

Summary Tabulation of Fatal Cases and Adverse Events by System Organ Class (SOC) and Preferred Terms (PT) by Age Group

BNT162B2;BNT162B2 OMI;BNT162B2S01 - ALL
 Reporting Period: 19-DEC-2021 Through 18-JUN-2022
 Total Number of Cases: 13659 (100%) (ALL) / 13659 (OVERALL)
 Total Number of Adverse Events (PT): 52858 (ALL)
 MedDRA Version: v.25.0.

CT

Total Number of Cases: 150
 Total Number of Adverse Events (PT): 228

MedDRA System Organ Class (SOC) and MedDRA Preferred Terms (PTs)	18 - 24 years	25 - 49 years	50 - 59 years	60 - 69 years	70+ years
Blood and lymphatic system disorders					
Number of Cases					2
Number of Events					2
Anaemia					1
Splenic vein thrombosis					1
Cardiac disorders					
Number of Cases		3	8	11	15
Number of Events		3	8	12	16
Acute myocardial infarction				1	1
Atrial fibrillation					1
Cardiac arrest		1	2	3	4
Cardiac disorder					1
Cardiac failure congestive			1		1
Cardio-respiratory arrest			3	2	4
Coronary artery disease				2	
Hypertensive heart disease				1	1
Myocardial infarction		2	2	2	3
Pericardial haemorrhage				1	
Eye disorders					
Number of Cases			1		1
Number of Events			1		1
Blindness unilateral			1		
Optic ischaemic neuropathy					1
Gastrointestinal disorders					
Number of Cases			1	6	2
Number of Events			1	6	2
Acute abdomen					1
Duodenal perforation					1
Gastrointestinal haemorrhage			1	1	
Intestinal ischaemia				1	
Intestinal obstruction				2	
Large intestine perforation				1	

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*Only post birth cases included

MedDRA System Organ Class (SOC) and MedDRA Preferred Terms (PTs)	18 - 24 years	25 - 49 years	50 - 59 years	60 - 69 years	70+ years
Gastrointestinal disorders					
Number of Cases			1	6	2
Number of Events			1	6	2
Pancreatitis				1	
General disorders and administration site conditions					
Number of Cases		5	5	8	8
Number of Events		5	5	8	8
Condition aggravated		1	2		1
Death		4	3	4	3
Disease progression					2
Drowning					1
Multiple organ dysfunction syndrome				1	1
Sudden cardiac death				1	
Sudden death				2	
Hepatobiliary disorders					
Number of Cases				1	2
Number of Events				1	5
Bile duct stone					1
Biliary cyst				1	1
Biliary obstruction					1
Cholangitis					1
Jaundice cholestatic					1
Infections and infestations					
Number of Cases		3	8	12	11
Number of Events		6	10	12	12
Acquired immunodeficiency syndrome		2			
COVID-19		1	2	3	
COVID-19 pneumonia			1	3	1
Emphysematous cholecystitis					1
HIV infection		1			
Infection					1
Kidney infection					1
Lower respiratory tract infection		1			
Peritonitis				1	
Pneumocystis jirovecii pneumonia		1			
Pneumonia			1	1	2
Pneumonia aspiration			1	1	
Pneumonia bacterial				1	
Postoperative wound infection			1		
Sepsis			2	1	2
Septic shock			1	1	3
Shigella sepsis					1
Staphylococcal sepsis			1		

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MedDRA System Organ Class (SOC) and MedDRA Preferred Terms (PTs)	18 - 24 years	25 - 49 years	50 - 59 years	60 - 69 years	70+ years
Injury, poisoning and procedural complications					
Number of Cases	1	7	2	3	2
Number of Events	1	10	2	4	3
Accidental overdose		1			
Fall					1
Gun shot wound	1	1	1		
Head injury		1			
Injury		3		1	
Overdose		1	1	1	
Road traffic accident		2		2	1
Spinal cord injury					1
Toxicity to various agents		1			
Metabolism and nutrition disorders					
Number of Cases			1		
Number of Events			1		
Type 2 diabetes mellitus			1		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Number of Cases			2	5	14
Number of Events			2	7	16
Acute myeloid leukaemia					1
Adenocarcinoma					1
Adenocarcinoma of colon					1
Adenocarcinoma pancreas					3
Adrenocortical carcinoma					1
Angiosarcoma				1	
Biliary cancer metastatic				1	
Bladder cancer					1
Gastric cancer				1	
Glioblastoma			1		1
Hepatic cancer				1	
Lung cancer metastatic			1		
Metastases to liver				1	
Metastases to lung					1
Neoplasm progression					1
Pancreatic carcinoma					1
Pancreatic carcinoma metastatic					2
Pancreatic neoplasm				1	
Penis carcinoma metastatic					1
Triple negative breast cancer					1
Vascular neoplasm				1	
Nervous system disorders					
Number of Cases			3	2	5
Number of Events			3	2	5

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MedDRA System Organ Class (SOC) and MedDRA Preferred Terms (PTs)	18 - 24 years	25 - 49 years	50 - 59 years	60 - 69 years	70+ years
Nervous system disorders					
Number of Cases			3	2	5
Number of Events			3	2	5
Amyotrophic lateral sclerosis			1		
Basal ganglia haemorrhage			1		
Cerebrovascular accident			1		1
Dementia Alzheimer's type					2
Haemorrhagic stroke				1	2
Ischaemic stroke				1	
Psychiatric disorders					
Number of Cases	2	8		2	
Number of Events	2	8		2	
Alcohol abuse		1			
Completed suicide	2	6		2	
Drug abuse		1			
Renal and urinary disorders					
Number of Cases				1	1
Number of Events				1	1
Acute kidney injury					1
Oliguria				1	
Respiratory, thoracic and mediastinal disorders					
Number of Cases		2	3	9	4
Number of Events		2	3	9	6
Acute respiratory distress syndrome				1	
Acute respiratory failure		1	1	2	2
Chronic obstructive pulmonary disease				2	1
Pulmonary embolism		1		3	3
Pulmonary fibrosis			1		
Respiratory arrest			1		
Respiratory failure				1	
Social circumstances					
Number of Cases		1			
Number of Events		1			
Victim of crime		1			
Vascular disorders					
Number of Cases			2	4	6
Number of Events			2	4	7
Aneurysm					1
Aortic aneurysm					1
Aortic dissection				1	
Aortic rupture					1
Arteriosclerosis			1	2	1

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Vascular disorders					
Number of Cases			2	4	6
Number of Events			2	4	7
Deep vein thrombosis					1
Hypertensive emergency			1		
Hypovolaemic shock				1	
Neurogenic shock					1
Shock haemorrhagic					1

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Non CT

Total Number of Cases: 13509
Total Number of Adverse Events (PT): 52630

MedDRA System Organ Class (SOC) and MedDRA Preferred Terms (PTs)	less or equal to 17 years	18 - 24 years	25 - 49 years	50 - 59 years	60 - 69 years	70+ years	Unknown
Blood and lymphatic system disorders							
Number of Cases	8	7	43	40	71	364	23
Number of Events	14	10	59	55	97	513	29
Acquired haemophilia					1	3	
Agranulocytosis	1	1				2	
Anaemia	3		1	3	16	60	2
Anaemia folate deficiency						1	
Anaemia macrocytic			1			3	
Anaemia megaloblastic						1	
Anaemia vitamin B12 deficiency						1	
Antiphospholipid syndrome					1	3	
Aplastic anaemia				2	1	1	
Autoimmune haemolytic anaemia					1	6	
Autoimmune pancytopenia						1	
Bicytopenia						2	
Blood disorder					1	2	2
Blood loss anaemia					1	1	
Bone marrow failure	1		1			3	
Coagulation factor deficiency					1		
Coagulopathy	3	2	6	4	2	22	3
Coombs negative haemolytic anaemia						1	
Cytopenia						1	
Disseminated intravascular coagulation	1		4	3	10	35	
Elephantiasis						1	
Eosinophilia						2	
Febrile neutropenia				1		1	2
Haemolysis				1	2	3	
Haemolytic anaemia			1		1	3	
Haemolytic uraemic syndrome			1			1	
Haemorrhagic diathesis		1	1		2	3	
Haemorrhagic disorder					2		
Heparin-induced thrombocytopenia						2	
Hilar lymphadenopathy				1		2	
Hyperchromic anaemia						1	
Hypercoagulation				1		5	
Hyper eosinophilic syndrome						1	
Hyperleukocytosis					1	9	
Hypochromasia						1	
Hypocoagulable state						1	

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Blood and lymphatic system disorders							
Number of Cases	8	7	43	40	71	364	23
Number of Events	14	10	59	55	97	513	29
Hypofibrinogenaemia						1	
Immune thrombocytopenia		1	1	2	3	18	1
Increased tendency to bruise						1	
Iron deficiency anaemia					1	2	
Leukocytosis			1	3	1	22	1
Leukopenia					2	8	
Lymphadenitis						2	
Lymphadenopathy			8	7	6	32	4
Lymphadenopathy mediastinal				2		1	
Lymph node haemorrhage						1	
Lymph node pain			1			2	
Lymphocytic infiltration			2	1		1	
Lymphocytosis				1		2	
Lymphopenia					1	18	
Microangiopathic haemolytic anaemia			1		1		
Microcytic anaemia						3	
Monoclonal B-cell lymphocytosis						1	
Monocytosis						2	
Myelocytosis						1	
Myelosuppression					1	2	
Neutropenia			1	1	2	7	1
Neutrophilia					1	6	
Normochromic anaemia						1	
Normochromic normocytic anaemia						3	
Normocytic anaemia						6	
Nucleated red cells						1	
Pancytopenia		1	3	1	3	18	1
Paratracheal lymphadenopathy						1	
Platelet anisocytosis						1	
Platelet disorder						1	
Poikilocytosis						1	
Polycythaemia						2	
Red blood cell abnormality	1						
Retroperitoneal lymphadenopathy						2	
Sickle cell anaemia with crisis			1				
Spleen congestion						1	
Spleen disorder						1	
Spleen ischaemia						1	
Splenic artery thrombosis					1		

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Blood and lymphatic system disorders							
Number of Cases	8	7	43	40	71	364	23
Number of Events	14	10	59	55	97	513	29
Splenic haemorrhage						2	
Splenic induration			1			1	
Splenic infarction			1		4	9	
Splenic lesion						2	
Splenic thrombosis						3	
Splenic vein thrombosis			1			1	
Splenitis						1	
Splenomegaly			1	2	3	7	
Spontaneous haematoma					1		
Thrombocytopenia	2	4	14	15	18	98	9
Thrombocytopenic purpura						7	1
Thrombocytosis			1			4	
Thrombosis with thrombocytopenia syndrome			2	1	2	10	
Thrombotic microangiopathy			3	1	1	3	
Thrombotic thrombocytopenic purpura	2			2	1	7	2
White blood cell disorder					1		
Cardiac disorders							
Number of Cases	52	41	412	332	551	2,568	159
Number of Events	87	74	681	507	865	3,799	193
Acute cardiac event						4	
Acute coronary syndrome			5	3	7	36	2
Acute left ventricular failure			2	1		5	
Acute myocardial infarction	1		12	33	57	161	5
Acute right ventricular failure						1	
Angina pectoris			3	3	8	13	
Angina unstable						1	
Aortic valve calcification						1	
Aortic valve disease				1			
Aortic valve incompetence	1		1			6	
Aortic valve sclerosis						1	
Aortic valve stenosis				2		11	
Arrhythmia	2	8	34	16	34	120	2
Arrhythmia supraventricular			1			3	
Arteriosclerosis coronary artery			7	6	8	27	1
Arteriospasm coronary				1			
Arteritis coronary			1	1			
Atrial fibrillation			3	4	22	152	2
Atrial flutter					1	12	
Atrial tachycardia						1	

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Cardiac disorders							
Number of Cases	52	41	412	332	551	2,568	159
Number of Events	87	74	681	507	865	3,799	193
Atrial thrombosis					1	3	
Atrioventricular block	1		1		1	7	2
Atrioventricular block complete				2		8	
Atrioventricular block first degree					2	1	
Atrioventricular block second degree			1				
Atrioventricular dissociation		1					
Bradycardia	3	1	2	2	13	48	1
Bundle branch block bilateral							1
Bundle branch block left					1	4	
Bundle branch block right			1		2	7	
Cardiac amyloidosis						1	
Cardiac aneurysm					2	2	1
Cardiac arrest	19	11	125	112	177	570	27
Cardiac asthma						9	
Cardiac contractility decreased						1	
Cardiac discomfort			2			4	
Cardiac disorder	2	2	8	6	12	64	10
Cardiac dysfunction			4		2	7	
Cardiac failure	4	3	15	15	49	477	8
Cardiac failure acute	3	3	12	6	19	97	2
Cardiac failure chronic		1				25	
Cardiac failure congestive	1	1	3	5	11	68	4
Cardiac failure high output					1		
Cardiac fibrillation					1	4	
Cardiac flutter			1		3	3	
Cardiac hypertrophy			4	5	8	13	1
Cardiac perforation					1	1	
Cardiac steatosis			1	1			
Cardiac tamponade		1	3	3	7	23	
Cardiac valve disease		1			1	5	
Cardiac ventricular disorder						1	
Cardiac ventricular thrombosis			1		2	3	
Cardiogenic shock	2	1	14	11	17	63	1
Cardiomegaly	4	1	9	8	7	48	3
Cardiomyopathy	1	1	8	2	2	16	
Cardiopulmonary failure	1	1	4	2	7	54	
Cardiorenal syndrome						3	
Cardio-respiratory arrest	8	6	75	39	69	444	4

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Cardiac disorders							
Number of Cases	52	41	412	332	551	2,568	159
Number of Events	87	74	681	507	865	3,799	193
Cardio-respiratory distress						5	
Cardiovascular disorder			5	3	9	48	1
Cardiovascular insufficiency				1	1	6	
Cardiovascular symptom					1	2	
Carditis			1				1
Conduction disorder						1	
Congestive cardiomyopathy			4		4	4	
Coronary artery disease			4	13	8	27	3
Coronary artery embolism						1	
Coronary artery insufficiency						2	
Coronary artery occlusion			4	2	4	16	1
Coronary artery stenosis			1	7	3	14	
Coronary artery thrombosis			7	3	7	19	1
Cor pulmonale						5	1
Cor pulmonale acute				1	1	2	
Cor pulmonale chronic			1				
Diastolic dysfunction	1				2	1	
Dilatation ventricular			1			2	
Endocarditis noninfective			1				
Eosinophilic myocarditis			1	1			
Extrasystoles					1	4	
Haemorrhage coronary artery			1			2	
Hypersensitivity myocarditis						1	
Hypertensive cardiomyopathy					1	1	
Hypertensive heart disease			2	3	2	14	1
Immune-mediated myocarditis					1		
Intracardiac thrombus			4	3	7	9	
Intrapericardial thrombosis					1	1	
Ischaemic cardiomyopathy			1		1	8	1
Kounis syndrome						1	
Left atrial dilatation						1	
Left atrial enlargement			1				
Left ventricular dilatation			1				
Left ventricular dysfunction			3		1	8	
Left ventricular failure				3	1	16	1
Left ventricular hypertrophy			1	1	2	10	
Low cardiac output syndrome					1		
Mitral valve calcification						3	
Mitral valve disease				1			

