

**Table 2.S.3.I Treatment Emergent Adverse Events by Treatment, System Organ Class and Preferred Term (Safety Population)**

System Organ Class Preferred Term	Statistic	Cohort 1 F3 (N = 3)	Cohort 1 F4 (N = 3)	Cohort 2 F3 (N = 3)	Cohort 2 F4 (N = 3)	Cohort 3 F3 (N = 3)	Cohort 3 F4 (N = 4)	Cohort 4 F3 (N = 2)	Cohort 4 F4 (N = 2)	Total (N = 23)
Blood and lymphatic system disorders	n (%) E	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	2 (8.70) 2
Anaemia	n (%) E	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Pancytopenia	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Gastrointestinal disorders	n (%) E	1 (33.33) 1	1 (33.33) 1	1 (33.33) 2	2 (66.67) 3	1 (33.33) 2	2 (50.00) 2	0 (0.00) 0	1 (50.00) 1	9 (39.13) 12
Abdominal Discomfort	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Abdominal Distension	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	2 (66.67) 2	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	3 (13.04) 3
Abdominal Pain Upper	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 2	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 2
Constipation	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Diarrhoea	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	1 (50.00) 1	2 (8.70) 2
Gastrointestinal Disorder	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Toothache	n (%) E	1 (33.33) 1	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	2 (8.70) 2
General disorders and administration site conditions	n (%) E	0 (0.00) 0	1 (33.33) 1	1 (33.33) 1	0 (0.00) 0	2 (66.67) 4	0 (0.00) 0	1 (50.00) 1	2 (100.00) 3	7 (30.43) 10
Injection Site Inflammation	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Oedema Peripheral	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	1 (4.35) 1
Pain	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Pyrexia	n (%) E	0 (0.00) 0	1 (33.33) 1	1 (33.33) 1	0 (0.00) 0	1 (33.33) 2	0 (0.00) 0	1 (50.00) 1	2 (100.00) 2	6 (26.09) 7
Hepatobiliary disorders	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	0 (0.00) 0	1 (4.35) 1
Hepatic Mass	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	0 (0.00) 0	1 (4.35) 1
Infections and infestations	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 2	1 (25.00) 1	1 (50.00) 2	1 (50.00) 1	4 (17.39) 6
Acarodermatitis	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 2	0 (0.00) 0	1 (4.35) 2
Bacteriuria	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	1 (4.35) 1
Influenza	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Lower Respiratory Tract Infection	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Pharyngitis	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Investigations	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	2 (50.00) 3	0 (0.00) 0	1 (50.00) 1	3 (13.04) 4
Blood Pressure Increased	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Fibrin D Dimer Increased	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	1 (50.00) 1	2 (8.70) 2
Transaminases Increased	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Metabolism and nutrition disorders	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Diabetes Mellitus	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1

System Organ Class Preferred Term	Statistic	Cohort 1 F3 (N = 3)	Cohort 1 F4 (N = 3)	Cohort 2 F3 (N = 3)	Cohort 2 F4 (N = 3)	Cohort 3 F3 (N = 3)	Cohort 3 F4 (N = 4)	Cohort 4 F3 (N = 2)	Cohort 4 F4 (N = 2)	Total (N = 23)
Prostate Cancer	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Nervous system disorders	n (%) E	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	1 (25.00) 1	1 (50.00) 1	2 (100.00) 3	6 (26.09) 7
Headache	n (%) E	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	1 (50.00) 1	0 (0.00) 0	3 (13.04) 3
Ischaemic Stroke	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	1 (4.35) 1
Paraesthesia	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	1 (4.35) 1
Tremor	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	1 (50.00) 1	2 (8.70) 2
Renal and urinary disorders	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Renal Colic	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Reproductive system and breast disorders	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Prostatitis	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Respiratory, thoracic and mediastinal disorders	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Hypoventilation	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Skin and subcutaneous tissue disorders	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Rash Maculo-Papular	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1

E: Number of events; MedDRA: Medical Dictionary for Regulatory Activities; N: The number of patients in the Safety population within the respective cohort and arm; n: Number of patients with adverse event; %: Calculated using N as the denominator (n/N\*100).

F3: F3 compensated. F4: F4 compensated. There are no patients in F4 early decompensated.

All adverse events are coded using MedDRA version 21.1.

