

**All Adverse Events in ACOVACT (overall)**

System Organ Class (SOC ***) Preferred Term	Overall N=336		
	#Event	Subject	n (%)
OVERALL	1141	277	(82)
SOC ***Blood and lymphatic system disorders	117	84	(25)
Anaemia	28	22	(7)
Coagulopathy	4	4	(1)
Heparin-induced thrombocytopenia	1	1	(0)
Leukocytosis	6	6	(2)
Leukopenia	1	1	(0)
Lymphadenopathy	1	1	(0)
Lymphopenia	31	29	(9)
Neutropenia	1	1	(0)
Neutrophilia	11	11	(3)
Splenomegaly	1	1	(0)
Thrombocytopenia	10	10	(3)
Thrombocytosis	22	22	(7)
SOC ***Cardiac disorders	41	35	(10)
Acute coronary syndrome	1	1	(0)
Acute myocardial infarction	1	1	(0)
Angina pectoris	1	1	(0)
Aortic valve stenosis	1	1	(0)
Arrhythmia	1	1	(0)
Atrial fibrillation	6	6	(2)
Atrial flutter	1	1	(0)
Bradycardia	8	6	(2)
Cardiac arrest	2	1	(0)
Cardiac failure	2	2	(1)
Cardiopulmonary failure	1	1	(0)
Cardiovascular disorder	1	1	(0)
Coronary artery disease	1	1	(0)
Left ventricular dysfunction	2	2	(1)
Sinus bradycardia	2	2	(1)
Sinus tachycardia	1	1	(0)
Tachycardia	7	7	(2)
Ventricular fibrillation	1	1	(0)
Ventricular hypertrophy	1	1	(0)
SOC ***Congenital, familial and genetic disorders	1	1	(0)
Von Willebrand's disease	1	1	(0)
SOC ***Ear and labyrinth disorders	5	5	(1)
Tinnitus	1	1	(0)
Vertigo	4	4	(1)

**All Adverse Events in ACOVACT (overall)**

	Overall N=336		
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System Organ Class (SOC ***) Preferred Term	#Event	Subject	n (%)
SOC ***Endocrine disorders	3	3	(1)
Diabetes insipidus	1	1	(0)
Hypothyroidism	2	2	(1)
SOC ***Eye disorders	3	3	(1)
Dry eye	1	1	(0)
Eye oedema	1	1	(0)
Eyelid oedema	1	1	(0)
SOC ***Gastrointestinal disorders	126	86	(26)
Abdominal pain	5	5	(1)
Abdominal pain upper	11	10	(3)
Colitis	1	1	(0)
Constipation	27	27	(8)
Diarrhoea	26	25	(7)
Diverticulum intestinal haemorrhagic	1	1	(0)
Dyspepsia	5	5	(1)
Dysphagia	1	1	(0)
Flatulence	1	1	(0)
Gastric haemorrhage	1	1	(0)
Gastritis	1	1	(0)
Gastrointestinal disorder	1	1	(0)
Gastrointestinal haemorrhage	2	2	(1)
Gastroesophageal reflux disease	6	6	(2)
Haematochezia	1	1	(0)
Impaired gastric emptying	2	2	(1)
Lip dry	1	1	(0)
Lip pain	1	1	(0)
Mouth haemorrhage	4	4	(1)
Nausea	12	11	(3)
Rectal haemorrhage	7	6	(2)
Regurgitation	1	1	(0)
Retching	1	1	(0)
Toothache	1	1	(0)
Vomiting	6	6	(2)
SOC ***General disorders and administration site conditions	96	74	(22)
Asthenia	2	2	(1)
Catheter site haemorrhage	1	1	(0)
Chest discomfort	2	2	(1)
Chest pain	8	8	(2)
Complication associated with device	2	2	(1)

**All Adverse Events in ACOVACT (overall)**

System Organ Class (SOC ***) Preferred Term	Overall N=336		
	#Event	Subject	n (%)
Discomfort	4	4	(1)
Drug interaction	1	1	(0)
Fatigue	7	7	(2)
General physical health deterioration	5	5	(1)
Generalised oedema	1	1	(0)
Hyperthermia malignant	1	1	(0)
Hypothermia	12	7	(2)
Multiple organ dysfunction syndrome	12	12	(4)
Oedema	5	5	(1)
Oedema peripheral	7	7	(2)
Pain	14	14	(4)
Pyrexia	12	10	(3)
SOC ***Hepatobiliary disorders	21	17	(5)
Acute hepatic failure	1	1	(0)
Cholangitis	1	1	(0)
Cholestasis	2	2	(1)
Hepatic failure	1	1	(0)
Hepatic function abnormal	4	4	(1)
Hepatic steatosis	1	1	(0)
Hyperbilirubinaemia	3	3	(1)
Hypertransaminasaemia	4	4	(1)
Liver disorder	1	1	(0)
Liver injury	3	3	(1)
SOC ***Immune system disorders	3	3	(1)
Cytokine storm	1	1	(0)
Drug hypersensitivity	1	1	(0)
Haemophagocytic lymphohistiocytosis	1	1	(0)
SOC ***Infections and infestations	142	89	(26)
Bacterial disease carrier	1	1	(0)
Bacterial infection	7	7	(2)
Bronchopulmonary aspergillosis	1	1	(0)
COVID-19 pneumonia	6	6	(2)
Candida infection	7	7	(2)
Candida sepsis	1	1	(0)
Clostridium difficile infection	1	1	(0)
Enterococcal infection	1	1	(0)
Eye infection	1	1	(0)
Folliculitis	2	2	(1)
Fournier's gangrene	1	1	(0)