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Cardiac disorders							
Number of Cases	52	41	412	332	551	2,568	159
Number of Events	87	74	681	507	865	3,799	193
Mitral valve incompetence	1		2		1	11	
Mitral valve sclerosis				1			
Mitral valve stenosis						1	
Myocardial fibrosis			6	6	3	11	
Myocardial haemorrhage			1			1	
Myocardial hypoxia				1	1		
Myocardial infarction	2	5	76	69	101	367	59
Myocardial injury			2	2		1	2
Myocardial ischaemia	1	1	11	13	15	86	6
Myocardial necrosis		1	1	3		6	
Myocardial oedema			2				
Myocardial rupture			1		6	14	
Myocarditis	12	10	60	19	32	65	21
Myopericarditis	1		2	1	2	2	
Nodal rhythm		1			1		
Palpitations	5		10	4	9	24	5
Papillary muscle disorder						1	
Papillary muscle rupture				1			
Paroxysmal arrhythmia			1			1	
Pericardial disease			1			1	
Pericardial effusion	2	1	6	4	6	32	1
Pericardial fibrosis						1	
Pericardial haemorrhage			1	4	3	17	
Pericardial mass		1					
Pericarditis		1	11	6	7	20	1
Pulmonary valve disease						1	
Pulseless electrical activity	2		8	3	4	13	
Rhythm idioventricular						1	
Right atrial dilatation						1	
Right atrial enlargement						2	
Right ventricular dilatation					1	3	
Right ventricular dysfunction		1			2		
Right ventricular enlargement			1			2	
Right ventricular failure		1	2		6	10	1
Right ventricular hypertrophy					1	1	
Sinus bradycardia						2	
Sinus node dysfunction						1	
Sinus tachycardia		1	3			5	
Stress cardiomyopathy			2	1	1	5	1

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Cardiac disorders							
Number of Cases	52	41	412	332	551	2,568	159
Number of Events	87	74	681	507	865	3,799	193
Subendocardial haemorrhage						1	
Subendocardial ischaemia				1			
Supraventricular extrasystoles						1	
Supraventricular tachyarrhythmia						1	
Supraventricular tachycardia					2	6	
Systolic dysfunction	1					1	
Tachyarrhythmia				1		4	
Tachycardia	2	3	24	12	13	114	4
Tachycardia induced cardiomyopathy			1				
Tachycardia paroxysmal						1	
Torsade de pointes						2	
Toxic cardiomyopathy			1				2
Tricuspid valve incompetance					1	3	
Ventricle rupture					1	2	
Ventricular arrhythmia			6		2	4	
Ventricular asystole			1				
Ventricular dysfunction			1	1		1	
Ventricular enlargement						1	
Ventricular extrasystoles	1		1			3	
Ventricular failure					1		
Ventricular fibrillation	2	3	23	18	19	45	2
Ventricular hypertrophy					1	3	
Ventricular hypokinesia		1	1	1	2	6	
Ventricular tachyarrhythmia					1		
Ventricular tachycardia	1		5	3	6	17	
Congenital, familial and genetic disorders							
Number of Cases	4	3	8	3	5	13	1
Number of Events	4	3	9	3	5	13	1
Aberrant aortic arch					1		
Accessory muscle						1	
Accessory spleen			1				
Aplasia						1	
Arrhythmogenic right ventricular dysplasia			1		1		
Arteriovenous malformation	1						
Branchial cyst						1	
Congenital anomaly							1
Congenital cystic kidney disease						1	
Factor V deficiency						1	
Factor VIII deficiency						1	

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Congenital, familial and genetic disorders							
Number of Cases	4	3	8	3	5	13	1
Number of Events	4	3	9	3	5	13	1
Factor XIII deficiency						1	
Falot's tetralogy	1	1	1			1	
Foramen magnum stenosis						1	
Heart disease congenital			1				
Hereditary ataxia						1	
Hereditary spherocytosis		1					
Huntington's disease				1			
Hypertrophic cardiomyopathy			3	1	2	3	
Hypoplastic left heart syndrome			1				
Long QT syndrome congenital	1						
Myocardial bridging	1						
Myotonic dystrophy			1				
Platybasia		1					
Ventricular septal defect				1			
VEXAS syndrome					1		
Ear and labyrinth disorders							
Number of Cases		1	5	1	3	36	5
Number of Events		1	6	1	4	39	6
Auditory disorder						1	
Deafness bilateral						1	
Ear discomfort					1		
Ear disorder					1		
Ear pain			2			5	2
Ear pruritus						1	
External ear pain					1		
Hypoacusis		1		1		3	1
Otolithiasis						1	
Otorrhoea						1	
Sudden hearing loss			1			1	
Tinnitus			1			3	3
Vertigo			1		1	22	
Vestibular disorder			1				
Endocrine disorders							
Number of Cases	1		5	3	3	18	1
Number of Events	1		5	3	3	18	1
Adrenal disorder						1	
Adrenal haemorrhage			1				
Adrenal insufficiency						2	
Adrenal mass					2		

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Endocrine disorders							
Number of Cases	1		5	3	3	18	1
Number of Events	1		5	3	3	18	1
Autoimmune thyroiditis							1
Cushing's syndrome						1	
Diabetes insipidus	1		1	1			
Goitre			1	1		2	
Growth hormone deficiency			1				
Hypercalcaemia of malignancy						1	
Hyperthyroidism						3	
Hypopituitarism				1			
Hypothyroidism						2	
Inappropriate antidiuretic hormone secretion						2	
Pituitary haemorrhage						1	
Pituitary infarction			1				
Thyroid disorder					1	1	
Thyroid mass						2	
Eye disorders							
Number of Cases	6	7	21	15	26	120	3
Number of Events	6	7	23	18	34	144	3
Amaurosis fugax						1	
Anisocoria	2	1		2	2	9	
Blindness			1	1	2	8	2
Blindness cortical				1	1		
Blindness unilateral						1	
Cataract cortical	1						
Conjunctival haemorrhage						2	
Conjunctival oedema						1	
Cystoid macular oedema						1	
Dark circles under eyes	1						
Diplopia			3		1	4	
Ectropion						1	
Exfoliation syndrome						1	
Eye discharge						1	
Eye disorder					1	5	
Eye haematoma						1	
Eye haemorrhage				1			
Eye infarction						1	
Eye inflammation						1	
Eyelid bleeding						1	
Eyelid haematoma						1	
Eyelid oedema						3	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

*Only post birth cases included

MedDRA System Organ Class (SOC) and MedDRA Preferred Terms (PTs)	less or equal to 17 years	18 - 24 years	25 - 49 years	50 - 59 years	60 - 69 years	70+ years	Unknown
Eye disorders							
Number of Cases	6	7	21	15	26	120	3
Number of Events	6	7	23	18	34	144	3
Eyelid ptosis						10	
Eye movement disorder			1	2		6	
Eye pain		1		1	4	2	
Eye pruritus				1		1	
Eye swelling					2	1	
Gaze palsy		1	2	1		9	
Keratic precipitates						1	
Lacrimation increased						4	
Lens disorder						1	
Lid sulcus deepened						1	
Miosis		1				3	
Mydriasis	2	1	4	3	2	7	
Ocular discomfort						1	
Ocular hyperaemia				1		4	
Ocular vascular disorder						1	
Ophthalmic vein thrombosis						1	
Ophthalmoplegia						1	
Orbital haematoma						1	
Orbital swelling						1	
Periorbital oedema					2		
Periorbital swelling					1	1	
Photophobia					1	1	
Pupil fixed			2		1	5	
Pupillary disorder						1	
Pupillary reflex impaired		1	1	2	2	5	
Retinal artery embolism						1	
Retinal artery occlusion						1	
Retinal degeneration			1				
Retinal detachment			1				
Retinal haemorrhage					1		
Retinal tear			1			1	
Strabismus			1			1	
Swelling of eyelid					1		
Vision blurred			3	1	2	5	
Visual acuity reduced						2	
Visual field defect						1	
Visual impairment		1	2	1	8	20	1

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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MedDRA System Organ Class (SOC) and MedDRA Preferred Terms (PTs)	less or equal to 17 years	18 - 24 years	25 - 49 years	50 - 59 years	60 - 69 years	70+ years	Unknown
Gastrointestinal disorders							
Number of Cases	29	20	126	107	203	1,302	54
Number of Events	46	32	184	157	312	1,970	76
Abdominal adhesions						1	
Abdominal discomfort		1		3	9	25	4
Abdominal distension		1	6	3	4	22	1
Abdominal hernia						2	
Abdominal incarcerated hernia						2	
Abdominal pain	4	2	21	11	34	126	6
Abdominal pain lower			1	1	1	5	
Abdominal pain upper	2	3	8	9	16	50	4
Abdominal rigidity						1	
Abdominal symptom						1	
Abdominal tenderness						4	
Abdominal wall haematoma					1	3	
Abdominal wall haemorrhage						1	
Abnormal faeces	1				1	2	
Acetonaemic vomiting				1			
Acute abdomen				1	1	7	
Anal haemorrhage						2	
Anal incontinence				1		12	
Anal sphincter atony	1				1	1	
Anorectal disorder						1	
Aphthous ulcer			1			2	
Ascites			4	1	4	17	
Autoimmune pancreatitis						1	
Change of bowel habit						1	
Chronic gastritis						1	
Coating in mouth						1	
Coeliac artery stenosis						1	
Colitis				1		2	2
Colitis ischaemic					1	4	
Constipation		2		1	4	28	
Crohn's disease				1	1		
Defaecation disorder	1					2	
Diarrhoea	7	2	21	17	32	213	9
Diarrhoea haemorrhagic						3	
Discoloured vomit				1		1	
Diverticular perforation						1	
Diverticulum						1	
Diverticulum intestinal					1	2	
Dry mouth				1		6	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Gastrointestinal disorders							
Number of Cases	29	20	126	107	203	1,302	54
Number of Events	46	32	184	157	312	1,970	76
Duodenal ulcer						2	1
Duodenal ulcer haemorrhage						1	
Duodenal ulcer perforation				1			
Duodenitis						1	
Dyschezia					1	1	
Dyspepsia			1	1	5	11	1
Dysphagia			5	2	10	119	5
Enteritis			2	1		1	1
Enterocolitis						2	
Enterovesical fistula					1	1	
Epigastric discomfort					1	3	
Eructation				1		2	
Faecaloma						7	
Faecal vomiting						8	
Faeces discoloured					3	11	
Flatulence						4	
Food poisoning						1	
Functional gastrointestinal disorder					1	2	
Gastric dilatation				1		1	
Gastric disorder	1			2	1	2	
Gastric haemorrhage						11	1
Gastric ulcer	1					3	
Gastric ulcer haemorrhage					1	2	
Gastric ulcer perforation		1					
Gastric volvulus						1	
Gastritis					1	3	1
Gastritis erosive	1					4	
Gastritis haemorrhagic			1			1	
Gastrointestinal disorder				2	3	13	
Gastrointestinal haemorrhage			4	3	8	41	4
Gastrointestinal hypomotility	1						
Gastrointestinal inflammation						4	
Gastrointestinal necrosis			1	2	4	14	
Gastrointestinal obstruction						2	
Gastrointestinal oedema					1		
Gastrointestinal pain						3	1
Gastrointestinal perforation			1				
Gastrointestinal sounds abnormal			1			1	
Gastrointestinal ulcer						1	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Gastrointestinal disorders							
Number of Cases	29	20	126	107	203	1,302	54
Number of Events	46	32	184	157	312	1,970	76
Gastroesophageal reflux disease					1	4	
Gingival bleeding			1	1		1	
Gingival pain						1	1
Gingival swelling			1	1			
Glossoptosis			1			1	
Haematemesis	2	1	2	2	6	46	6
Haematochezia					2	15	1
Haemoperitoneum			1		1	1	
Haemorrhagic necrotic pancreatitis			1				
Haemorrhoidal haemorrhage						2	
Haemorrhoids					1	2	1
Hiatus hernia					2	3	
Hiatus hernia strangulated						1	
Hypoaesthesia oral			1			2	
Ileus			1	3	1	9	
Ileus paralytic			1		1	12	
Inguinal hernia						2	
Intestinal dilatation					1	1	
Intestinal haemorrhage						7	
Intestinal infarction				1	2	12	
Intestinal ischaemia	1	1		3	10	48	
Intestinal obstruction		1	2			16	
Intestinal perforation			1		1	7	
Intestinal pseudo-obstruction			1				
Intestinal ulcer						1	
Intra-abdominal fluid collection						1	
Intra-abdominal haematoma						1	
Intra-abdominal haemorrhage	1					1	
Ischaemic enteritis						1	
Large intestinal haemorrhage				1			
Large intestinal obstruction				1		2	1
Large intestine perforation					2	3	
Lip discolouration						2	
Lip dry						1	
Lip erosion						1	
Lip haemorrhage			1				
Lip oedema						2	
Lip pain						1	
Lip swelling			1		2	2	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Gastrointestinal disorders							
Number of Cases	29	20	126	107	203	1,302	54
Number of Events	46	32	184	157	312	1,970	76
Lower gastrointestinal haemorrhage						2	
Mallory-Weiss syndrome				1			
Megacolon						1	
Melaena			2		2	19	
Mesenteric arterial occlusion						3	
Mesenteric artery embolism						3	
Mesenteric artery thrombosis						5	
Mesenteric vascular insufficiency						1	
Mesenteric vascular occlusion						1	
Mesenteric vein thrombosis			1	2	2	6	
Mouth haemorrhage			1	1	3	10	1
Mouth swelling						2	1
Mouth ulceration					1		
Nausea	5	5	31	24	32	276	7
Noninfective gingivitis						2	
Obturator hernia						1	
Odynophagia						1	
Oesophageal haemorrhage				1			
Oesophageal pain						1	
Oesophageal ulcer haemorrhage						1	
Oesophageal varices haemorrhage				1	1	3	
Oesophagitis					1		
Oral discharge						1	
Oral disorder						2	
Oral mucosal blistering					1		
Oral mucosal exfoliation						1	
Oral pain						1	
Overflow diarrhoea						1	
Pancreatic disorder		1					
Pancreatic enlargement						1	
Pancreatic infarction						1	
Pancreatic steatosis						3	
Pancreatitis			3	1		5	1
Pancreatitis acute			1		4	9	1
Pancreatitis chronic					1		
Pancreatitis necrotising						2	
Pancreatitis relapsing						1	
Paraesthesia oral				1		2	
Peptic ulcer						1	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Gastrointestinal disorders							
Number of Cases	29	20	126	107	203	1,302	54
Number of Events	46	32	184	157	312	1,970	76
Peptic ulcer haemorrhage						1	
Peritoneal disorder					1		
Peritoneal perforation						1	
Pneumatosis intestinalis					1		
Pneumoperitoneum		1				2	
Poor dental condition						1	
Portal hypertensive gastropathy						1	
Portal venous gas					1		
Rectal haemorrhage						13	
Rectal perforation					1		
Rectal ulcer						1	
Regurgitation						4	
Retching			1			10	1
Retroperitoneal haematoma			1			1	
Retroperitoneal haemorrhage						1	
Retroperitoneal mass				1			
Salivary hypersecretion				2		4	
Small intestinal haemorrhage						3	
Small intestinal obstruction					1	3	
Stasis syndrome					1		
Stomatitis					1	2	
Subileus					1	6	
Swollen tongue				1	1	4	
Thrombosis mesenteric vessel					1	2	
Tongue erythema		1					
Tongue oedema						1	
Toothache					1	3	
Tooth loss						1	
Truncus coeliacus thrombosis						3	
Umbilical hernia						1	
Upper gastrointestinal haemorrhage					2	11	
Varices oesophageal							1
Visceral venous thrombosis				1			
Volvulus						4	
Vomiting	17	9	49	38	66	466	12
General disorders and administration site conditions							
Number of Cases	99	77	586	527	931	5,423	877
Number of Events	153	98	926	757	1,447	8,225	1,021
Administration site reaction			1				

