

All Adverse Events in ACOVACT (overall)

<i>System Organ Class (SOC ***) Preferred Term</i>	<i>Overall N=336</i>		<i>n (%)</i>
	<i>#Event</i>	<i>Subject</i>	
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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<i>System Organ Class (SOC ***) Preferred Term</i>	#Event	Subject <i>n</i> (%)
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)
Gastrooesophageal 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)

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<i>System Organ Class (SOC ***) Preferred Term</i>	#Event	Subject	<i>n (%)</i>
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)
Hypertransaminaemia	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)

<i>System Organ Class (SOC ***) Preferred Term</i>	<i>Overall N=336</i>		
	<i>#Event</i>	<i>Subject</i>	<i>n (%)</i>
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)

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<i>System Organ Class (SOC ***) Preferred Term</i>	<i>#Event</i>	<i>Subject n (%)</i>
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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System Organ Class (SOC ***) Preferred Term	#Event	Subject	n (%)
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>	Overall N=336	
	<i>#Event</i>	<i>Subject 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)

	Overall N=336		
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System Organ Class (SOC ***) Preferred Term	#Event	Subject	n (%)
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)

System Organ Class Preferred Term	Number of Subjects N=336											
	#E... number of events											
	n... number of subjects											
	Non-Serious						Serious					
	Not Related			Related			Not Related			Related		
	#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)

System Organ Class Preferred Term	Number of Subjects N=336											
	#E... number of events											
	n... number of subjects											
	Non-Serious						Serious					
	Not Related			Related			Not Related			Related		
	#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)

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System Organ Class Preferred Term	Number of Subjects N=336											
	#E... number of events											
	n... number of subjects											
	Non-Serious						Serious					
	Not Related			Related			Not Related			Related		
	#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)

System Organ Class Preferred Term	Number of Subjects N=336											
	#E... number of events											
	n... number of subjects											
	Non-Serious						Serious					
	Not Related			Related			Not Related			Related		
	#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)

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

System Organ Class Preferred Term	Number of Subjects N=336											
	#E... number of events											
	n... number of subjects											
	Non-Serious						Serious					
	Not Related			Related			Not Related			Related		
	#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)

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

System Organ Class Preferred Term	Number of Subjects N=336											
	#E... number of events											
	n... number of subjects											
	Non-Serious						Serious					
	Not Related			Related			Not Related			Related		
	#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)

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

System Organ Class Preferred Term	Number of Subjects N=336											
	#E... number of events											
	n... number of subjects											
	Non-Serious						Serious					
	Not Related			Related			Not Related			Related		
	#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)

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

System Organ Class Preferred Term	Number of Subjects N=336											
	#E... number of events											
	n... number of subjects											
	Non-Serious						Serious					
	Not Related			Related			Not Related			Related		
	#E	n	(%)	#E	n	(%)	#E	n	(%)	#E	n	(%)
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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System Organ Class Preferred Term	Number of Subjects N=336											
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	n... number of subjects											
	Non-Serious						Serious					
	Not Related			Related			Not Related			Related		
	#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		
	#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)

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	#E... number of events											
	n... number of subjects											
	Non-Serious						Serious					
	Not Related			Related			Not Related			Related		
	#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)

System Organ Class Preferred Term	Number of Subjects N=336											
	#E... number of events											
	n... number of subjects											
	Non-Serious						Serious					
	Not Related			Related			Not Related			Related		
	#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)

System Organ Class Preferred Term	Number of Subjects N=336											
	#E... number of events											
	n... number of subjects											
	Non-Serious						Serious					
	Not Related			Related			Not Related			Related		
	#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)

System Organ Class Preferred Term	Number of Subjects N=336											
	#E... number of events											
	n... number of subjects											
	Non-Serious						Serious					
	Not Related			Related			Not Related			Related		
	#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)

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

<i>System Organ Class Preferred Term</i>		<i>Number of Subjects N=336</i>											
		<i>#E... number of events</i>											
		<i>n... number of subjects</i>											
		<i>Non-Serious</i>						<i>Serious</i>					
		<i>Not Related</i>			<i>Related</i>			<i>Not Related</i>			<i>Related</i>		
		<i>#E</i>	<i>n</i>	<i>(%)</i>	<i>#E</i>	<i>n</i>	<i>(%)</i>	<i>#E</i>	<i>n</i>	<i>(%)</i>	<i>#E</i>	<i>n</i>	<i>(%)</i>
Hypotension		8	8	(2)	0	0	(0)	0	0	(0)	0	0	(0)
Peripheral vascular disorder		1	1	(0)	0	0	(0)	0	0	(0)	0	0	(0)
Thrombosis		3	3	(1)	0	0	(0)	0	0	(0)	0	0	(0)

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 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)