**All Adverse Events in ACOVACT (overall)**

	Overall N=336		
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System Organ Class (SOC ***) Preferred Term	#Event	Subject	n (%)
Fungal skin infection	1	1	(0)
Gangrene	1	1	(0)
Haemophilus infection	2	2	(1)
Herpes simplex	2	2	(1)
Herpes simplex reactivation	1	1	(0)
Herpes zoster	4	4	(1)
Infection	4	4	(1)
Klebsiella infection	3	3	(1)
Klebsiella sepsis	1	1	(0)
Oral candidiasis	2	2	(1)
Oral herpes	4	4	(1)
Oral infection	1	1	(0)
Otitis externa	1	1	(0)
Otitis media	2	2	(1)
Pneumonia	13	13	(4)
Pneumonia bacterial	3	3	(1)
Pneumonia pneumococcal	1	1	(0)
Pneumonia staphylococcal	1	1	(0)
Pseudomonas infection	1	1	(0)
Sepsis	8	8	(2)
Septic shock	4	4	(1)
Severe acute respiratory syndrome	1	1	(0)
Sinusitis	3	3	(1)
Staphylococcal bacteraemia	1	1	(0)
Staphylococcal infection	9	6	(2)
Superinfection	10	8	(2)
Superinfection bacterial	14	13	(4)
Tonsillitis	2	2	(1)
Urinary tract infection	11	11	(3)
Urinary tract infection bacterial	1	1	(0)
Vaginal infection	1	1	(0)
SOC ***Injury, poisoning and procedural complications	8	8	(2)
Bronchial injury	1	1	(0)
Facial bones fracture	1	1	(0)
Fall	1	1	(0)
Post procedural haemorrhage	2	2	(1)
Seroma	1	1	(0)
Tracheal haemorrhage	1	1	(0)
Weaning failure	1	1	(0)

**All Adverse Events in ACOVACT (overall)**

System Organ Class (SOC ***) Preferred Term	Overall N=336		
	#Event	Subject	n (%)
SOC ***Investigations	148	104	(31)
Alanine aminotransferase increased	11	11	(3)
Amylase increased	1	1	(0)
Aspartate aminotransferase increased	6	6	(2)
Blood albumin decreased	2	2	(1)
Blood alkaline phosphatase increased	2	2	(1)
Blood bilirubin increased	3	3	(1)
Blood chloride increased	2	2	(1)
Blood creatine phosphokinase increased	1	1	(0)
Blood creatinine increased	2	2	(1)
Blood lactate dehydrogenase abnormal	1	1	(0)
Blood magnesium increased	1	1	(0)
Blood pressure decreased	1	1	(0)
Blood pressure increased	1	1	(0)
C-reactive protein increased	5	5	(1)
Cardiovascular examination	1	1	(0)
Echocardiogram abnormal	1	1	(0)
Electrocardiogram QT prolonged	8	8	(2)
Electrocardiogram abnormal	1	1	(0)
Endoscopy upper gastrointestinal tract	1	1	(0)
Fibrin D dimer increased	1	1	(0)
Gamma-glutamyltransferase increased	2	2	(1)
Haemoglobin decreased	1	1	(0)
Hepatic enzyme increased	68	67	(20)
Lipase increased	6	6	(2)
N-terminal prohormone brain natriuretic peptide increased	4	4	(1)
Neutrophil count increased	1	1	(0)
Pancreatic enzymes increased	1	1	(0)
Platelet count increased	1	1	(0)
Staphylococcus test positive	1	1	(0)
Transaminases increased	8	6	(2)
Troponin T increased	3	3	(1)
SOC ***Metabolism and nutrition disorders	95	63	(19)
Cachexia	1	1	(0)
Dehydration	4	4	(1)
Diabetes mellitus	1	1	(0)
Hyperchloraemia	2	2	(1)
Hypercholesterolaemia	1	1	(0)
Hyperferritinaemia	2	2	(1)