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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General disorders and administration site conditions							
Number of Cases	99	77	586	527	931	5,423	877
Number of Events	153	98	926	757	1,447	8,225	1,021
Adverse drug reaction			1				
Adverse event					1	1	
Adverse reaction						1	
Apparent death					1		
Asthenia	7	2	38	31	77	477	13
Atrophy						1	
Axillary pain			1			2	
Brain death	3	4	12	9	7	10	3
Cardiac death			8	6	11	48	1
Chest discomfort	1	2	11	12	17	61	3
Chest pain	2	5	68	39	61	179	9
Chills	4	3	27	11	32	137	4
Chronic disease						1	
Clinical death						1	
Concomitant disease aggravated				2	4	6	1
Concomitant disease progression			1		3	14	
Condition aggravated	1	1	10	9	21	189	9
Crepitations	1					8	1
Critical illness	1					1	
Crying					1	1	
Cyst			1				
Death	42	25	210	211	296	1,628	604
Decapitation							1
Decreased activity			1			7	1
Device related thrombosis						1	
Discomfort			9	8	4	37	2
Disease complication					1		
Disease progression					1	15	2
Disease recurrence			4	5	11	65	3
Drowning	1		2	2	2	18	1
Drug ineffective	5	4	21	27	85	532	178
Drug ineffective for unapproved indication						1	
Drug interaction			2		1	5	1
Drug resistance						1	
Effusion	1		1			4	
Enanthema						1	
Exercise tolerance decreased			1		1	3	
Extensive swelling of vaccinated limb	1		1				
Extravasation					1		

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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General disorders and administration site conditions							
Number of Cases	99	77	586	527	931	5,423	877
Number of Events	153	98	926	757	1,447	8,225	1,021
Face oedema					1	9	
Facial pain			1				
Fatigue	7	7	57	37	79	476	23
Fat necrosis						1	
Feeling abnormal	3	1	14	4	9	46	4
Feeling cold	1		4	1	5	22	4
Feeling drunk						2	
Feeling hot	1		1	2	3	18	1
Feeling jittery				1			
Feeling of body temperature change			3		1	2	
Fibrosis			1		2		
Foaming at mouth	1		2	3	2	6	
Gait disturbance	1		4	6	19	71	2
Gait inability	1		3	1	2	38	4
Generalised oedema			4	1	3	13	
General physical health deterioration		2	10	12	35	482	12
General symptom				1		1	
Glassy eyes						1	
Gravitational oedema				1		1	
Hernia		1			1	1	
Hernia pain						1	
Hyperpyrexia			3	3	5	18	
Hyperthermia		1	3	1	4	31	
Hypertrophy				1	2		
Hypothermia		1	2		2	32	
Ill-defined disorder						1	
Illness	1	1	7	3	15	30	10
Induration						1	
Inflammation			2	2	19	53	
Influenza like illness	1		13	12	9	48	1
Infusion site pain			1				
Injected limb mobility decreased			1			1	
Injection site discomfort						1	
Lithiasis			1				
Localised oedema						1	
Local reaction					4	5	1
Loss of control of legs						2	
Loss of therapeutic response						1	
Melaise	7	6	59	56	130	545	28

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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General disorders and administration site conditions							
Number of Cases	99	77	586	527	931	5,423	877
Number of Events	153	98	926	757	1,447	8,225	1,021
Mass				1		3	
Moaning			1			7	
Mucosal dryness						1	
Mucosal haemorrhage						1	
Mucosal inflammation						1	
Mucosal necrosis					1		
Mucosal ulceration						1	
Multimorbidity				1		1	
Multi-organ disorder	1		1			3	
Multiple organ dysfunction syndrome	3	2	23	15	35	158	5
Necrosis			2	1	1	4	
Nodule			1			2	1
Obstruction						1	
Oedema	2		5		2	30	2
Oedema peripheral	1		4	6	9	99	4
Organ failure			4	3	2	19	3
Pain	2	1	16	17	31	148	7
Perforation					2		
Performance status decreased			1			3	
Peripheral swelling	1		8	5	7	47	10
Physical deconditioning			5	4	8	34	
Pneumatosis						1	
Polyp					1		
Prolapse						2	
Prosthetic cardiac valve thrombosis						2	
Puncture site haematoma					1		
Puncture site haemorrhage					1		
Pyrexia	30	16	109	60	143	866	29
Secretion discharge				2	1	5	
Sensation of foreign body						1	
Sense of oppression					1	1	
Sluggishness			1			2	
Stenosis					1	4	
Stent-graft endoleak						1	
Sudden cardiac death	3	2	12	15	21	49	4
Sudden death	8	5	62	61	94	466	9
Sudden unexplained death in epilepsy			1				
Suprapubic pain						1	
Swelling		1	3	1	3	18	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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General disorders and administration site conditions							
Number of Cases	99	77	586	527	931	5,423	877
Number of Events	153	98	926	757	1,447	8,225	1,021
Swelling face		1			3	11	
Systemic inflammatory response syndrome			2	1		9	1
Temperature regulation disorder					1		
Tenderness			1		1	2	
Terminal state				1		5	1
Therapeutic response decreased					1		
Therapeutic response unexpected						1	
Thirst	1	1		1		3	
Unevaluable event			1				
Unmasking of previously unidentified disease						1	
Vaccination failure	1	2	9	22	58	680	13
Vaccination site bruising						1	
Vaccination site dermatitis				1			
Vaccination site discolouration					1		
Vaccination site discomfort			1			1	
Vaccination site erythema			1		2	13	1
Vaccination site haematoma						1	
Vaccination site haemorrhage				1		2	
Vaccination site hypoaesthesia			1				
Vaccination site induration			1				
Vaccination site inflammation				2		6	
Vaccination site joint discomfort						1	
Vaccination site mass						1	
Vaccination site nodule						1	
Vaccination site oedema						1	
Vaccination site pain	5	1	18	14	20	65	2
Vaccination site paraesthesia						1	
Vaccination site pruritus			1		1	2	
Vaccination site rash					1	1	
Vaccination site reaction	1		2		1	1	2
Vaccination site scar						1	
Vaccination site swelling			2	1		8	
Vaccination site warmth						4	
Vascular stent stenosis					1	1	
Vascular stent thrombosis						2	
Visceral pain				1			
Hepatobiliary disorders							
Number of Cases	2	2	32	26	51	150	9
Number of Events	2	2	44	31	79	209	10

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Hepatobiliary disorders							
Number of Cases	2	2	32	26	51	150	9
Number of Events	2	2	44	31	79	209	10
Acute hepatic failure				1	2	2	
Autoimmune cholangitis						1	
Autoimmune hepatitis						3	
Bile duct stone					2		
Biliary colic						1	
Cardiac cirrhosis					1		
Cholangitis					3	5	
Cholangitis acute						2	
Cholecystitis					3	7	
Cholecystitis acute						1	
Cholelithiasis				2	4	18	
Cholestasis			1			1	
Chronic hepatic failure					1		
Cirrhosis alcoholic			1			1	
Congestive hepatopathy			4	1	2	5	1
Drug-induced liver injury					1	2	
Fatty liver alcoholic					1		
Gallbladder cholesterosis					1		
Gallbladder disorder						1	
Gallbladder enlargement						1	
Gallbladder hypofunction						1	
Gallbladder oedema						1	
Gallbladder polyp						1	
Hepatic atrophy						1	
Hepatic cirrhosis			1		2	7	1
Hepatic cyst				1		1	
Hepatic cytolysis			1	1	1	4	
Hepatic failure	1		6	3	12	27	
Hepatic fibrosis			1	1	1		
Hepatic function abnormal			1	4	3	15	1
Hepatic haemorrhage			2	1	1		
Hepatic infarction					4	3	
Hepatic ischaemia						1	
Hepatic lesion						5	
Hepatic mass			1			1	
Hepatic necrosis			1			1	
Hepatic pain					1	2	
Hepatic steatosis			5	4	3	5	1
Hepatic vein thrombosis				1			

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Hepatobiliary disorders							
Number of Cases	2	2	32	26	51	150	9
Number of Events	2	2	44	31	79	209	10
Hepatitis			1			5	1
Hepatitis acute			2			4	
Hepatitis fulminant						1	
Hepatitis toxic						1	
Hepatocellular injury				1		1	
Hepatomegaly			2	1	3	2	
Hepatorenal failure						1	
Hepatorenal syndrome			1		1	3	1
Hepatosplenomegaly						2	
Hepatotoxicity						2	
Hydrocholecystis					1		
Hyperbilirubinaemia			1			4	
Hypertransaminaemia		2			2	1	1
Ischaemic hepatitis					3	1	
Jaundice			4	1	4	22	
Jaundice cholestatic						3	
Liver disorder	1		3	2	7	15	
Liver injury			2	1		2	1
Non-alcoholic fatty liver			1				
Ocular icterus			1		1	3	
Portal hypertension						2	
Portal vein embolism							1
Portal vein phlebitis						1	
Portal vein thrombosis			1	5	7	5	1
Portosplenomesenteric venous thrombosis						1	
Subacute hepatic failure					1		
Immune system disorders							
Number of Cases	7	2	22	24	20	121	18
Number of Events	8	2	24	26	21	131	19
Allergy to vaccine						1	
Amyloidosis						1	2
Anamnestic reaction						2	
Anaphylactic reaction	3		3	3	6	32	4
Anaphylactic shock	2		2	4	2	8	
Anaphylactoid reaction						1	
Anti-neutrophil cytoplasmic antibody positive vasculitis						6	
Autoimmune disorder		1	2	3		5	2
Corneal graft rejection						1	
Cytokine release syndrome				2			

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Immune system disorders							
Number of Cases	7	2	22	24	20	121	18
Number of Events	8	2	24	26	21	131	19
Cytokine storm	1		1	1	1	2	1
Drug hypersensitivity					1		1
Eosinophilic granulomatosis with polyangiitis				1		1	
Food allergy							1
Haemophagocytic lymphohistiocytosis			3	3	4	11	1
Heart transplant rejection			1				
Hypersensitivity		1	3	1	2	14	2
Hypogammaglobulinaemia						1	
Immune-mediated adverse reaction				1		1	
Immune reconstitution inflammatory syndrome				1			
Immune system disorder			2	2	3	13	3
Immunisation reaction			2	2	1	10	1
Immunodeficiency				1		1	
Immunosuppression						3	
Kidney transplant rejection	1						
Lung transplant rejection			1		1		
Multisystem inflammatory syndrome	1					2	
Multisystem inflammatory syndrome in adults			1				
Overlap syndrome						1	
Primary amyloidosis						1	
Reaction to excipient						1	
Sarcoidosis			1			1	
Serum sickness							1
Systemic immune activation						2	
Transplant rejection			1	1			
Type I hypersensitivity						1	
Type IV hypersensitivity reaction						1	
Vaccine associated enhanced disease						6	
Vaccine associated enhanced respiratory disease			1			1	
Infections and infestations							
Number of Cases	22	22	114	130	336	2,533	331
Number of Events	33	30	167	165	476	3,277	348
Abdominal infection						1	
Abdominal sepsis					1	1	
Abscess					1	3	
Acarodermatitis						1	
Achromobacter infection				1			
Acinetobacter bacteraemia					1		
Acinetobacter infection			1				

