1 (7.1)	1	0	0	1 (4.8)	1
Hyperlipidaemia	0	0	1 (14.3)	1	1 (4.8)	1
Hyperuricaemia	1 (7.1)	1	0	0	1 (4.8)	1
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	11 (78.6)	36	2 (28.6)	5	13 (61.9)	41
Arthralgia	4 (28.6)	4	0	0	4 (19.0)	4
Back pain	2 (14.3)	2	0	0	2 (9.5)	2
Foot deformity	1 (7.1)	1	0	0	1 (4.8)	1
Groin pain	2 (14.3)	2	0	0	2 (9.5)	2
Limb mass	2 (14.3)	2	0	0	2 (9.5)	2
Muscle spasms	0	0	1 (14.3)	1	1 (4.8)	1
Musculoskeletal chest pain	2 (14.3)	3	1 (14.3)	1	3 (14.3)	4
Musculoskeletal pain	3 (21.4)	4	2 (28.6)	2	5 (23.8)	6
Myalgia	1 (7.1)	3	0	0	1 (4.8)	3
Neck pain	2 (14.3)	3	0	0	2 (9.5)	3
Osteoarthritis	0	0	1 (14.3)	1	1 (4.8)	1
Pain in extremity	3 (21.4)	11	0	0	3 (14.3)	11
Pain in jaw	1 (7.1)	1	0	0	1 (4.8)	1

Coded using MedDRA version 23.0.
Source: Listing 16.2.7.1

Table 14.3.1.2
TEAEs by Primary System Organ Class and Preferred Term
Safety Analysis Set

MedDRA Primary System Organ Class Preferred Term	ACI-24 1000ug (N=14)		Placebo (N=7)		Overall (N=21)	
	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events
NERVOUS SYSTEM DISORDERS	6 (42.9)	16	4 (57.1)	5	10 (47.6)	21
Cerebral infarction	1 (7.1)	1	0	0	1 (4.8)	1
Cerebral microhaemorrhage	1 (7.1)	1	0	0	1 (4.8)	1
Dementia Alzheimer's type	1 (7.1)	1	0	0	1 (4.8)	1
Dizziness	1 (7.1)	1	1 (14.3)	2	2 (9.5)	3
Headache	2 (14.3)	2	2 (28.6)	2	4 (19.0)	4
Hypoaesthesia	2 (14.3)	3	0	0	2 (9.5)	3
Memory impairment	1 (7.1)	1	0	0	1 (4.8)	1
Paraesthesia	2 (14.3)	4	0	0	2 (9.5)	4
Presyncope	1 (7.1)	1	0	0	1 (4.8)	1
Sciatica	1 (7.1)	1	0	0	1 (4.8)	1
Transient ischaemic attack	0	0	1 (14.3)	1	1 (4.8)	1

Coded using MedDRA version 23.0.
Source: Listing 16.2.7.1

Table 14.3.1.2
TEAEs by Primary System Organ Class and Preferred Term
Safety Analysis Set

MedDRA Primary System Organ Class Preferred Term	ACI-24 1000ug (N=14)		Placebo (N=7)		Overall (N=21)	
	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events
PSYCHIATRIC DISORDERS	3 (21.4)	5	3 (42.9)	3	6 (28.6)	8
Aggression	1 (7.1)	1	0	0	1 (4.8)	1
Agitation	1 (7.1)	1	0	0	1 (4.8)	1
Alcohol use disorder	1 (7.1)	1	0	0	1 (4.8)	1
Depression	1 (7.1)	1	0	0	1 (4.8)	1
Depressive symptom	1 (7.1)	1	0	0	1 (4.8)	1
Insomnia	0	0	1 (14.3)	1	1 (4.8)	1
Post-traumatic amnestic disorder	0	0	1 (14.3)	1	1 (4.8)	1
Sleep disorder	0	0	1 (14.3)	1	1 (4.8)	1
RENAL AND URINARY DISORDERS	3 (21.4)	4	2 (28.6)	3	5 (23.8)	7
Acute kidney injury	1 (7.1)	1	0	0	1 (4.8)	1
Haematuria	1 (7.1)	2	1 (14.3)	1	2 (9.5)	3
Urinary incontinence	1 (7.1)	1	0	0	1 (4.8)	1
Urinary retention	0	0	1 (14.3)	2	1 (4.8)	2

Coded using MedDRA version 23.0.
Source: Listing 16.2.7.1

Table 14.3.1.2
TEAEs by Primary System Organ Class and Preferred Term
Safety Analysis Set