**All Adverse Events in ACOVACT (overall)**

System Organ Class (SOC ***) Preferred Term	Overall N=336		
	#Event	Subject	n (%)
Hyperglycaemia	5	5	(1)
Hyperkalaemia	6	6	(2)
Hyperlipasaemia	3	3	(1)
Hypermagnesaemia	3	3	(1)
Hypernatraemia	6	6	(2)
Hyperphosphataemia	1	1	(0)
Hypertriglyceridaemia	1	1	(0)
Hypocalcaemia	18	15	(4)
Hypochloraemia	3	3	(1)
Hypokalaemia	23	21	(6)
Hyponatraemia	1	1	(0)
Hypophosphataemia	12	10	(3)
Vitamin D deficiency	2	2	(1)
SOC ***Musculoskeletal and connective tissue disorders	33	29	(9)
Arthralgia	3	3	(1)
Back pain	9	9	(3)
Bone pain	2	2	(1)
Flank pain	1	1	(0)
Intervertebral disc protrusion	1	1	(0)
Joint swelling	1	1	(0)
Muscle haemorrhage	1	1	(0)
Muscle spasms	2	2	(1)
Muscular weakness	1	1	(0)
Musculoskeletal chest pain	1	1	(0)
Myositis	1	1	(0)
Neck pain	3	3	(1)
Osteoarthritis	1	1	(0)
Pain in extremity	6	6	(2)
SOC ***Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	2	(1)
Haemangioma	1	1	(0)
Lung neoplasm malignant	1	1	(0)
SOC ***Nervous system disorders	43	36	(11)
Acute polyneuropathy	1	1	(0)
Cerebellar stroke	1	1	(0)
Cerebral haemorrhage	2	2	(1)
Cerebrovascular accident	1	1	(0)
Disturbance in attention	1	1	(0)
Dizziness	3	3	(1)
Epilepsy	1	1	(0)

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	Overall N=336		
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<i>System Organ Class (SOC ***) Preferred Term</i>	<i>#Event</i>	<i>Subject</i>	<i>n (%)</i>
Haemorrhage intracranial	1	1	(0)
Headache	9	9	(3)
Hypertonia	1	1	(0)
Hypoaesthesia	6	6	(2)
Hypotonia	3	3	(1)
Ischaemic stroke	1	1	(0)
Leukoencephalopathy	1	1	(0)
Memory impairment	4	4	(1)
Myoclonus	1	1	(0)
Nervous system disorder	1	1	(0)
Paraplegia	1	1	(0)
Peroneal nerve palsy	1	1	(0)
Quadriparesis	1	1	(0)
Sleep deficit	1	1	(0)
Tremor	1	1	(0)
SOC ***Product issues	1	1	(0)
Drug delivery system issue	1	1	(0)
SOC ***Psychiatric disorders	66	52	(15)
Adjustment disorder	1	1	(0)
Agitation	3	3	(1)
Anxiety	11	10	(3)
Confusional state	4	4	(1)
Delirium	14	13	(4)
Depression	3	3	(1)
Hallucination	1	1	(0)
Insomnia	6	6	(2)
Panic attack	1	1	(0)
Poor quality sleep	5	5	(1)
Sleep disorder	17	17	(5)
SOC ***Renal and urinary disorders	37	32	(10)
Acute kidney injury	19	19	(6)
Dysuria	1	1	(0)
Haematuria	7	7	(2)
Hydronephrosis	2	2	(1)
Pollakiuria	1	1	(0)
Renal colic	1	1	(0)
Renal failure	1	1	(0)
Renal impairment	1	1	(0)
Renal injury	1	1	(0)

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<i>System Organ Class (SOC ***) Preferred Term</i>	<i>Overall N=336</i>		
	<i>#Event</i>	<i>Subject</i>	<i>n (%)</i>
Urethral haemorrhage	1	1	(0)
Urinary retention	1	1	(0)
Urinary tract inflammation	1	1	(0)
SOC ***Respiratory, thoracic and mediastinal disorders	87	68	(20)
Acute respiratory distress syndrome	1	1	(0)
Acute respiratory failure	1	1	(0)
Atelectasis	1	1	(0)
Chronic obstructive pulmonary disease	1	1	(0)
Cough	6	6	(2)
Dysphonia	1	1	(0)
Dyspnoea	7	7	(2)
Dyspnoea exertional	1	1	(0)
Epistaxis	2	2	(1)
Haemoptysis	1	1	(0)
Haemothorax	1	1	(0)
Hiccups	1	1	(0)
Lung infiltration	1	1	(0)
Organising pneumonia	1	1	(0)
Oropharyngeal pain	1	1	(0)
Pharyngeal haemorrhage	2	2	(1)
Pleural effusion	3	3	(1)
Pleurisy	1	1	(0)
Pneumothorax	4	4	(1)
Pulmonary embolism	3	3	(1)
Pulmonary fibrosis	1	1	(0)
Pulmonary oedema	1	1	(0)
Respiratory acidosis	1	1	(0)
Respiratory failure	43	40	(12)
Sleep apnoea syndrome	1	1	(0)
SOC ***Skin and subcutaneous tissue disorders	22	20	(6)
Alopecia	2	2	(1)
Butterfly rash	1	1	(0)
Cold sweat	1	1	(0)
Decubitus ulcer	2	1	(0)
Dermatitis	1	1	(0)
Drug eruption	4	4	(1)
Eczema	1	1	(0)
Erythema	2	2	(1)
Hyperhidrosis	1	1	(0)