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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MedDRA System Organ Class (SOC) and MedDRA Preferred Terms (PTs)	less or equal to 17 years	18 - 24 years	25 - 49 years	50 - 59 years	60 - 69 years	70+ years	Unknown
Infections and infestations							
Number of Cases	22	22	114	130	336	2,533	331
Number of Events	33	30	167	165	476	3,277	348
Acute hepatitis B					1		
Aerococcus urinae infection						1	
Anal abscess		1					
Appendicitis							1
Arteriosclerotic gangrene						1	
Aspergillus infection						2	
Asymptomatic bacteriuria						2	
Asymptomatic COVID-19				1	1	19	1
Atypical mycobacterial infection						1	
Atypical pneumonia			1			5	
Bacteraemia			1		1	6	
Bacterial infection		1	1		2	10	1
Bacterial pyelonephritis						1	
Bacterial sepsis					1	7	
Bacteriuria					1	1	
Bacteroides bacteraemia				1	1		
Beta haemolytic streptococcal infection			1				
Biliary tract infection						1	
Blister infected							1
Bone abscess						1	
Brain abscess						1	
Bronchiolitis					1	1	1
Bronchitis				2	4	26	1
Bronchitis bacterial					1	1	
Bronchopulmonary aspergillosis						2	
Campylobacter infection						1	
Candida infection						1	
Candida sepsis			1			2	
Cardiac infection			1			3	3
Cardiac valve vegetation						1	
Catheter site infection						1	
Cavernous sinus thrombosis		1					
Cellulitis					3	13	
Central nervous system infection	1					1	
Chronic active Epstein-Barr virus infection						1	
Clostridium difficile colitis						2	
Clostridium difficile infection			1			4	2
Colon gangrene						1	
Community acquired infection						1	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Infections and infestations							
Number of Cases	22	22	114	130	336	2,533	331
Number of Events	33	30	167	165	476	3,277	348
Conjunctivitis					2	4	
Conjunctivitis bacterial						1	
Coronavirus infection						4	
Coronavirus pneumonia					1		
COVID-19	6	4	30	44	138	1,106	252
COVID-19 pneumonia		1	9	14	49	392	4
Creutzfeldt-Jakob disease				2	9	14	2
Cystitis				1		5	
Cytomegalovirus enterocolitis						1	
Cytomegalovirus infection				1	1		
Cytomegalovirus infection reactivation					1		
Cytomegalovirus viraemia						1	
Dermo-hypodermatitis						1	
Device related infection			1			1	
Diarrhoea infectious						1	
Disseminated Bacillus Calmette-Guerin infection						1	
Diverticulitis						3	1
Dysentery					1	1	
Ear infection						1	
Eczema herpeticum						1	
Encephalitis			4	2	4	13	3
Encephalitis brain stem						1	
Encephalitis viral						3	
Encephalomyelitis viral						1	
Endocarditis		1	4	2	4	13	
Endocarditis staphylococcal						1	
Endotoxic shock						1	
Enteritis infectious						2	
Enterobacter infection						2	
Enterobacter sepsis						1	
Enterococcal infection			1		1	1	
Enterococcal sepsis				1			
Enterovirus infection	1						
Epstein-Barr virus infection	1					1	
Epstein-Barr virus infection reactivation						1	
Erysipelas				1	2	12	
Escherichia infection			1			3	
Escherichia pyelonephritis						1	
Escherichia sepsis			1		1	5	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Infections and infestations							
Number of Cases	22	22	114	130	336	2,533	331
Number of Events	33	30	167	165	476	3,277	348
Escherichia urinary tract infection						6	
Febrile infection						3	
Focal peritonitis						1	
Fournier's gangrene			1				
Fungaemia						1	
Fungal infection			1			1	1
Fungal skin infection						1	
Furuncle						1	
Gangrene					1	4	
Gastric infection				1			
Gastroenteritis		1	1	1	1	5	
Gastroenteritis bacterial					1		
Gastrointestinal infection			1			1	
Genital herpes						1	
Gingival abscess						1	
Haemorrhagic pneumonia			2				
Hepatitis C						2	1
Herpes simplex					1		
Herpes simplex encephalitis						3	
Herpes virus infection			1			1	
Herpes zoster				2	4	27	1
Herpes zoster meningitis						1	
Herpes zoster meningoencephalitis						3	
Human herpesvirus 6 infection	1						
Human herpesvirus 7 infection	1						
Ileal gangrene					1		
Infected skin ulcer							1
Infection		1	5	2	10	55	1
Infection susceptibility increased						1	
Infective aneurysm						1	
Infective exacerbation of chronic obstructive airways disease				1	1		
Infective myositis						1	
Infective spondylitis						1	
Influenza			2	2	4	22	1
Infusion site infection		1					
Intervertebral discitis						3	
Intestinal gangrene				1			
Kidney infection						1	1
Klebsiella bacteraemia					1		

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Infections and infestations							
Number of Cases	22	22	114	130	336	2,533	331
Number of Events	33	30	167	165	476	3,277	348
Klebsiella infection		1	2		2	6	
Labyrinthitis				1			
Laryngitis						1	
Legionella infection						2	
Leptospirosis				1			
Listeriosis						1	
Liver abscess					2		
Localised infection					1	3	
Lower respiratory tract infection			1	3	5	26	3
Lower respiratory tract infection bacterial					1		
Lower respiratory tract infection viral						1	
Lung abscess						3	
Lymphangitis						1	
Mastoiditis						1	
Meningitis			1		1	6	
Meningitis aseptic			1				
Meningitis bacterial						3	
Meningitis herpes						1	
Meningitis meningococcal	1						
Meningitis pneumococcal						1	
Meningitis viral			1				
Meningoencephalitis bacterial						1	
Meningoencephalitis herpetic				1		2	1
Meningoencephalitis viral			2			2	
Mucormycosis					1		
Mycobacterial infection						1	
Myelitis			1		1	3	
Myocarditis infectious						1	1
Myocarditis septic						2	
Nasopharyngitis	3	1	7	4	6	34	1
Necrotising fasciitis			2		1	2	
Neutropenic sepsis					1	1	
Nosocomial infection			1		2	1	
Ophthalmic herpes zoster						2	1
Oral candidiasis					1	5	
Oral fungal infection						4	
Oral herpes			1			3	
Orchitis					1		
Osteomyelitis						3	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Infections and infestations							
Number of Cases	22	22	114	130	336	2,533	331
Number of Events	33	30	167	165	476	3,277	348
Otitis media						1	
Overgrowth bacterial						1	
Parainfluenzae virus infection						1	
Parotitis						1	
Pathogen resistance					1		
Peptostreptococcus infection					1		
Pericarditis tuberculous						1	
Periorbital infection						1	
Peritonitis		1	1	2	2	5	
Peritonitis bacterial						1	1
Pertussis			1				
Pharyngitis		1	1	1		2	
Pharyngotonsillitis			1				
Pleurisy viral	1						
Pneumococcal bacteraemia						1	
Pneumococcal infection						2	
Pneumococcal sepsis	1						
Pneumocystis jirovecii infection						2	
Pneumocystis jirovecii pneumonia						2	
Pneumonia	4	4	17	20	57	476	14
Pneumonia aspiration		2	8	5	10	135	5
Pneumonia bacterial	1		2		4	31	1
Pneumonia escherichia						1	
Pneumonia fungal					1		
Pneumonia klebsiella			1	1	1	6	
Pneumonia legionella						1	
Pneumonia moraxella						1	
Pneumonia pneumococcal	1				1	2	
Pneumonia pseudomonal					1	1	
Pneumonia staphylococcal			1		1	2	
Pneumonia viral	1				1	6	1
Post-acute COVID-19 syndrome						1	
Prion disease			1		1		
Progressive multifocal leukoencephalopathy				1			
Proteus infection			1				
Pseudomembranous colitis						1	
Pseudomonal bacteraemia						1	
Pseudomonas infection						5	
Pulmonary sepsis	1				1	9	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Infections and infestations							
Number of Cases	22	22	114	130	336	2,533	331
Number of Events	33	30	167	165	476	3,277	348
Pulmonary tuberculosis					2		
Purulent discharge						1	
Pustule						1	
Pyelonephritis					2	11	
Pyelonephritis acute						4	
Renal graft infection						1	
Respiratory tract infection				2		26	
Respiratory tract infection bacterial						2	
Respiratory tract infection viral						1	
Retroperitoneal abscess						1	
Rhinitis			2			4	
Rhinovirus infection	1				1		
Salmonella sepsis						1	
Salmonellosis						1	
SARS-CoV-2 sepsis					1		
Scrub typhus				1			
Sepsis	1	1	11	14	35	156	12
Sepsis syndrome						3	
Septic arthritis staphylococcal						1	
Septic embolus						1	
Septic encephalopathy					1	1	
Septic rash					1		
Septic shock	4	4	11	12	33	93	2
Serratia infection					1	1	
Severe acute respiratory syndrome				1		5	
Severe fever with thrombocytopenia syndrome				1		2	
Severe invasive streptococcal infection						1	
Sinusitis			1	1	1	4	
Skin bacterial infection						1	
Skin infection						2	
Soft tissue infection						3	
Spinal cord infection				1			
Splenic infection						2	
Sputum purulent						1	
Staphylococcal bacteraemia				1		5	
Staphylococcal infection			2		1	8	
Staphylococcal sepsis						9	
Streptococcal infection						1	
Streptococcal sepsis						2	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Infections and infestations							
Number of Cases	22	22	114	130	336	2,533	331
Number of Events	33	30	167	165	476	3,277	348
Subcutaneous abscess							1
Superinfection						3	
Superinfection bacterial					1	7	
Suspected COVID-19	1	2	4	4	10	42	21
Systemic bacterial infection			1				
Systemic infection						1	
Systemic viral infection			1				
Testicular abscess					1		
Tonsillitis					1	2	
Tooth abscess						2	
Tooth infection			1			2	
Toxic shock syndrome				1	1	1	
Toxoplasmosis						1	
Tracheobronchitis						1	
Tracheobronchitis bacterial						2	
Tuberculosis						2	
Tuberculosis of central nervous system						1	
Upper respiratory tract infection					1	6	
Urinary tract infection			1	1	7	94	3
Urinary tract infection bacterial					1	10	
Urinary tract infection enterococcal						1	
Urinary tract infection fungal						2	
Urosepsis					3	27	
Vaccination site abscess					1	1	
Vaccine associated paralytic poliomyelitis						1	
Vaccine breakthrough infection			1			4	
Variant Creutzfeldt-Jakob disease				1			
Varicella					1		
Varicella zoster virus infection	1						
Vascular device infection						2	
Viral infection		1		1		3	
Viral myocarditis			1		1	2	
Viral pericarditis						1	
Viral sepsis						1	
Virologic failure						1	
Waterhouse-Friderichsen syndrome			1				
Zoonotic bacterial infection			1				

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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MedDRA System Organ Class (SOC) and MedDRA Preferred Terms (PTs)	less or equal to 17 years	18 - 24 years	25 - 49 years	50 - 59 years	60 - 69 years	70+ years	Unknown
Injury, poisoning and procedural complications	24	19	122	114	186	983	85
Number of Cases	27	22	133	131	216	1,217	93
Number of Events							
Accident	1						
Accident at home						1	
Acetabulum fracture						1	
Adverse event following immunisation	3	1	12	8	7	11	4
Alcohol poisoning			1	1		2	
Anaemia postoperative						1	
Anastomotic complication				1			
Animal bite			1				
Ankle fracture						1	
Arthropod bite						1	
Back injury						1	
Bone contusion						2	
Brain contusion						1	
Brain herniation	2	2	2	6	4	13	
Burn oral cavity							1
Carbon monoxide poisoning						1	
Cardiac procedure complication			1	1			
Central nervous system injury						1	
Cerebral ventricle collapse				1			
Chest injury						6	
Chillblains		1					
Complications of transplanted kidney					1		
Concussion					1		
Contusion	1	1	2	3	7	35	1
Craniocerebral injury				1		5	
Eschar						1	
Expired product administered		1				2	
Exposure during pregnancy			2				
Exposure to SARS-CoV-2						1	
Exposure to toxic agent			1				
Exposure to vaccinated person				1			
Extra dose administered				2	2	16	1
Extradural haematoma			1			2	
Eye injury			1			1	
Face crushing					1		
Face injury						3	
Facial bones fracture				1		2	
Fall	2	1	14	17	33	377	5
Fat embolism						1	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Injury, poisoning and procedural complications	24	19	122	114	186	983	85
Number of Cases	27	22	133	131	216	1,217	93
Number of Events							
Femoral neck fracture						9	
Femur fracture						4	
Foetal exposure during pregnancy		1					
Foot fracture					1		
Foreign body aspiration			1				
Foreign body in respiratory tract						2	
Foreign body in throat					1		
Fracture	1			2		5	
Gun shot wound							1
Haemolytic transfusion reaction		1					
Hand fracture						1	
Head injury	1		1	3	3	30	
Heat illness					3	5	
Heat oedema			1				
Hip fracture						5	
Humerus fracture						1	
Inappropriate schedule of product administration	4	8	31	26	44	166	4
Incisional hernia						1	
Incomplete course of vaccination				1		1	
Incorrect dosage administered					1		
Incorrect dose administered					1	8	1
Incorrect route of product administration			5	4	6	35	1
Injection related reaction				1			
Injury				1	1	4	2
Intentional product misuse							1
Intentional product use issue				1		1	
Joint injury			1			3	
Limb injury					1	2	
Liver contusion			1				1
Lower limb fracture						1	
Lumbar vertebral fracture						1	
Maternal exposure during pregnancy		2	5	1			
Maternal exposure timing unspecified			1				3
Medication error				1			
Multiple fractures						2	
Multiple injuries	1				1	1	
Muscle rupture						1	
Muscle strain			1			1	
Near drowning		1				8	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Injury, poisoning and procedural complications	24	19	122	114	186	983	85
Number of Cases	27	22	133	131	216	1,217	93
Number of Events							
Neck injury				1			
Nerve injury	1					1	
Off label use	4	2	33	31	67	261	27
Optic nerve injury					1		
Overdose			2	2	2	11	
Patella fracture						1	
Pelvic fracture						3	
Periprosthetic fracture						1	
Pneumoconiosis						3	
Poisoning					1	2	
Poor quality product administered			2				2
Postoperative delirium						1	
Postoperative ileus						1	
Post procedural haemorrhage						2	
Post vaccination syndrome			1				
Procedural pain						1	
Product administered at inappropriate site						5	
Product administered to patient of inappropriate age	3						
Product administration interrupted							1
Product dose omission issue				1			
Product prescribing error						1	
Product use in unapproved indication						1	
Product use issue			2	2	5	27	2
Radiation pneumonitis						1	
Radius fracture						1	
Recalled product administered						1	
Rib fracture			2	1	2	9	
Road traffic accident	1			2	4	1	
Scapula fracture						1	
Scar					1	1	
Scratch						1	
Scrotal injury						1	
Shunt stenosis						1	
Shunt thrombosis					1	1	
Skin abrasion						5	
Skin injury						1	
Skin laceration				1		6	
Skin wound						1	
Skull fracture				1	1	1	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Injury, poisoning and procedural complications	24	19	122	114	186	983	85
Number of Cases	27	22	133	131	216	1,217	93
Number of Events							
Spinal fracture						4	
Splenic rupture			1		2	1	
Sternal fracture					1		
Stoma site discharge						1	
Subcutaneous haematoma						2	
Subdural haematoma	1				4	14	1
Subdural haemorrhage						4	
Thermal burn						1	1
Thoracic vertebral fracture						1	
Tibia fracture						1	
Tissue injury							2
Toxicity to various agents	1				1	5	1
Tracheal haemorrhage						1	
Tracheal obstruction				2			
Tracheostomy malfunction						2	
Transfusion related complication					1		
Transplant failure			1				
Traumatic haematoma						1	
Traumatic haemorrhage				1		3	
Traumatic haemothorax						2	
Traumatic intracranial haemorrhage					1	4	
Ulna fracture						1	
Underdose						1	28
Upper limb fracture						3	
Vaccination complication						3	1
Vaccination error				1		1	
Vascular injury					1		
Vascular procedure complication						1	
Vascular pseudoaneurysm			1				
Vasoplegia syndrome						3	
Weaning failure						1	
Wound						8	1
Wound complication						1	
Wound necrosis						1	
Wrist fracture						1	
Wrong patient received product						1	
Wrong product administered			1	1	1	2	
Wrong technique in product usage process			1				