MedDRA Primary System Organ Class Preferred Term	ACI-24 1000ug (N=14)		Placebo (N=7)		Overall (N=21)	
	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	4 (28.6)	10	0	0	4 (19.0)	10
Asthma	1 (7.1)	1	0	0	1 (4.8)	1
Chronic obstructive pulmonary disease	1 (7.1)	1	0	0	1 (4.8)	1
Cough	2 (14.3)	2	0	0	2 (9.5)	2
Epistaxis	1 (7.1)	1	0	0	1 (4.8)	1
Oropharyngeal pain	1 (7.1)	3	0	0	1 (4.8)	3
Pulmonary fibrosis	1 (7.1)	1	0	0	1 (4.8)	1
Rhinitis allergic	1 (7.1)	1	0	0	1 (4.8)	1
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	3 (21.4)	3	2 (28.6)	3	5 (23.8)	6
Eczema	0	0	1 (14.3)	2	1 (4.8)	2
Hyperhidrosis	0	0	1 (14.3)	1	1 (4.8)	1
Psoriasis	1 (7.1)	1	0	0	1 (4.8)	1
Rash	1 (7.1)	1	0	0	1 (4.8)	1
Skin lesion	1 (7.1)	1	0	0	1 (4.8)	1
VASCULAR DISORDERS	2 (14.3)	2	0	0	2 (9.5)	2
Hypertension	1 (7.1)	1	0	0	1 (4.8)	1
Phlebitis superficial	1 (7.1)	1	0	0	1 (4.8)	1

Coded using MedDRA version 23.0.
Source: Listing 16.2.7.1
Program: table_14_03_01_02.sas

Table 14.3.1.3
Treatment-Related TEAEs by Primary System Organ Class and Preferred Term
Safety Analysis Set

MedDRA Primary System Organ Class Preferred Term	ACI-24 1000ug (N=14)		Placebo (N=7)		Overall (N=21)	
	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events
ANY	4 (28.6)	16	1 (14.3)	3	5 (23.8)	19
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (7.1)	1	1 (14.3)	1	2 (9.5)	2
Feeling abnormal	0	0	1 (14.3)	1	1 (4.8)	1
Injection site pain	1 (7.1)	1	0	0	1 (4.8)	1
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	1 (7.1)	1	0	0	1 (4.8)	1
Procedural pain	1 (7.1)	1	0	0	1 (4.8)	1
INVESTIGATIONS	1 (7.1)	1	1 (14.3)	1	2 (9.5)	2
Blood creatinine increased	1 (7.1)	1	0	0	1 (4.8)	1
Gamma-glutamyltransferase increased	0	0	1 (14.3)	1	1 (4.8)	1
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	2 (14.3)	7	0	0	2 (9.5)	7
Limb mass	1 (7.1)	1	0	0	1 (4.8)	1
Myalgia	1 (7.1)	2	0	0	1 (4.8)	2
Pain in extremity	1 (7.1)	4	0	0	1 (4.8)	4

Coded using MedDRA version 23.0.
Source: Listing 16.2.7.1

Table 14.3.1.3
Treatment-Related TEAEs by Primary System Organ Class and Preferred Term
Safety Analysis Set

MedDRA Primary System Organ Class Preferred Term	ACI-24 1000ug (N=14) No. of Patients (%)	 No. of Events	Placebo (N=7) No. of Patients (%)	 No. of Events	Overall (N=21) No. of Patients (%)	 No. of Events
NERVOUS SYSTEM DISORDERS	2 (14.3)	4	0	0	2 (9.5)	4
Cerebral microhaemorrhage	1 (7.1)	1	0	0	1 (4.8)	1
Headache	1 (7.1)	1	0	0	1 (4.8)	1
Hypoaesthesia	1 (7.1)	1	0	0	1 (4.8)	1
Presyncope	1 (7.1)	1	0	0	1 (4.8)	1
RENAL AND URINARY DISORDERS	1 (7.1)	1	0	0	1 (4.8)	1
Haematuria	1 (7.1)	1	0	0	1 (4.8)	1
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	1 (7.1)	1	0	0	1 (4.8)	1
Epistaxis	1 (7.1)	1	0	0	1 (4.8)	1
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	0	0	1 (14.3)	1	1 (4.8)	1
Eczema	0	0	1 (14.3)	1	1 (4.8)	1

Coded using MedDRA version 23.0.
Source: Listing 16.2.7.1

Table 14.3.1.4
Serious TEAEs by Primary System Organ Class and Preferred Term
Safety Analysis Set

MedDRA Primary System Organ Class Preferred Term	ACI-24 1000ug (N=14)		Placebo (N=7)		Overall (N=21)	
	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events	No. of Patients (%)	No. of Events
ANY	3 (21.4)	3	2 (28.6)	4	5 (23.8)	7
INFECTIONS AND INFESTATIONS	2 (14.3)	2	0	0	2 (9.5)	2
COVID-19	1 (7.1)	1	0	0	1 (4.8)	1
Pneumonia	1 (7.1)	1	0	0	1 (4.8)	1
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	0	0	1 (14.3)	1	1 (4.8)	1
Concussion	0	0	1 (14.3)	1	1 (4.8)	1
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (7.1)	1	0	0	1 (4.8)	1
Foot deformity	1 (7.1)	1	0	0	1 (4.8)	1
NERVOUS SYSTEM DISORDERS	0	0	1 (14.3)	1	1 (4.8)	1
Transient ischaemic attack	0	0	1 (14.3)	1	1 (4.8)	1
RENAL AND URINARY DISORDERS	0	0	1 (14.3)	2	1 (4.8)	2
Urinary retention	0	0	1 (14.3)	2	1 (4.8)	2

Coded using MedDRA version 23.0.
Source: Listing 16.2.7.1.
Program: table_14_03_01_04.sas