**All Adverse Events in ACOVACT (overall)**

<i>System Organ Class (SOC ***) Preferred Term</i>	<i>Overall N=336</i>		
	<i>#Event</i>	<i>Subject</i>	<i>n (%)</i>
Rash	4	4	(1)
Skin atrophy	1	1	(0)
Skin lesion	1	1	(0)
Skin mass	1	1	(0)
SOC ***Social circumstances	1	1	(0)
Refusal of treatment by patient	1	1	(0)
SOC ***Surgical and medical procedures	6	5	(1)
Central venous catheterisation	1	1	(0)
Coronary arterial stent insertion	1	1	(0)
Endotracheal intubation	1	1	(0)
Tracheostomy	3	3	(1)
SOC ***Vascular disorders	34	29	(9)
Circulatory collapse	2	2	(1)
Deep vein thrombosis	1	1	(0)
Haematoma	1	1	(0)
Haemodynamic instability	1	1	(0)
Hypertension	10	9	(3)
Hypertensive crisis	7	6	(2)
Hypotension	8	8	(2)
Peripheral vascular disorder	1	1	(0)
Thrombosis	3	3	(1)

**All Adverse Events with SERIOUSNESS (Yes/No) AND RELATEDNESS (related/not related) in ACOVACT (overall)**

			Number of Subjects N=336											
			#E... number of events											
			n... number of subjects											
			Non-Serious						Serious					
			Not Related			Related			Not Related			Related		
System	Organ Class	Preferred Term	#E	n	(%)	#E	n	(%)	#E	n	(%)	#E	n	(%)
OVERALL			1004	263	(78)	40	37	(11)	97	72	(21)	0	0	(0)
SOC ***	Blood and lymphatic system disorders		115	82	(24)	1	1	(0)	1	1	(0)	0	0	(0)
	Anaemia		28	22	(7)	0	0	(0)	0	0	(0)	0	0	(0)
	Coagulopathy		3	3	(1)	0	0	(0)	1	1	(0)	0	0	(0)
	Heparin-induced thrombocytopenia		1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Leukocytosis		6	6	(2)	0	0	(0)	0	0	(0)	0	0	(0)
	Leukopenia		1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Lymphadenopathy		1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Lymphopenia		31	29	(9)	0	0	(0)	0	0	(0)	0	0	(0)
	Neutropenia		1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Neutrophilia		11	11	(3)	0	0	(0)	0	0	(0)	0	0	(0)
	Splenomegaly		1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Thrombocytopenia		10	10	(3)	0	0	(0)	0	0	(0)	0	0	(0)
	Thrombocytosis		21	21	(6)	1	1	(0)	0	0	(0)	0	0	(0)
SOC ***	Cardiac disorders		35	32	(10)	0	0	(0)	6	6	(2)	0	0	(0)
	Acute coronary syndrome		0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	Acute myocardial infarction		0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	Angina pectoris		1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Aortic valve stenosis		1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Arrhythmia		1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Atrial fibrillation		5	5	(1)	0	0	(0)	1	1	(0)	0	0	(0)
	Atrial flutter		1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)

**All Adverse Events with *SERIOUSNESS* (Yes/No) AND *RELATEDNESS* (related/not related) in ACOVACT (overall)**

		Number of Subjects N=336											
		#E... number of events											
		n... number of subjects											
		Non-Serious						Serious					
		Not Related			Related			Not Related			Related		
System	Organ Class Preferred Term	#E	n	(%)	#E	n	(%)	#E	n	(%)	#E	n	(%)
	Bradycardia	8	6	(2)	0	0	(0)	0	0	(0)	0	0	(0)
	Cardiac arrest	1	1	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	Cardiac failure	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Cardiopulmonary failure	0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	Cardiovascular disorder	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Coronary artery disease	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Left ventricular dysfunction	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Sinus bradycardia	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Sinus tachycardia	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Tachycardia	7	7	(2)	0	0	(0)	0	0	(0)	0	0	(0)
	Ventricular fibrillation	0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	Ventricular hypertrophy	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	SOC ***Congenital, familial and genetic disorders	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Von Willebrand's disease	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	SOC ***Ear and labyrinth disorders	5	5	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Tinnitus	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Vertigo	4	4	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	SOC ***Endocrine disorders	3	3	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Diabetes insipidus	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Hypothyroidism	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	SOC ***Eye disorders	3	3	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Dry eye	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)

**All Adverse Events with SERIOUSNESS (Yes/No) AND RELATEDNESS (related/not related) in ACOVACT (overall)**

		Number of Subjects N=336											
		#E... number of events											
		n... number of subjects											
		Non-Serious						Serious					
		Not Related			Related			Not Related			Related		
System	Organ Class Preferred Term	#E	n	(%)	#E	n	(%)	#E	n	(%)	#E	n	(%)
	Eye oedema	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Eyelid oedema	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	SOC ***Gastrointestinal disorders	103	71	(21)	21	20	(6)	2	2	(1)	0	0	(0)
	Abdominal pain	4	4	(1)	1	1	(0)	0	0	(0)	0	0	(0)
	Abdominal pain upper	10	9	(3)	1	1	(0)	0	0	(0)	0	0	(0)
	Colitis	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Constipation	27	27	(8)	0	0	(0)	0	0	(0)	0	0	(0)
	Diarrhoea	11	11	(3)	15	15	(4)	0	0	(0)	0	0	(0)
	Diverticulum intestinal haemorrhagic	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Dyspepsia	5	5	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Dysphagia	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Flatulence	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Gastric haemorrhage	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Gastritis	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Gastrointestinal disorder	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Gastrointestinal haemorrhage	1	1	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	Gastrooesophageal reflux disease	6	6	(2)	0	0	(0)	0	0	(0)	0	0	(0)
	Haematochezia	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Impaired gastric emptying	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Lip dry	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Lip pain	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Mouth haemorrhage	3	3	(1)	0	0	(0)	1	1	(0)	0	0	(0)