Any missing or inconsistent data from individual visits is due to the incompleteness of the database.

System Organ Class			Cohort 1 F3	Cohort 1 F4	Cohort 2 F3	Cohort 2 F4	Cohort 3 F3	Cohort 3 F4	Cohort 4 F3	Cohort 4 F4	Total
Preferred Term	Causality	Statistic	(N = 3)	(N = 3)	(N = 3)	(N = 3)	(N = 3)	(N = 4)	(N = 2)	(N = 2)	(N = 23)
Blood and lymphatic system disorders	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	2 (8.70) 2
Anaemia	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Pancytopenia	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Gastrointestinal disorders	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	2 (66.67) 2	0 (0.00) 0	2 (50.00) 2	0 (0.00) 0	0 (0.00) 0	5 (21.74) 5
	NOT RELATED	n (%) E	1 (33.33) 1	1 (33.33) 1	1 (33.33) 1	1 (33.33) 1	1 (33.33) 2	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	6 (26.09) 7
Abdominal Discomfort	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Abdominal Distension	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	2 (66.67) 2	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	3 (13.04) 3
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Abdominal Pain Upper	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 2	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 2
Constipation	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Diarrhoea	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	1 (4.35) 1
Gastrointestinal Disorder	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Toothache	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	1 (33.33) 1	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	2 (8.70) 2
General disorders and administration site conditions	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	2 (66.67) 2	0 (0.00) 0	1 (50.00) 1	2 (100.00) 2	5 (21.74) 5
	NOT RELATED	n (%) E	0 (0.00) 0	1 (33.33) 1	1 (33.33) 1	0 (0.00) 0	2 (66.67) 2	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	5 (21.74) 5
Injection Site Inflammation	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00)				

System Organ Class Preferred Term	Causality	Statistic	Cohort 1 F3 (N = 3)	Cohort 1 F4 (N = 3)	Cohort 2 F3 (N = 3)	Cohort 2 F4 (N = 3)	Cohort 3 F3 (N = 3)	Cohort 3 F4 (N = 4)	Cohort 4 F3 (N = 2)	Cohort 4 F4 (N = 2)	Total (N = 23)
Hepatobiliary disorders	NOT RELATED	n (%) E	0 (0.00) 0	1 (33.33) 1	1 (33.33) 1	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	3 (13.04) 3
	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	0 (0.00) 0	1 (4.35) 1
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Hepatic Mass	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	0 (0.00) 0	1 (4.35) 1
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Infections and infestations	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 2	1 (25.00) 1	1 (50.00) 2	1 (50.00) 1	4 (17.39) 6
	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Acarodermatitis	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 2	0 (0.00) 0	1 (4.35) 2
	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	1 (4.35) 1
Bacteriuria	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	1 (4.35) 1
	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Influenza	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Lower Respiratory Tract Infection	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Pharyngitis	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	2 (50.00) 3	0 (0.00) 0	1 (50.00) 1	3 (13.04) 4
Investigations	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Blood Pressure Increased	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Fibrin D Dimer Increased	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	1 (50.00) 1	2 (8.70) 2
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Transaminases Increased	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Metabolism and nutrition disorders	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Diabetes Mellitus	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Prostate Cancer	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1

System Organ Class Preferred Term	Causality	Statistic	Cohort 1 F3 (N = 3)	Cohort 1 F4 (N = 3)	Cohort 2 F3 (N = 3)	Cohort 2 F4 (N = 3)	Cohort 3 F3 (N = 3)	Cohort 3 F4 (N = 4)	Cohort 4 F3 (N = 2)	Cohort 4 F4 (N = 2)	Total (N = 23)
Nervous system disorders	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 2	1 (4.35) 2
	NOT RELATED	n (%) E	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	1 (25.00) 1	1 (50.00) 1	1 (50.00) 1	5 (21.74) 5
Headache	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	1 (50.00) 1	0 (0.00) 0	3 (13.04) 3
Ischaemic Stroke	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	1 (4.35) 1
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Paraesthesia	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	1 (4.35) 1
Tremor	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	1 (4.35) 1
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Renal and urinary disorders	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Renal Colic	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Reproductive system and breast disorders	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Prostatitis	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Respiratory, thoracic and mediastinal disorders	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Hypoventilation	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Skin and subcutaneous tissue disorders	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Rash Maculo-Papular	RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	NOT RELATED	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0

E: Number of events; N: The number of patients in the Safety population within the respective cohort and arm; n: Number of patients with adverse event with particular causality; %: Calculated using N as the denominator (n/N\*100).