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Investigations							
Number of Cases	14	17	75	71	163	1,023	36
Number of Events	23	34	163	138	262	1,920	47
Activated partial thromboplastin time abnormal						1	
Activated partial thromboplastin time prolonged			1	1	3	6	
Activated partial thromboplastin time ratio decreased						1	
Activated partial thromboplastin time ratio increased						1	
Activated partial thromboplastin time shortened					1	5	
ADAMTS13 activity decreased	1			1			
Airway peak pressure increased						1	
Alanine aminotransferase decreased						2	
Alanine aminotransferase increased		1	2	1	2	11	
Albumin globulin ratio decreased						3	
Albumin urine absent						1	
Ammonia increased						1	
Amylase decreased				1			
Amylase increased						4	
Angiogram abnormal					1		
Angiogram cerebral abnormal			1				
Anion gap increased						1	
Antibody test abnormal						1	
Antibody test positive						1	
Anticoagulation drug level below therapeutic						1	
Anti factor VIII antibody positive						1	
Anti-melanoma differentiation-associated protein 5 antibody positive					1		
Antimitochondrial antibody positive						1	
Antineutrophil cytoplasmic antibody positive						1	
Antinuclear antibody positive						1	
Aspartate aminotransferase abnormal						1	
Aspartate aminotransferase increased			2	1	2	12	
Aspergillus test positive						1	
AST/ALT ratio abnormal						1	
Auscultation						1	
Bacterial test						1	
Bacterial test positive				1	1	5	
Band neutrophil count increased						1	
Base excess decreased						1	
Base excess increased						1	
Basophil count decreased						2	
Basophil count increased						2	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Investigations							
Number of Cases	14	17	75	71	163	1,023	36
Number of Events	23	34	163	138	262	1,920	47
Blast cell count increased						1	
Blast cells						1	
Bleeding time prolonged						1	
Blood albumin decreased				1		9	
Blood albumin increased						1	
Blood alcohol decreased						1	
Blood alkaline phosphatase decreased					2		
Blood alkaline phosphatase increased						7	
Blood bicarbonate decreased			1			7	
Blood bilirubin decreased					1		
Blood bilirubin increased					3	6	1
Blood calcium decreased						6	
Blood chloride decreased						2	
Blood chloride increased	1				1	3	
Blood cholesterol increased				2			
Blood cholinesterase increased						1	
Blood creatine decreased							1
Blood creatine increased						4	1
Blood creatine phosphokinase increased			2	2	3	19	1
Blood creatine phosphokinase MB increased			4	2		2	
Blood creatinine decreased				1	1	1	
Blood creatinine increased	1	1		3	2	21	
Blood culture positive		1					
Blood electrolytes decreased						1	
Blood fibrinogen decreased						1	
Blood fibrinogen increased			2	1		5	
Blood folate decreased						1	
Blood gases abnormal					1		
Blood glucose abnormal		1	2		1	3	
Blood glucose decreased		1	2	1	3	5	
Blood glucose fluctuation						2	
Blood glucose increased			2	5	8	29	
Blood immunoglobulin E increased						2	
Blood immunoglobulin G decreased						1	
Blood immunoglobulin G increased						2	
Blood iron decreased		1				2	
Blood iron increased						1	
Blood lactate dehydrogenase decreased					1		
Blood lactate dehydrogenase increased			1	1		21	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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MedDRA System Organ Class (SOC) and MedDRA Preferred Terms (PTs)	less or equal to 17 years	18 - 24 years	25 - 49 years	50 - 59 years	60 - 69 years	70+ years	Unknown
Investigations							
Number of Cases	14	17	75	71	163	1,023	36
Number of Events	23	34	163	138	262	1,920	47
Blood lactic acid			1				
Blood lactic acid increased			2	1		10	
Blood magnesium decreased						2	
Blood magnesium increased				1			
Blood methaemoglobin present						1	
Blood osmolarity decreased						1	
Blood osmolarity increased						1	
Blood pH decreased			2				
Blood phosphorus decreased				1		1	
Blood phosphorus increased			1	1		3	
Blood potassium decreased				3		7	
Blood potassium increased		1	1		1	8	
Blood pressure abnormal			1	2	1	7	
Blood pressure decreased	1	1	5	3	15	103	3
Blood pressure diastolic decreased					1	3	
Blood pressure diastolic increased						2	
Blood pressure immeasurable	1					8	
Blood pressure increased			10	14	13	50	2
Blood pressure systolic decreased				1		6	
Blood pressure systolic increased					1	7	
Blood sodium decreased						9	
Blood sodium increased				1		4	1
Blood test abnormal			2			2	
Blood thyroid stimulating hormone abnormal		1					
Blood thyroid stimulating hormone decreased					1		
Blood thyroid stimulating hormone increased			1			1	
Blood triglycerides increased				3			
Blood urea decreased						2	
Blood urea increased				1	3	22	
Blood urea nitrogen/creatinine ratio increased						1	
Blood uric acid increased			1	1	1	6	
Blood urine present					1	3	
Blood viscosity increased					1		
Body mass index abnormal		1					
Body temperature					1		
Body temperature abnormal					1	1	
Body temperature decreased					1	12	
Body temperature fluctuation					1		
Body temperature increased		1	3	2	5	33	1

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Investigations							
Number of Cases	14	17	75	71	163	1,023	36
Number of Events	23	34	163	138	262	1,920	47
Bone marrow myelogram abnormal					1		
Brain natriuretic peptide abnormal						1	
Brain natriuretic peptide increased						10	
Brain scan normal							1
Breath sounds	1					1	
Breath sounds abnormal			1	1		13	
Capillary nail refill test abnormal						1	
Carbohydrate antigen 19-9 increased				1			
Carbon dioxide decreased						1	
Carbon dioxide increased			1				
Carboxyhaemoglobin increased						1	
Carcinoembryonic antigen increased				1			
Cardiac murmur						1	
Cardiac output decreased						1	
Cardiothoracic ratio increased					1		
Catheterisation cardiac						1	
Cells in urine						1	
Central venous pressure abnormal					1		
Chest X-ray abnormal					1	5	
Clot retraction						1	
Coagulation factor V level decreased						1	
Coma scale						2	
Coma scale abnormal		2	1		3	16	
Computerised tomogram abnormal	1						
Computerised tomogram head abnormal			1				
Computerised tomogram thorax abnormal						1	
Corneal reflex decreased						1	
Coronavirus test positive						1	1
C-reactive protein abnormal						2	
C-reactive protein decreased					1		
C-reactive protein increased	1	1	7	2	7	108	1
Creatinine renal clearance decreased						1	
Creatinine renal clearance increased						1	
CSF glucose increased			1			1	
CSF mononuclear cell count decreased					1		
CSF polymorphonuclear cell count increased					1		
CSF pressure increased					1		
CSF protein increased				1	2	3	
CSF test abnormal			1		1		

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Investigations							
Number of Cases	14	17	75	71	163	1,023	36
Number of Events	23	34	163	138	262	1,920	47
Culture positive		1					
Cultura urine positive						2	
Cytology abnormal						1	
Cytomegalovirus test positive						3	
Drug specific antibody absent						1	
Eastern Cooperative Oncology Group performance status worsened						2	
Echocardiogram			1				
Ejection fraction decreased			4	1	2	4	
Electrocardiogram						1	
Electrocardiogram abnormal						3	
Electrocardiogram QRS complex prolonged			1				
Electrocardiogram QT prolonged	1	1			1		
Electrocardiogram Q wave abnormal						1	
Electrocardiogram repolarisation abnormality						2	
Electrocardiogram ST segment abnormal						1	
Electrocardiogram ST segment depression	1		1	1			
Electrocardiogram ST segment elevation			1		4	3	
Electrocardiogram ST-T segment elevation						2	
Electrocardiogram T wave inversion						1	
Electroencephalogram abnormal					1	2	
Enzyme level abnormal						2	
Enzyme level increased			1				
Eosinophil count decreased				1		4	
Eosinophil count increased					1	4	
Epstein-Barr virus antigen positive						1	
Escherichia test positive				1	1	3	
Exercise electrocardiogram abnormal					1		
Face and mouth X-ray							1
Fibrin abnormal					1		
Fibrin D dimer decreased						1	
Fibrin D dimer increased	1		9	4	8	41	
Fibrin degradation products increased				1		2	
Fibrinolysis increased					1		
Full blood count abnormal			2			3	
Full blood count decreased						1	
Fungal test positive					1	1	
Gamma-glutamyltransferase increased			1	1		3	
General physical condition abnormal						12	
Glomerular filtration rate decreased						17	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Investigations							
Number of Cases	14	17	75	71	163	1,023	36
Number of Events	23	34	163	138	262	1,920	47
Glycosylated haemoglobin increased			1	1		2	
Granulocyte count decreased						1	
Grip strength decreased					2	2	
Haematocrit abnormal						1	
Haematocrit decreased			1	1	1	18	
Haematocrit increased					1		
Haematology test abnormal					1		
Haemoglobin abnormal						3	
Haemoglobin decreased	1	1	3	2	5	39	
Haemoglobin increased					1		
Haptoglobin decreased						1	
Haptoglobin increased					1		
Heart rate abnormal				1		2	1
Heart rate decreased	1		1	2	5	21	
Heart rate increased	1	3	7	3	6	48	4
Heart rate irregular						6	
Heart sounds abnormal						3	
Hepatic enzyme increased			2		3	9	
Hepatitis C virus test positive					1		
Herpes simplex test positive						1	
Histamine level increased						1	
HIV antibody positive						1	
Human epidermal growth factor receptor decreased						1	
Human epidermal growth factor receptor increased					1		
Immature granulocyte count increased						3	
Immunoglobulins increased						1	
Inflammatory marker increased			1	1	3	15	
Interleukin level decreased					1		
Interleukin level increased					1	4	
International normalised ratio abnormal						1	
International normalised ratio decreased				1		1	
International normalised ratio increased						22	1
Intraocular pressure increased						2	
Klebsiella test positive						1	
Laboratory test abnormal						1	
Lactobacillus test positive						1	
Legionella test positive						1	
Lipase decreased					1		

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Investigations							
Number of Cases	14	17	75	71	163	1,023	36
Number of Events	23	34	163	138	262	1,920	47
Lipase increased			1			1	
Lipids increased						1	
Liver function test abnormal					2	7	
Liver function test decreased					2		
Liver function test increased						1	
Low density lipoprotein increased						2	
Lumbar puncture						1	
Lymphocyte count decreased			1	1	1	10	
Lymphocyte count increased			1	1	1	1	
Lymphocyte percentage decreased						2	
Lymphocyte percentage increased			1				
Magnetic resonance imaging head abnormal						1	
Mean cell haemoglobin concentration decreased			1		1	8	
Mean cell haemoglobin concentration increased						1	
Mean cell haemoglobin decreased						1	
Mean cell haemoglobin increased						1	
Mean cell volume abnormal					1		
Mean cell volume decreased					1	1	
Mean cell volume increased						4	
Mean platelet volume decreased						1	
Metamyelocyte count increased			1			1	
Metamyelocyte percentage increased			1				
Monocyte count abnormal						2	
Monocyte count decreased						2	
Monocyte count increased						4	
Myelocyte count increased			1			1	
Myocardial necrosis marker increased		1	1			3	
Myocardial strain imaging						1	
Neutrophil count abnormal						1	
Neutrophil count decreased					1	4	
Neutrophil count increased				1		17	
Neutrophil percentage decreased			1				
Neutrophil percentage increased						3	
NIH stroke scale score decreased						1	
Nitrite urine present						1	
N-terminal prohormone brain natriuretic peptide increased			1			12	
Nutritional assessment			1				
Osmolar gap increased				1			