**All Adverse Events with *SERIOUSNESS* (Yes/No) AND *RELATEDNESS* (related/not related) in ACOVACT (overall)**

		Number of Subjects N=336											
		#E... number of events											
		n... number of subjects											
		Non-Serious						Serious					
		Not Related			Related			Not Related			Related		
System	Organ Class Preferred Term	#E	n	(%)	#E	n	(%)	#E	n	(%)	#E	n	(%)
	Nausea	10	9	(3)	2	2	(1)	0	0	(0)	0	0	(0)
	Rectal haemorrhage	7	6	(2)	0	0	(0)	0	0	(0)	0	0	(0)
	Regurgitation	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Retching	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Toothache	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Vomiting	4	4	(1)	2	2	(1)	0	0	(0)	0	0	(0)
	SOC ***General disorders and administration site conditions	82	62	(18)	1	1	(0)	13	13	(4)	0	0	(0)
	Asthenia	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Catheter site haemorrhage	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Chest discomfort	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Chest pain	8	8	(2)	0	0	(0)	0	0	(0)	0	0	(0)
	Complication associated with device	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Discomfort	4	4	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Drug interaction	0	0	(0)	1	1	(0)	0	0	(0)	0	0	(0)
	Fatigue	7	7	(2)	0	0	(0)	0	0	(0)	0	0	(0)
	General physical health deterioration	5	5	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Generalised oedema	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Hyperthermia malignant	0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	Hypothermia	12	7	(2)	0	0	(0)	0	0	(0)	0	0	(0)
	Multiple organ dysfunction syndrome	0	0	(0)	0	0	(0)	12	12	(4)	0	0	(0)
	Oedema	5	5	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Oedema peripheral	7	7	(2)	0	0	(0)	0	0	(0)	0	0	(0)

**All Adverse Events with *SERIOUSNESS* (Yes/No) AND *RELATEDNESS* (related/not related) in ACOVACT (overall)**

		Number of Subjects N=336											
		#E... number of events											
		n... number of subjects											
		Non-Serious						Serious					
		Not Related			Related			Not Related			Related		
System	Organ Class Preferred Term	#E	n	(%)	#E	n	(%)	#E	n	(%)	#E	n	(%)
	Pain	14	14	(4)	0	0	(0)	0	0	(0)	0	0	(0)
	Pyrexia	12	10	(3)	0	0	(0)	0	0	(0)	0	0	(0)
	SOC ***Hepatobiliary disorders	18	16	(5)	2	2	(1)	1	1	(0)	0	0	(0)
	Acute hepatic failure	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Cholangitis	0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	Cholestasis	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Hepatic failure	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Hepatic function abnormal	4	4	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Hepatic steatosis	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Hyperbilirubinaemia	2	2	(1)	1	1	(0)	0	0	(0)	0	0	(0)
	Hypertransaminasaemia	3	3	(1)	1	1	(0)	0	0	(0)	0	0	(0)
	Liver disorder	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Liver injury	3	3	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	SOC ***Immune system disorders	1	1	(0)	1	1	(0)	1	1	(0)	0	0	(0)
	Cytokine storm	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Drug hypersensitivity	0	0	(0)	1	1	(0)	0	0	(0)	0	0	(0)
	Haemophagocytic lymphohistiocytosis	0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	SOC ***Infections and infestations	131	83	(25)	0	0	(0)	11	11	(3)	0	0	(0)
	Bacterial disease carrier	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Bacterial infection	7	7	(2)	0	0	(0)	0	0	(0)	0	0	(0)
	Bronchopulmonary aspergillosis	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	COVID-19 pneumonia	4	4	(1)	0	0	(0)	2	2	(1)	0	0	(0)

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		Number of Subjects N=336											
		#E... number of events											
		n... number of subjects											
		Non-Serious						Serious					
		Not Related			Related			Not Related			Related		
System	Organ Class Preferred Term	#E	n	(%)	#E	n	(%)	#E	n	(%)	#E	n	(%)
	Candida infection	7	7	(2)	0	0	(0)	0	0	(0)	0	0	(0)
	Candida sepsis	0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	Clostridium difficile infection	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Enterococcal infection	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Eye infection	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Folliculitis	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Fournier's gangrene	0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	Fungal skin infection	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Gangrene	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Haemophilus infection	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Herpes simplex	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Herpes simplex reactivation	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Herpes zoster	4	4	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Infection	4	4	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Klebsiella infection	3	3	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Klebsiella sepsis	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Oral candidiasis	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Oral herpes	4	4	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Oral infection	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Otitis externa	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Otitis media	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Pneumonia	13	13	(4)	0	0	(0)	0	0	(0)	0	0	(0)