F3: F3 compensated. F4: F4 compensated. There are no patients in F4 early decompensated.

All adverse events are coded using MedDRA version 21.1.

Any missing or inconsistent data from individual visits is due to the incompleteness of the database.

System Organ Class Preferred Term			Cohort 1 F3 (N = 3)	Cohort 1 F4 (N = 3)	Cohort 2 F3 (N = 3)	Cohort 2 F4 (N = 3)	Cohort 3 F3 (N = 3)	Cohort 3 F4 (N = 4)	Cohort 4 F3 (N = 2)	Cohort 4 F4 (N = 2)	Total (N = 23)		
Blood and lymphatic system disorders			Grade 1	n (%) E	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	2 (8.70) 2	
			Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	
			Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	
			Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	
			Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	
Anaemia			Grade 1	n (%) E	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1	
			Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	
			Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	
			Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	
			Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	
Pancytopenia			Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1	
			Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	
			Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	
			Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	
			Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	
Gastrointestinal disorders			Grade 1	n (%) E	1 (33.33) 1	1 (33.33) 1	1 (33.33) 2	2 (66.67) 3	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	1 (50.00) 1	7 (30.43) 9
			Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 2	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	2 (8.70) 3
			Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
			Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
			Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Abdominal Discomfort			Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1	
			Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	
			Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	
			Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	
			Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	
Abdominal Distension			Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	2 (66.67) 2	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	3 (13.04) 3	
			Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	
			Grade 3	n (%) E	0 (0.00) 0	0 (0.00							

System Organ Class Preferred Term			Severity	Statistic	Cohort 1 F3 (N = 3)	Cohort 1 F4 (N = 3)	Cohort 2 F3 (N = 3)	Cohort 2 F4 (N = 3)	Cohort 3 F3 (N = 3)	Cohort 3 F4 (N = 4)	Cohort 4 F3 (N = 2)	Cohort 4 F4 (N = 2)	Total (N = 23)
Constipation	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 2	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 2
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Diarrhoea	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	1 (50.00) 1	2 (8.70) 2
Gastrointestinal Disorder	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Toothache	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	1 (33.33) 1	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	2 (8.70) 2
General disorders and administration site conditions	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	2 (66.67) 3	0 (0.00) 0	1 (50.00) 1	2 (100.00) 3	6 (26.09) 8	
Injection Site Inflammation	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	2 (8.70) 2
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Injection Site Inflammation	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0

System Organ Class Preferred Term	Severity	Statistic	Cohort 1 F3 (N = 3)	Cohort 1 F4 (N = 3)	Cohort 2 F3 (N = 3)	Cohort 2 F4 (N = 3)	Cohort 3 F3 (N = 3)	Cohort 3 F4 (N = 4)	Cohort 4 F3 (N = 2)	Cohort 4 F4 (N = 2)	Total (N = 23)
Oedema Peripheral	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	1 (4.35) 1
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Pain	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Pyrexia	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	1 (33.33) 2	0 (0.00) 0	1 (50.00) 1	2 (100.00) 2	5 (21.74) 6
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Hepatobiliary disorders	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	0 (0.00) 0	1 (4.35) 1
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Hepatic Mass	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	0 (0.00) 0	1 (4.35) 1
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Infections and infestations	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	1 (25.00) 1	0 (0.00) 0	1 (50.00) 1	3 (13.04) 3
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	1 (50.00) 2	0 (0.00) 0	2 (8.70) 3
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Acarodermatitis	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 2	0 (0.00) 0	1 (4.35) 2



System Organ Class Preferred Term			Severity	Statistic	Cohort 1 F3 (N = 3)	Cohort 1 F4 (N = 3)	Cohort 2 F3 (N = 3)	Cohort 2 F4 (N = 3)	Cohort 3 F3 (N = 3)	Cohort 3 F4 (N = 4)	Cohort 4 F3 (N = 2)	Cohort 4 F4 (N = 2)	Total (N = 23)
Bacteriuria	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	1 (4.35) 1
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Influenza	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Lower Respiratory Tract Infection	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Pharyngitis	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Investigations	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	1 (4.35) 1
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	2 (50.00) 3	0 (0.00) 0	0 (0.00) 0	2 (8.70) 3
Blood Pressure Increased	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0