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Investigations							
Number of Cases	14	17	75	71	163	1,023	36
Number of Events	23	34	163	138	262	1,920	47
Oxygen consumption decreased				1			
Oxygen consumption increased					1		
Oxygen saturation						2	
Oxygen saturation abnormal					1	10	
Oxygen saturation decreased	2	3	15	14	40	317	5
Oxygen saturation immeasurable	1					1	
PCO2 abnormal						1	
PCO2 decreased						2	
PCO2 increased		1	1			5	1
pH body fluid			1				
pH body fluid decreased						2	
Platelet count abnormal					1	2	
Platelet count decreased	2	1	6	5	5	60	9
Platelet count increased		1		2		4	
Plateletcrit decreased						1	
Plateletcrit increased						1	
Platelet factor 4			1				
PO2 decreased			1			2	
PO2 increased						1	
Prealbumin decreased						1	
Procalcitonin increased					1	6	
Prohormone brain natriuretic peptide abnormal						1	
Prohormone brain natriuretic peptide increased						1	
Prostatic specific antigen increased					1		
Protein C increased		1					
Protein total decreased			1	2		5	
Protein total increased						1	
Protein urine present					1		
Prothrombin level abnormal						1	
Prothrombin level increased						1	
Prothrombin time prolonged				1	2	4	
Prothrombin time ratio decreased						1	
Prothrombin time ratio increased						3	
Prothrombin time shortened						1	
Pseudomonas test positive						1	
Pulmonary arterial pressure increased						4	
Pulse abnormal				1	1	7	
Pulse absent	1	1	1	1	6	11	
Pulse pressure decreased						1	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Investigations							
Number of Cases	14	17	75	71	163	1,023	36
Number of Events	23	34	163	138	262	1,920	47
Pulse volume decreased						1	
Pyruvate kinase increased						1	
Quality of life decreased			1			4	
Radial pulse abnormal						1	
Red blood cell count abnormal						1	
Red blood cell count decreased			2	1	1	14	
Red blood cell count increased					1		1
Red blood cell morphology abnormal						1	
Red blood cell schistocytes present						1	
Red blood cell sedimentation rate increased			1			5	
Red blood cells urine positive						2	
Red cell distribution width increased			1			5	
Renal function test abnormal						2	
Respiratory rate decreased			1			8	
Respiratory rate increased			2	1	1	21	
Reticulocyte count decreased					1	1	
Reticulocyte count increased						1	
Right ventricular systolic pressure increased						1	
SARS-CoV-2 antibody test positive					1	1	
SARS-CoV-2 test negative		1				1	
SARS-CoV-2 test positive				3	2	42	2
Serratia test positive						2	
Serum ferritin abnormal						1	
Serum ferritin increased	1		2		2	5	
Sinus rhythm	1					1	
Somatosensory evoked potentials abnormal						1	
Sputum abnormal					1	1	
Staphylococcus test positive						1	
Stenotrophomonas test positive						1	
Streptococcus test positive						1	
Tidal volume decreased			1				
Total cholesterol/HDL ratio decreased				1			
Total lung capacity decreased						1	
Transaminases increased			1			3	
Troponin abnormal				1		1	
Troponin I			1				
Troponin I increased			3		1	5	
Troponin increased		1	1	4	1	10	
Troponin T increased					1	10	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Investigations							
Number of Cases	14	17	75	71	163	1,023	36
Number of Events	23	34	163	138	262	1,920	47
Tryptase increased						1	
Tumour marker increased						2	
Tympanometry abnormal							1
Urine chromium increased						1	
Urine copper						1	
Urine ketone body					1		
Urine output decreased			1			12	
Venous oxygen saturation decreased						2	
Very low density lipoprotein increased				1			
Viral test positive						1	
Vital capacity decreased				1			
Vital functions abnormal						1	
Vitamin B12 abnormal						1	
Vitamin B12 decreased		1					
Waist circumference increased						1	
Weight decreased	1		1	3	11	40	5
Weight increased			2		1	7	1
White blood cell count abnormal						1	
White blood cell count decreased		2			2	12	1
White blood cell count increased			1	3	1	46	
White blood cell morphology abnormal						1	
White blood cells urine positive						2	
Metabolism and nutrition disorders							
Number of Cases	9	6	42	41	93	711	18
Number of Events	12	8	51	47	120	891	18
Abnormal loss of weight			2			2	
Abnormal weight gain						1	
Acetonaemia						1	
Acidosis			1	1	5	10	
Adult failure to thrive						4	
Alcoholic ketoacidosis				1			
Cachexia			1		3	25	
Cell death					1	2	
Cerebral salt-wasting syndrome			1				
Decreased appetite	3	2	17	12	40	271	9
Dehydration	1	2		4	7	121	1
Diabetes mellitus	1		1	3	6	11	1
Diabetes mellitus inadequate control						5	
Diabetic complication					1	2	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Metabolism and nutrition disorders							
Number of Cases	9	6	42	41	93	711	18
Number of Events	12	8	51	47	120	891	18
Diabetic ketoacidosis	2	1	2	3	2	4	
Diabetic ketosis				1			
Diabetic metabolic decompensation						2	
Diet refusal					1	8	
Dyslipidaemia						2	
Electrolyte depletion						1	
Electrolyte imbalance		1	1		1	8	
Failure to thrive						2	
Feeding disorder			1	2	3	38	
Fluid imbalance						1	
Fluid intake reduced						12	
Fluid retention		1			2	13	
Folate deficiency						1	1
Food refusal			1			9	
Gout						4	
Haemosiderosis			3				
Hypercalcaemia						6	
Hyperchloraemia						1	
Hypercholesterolaemia						3	1
Hypercreatininaemia						1	
Hyperglycaemia	1		1	3	1	22	
Hyperglycaemic hyperosmolar nonketotic syndrome						4	
Hyperkalaemia			3	2	7	20	1
Hyperlactacidaemia					3	5	
Hyperlipidaemia					1		
Hypermatraemia	1				2	24	
Hyperphagia						1	
Hypertriglyceridaemia						1	
Hyperuricaemia					2	5	1
Hypervitaminosis B12						1	
Hypervolaemia					1	3	
Hypoalbuminaemia				1	2	7	
Hypocalcaemia						1	
Hypochloraemia						2	
Hypoglycaemia					1	20	
Hypokalaemia	1		1	1	2	24	
Hyponatraemia			3	2	4	30	
Hypophagia			2	1	6	48	
Hypophosphataemia						1	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Metabolism and nutrition disorders							
Number of Cases	9	6	42	41	93	711	18
Number of Events	12	8	51	47	120	891	18
Hypoproteinaemia						1	
Hypovolaemia						2	
Ketoacidosis				1	1	1	
Lactic acidosis				2	2	12	
Lipid metabolism disorder			1				
Lipomatosis			1		1		
Malnutrition					2	17	1
Marasmus						33	1
Metabolic acidosis	1		2	2	8	17	
Metabolic alkalosis					1		
Metabolic disorder						2	
Obesity	1		2	3		2	
Polydipsia						1	
Propofol infusion syndrome			1				
Protein deficiency						1	
Starvation						2	
Tetany			2				
Tumour lysis syndrome						1	
Type 1 diabetes mellitus		1			1	1	
Type 2 diabetes mellitus			1	2		5	1
Underweight						1	
Vitamin D deficiency						2	
Musculoskeletal and connective tissue disorders							
Number of Cases	11	12	96	83	112	545	29
Number of Events	12	15	123	100	139	695	38
Antisynthetase syndrome					1		
Arthralgia		3	15	11	24	79	5
Arthritis			1			2	
Arthropathy							1
Back disorder				1	1	1	
Back pain	1		12	8	14	75	6
Bone disorder						2	
Bone lesion						1	
Bone pain			2		1	4	
Bone swelling						1	
Cervical spinal stenosis					1		
Coccydynia						1	
Collagen disorder						1	
Compartment syndrome	1		1	1			

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Musculoskeletal and connective tissue disorders	11	12	96	83	112	545	29
Number of Cases	12	15	123	100	139	695	38
Number of Events							
Costochondritis						1	
Facial asymmetry		1	2				
Fasciitis						1	
Fibromyalgia				1		1	
Flank pain			1			5	
Foot deformity						1	
Groin pain		1		3	1	4	
Haemarthrosis						1	
Haematoma muscle					1	3	
Hand deformity						1	
Immobilisation syndrome						2	
Immune-mediated myositis					1		
Intervertebral disc disorder						1	
Intervertebral disc protrusion					1		
Joint range of motion decreased				1		1	
Joint stiffness				2		2	
Joint swelling			1	1	1	8	1
Limb discomfort			2	2	1	19	
Mixed connective tissue disease						1	
Mobility decreased			2	2	5	39	3
Muscle atrophy						1	
Muscle disorder						2	
Muscle fatigue					1	1	
Muscle rigidity		1			1	8	
Muscle spasms			2	2	3	17	
Muscle tightness				1		2	
Muscle twitching			2	2		9	
Muscular weakness	1		6	5	12	70	3
Musculoskeletal chest pain					1	4	1
Musculoskeletal discomfort				2		3	
Musculoskeletal disorder			1			1	
Musculoskeletal pain				2	1	10	1
Musculoskeletal stiffness	2	2	5	7	2	9	
Myalgia	1	2	27	11	22	101	7
Myopathy				3		2	
Myositis				1		4	
Neck mass						1	
Neck pain		1	7	5	2	16	
Nuchal rigidity						1	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Musculoskeletal and connective tissue disorders							
Number of Cases	11	12	96	83	112	545	29
Number of Events	12	15	123	100	139	695	38
Oligoarthritis						1	
Osteitis						1	
Osteoarthritis						1	
Osteolysis						1	
Osteopenia						1	
Pain in extremity	6	2	30	20	29	133	7
Pain in jaw			2		1	3	
Polyarthritis						1	
Polymyositis						2	
Posture abnormal						1	
Psoriatic arthropathy		1					
Rhabdomyolysis		1		3	4	11	
Rheumatoid arthritis					1	1	1
Sarcopenia						2	
Scoliosis						1	
Slipping rib syndrome						2	
Soft tissue haemorrhage				1			
Soft tissue necrosis					1		
Spinal disorder						4	
Spinal osteoarthritis					1	2	
Spinal pain			1		1	3	1
Spinal stenosis						1	
Still's disease			1		1		
Systemic lupus erythematosus					1		1
Tendonitis				1			
Torticollis						1	
Trismus				1	1	1	
Vertebral lesion						1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Number of Cases	2	4	18	33	71	232	28
Number of Events	2	4	25	46	96	293	29
Abdominal neoplasm						2	
Acute leukaemia					5	6	2
Acute lymphocytic leukaemia			1	1		1	
Acute megakaryocytic leukaemia					1		
Acute myeloid leukaemia			1		2	13	1
Acute myeloid leukaemia recurrent					1	1	
Acute myelomonocytic leukaemia						1	
Adenocarcinoma						1	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	4	18	33	71	232	28
Number of Cases	2	4	25	46	96	293	29
Number of Events							
Adenocarcinoma metastatic						1	
Adenocarcinoma of colon						1	
Adenocarcinoma pancreas					1		
Adenoma benign						1	
Adrenal gland cancer			1		1		
Anaplastic thyroid cancer			1				
Angiocentric lymphoma				1			
Appendix cancer					1		
B-cell lymphoma						4	
B-cell type acute leukaemia	1						
Benign breast neoplasm						1	
Bile duct cancer						2	
Bladder adenocarcinoma stage unspecified						1	
Bladder cancer						1	
Bladder cancer recurrent						1	
Bone cancer					1	1	
Bone cancer metastatic						1	
Brain cancer metastatic			1			1	
Brain neoplasm			2	2		2	2
Breast cancer						2	1
Breast cancer female						1	1
Breast cancer metastatic					1	2	
Breast cancer recurrent						1	
Breast cancer stage IV			1				
Breast neoplasm						1	
Bronchial neoplasm					1		
Burkitt's lymphoma						1	
Carcinoid tumour pulmonary						1	
Cardiac neoplasm unspecified						1	
Castleman's disease			1	1	1	1	
Cerebral haemangioma			1				
Cholangiocarcinoma					1		
Cholangiosarcoma						1	
Chronic leukaemia						1	
Chronic lymphocytic leukaemia						3	
Chronic myeloid leukaemia				1		1	
Colon cancer					2	1	
Colon neoplasm						2	
Cutaneous lymphoma				1			

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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MedDRA System Organ Class (SOC) and MedDRA Preferred Terms (PTs)	less or equal to 17 years	18 - 24 years	25 - 49 years	50 - 59 years	60 - 69 years	70+ years	Unknown
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	4	18	33	71	232	28
Number of Cases	2	4	25	46	96	293	29
Number of Events							
Diffuse large B-cell lymphoma				1		2	
Endocrine neoplasm malignant						1	
Essential thrombocythaemia						1	
Fallopian tube neoplasm						1	
Follicular lymphoma						2	
Follicular lymphoma stage IV					1		
Gastric cancer						4	
Gastric cancer recurrent						1	
Gastrointestinal adenocarcinoma					1		
Gastrointestinal carcinoma						1	
Glioblastoma			1			3	
Glioblastoma multiforme					1		
Haemangioma				1			
Haematopoietic neoplasm						1	
Hepatic cancer					1	3	3
Hepatic cancer metastatic						1	
Hepatic neoplasm						4	
Hepatocellular carcinoma					1	1	
Histiocytosis						1	
Hodgkin's disease recurrent					1		
Invasive ductal breast carcinoma				1			
Invasive lobular breast carcinoma					1		
Kaposi's sarcoma AIDS related						1	
Leiomyosarcoma				1			
Leukaemia	1		1	1	1	11	2
Lip and/or oral cavity cancer				1			
Lip and/or oral cavity cancer recurrent						1	
Lipoma						1	
Lung adenocarcinoma				1	3	1	
Lung cancer metastatic			1	2	3	4	1
Lung carcinoma cell type unspecified stage 0						1	
Lung carcinoma cell type unspecified stage IV					1		
Lung neoplasm					1		
Lung neoplasm malignant				2	3	14	1
Lymphangioma				1			
Lymphoma					5	10	1
Lymphoproliferative disorder				1		2	
Malignant ascites						1	
Malignant neoplasm of renal pelvis						1	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Number of Cases	2	4	18	33	71	232	28
Number of Events	2	4	25	46	96	293	29
Malignant neoplasm progression					2	5	
Malignant nervous system neoplasm						1	
Malignant palate neoplasm						1	
Malignant peritoneal neoplasm			1	1			
Malignant pleural effusion						2	
Malignant splenic neoplasm				1			
Mantle cell lymphoma						1	
Marrow hyperplasia					1		
Melanoma recurrent						1	
Meningioma			1			2	
Mesothelioma						1	
Metastases to abdominal cavity					1		
Metastases to adrenals						2	
Metastases to bone						3	
Metastases to central nervous system				1	1	3	
Metastases to liver					4	7	
Metastases to lung				1	4	2	
Metastases to lymph nodes				1	3	2	
Metastases to neck				1			
Metastases to peritoneum						2	
Metastases to pituitary gland				1			
Metastases to spleen					1		
Metastases to the mediastinum						1	
Metastasis			1	1	3	2	
Metastatic bronchial carcinoma						1	
Metastatic lymphoma					1		
Metastatic malignant melanoma						1	
Metastatic neoplasm				1		1	
Myelodysplastic syndrome					2	13	1
Myelofibrosis			1			1	
Myeloid leukaemia						1	
Myeloproliferative neoplasm						3	
Nasal cavity cancer					1		
Neoplasm						3	
Neoplasm malignant			2	3	6	13	8
Neoplasm progression		1	1	6	7	24	3
Neoplasm recurrence					1	3	
Neuroendocrine carcinoma metastatic							1
Neuroendocrine carcinoma of the skin						1	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	4	18	33	71	232	28
Number of Cases	2	4	25	46	96	293	29
Number of Events							
Neuroendocrine tumour of the rectum						1	
Non-Hodgkin's lymphoma		1			1	4	
Oesophageal adenocarcinoma					1		
Oesophageal carcinoma			1			2	
Oropharyngeal neoplasm benign					1		
Ovarian cancer			2	1		1	
Pancreatic carcinoma				1	3	7	1
Pancreatic neoplasm					1	1	
Papillary cystadenoma lymphomatosum						1	
Papilloma						1	
Paraneoplastic syndrome					1		
Pelvic neoplasm				1			
Pericardial mesothelioma malignant		1					
Pharyngeal neoplasm						1	
Plasma cell leukaemia						1	
Plasmacytoma						1	
Pleural mesothelioma						1	
Pleural neoplasm						1	
Polycythaemia vera		1			1		
Poorly differentiated thyroid carcinoma				1			
Prostate cancer						7	
Prostate cancer metastatic						1	
Recurrent cancer					1		
Renal cancer						3	
Renal cancer metastatic						1	
Renal cell carcinoma						1	
Renal neoplasm					1	2	
Salivary gland neoplasm						1	
Skin squamous cell carcinoma metastatic						1	
Small cell lung cancer					1	3	
Small cell lung cancer metastatic						1	
Spinal meningioma benign						1	
Squamous cell carcinoma of the tongue						1	
T-cell lymphoma			1	2			
Testis cancer						1	
Thymoma				1			
Transitional cell carcinoma					1		
Tumour flare					1		
Tumour haemorrhage			1				