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		#E... number of events											
		n... number of subjects											
		Non-Serious						Serious					
		Not Related			Related			Not Related			Related		
System	Organ Class Preferred Term	#E	n	(%)	#E	n	(%)	#E	n	(%)	#E	n	(%)
	Pneumonia bacterial	2	2	(1)	0	0	(0)	1	1	(0)	0	0	(0)
	Pneumonia pneumococcal	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Pneumonia staphylococcal	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Pseudomonas infection	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Sepsis	6	6	(2)	0	0	(0)	2	2	(1)	0	0	(0)
	Septic shock	2	2	(1)	0	0	(0)	2	2	(1)	0	0	(0)
	Severe acute respiratory syndrome	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Sinusitis	3	3	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Staphylococcal bacteraemia	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Staphylococcal infection	9	6	(2)	0	0	(0)	0	0	(0)	0	0	(0)
	Superinfection	8	6	(2)	0	0	(0)	2	2	(1)	0	0	(0)
	Superinfection bacterial	14	13	(4)	0	0	(0)	0	0	(0)	0	0	(0)
	Tonsillitis	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Urinary tract infection	11	11	(3)	0	0	(0)	0	0	(0)	0	0	(0)
	Urinary tract infection bacterial	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Vaginal infection	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	SOC ***Injury, poisoning and procedural complications	7	7	(2)	0	0	(0)	1	1	(0)	0	0	(0)
	Bronchial injury	0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	Facial bones fracture	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Fall	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Post procedural haemorrhage	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Seroma	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)



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		Non-Serious						Serious					
		Not Related			Related			Not Related			Related		
System	Organ Class Preferred Term	#E	n	(%)	#E	n	(%)	#E	n	(%)	#E	n	(%)
	Tracheal haemorrhage	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Weaning failure	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	SOC ***Investigations	134	91	(27)	14	14	(4)	0	0	(0)	0	0	(0)
	Alanine aminotransferase increased	11	11	(3)	0	0	(0)	0	0	(0)	0	0	(0)
	Amylase increased	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Aspartate aminotransferase increased	6	6	(2)	0	0	(0)	0	0	(0)	0	0	(0)
	Blood albumin decreased	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Blood alkaline phosphatase increased	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Blood bilirubin increased	2	2	(1)	1	1	(0)	0	0	(0)	0	0	(0)
	Blood chloride increased	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Blood creatine phosphokinase increased	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Blood creatinine increased	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Blood lactate dehydrogenase abnormal	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Blood magnesium increased	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Blood pressure decreased	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Blood pressure increased	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	C-reactive protein increased	5	5	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Cardiovascular examination	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Echocardiogram abnormal	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Electrocardiogram QT prolonged	7	7	(2)	1	1	(0)	0	0	(0)	0	0	(0)
	Electrocardiogram abnormal	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Endoscopy upper gastrointestinal tract	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)

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			Number of Subjects N=336											
			#E... number of events											
			n... number of subjects											
			Non-Serious						Serious					
			Not Related			Related			Not Related			Related		
System	Organ	Class	#E	n	(%)	#E	n	(%)	#E	n	(%)	#E	n	(%)
Preferred Term														
Fibrin D dimer increased			1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
Gamma-glutamyltransferase increased			2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
Haemoglobin decreased			1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
Hepatic enzyme increased			56	56	(17)	12	12	(4)	0	0	(0)	0	0	(0)
Lipase increased			6	6	(2)	0	0	(0)	0	0	(0)	0	0	(0)
N-terminal prohormone brain natriuretic peptide increased			4	4	(1)	0	0	(0)	0	0	(0)	0	0	(0)
Neutrophil count increased			1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
Pancreatic enzymes increased			1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
Platelet count increased			1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
Staphylococcus test positive			1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
Transaminases increased			8	6	(2)	0	0	(0)	0	0	(0)	0	0	(0)
Troponin T increased			3	3	(1)	0	0	(0)	0	0	(0)	0	0	(0)
SOC ***Metabolism and nutrition disorders			95	63	(19)	0	0	(0)	0	0	(0)	0	0	(0)
Cachexia			1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
Dehydration			4	4	(1)	0	0	(0)	0	0	(0)	0	0	(0)
Diabetes mellitus			1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
Hyperchloraemia			2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
Hypercholesterolaemia			1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
Hyperferritinaemia			2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
Hyperglycaemia			5	5	(1)	0	0	(0)	0	0	(0)	0	0	(0)
Hyperkalaemia			6	6	(2)	0	0	(0)	0	0	(0)	0	0	(0)
Hyperlipasaemia			3	3	(1)	0	0	(0)	0	0	(0)	0	0	(0)