System Organ Class Preferred Term	Severity	Statistic	Cohort 1 F3 (N = 3)	Cohort 1 F4 (N = 3)	Cohort 2 F3 (N = 3)	Cohort 2 F4 (N = 3)	Cohort 3 F3 (N = 3)	Cohort 3 F4 (N = 4)	Cohort 4 F3 (N = 2)	Cohort 4 F4 (N = 2)	Total (N = 23)
Fibrin D Dimer Increased	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (50.00) 1	1 (4.35) 1
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Transaminases Increased	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Metabolism and nutrition disorders	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Diabetes Mellitus	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Prostate Cancer	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
Nervous system disorders	Grade 1	n (%) E	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	1 (25.00) 1	1 (50.00) 1	2 (100.00) 3	6 (26.09) 7
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0

System	Organ Class	Preferred Term	Severity	Statistic	Cohort 1 F3 (N = 3)	Cohort 1 F4 (N = 3)	Cohort 2 F3 (N = 3)	Cohort 2 F4 (N = 3)	Cohort 3 F3 (N = 3)	Cohort 3 F4 (N = 4)	Cohort 4 F3 (N = 2)	Cohort 4 F4 (N = 2)	Total (N = 23)							
Headache		Grade 4	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0						
		Grade 5	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0						
		Grade 1	n (%)	E	0 (0.00)	0	1 (33.33)	1	0 (0.00)	0	1 (33.33)	1	0 (0.00)	0	3 (13.04)	3				
		Grade 2	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0				
		Grade 3	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0				
Ischaemic Stroke		Grade 4	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0				
		Grade 5	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0				
		Grade 1	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	1 (50.00)	1	1 (4.35)	1		
		Grade 2	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0		
		Grade 3	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0		
Paraesthesia		Grade 4	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0		
		Grade 5	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0		
		Grade 1	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	1 (50.00)	1	1 (4.35)	1		
		Grade 2	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0		
		Grade 3	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0		
Tremor		Grade 4	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0		
		Grade 5	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0		
		Grade 1	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	1 (25.00)	1	0 (0.00)	0	1 (50.00)	1	2 (8.70)	2
		Grade 2	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0
		Grade 3	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0
Renal and urinary disorders		Grade 4	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0
		Grade 5	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0
		Grade 1	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	1 (25.00)	1	0 (0.00)	0	0 (0.00)	0	1 (4.35)	1
		Grade 2	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0
		Grade 3	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0
Renal Colic		Grade 4	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0
		Grade 5	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0
		Grade 1	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	1 (25.00)	1	0 (0.00)	0	0 (0.00)	0	1 (4.35)	1
		Grade 2	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0
		Grade 3	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0
Reproductive system and breast disorders		Grade 4	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0
		Grade 5	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0
		Grade 1	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0
		Grade 2	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0
		Grade 3	n (%)	E	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0	0 (0.00)	0

System Organ Class Preferred Term	Severity	Statistic	Cohort 1 F3 (N = 3)	Cohort 1 F4 (N = 3)	Cohort 2 F3 (N = 3)	Cohort 2 F4 (N = 3)	Cohort 3 F3 (N = 3)	Cohort 3 F4 (N = 4)	Cohort 4 F3 (N = 2)	Cohort 4 F4 (N = 2)	Total (N = 23)
Prostatitis	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Respiratory, thoracic and mediastinal disorders	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Hypoventilation	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	1 (33.33) 1	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Skin and subcutaneous tissue disorders	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	1 (25.00) 1	0 (0.00) 0	0 (0.00) 0	1 (4.35) 1
Rash Maculo-Papular	Grade 2	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 3	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 4	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 5	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0
	Grade 1	n (%) E	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0	0 (0.00) 0

E: Number of events; N: The number of patients in the Safety population within the respective cohort and arm; n: Number of patients with adverse event with particular severity; %: Calculated using N as the denominator (n/N\*100).

F3: F3 compensated. F4: F4 compensated. There are no patients in F4 early decompensated.

All adverse events are coded using MedDRA version 21.1.

Any missing or inconsistent data from individual visits is due to the incompleteness of the database.