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Number of Cases	2	4	18	33	71	232	28
Number of Events	2	4	25	46	96	293	29
Tumour perforation						1	
Tumour rupture				1			
Tumour thrombosis						1	
Uterine leiomyoma					1	2	
Vaginal cancer recurrent						1	
Nervous system disorders							
Number of Cases	48	54	318	268	448	2,338	141
Number of Events	93	101	566	487	816	4,083	190
Acute disseminated encephalomyelitis			4	1	1	1	
Acute polyneuropathy						1	
Ageusia			1	2	1	10	1
Akinesia			2				
Alexia						1	
Altered state of consciousness	1		11	9	14	117	
Amnesia					6	8	1
Anosmia			1	1	1	6	1
Anosognosia						1	
Apallic syndrome						6	
Aphasia			3	4	8	66	1
Apraxia				1	1	1	
Areflexia			1		1	4	
Ataxia				1	2	5	
Autoimmune encephalopathy						1	
Autonomic nervous system imbalance						1	
Axonal neuropathy				1			
Balance disorder				3	3	29	1
Ballismus						2	
Basal ganglia haematoma						1	
Basal ganglia haemorrhage			1			3	
Basal ganglia infarction					1		
Basilar artery occlusion					1	3	
Basilar artery thrombosis			2	1	4	4	1
Bell's palsy			1		1		
Bickerstaff's encephalitis						1	
Bradykinesia						7	
Brain compression		1	2			3	
Brain hypoxia	1	1			1	5	
Brain injury	2	3	7	6	13	19	3
Brain oedema	4	4	18	16	15	21	1

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Nervous system disorders							
Number of Cases	48	54	318	268	448	2,338	141
Number of Events	93	101	566	487	816	4,083	190
Brain stem haemorrhage		1	2	1	5	12	
Brain stem infarction			2		1	4	
Brain stem ischaemia						1	
Brain stem stroke			1			3	
Brain stem syndrome			1	1	1		
Brain stem thrombosis					1		
Bulbar palsy						1	
Burning sensation			1		4	3	
Carotid aneurysm rupture			1				
Carotid arteriosclerosis						3	
Carotid artery disease		1					
Carotid artery dissection			2				
Carotid artery occlusion			1		3	7	
Carotid artery stenosis					1	4	
Carotid artery thrombosis		1	1		1	2	
Central nervous system lesion					1	1	
Central nervous system necrosis					1		
Central nervous system vasculitis				1	1		
Cerebellar ataxia					1		
Cerebellar atrophy						2	
Cerebellar haematoma						1	
Cerebellar haemorrhage	1		1	1	3	7	
Cerebellar infarction			2	2	2	4	
Cerebellar stroke						3	
Cerebellar tonsillar ectopia		1					
Cerebral amyloid angiopathy						3	
Cerebral arteriosclerosis			1	1		5	
Cerebral arteritis						1	
Cerebral artery embolism					2	12	1
Cerebral artery occlusion				1		4	1
Cerebral artery perforation			1				
Cerebral artery stenosis				1			
Cerebral artery thrombosis			1		2	6	
Cerebral atrophy						12	
Cerebral circulatory failure						1	
Cerebral congestion			1		1		
Cerebral cyst							1
Cerebral disorder				1	2	6	
Cerebral haematoma	1		1		7	17	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Nervous system disorders							
Number of Cases	48	54	318	268	448	2,338	141
Number of Events	93	101	566	487	816	4,083	190
Cerebral haemorrhage	3	2	21	29	60	252	16
Cerebral infarction			6	4	22	139	5
Cerebral ischaemia			4	4		22	
Cerebral mass effect					1		
Cerebral microhaemorrhage						1	
Cerebral microinfarction			1				
Cerebral thrombosis		1	4	5	4	26	10
Cerebral vascular occlusion						1	
Cerebral venous sinus thrombosis	1	4	15	4	3	10	
Cerebral venous thrombosis			3	5	2	2	
Cerebral ventricular rupture					4	4	
Cerebrospinal fluid retention					1		
Cerebrovascular accident		1	22	16	43	338	37
Cerebrovascular disorder				3	1	16	
Cerebrovascular stenosis					1		
Cholinergic syndrome						1	
Chorea						1	
Chronic inflammatory demyelinating polyradiculoneuropathy					1	1	
Clonic convulsion					1	1	
Clonus						1	
Clumsiness						2	
Cognitive disorder			1	1	3	30	2
Coma	2		11	20	23	93	4
Coma hepatic					3	1	1
Consciousness fluctuating						2	
Coordination abnormal				1		5	
Cranial nerve disorder						1	
Decerebrate posture						1	
Delayed ischaemic neurological deficit						1	
Dementia				1	1	46	3
Dementia Alzheimer's type						18	
Dementia of the Alzheimer's type, with delirium						1	
Dementia with Lewy bodies						1	
Demyelinating polyneuropathy					1	2	
Demyelination			2	2			
Depressed level of consciousness	3	2	6	12	15	148	
Diabetic coma			1		1	2	
Diabetic hyperosmolar coma					1	2	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Nervous system disorders							
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Number of Events	93	101	566	487	816	4,083	190
Diplegia					2	3	
Disturbance in attention		1		3	3	30	1
Dizziness	6	8	27	25	36	144	5
Dizziness postural			1				
Drooling		3				3	
Dropped head syndrome						1	
Dysarthria			7	5	8	45	1
Dysgeusia					2	4	
Dyskinesia	1		1	1	1	10	
Dyslalia						5	
Dyslexia			1			1	
Dyspraxia						1	1
Dysstasia		1	2	1	4	26	
Embolic cerebral infarction					1	2	
Embolic stroke						9	
Encephalitis autoimmune		1	1		1	5	
Encephalomalacia			1				
Encephalopathy			2	1	3	11	
Epilepsy	1	3	5	6	8	36	1
Extensor plantar response						2	
Extrapyramidal disorder					1	1	
Facial nerve disorder			1				
Facial paralysis				2	3	23	
Facial paresis			1		3	6	
Febrile convulsion						2	
Fine motor skill dysfunction						1	
Frontotemporal dementia						1	
Fumbling						1	
Generalised onset non-motor seizure						1	
Generalised tonic-clonic seizure		1	1	4		10	
Guillain-Barre syndrome		1	3	1	4	32	1
Haemorrhage intracranial	1	1	6	3	3	22	1
Haemorrhagic cerebellar infarction				1			
Haemorrhagic cerebral infarction			1		1	5	
Haemorrhagic stroke			4	3	14	55	3
Haemorrhagic transformation stroke				1	4	6	
Headache	18	18	85	57	59	189	16
Head discomfort			1			4	1
Hemianaesthesia						1	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Nervous system disorders							
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Hemianopia				1	1	2	
Hemianopia homonymous					1	1	
Hemiapraxia						1	
Hemiparaesthesia			1				
Hemiparesis	3	1	5	3	8	70	
Hemiplegia		1	6	2	7	50	
Hepatic encephalopathy			2		1	2	
Hydrocephalus		1	2	1	6	7	
Hyperaesthesia						2	
Hyperammonaemic encephalopathy						1	
Hypercapnic coma		1				3	
Hyperkinesia						1	
Hypersomnia	1				3	16	
Hypertensive encephalopathy						3	
Hypertonia						2	
Hypoaesthesia	4	3	9	4	9	28	1
Hypogeusia						2	
Hypoglycaemic coma						1	
Hypokinesia						13	1
Hyporeflexia			1			3	
Hyporesponsive to stimuli						8	
Hyposmia						1	
Hypotonia		1	1		6	18	
Hypotonic-hyporesponsive episode				1	2	5	
Hypoxic-ischaeamic encephalopathy	1	1	3	2	5	12	
IIIrd nerve disorder					1	1	
IIIrd nerve paralysis			1				
Immune-mediated encephalitis			1			1	
Incoherent					2	9	
Intellectual disability			1				
Intracranial aneurysm			4	5	5	5	
Intracranial haematoma					1	1	
Intracranial pressure increased	2	1	8	1	5	2	
Intraventricular haemorrhage				3		7	
Ischaemic cerebral infarction			1	1	2	12	
Ischaemic stroke			8	6	12	86	1
Lacunar infarction						3	
Language disorder				1	1	8	
Lethargy	1	1	6	6	11	50	2

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Number of Events	93	101	566	487	816	4,083	190
Leukoencephalopathy			1			5	
Limbic encephalitis						1	
Locked-in syndrome			1			1	
Loss of consciousness	7	7	43	56	75	318	13
Memory impairment				1	4	18	2
Meningism						1	
Meningoradiculitis			1				
Meningorrhagia				1		2	
Mental impairment						16	1
Metabolic encephalopathy					1	1	
Migraine			4		2	3	
Miller Fisher syndrome						2	1
Mononeuropathy multiplex				1			
Monoparesis					1	6	
Monoplegia			1		2	14	
Motor dysfunction					1	12	
Motor neurone disease				1			1
Movement disorder		1	1		2	21	2
Multiple sclerosis				1		1	1
Multiple sclerosis relapse					1	1	
Multiple system atrophy						1	
Muscle contractions involuntary						1	
Muscle spasticity						1	
Myasthenia gravis						6	
Myelitis transverse						1	2
Myelopathy						1	
Myoclonus				1	1	2	
Narcolepsy						2	
Nerve compression						1	
Nervous system disorder	3		3	2	6	29	2
Neuralgia			2		2	5	1
Neuralgic amyotrophy						2	
Neuritis							1
Neuritis cranial						1	
Neurodegenerative disorder						2	
Neuroleptic malignant syndrome			1		2		
Neurological decompensation				1		2	
Neurological symptom			1		1	8	1
Neurologic neglect syndrome						1	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Nervous system disorders							
Number of Cases	48	54	318	268	448	2,338	141
Number of Events	93	101	566	487	816	4,083	190
Neuromyelitis optica spectrum disorder						1	
Neuromyopathy						2	
Neuromyotonia						1	
Neuropathy peripheral						2	1
Normal pressure hydrocephalus						1	
Nystagmus						5	
Opisthotonus						1	
Optic neuritis					1		
Pachymeningitis						1	
Paraesthesia	1		5	3	2	21	1
Paralysis		1	2	3	2	20	4
Paraparesis					1		
Paraplegia					1	3	
Paresis						14	
Parkinsonism						2	
Parkinson's disease			1		1	6	
Partial seizures				1		1	
Patient elopement						1	
Peroneal nerve palsy				1			
Petit mal epilepsy			1	1		2	
Pleocytosis					1	2	
Polyneuropathy					1	5	
Post cardiac arrest syndrome				1		2	
Posterior reversible encephalopathy syndrome				1			
Postictal paralysis						1	
Postictal state	1						
Post stroke epilepsy						1	
Precerebral artery occlusion					1		
Presyncope			3	1	3	13	
Progressive supranuclear palsy						1	
Psychomotor disadaptation syndrome						1	
Psychomotor hyperactivity	1		1	2		5	
Psychomotor skills impaired			2		1	1	
Putamen haemorrhage					1		
Pyramidal tract syndrome			1				
Quadriparesis					2	8	
Quadriplegia				1	1	7	
Radiculopathy						3	
Restless legs syndrome					2		

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Nervous system disorders							
Number of Cases	48	54	318	268	448	2,338	141
Number of Events	93	101	566	487	816	4,083	190
Ruptured cerebral aneurysm			4	5	4	8	
Sciatica					1	3	
Secondary cerebellar degeneration						1	
Sedation			2			5	
Seizure	8	12	27	14	25	73	6
Seizure like phenomena						1	
Sensorimotor disorder						2	
Sensory disturbance			2	1		2	
Sensory loss						4	1
Slow response to stimuli	1	1	1		1	5	
Slow speech					1	4	
Somnolence	3		7	5	15	153	2
Speech disorder		1	3	2	4	51	1
Spinal cord compression					1	2	
Spinal cord haemorrhage						1	
Spinal epidural haemorrhage						1	
Spinal meningeal cyst						1	
Spinal stroke						1	
Status epilepticus	1		1	3		17	
Stroke in evolution						1	
Stupor			1			3	
Subarachnoid haemorrhage	1		18	23	23	51	2
Superior sagittal sinus thrombosis		1		1			
Syncope	4	3	25	22	35	115	8
Taste disorder		1		1		4	
Thalamic infarction						3	
Thalamus haemorrhage			1		2	4	
Thrombotic cerebral infarction						6	
Thrombotic stroke				1	2	5	
Thunderclap headache						1	
Tongue biting						1	
Tongue paralysis						1	
Tonic convulsion			1	1			
Toxic encephalopathy					1		
Transient aphasia						1	
Transient ischaemic attack			1	1	2	20	1
Transverse sinus thrombosis						1	
Tremor			3	3	6	49	5
Tumefactive multiple sclerosis			1				

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Nervous system disorders							
Number of Cases	48	54	318	268	448	2,338	141
Number of Events	93	101	566	487	816	4,083	190
Unresponsive to stimuli	4	1	8	9	13	80	2
Upper motor neurone lesion					1		
Vascular dementia						10	
Vascular encephalopathy						1	
Vascular parkinsonism						1	
Vertebral artery aneurysm			1				
Vertebral artery dissection			1	1	1		
Vertebral artery stenosis						2	
Vertebrobasilar insufficiency						1	
Vertebrobasilar stroke						1	
Visual agnosia						1	
Vlth nerve paralysis			1			1	
Vocal cord paralysis						1	
White matter lesion						1	1
Pregnancy, puerperium and perinatal conditions							
Number of Cases			3			1	
Number of Events			3			1	
Cephalhaematoma						1	
Hyperemesis gravidarum			1				
Labour pain			1				
Pre-eclampsia			1				
Product issues							
Number of Cases			1		1	2	3
Number of Events			2		1	2	3
Device breakage						1	
Product contamination chemical			1				
Product contamination microbial			1				
Product quality issue						1	
Product temperature excursion issue							2
Suspected counterfeit product					1		1
Psychiatric disorders							
Number of Cases	7	8	51	27	70	513	18
Number of Events	10	11	66	41	102	654	25
Abnormal behaviour		1			2	11	2
Abnormal dreams						1	
Adjustment disorder	1		1				
Aerophobia			1				
Affective disorder			1				1
Affect lability					1	1	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Psychiatric disorders							
Number of Cases	7	8	51	27	70	513	18
Number of Events	10	11	66	41	102	654	25
Aggression						6	
Agitation		2	2	1	2	39	
Alcoholism					1		
Anger			2		1		
Anxiety		1	5	5	6	33	1
Apathy			2		4	15	
Autism spectrum disorder							1
Autoscopy						1	
Behaviour disorder					2	5	
Bipolar disorder			1				
Bradyphrenia					1	5	
Catatonia						1	
Communication disorder			1		3	10	1
Completed suicide	3		9	1	4	9	3
Confusional state		4	7	6	21	166	4
Decreased eye contact				1			
Decreased interest						1	
Delirium				1	6	42	1
Delusion					2	9	
Delusional perception							1
Depressed mood				1	1	7	
Depression			1		1	6	1
Disinhibition						1	
Disorganised speech					1	2	
Disorientation		1	2		3	51	
Dissociative amnesia						1	
Dysphoria				1		3	
Eating disorder				1	1	21	
Emotional distress			1		1	1	
Enuresis						1	
Executive dysfunction						1	
Fear						3	
Fear of death			1				
Fear of falling						3	
Feeling of despair						1	
Gastrointestinal somatic symptom disorder						1	
Hallucination			2	3	3	20	
Hallucination, auditory						4	
Hallucinations, mixed						1	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