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		Number of Subjects N=336											
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		n... number of subjects											
		Non-Serious						Serious					
		Not Related			Related			Not Related			Related		
System	Organ Class Preferred Term	#E	n	(%)	#E	n	(%)	#E	n	(%)	#E	n	(%)
	Hypermagnesaemia	3	3	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Hypernatraemia	6	6	(2)	0	0	(0)	0	0	(0)	0	0	(0)
	Hyperphosphataemia	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Hypertriglyceridaemia	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Hypocalcaemia	18	15	(4)	0	0	(0)	0	0	(0)	0	0	(0)
	Hypochloraemia	3	3	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Hypokalaemia	23	21	(6)	0	0	(0)	0	0	(0)	0	0	(0)
	Hyponatraemia	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Hypophosphataemia	12	10	(3)	0	0	(0)	0	0	(0)	0	0	(0)
	Vitamin D deficiency	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	SOC ***Musculoskeletal and connective tissue disorders	31	27	(8)	0	0	(0)	2	2	(1)	0	0	(0)
	Arthralgia	3	3	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Back pain	9	9	(3)	0	0	(0)	0	0	(0)	0	0	(0)
	Bone pain	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Flank pain	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Intervertebral disc protrusion	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Joint swelling	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Muscle haemorrhage	0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	Muscle spasms	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Muscular weakness	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Musculoskeletal chest pain	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Myositis	0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)

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		#E... number of events											
		n... number of subjects											
		Non-Serious						Serious					
		Not Related			Related			Not Related			Related		
System	Organ Class Preferred Term	#E	n	(%)	#E	n	(%)	#E	n	(%)	#E	n	(%)
	Neck pain	3	3	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Osteoarthritis	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Pain in extremity	6	6	(2)	0	0	(0)	0	0	(0)	0	0	(0)
	SOC ***Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Haemangioma	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Lung neoplasm malignant	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	SOC ***Nervous system disorders	34	28	(8)	0	0	(0)	9	9	(3)	0	0	(0)
	Acute polyneuropathy	0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	Cerebellar stroke	0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	Cerebral haemorrhage	0	0	(0)	0	0	(0)	2	2	(1)	0	0	(0)
	Cerebrovascular accident	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Disturbance in attention	0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	Dizziness	3	3	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Epilepsy	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Haemorrhage intracranial	0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	Headache	9	9	(3)	0	0	(0)	0	0	(0)	0	0	(0)
	Hypertonia	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Hypoaesthesia	6	6	(2)	0	0	(0)	0	0	(0)	0	0	(0)
	Hypotonia	2	2	(1)	0	0	(0)	1	1	(0)	0	0	(0)
	Ischaemic stroke	0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	Leukoencephalopathy	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Memory impairment	4	4	(1)	0	0	(0)	0	0	(0)	0	0	(0)

**All Adverse Events with SERIOUSNESS (Yes/No) AND RELATEDNESS (related/not related) in ACOVACT (overall)**

			Number of Subjects N=336											
			#E... number of events											
			n... number of subjects											
			Non-Serious						Serious					
			Not Related			Related			Not Related			Related		
System	Organ Class	Preferred Term	#E	n	(%)	#E	n	(%)	#E	n	(%)	#E	n	(%)
		Myoclonus	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Nervous system disorder	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Paraplegia	0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
		Peroneal nerve palsy	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Quadriparesis	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Sleep deficit	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Tremor	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		SOC ***Product issues	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Drug delivery system issue	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		SOC ***Psychiatric disorders	65	51	(15)	0	0	(0)	1	1	(0)	0	0	(0)
		Adjustment disorder	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Agitation	3	3	(1)	0	0	(0)	0	0	(0)	0	0	(0)
		Anxiety	11	10	(3)	0	0	(0)	0	0	(0)	0	0	(0)
		Confusional state	3	3	(1)	0	0	(0)	1	1	(0)	0	0	(0)
		Delirium	14	13	(4)	0	0	(0)	0	0	(0)	0	0	(0)
		Depression	3	3	(1)	0	0	(0)	0	0	(0)	0	0	(0)
		Hallucination	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Insomnia	6	6	(2)	0	0	(0)	0	0	(0)	0	0	(0)
		Panic attack	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Poor quality sleep	5	5	(1)	0	0	(0)	0	0	(0)	0	0	(0)
		Sleep disorder	17	17	(5)	0	0	(0)	0	0	(0)	0	0	(0)
		SOC ***Renal and urinary disorders	35	31	(9)	0	0	(0)	2	2	(1)	0	0	(0)

**All Adverse Events with *SERIOUSNESS* (Yes/No) AND *RELATEDNESS* (related/not related) in ACOVACT (overall)**

		Number of Subjects N=336											
		#E... number of events											
		n... number of subjects											
		Non-Serious						Serious					
		Not Related			Related			Not Related			Related		
System	Organ Class Preferred Term	#E	n	(%)	#E	n	(%)	#E	n	(%)	#E	n	(%)
	Acute kidney injury	18	18	(5)	0	0	(0)	1	1	(0)	0	0	(0)
	Dysuria	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Haematuria	6	6	(2)	0	0	(0)	1	1	(0)	0	0	(0)
	Hydronephrosis	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Pollakiuria	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Renal colic	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Renal failure	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Renal impairment	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Renal injury	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Urethral haemorrhage	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Urinary retention	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Urinary tract inflammation	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	SOC ***Respiratory, thoracic and mediastinal disorders	40	32	(10)	0	0	(0)	47	44	(13)	0	0	(0)
	Acute respiratory distress syndrome	0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	Acute respiratory failure	0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	Atelectasis	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Chronic obstructive pulmonary disease	0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
	Cough	6	6	(2)	0	0	(0)	0	0	(0)	0	0	(0)
	Dysphonia	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Dyspnoea	6	6	(2)	0	0	(0)	1	1	(0)	0	0	(0)
	Dyspnoea exertional	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Epistaxis	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)

**All Adverse Events with SERIOUSNESS (Yes/No) AND RELATEDNESS (related/not related) in ACOVACT (overall)**

			Number of Subjects N=336											
			#E... number of events											
			n... number of subjects											
			Non-Serious						Serious					
			Not Related			Related			Not Related			Related		
System	Organ Class	Preferred Term	#E	n	(%)	#E	n	(%)	#E	n	(%)	#E	n	(%)
		Haemoptysis	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Haemothorax	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Hiccups	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Lung infiltration	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Organising pneumonia	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Oropharyngeal pain	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Pharyngeal haemorrhage	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
		Pleural effusion	3	3	(1)	0	0	(0)	0	0	(0)	0	0	(0)
		Pleurisy	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Pneumothorax	2	2	(1)	0	0	(0)	2	2	(1)	0	0	(0)
		Pulmonary embolism	1	1	(0)	0	0	(0)	2	2	(1)	0	0	(0)
		Pulmonary fibrosis	0	0	(0)	0	0	(0)	1	1	(0)	0	0	(0)
		Pulmonary oedema	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Respiratory acidosis	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Respiratory failure	5	4	(1)	0	0	(0)	38	38	(11)	0	0	(0)
		Sleep apnoea syndrome	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		SOC ***Skin and subcutaneous tissue disorders	22	20	(6)	0	0	(0)	0	0	(0)	0	0	(0)
		Alopecia	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
		Butterfly rash	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Cold sweat	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Decubitus ulcer	2	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
		Dermatitis	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)

**All Adverse Events with SERIOUSNESS (Yes/No) AND RELATEDNESS (related/not related) in ACOVACT (overall)**

		Number of Subjects N=336											
		#E... number of events											
		n... number of subjects											
		Non-Serious						Serious					
		Not Related			Related			Not Related			Related		
System	Organ Class Preferred Term	#E	n	(%)	#E	n	(%)	#E	n	(%)	#E	n	(%)
	Drug eruption	4	4	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Eczema	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Erythema	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Hyperhidrosis	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Rash	4	4	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Skin atrophy	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Skin lesion	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Skin mass	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	SOC ***Social circumstances	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Refusal of treatment by patient	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	SOC ***Surgical and medical procedures	6	5	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Central venous catheterisation	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Coronary arterial stent insertion	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Endotracheal intubation	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Tracheostomy	3	3	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	SOC ***Vascular disorders	34	29	(9)	0	0	(0)	0	0	(0)	0	0	(0)
	Circulatory collapse	2	2	(1)	0	0	(0)	0	0	(0)	0	0	(0)
	Deep vein thrombosis	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Haematoma	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Haemodynamic instability	1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
	Hypertension	10	9	(3)	0	0	(0)	0	0	(0)	0	0	(0)
	Hypertensive crisis	7	6	(2)	0	0	(0)	0	0	(0)	0	0	(0)



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Number of Subjects N=336												
#E... number of events												
n... number of subjects												

**Adverse Events with outcome Death in ACOVACT (overall)**

<i>System Organ Class (SOC ***) Preferred Term</i>	<i>Overall N=336</i>		
	<i>#Event</i>	<i>Subject</i>	<i>n (%)</i>
OVERALL	40	35	(10)
SOC ***Cardiac disorders	2	2	(1)
Cardiopulmonary failure	1	1	(0)
Ventricular fibrillation	1	1	(0)
SOC ***Gastrointestinal disorders	1	1	(0)
Gastrointestinal haemorrhage	1	1	(0)
SOC ***General disorders and administration site conditions	12	12	(4)
Multiple organ dysfunction syndrome	12	12	(4)
SOC ***Hepatobiliary disorders	1	1	(0)
Cholangitis	1	1	(0)
SOC ***Infections and infestations	6	6	(2)
COVID-19 pneumonia	1	1	(0)
Pneumonia bacterial	1	1	(0)
Sepsis	2	2	(1)
Septic shock	1	1	(0)
Superinfection	1	1	(0)
SOC ***Nervous system disorders	5	5	(1)
Cerebral haemorrhage	2	2	(1)
Haemorrhage intracranial	1	1	(0)
Hypotonia	1	1	(0)
Ischaemic stroke	1	1	(0)
SOC ***Respiratory, thoracic and mediastinal disorders	13	13	(4)
Pneumothorax	1	1	(0)
Respiratory failure	12	12	(4)