*Only post birth cases included

MedDRA System Organ Class (SOC) and MedDRA Preferred Terms (PTs)	less or equal to 17 years	18 - 24 years	25 - 49 years	50 - 59 years	60 - 69 years	70+ years	Unknown
Psychiatric disorders							
Number of Cases	7	8	51	27	70	513	18
Number of Events	10	11	66	41	102	654	25
Hallucination, visual						6	
Head banging	1					1	
Hostility			1				
Hydrophobia			1				
Illusion						1	
Indifference							1
Insomnia			7	5	10	25	
Intrusive thoughts				1			
Irritability	1			1	2	3	
Lack of spontaneous speech			1			2	
Listless					2	5	1
Logorrhoea			1				
Major depression					1	1	
Mental disorder			2	1	2	6	
Mental fatigue						1	
Mental status changes				1	2	1	
Mood altered						2	
Mood swings			1			1	
Mutism				1		4	
Near death experience			1			1	
Nervousness					1	2	
Neuroleptic-induced deficit syndrome						1	
Neuropsychiatric symptoms						1	
Neurosis				1	1		
Nightmare						1	
Obsessive thoughts						1	
Organic brain syndrome					1	1	1
Panic attack			2		1	1	
Panic disorder			1				1
Panic reaction	1					1	
Paranoia	1		1		1		
Persecutory delusion					1		
Persistent depressive disorder						1	
Personality change		1	1	2		6	1
Personality change due to a general medical condition						1	
Poor quality sleep					1	4	
Post-traumatic stress disorder						1	
Posturing					1		
Psychiatric symptom						2	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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MedDRA System Organ Class (SOC) and MedDRA Preferred Terms (PTs)	less or equal to 17 years	18 - 24 years	25 - 49 years	50 - 59 years	60 - 69 years	70+ years	Unknown
Psychiatric disorders							
Number of Cases	7	8	51	27	70	513	18
Number of Events	10	11	66	41	102	654	25
Psychomotor retardation						3	
Psychotic disorder							1
Restlessness		1	2	2	6	43	
Schizophrenia			1				
Sleep disorder			1	1		8	
Sleep talking						1	
Social avoidant behaviour							1
Soliloquy						1	
Sopor			2	1		18	
Speech sound disorder						1	
Staring						1	
Stress					1	2	1
Substance abuse	1						
Suicidal ideation	1				1	2	
Suicide attempt			1	1			
Suspected suicide							1
Suspiciousness						1	
Tachyphrenia				1			
Tearfulness						1	
Tension				1		4	
Tic						1	
Renal and urinary disorders							
Number of Cases	6	5	35	32	80	511	21
Number of Events	8	5	47	44	93	604	23
Acute kidney injury	1	3	8	9	20	153	4
Albuminuria							1
Anuria	2		2	3	3	27	
Atonic urinary bladder						1	
Azotaemia						8	
Bladder dilatation				1		2	
Bladder disorder			1		1	3	
Bladder dysfunction						1	
Bladder irritation						1	
Bladder necrosis						1	
Bladder sphincter atony	1						
Calculus bladder					1		
Chromaturia						3	
Chronic kidney disease			1		6	23	
Crush syndrome			1				

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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MedDRA System Organ Class (SOC) and MedDRA Preferred Terms (PTs)	less or equal to 17 years	18 - 24 years	25 - 49 years	50 - 59 years	60 - 69 years	70+ years	Unknown
Renal and urinary disorders							
Number of Cases	6	5	35	32	80	511	21
Number of Events	8	5	47	44	93	604	23
Cystitis haemorrhagic					1		
Cystitis noninfective						2	
Diabetic nephropathy					1	1	
Dysuria			2	1	3	12	2
End stage renal disease					1	4	
Glomerulonephritis						2	
Glomerulonephritis chronic						1	
Glomerulonephritis rapidly progressive						1	
Glomerulosclerosis					1		
Haematuria			1	3	1	13	
Haemoglobinuria			1			1	
Haemorrhage urinary tract						2	1
Hydronephrosis			1	1		2	
Hypertensive nephropathy					1	1	
Incontinence			1		1	18	1
Kidney congestion			1	1			
Kidney enlargement			2				
Kidney fibrosis						1	
Leukocyturia						3	
Mesangioproliferative glomerulonephritis				1			
Micturition urgency			1			2	
Nephritis			1			2	
Nephrolithiasis				1		2	
Nephropathy					1	2	
Nephrosclerosis					3	4	
Nephrotic syndrome			1			3	
Oliguria					2	7	
Paroxysmal nocturnal haemoglobinuria						1	
Pollakiuria			1	1		6	
Polyuria			1			6	
Prerenal failure						2	
Proteinuria			1	1		2	
Renal artery thrombosis						1	
Renal atrophy						3	
Renal cyst			1			7	
Renal cyst haemorrhage						1	
Renal disorder	1		2	1	4	12	4
Renal failure	1	2	10	11	22	150	5
Renal haemorrhage					1	1	1

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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MedDRA System Organ Class (SOC) and MedDRA Preferred Terms (PTs)	less or equal to 17 years	18 - 24 years	25 - 49 years	50 - 59 years	60 - 69 years	70+ years	Unknown
Renal and urinary disorders							
Number of Cases	6	5	35	32	80	511	21
Number of Events	8	5	47	44	93	604	23
Renal hypertrophy						1	
Renal impairment	1		1	1	9	42	
Renal infarct			1	1	3	2	
Renal mass						1	
Renal pain						3	
Renal tubular necrosis			1	2	1	1	
Renal vasculitis							1
Renal vein thrombosis						1	
Ureteral disorder					1		
Ureteric obstruction						1	
Urge incontinence						1	
Urinary bladder atrophy				1			
Urinary bladder haemorrhage	1			1			1
Urinary incontinence				2	1	23	1
Urinary retention			2		3	23	1
Urinary tract inflammation						2	
Urinary tract obstruction				1		1	
Urine abnormality			1		1	1	
Reproductive system and breast disorders							
Number of Cases	1	1	8	3	1	21	4
Number of Events	1	1	11	3	1	24	4
Amenorrhoea			1				
Benign prostatic hyperplasia						1	1
Breast haematoma						1	
Breast hyperplasia						1	
Breast mass						1	
Breast pain			1			3	
Breast swelling						1	1
Erectile dysfunction						1	
Genital haemorrhage			1				
Genital rash							1
Genital ulceration						1	
Infertility male		1					
Intermenstrual bleeding			1				
Menstruation irregular			1				
Nipple pain							1
Ovarian cyst						1	
Ovarian enlargement	1						
Pelvic haematoma						1	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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MedDRA System Organ Class (SOC) and MedDRA Preferred Terms (PTs)	less or equal to 17 years	18 - 24 years	25 - 49 years	50 - 59 years	60 - 69 years	70+ years	Unknown
Reproductive system and breast disorders							
Number of Cases	1	1	8	3	1	21	4
Number of Events	1	1	11	3	1	24	4
Pelvic pain						2	
Penile erosion						1	
Polymenorrhoea			1				
Prostatic disorder						1	
Prostatitis			1			2	
Prostatomegaly						2	
Scrotal erythema			1				
Scrotal pain			1				
Scrotal swelling			1				
Testicular oedema						2	
Testicular pain				1			
Testicular swelling				1			
Uterine haemorrhage			1				
Uterine mass						1	
Vaginal discharge						1	
Vaginal haemorrhage				1	1		
Respiratory, thoracic and mediastinal disorders							
Number of Cases	50	31	295	246	444	2,489	102
Number of Events	80	54	436	375	721	3,861	124
Acute chest syndrome			1				
Acute pulmonary oedema	1		2	3	4	37	
Acute respiratory distress syndrome	1		2	5	28	84	
Acute respiratory failure	3		5	9	13	107	2
Agonal respiration			2	1	2	1	
Alveolar lung disease						2	
Alveolitis						2	
Anoxia			1				
Aphonia						3	
Apnoea	1	1	2	3	5	38	
Apnoeic attack					1	1	
Asphyxia		1	2	2	5	27	
Aspiration			4	2	5	44	
Asthma		1	4	3	4	14	1
Atelectasis		1	1	1		8	
Autoimmune lung disease			1				1
Bradypnoea					2	1	
Bronchial disorder						1	
Bronchial haemorrhage					2	1	
Bronchial hyperreactivity						2	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Respiratory, thoracic and mediastinal disorders							
Number of Cases	50	31	295	246	444	2,489	102
Number of Events	80	54	436	375	721	3,861	124
Bronchial obstruction					1	1	
Bronchial secretion retention						1	
Bronchial wall thickening					1	1	
Bronchiectasis						6	
Bronchitis chronic			2			1	
Bronchopneumopathy						7	
Bronchospasm	1		1	2	4	8	
Catarrh					1	1	
Cheyne-Stokes respiration						2	
Choking			4	2	3	15	
Choking sensation			1		1		
Chronic hyperplastic eosinophilic sinusitis					1		
Chronic obstructive pulmonary disease				1	12	62	
Chronic respiratory failure					1	5	
Cough	5	5	40	24	52	213	12
Cyanosis central				1		1	
Cystic lung disease						1	
Dependence on respirator			1				
Diaphragmalgia						1	
Diaphragm muscle weakness						1	
Diffuse alveolar damage				1	3	2	
Dry throat						1	
Dysphonia					2	16	1
Dyspnoea	24	10	117	109	187	955	41
Dyspnoea at rest						7	
Dyspnoea exertional		1	5	2	3	29	
Emphysema			2	2	1	10	1
Eosinophilic pneumonia						1	
Eosinophilic pneumonia acute						1	
Epiglottic oedema						1	
Epistaxis	2	1		3	4	24	2
Granulomatous pneumonitis			1				
Grunting						2	
Haemoptysis	1		3	5	7	30	2
Haemothorax			1	1	1	4	
Hiccups			1	1		1	
Hydrothorax					2	7	
Hypercapnia		1			1	9	
Hypersensitivity pneumonitis						2	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Respiratory, thoracic and mediastinal disorders							
Number of Cases	50	31	295	246	444	2,489	102
Number of Events	80	54	436	375	721	3,861	124
Hyperventilation			4	1	1	12	
Hypocapnia						3	
Hypopnoea		2	1	1	1	19	
Hypoventilation	2	1	1		1	3	
Hypoxia	2	3	8	3	16	116	12
Idiopathic interstitial pneumonia						1	
Idiopathic pulmonary fibrosis					2	3	
Immune-mediated lung disease						1	
Increased bronchial secretion			1			8	
Increased upper airway secretion					1	7	
Increased viscosity of bronchial secretion						1	
Interstitial lung disease			3	3	10	58	1
Irregular breathing						3	
Laryngeal dyspnoea						1	
Laryngeal haemorrhage						1	
Laryngeal obstruction						1	
Laryngeal oedema			1			5	
Laryngospasm						1	
Lower respiratory tract congestion			2			16	
Lung consolidation				1	1	6	
Lung disorder	2		1	3	8	46	4
Lung infiltration			2		3	13	1
Lung opacity			1	1		4	
Mediastinal disorder					2		
Mediastinal haematoma						1	
Mediastinal haemorrhage					1	1	
Mouth breathing			1		1	6	
Nasal congestion	1	1			3	2	
Nasal crusting				1			
Nasal discharge discolouration					1		
Nasal disorder						1	
Nasal mucosal disorder						1	
Nasal mucosal erosion						1	
Nasal oedema		1					
Nasal polyps					1		
Obstructive airways disorder	1		1	2	2	9	
Organising pneumonia			3		2	7	
Oropharyngeal discomfort						3	
Oropharyngeal pain	1	2	8	6	7	22	1

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Respiratory, thoracic and mediastinal disorders							
Number of Cases	50	31	295	246	444	2,489	102
Number of Events	80	54	436	375	721	3,861	124
Orthopnoea				1	3	3	
Painful respiration			1		2	1	
Paranasal cyst		1	1				
Paranasal sinus haemorrhage		1					
Pharyngeal erythema							1
Pharyngeal haemorrhage					1		
Pharyngeal inflammation						1	
Pharyngeal oedema			1			2	
Pharyngeal swelling			1		2	4	1
Pleural effusion	1		12	6	9	81	
Pleural fibrosis						1	
Pleurisy				1	1	3	
Pleuritic pain						1	
Pneumomediastinum	1				1		
Pneumonitis	1				3	28	1
Pneumonitis aspiration						2	
Pneumothorax			2	1	2	10	1
Productive cough					7	44	1
Prolonged expiration						1	
Pulmonary alveolar haemorrhage				1	3	15	
Pulmonary arterial hypertension	1					3	
Pulmonary artery occlusion					1	1	
Pulmonary artery thrombosis			1	1	1	8	
Pulmonary congestion	1		9	5	6	27	1
Pulmonary embolism	6	6	67	75	86	335	15
Pulmonary fibrosis					1	13	
Pulmonary granuloma						1	
Pulmonary haemorrhage	1		3	2	1	10	1
Pulmonary hypertension		1		1	6	12	
Pulmonary infarction		2	1	2	2	7	
Pulmonary mass			1	2		3	1
Pulmonary microemboli						1	
Pulmonary necrosis						1	
Pulmonary oedema	4	2	22	16	31	117	7
Pulmonary pain							1
Pulmonary sarcoidosis						1	
Pulmonary thrombosis			8	5	5	16	1
Pulmonary vasculitis						2	
Pulmonary veno-occlusive disease	1						

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Respiratory, thoracic and mediastinal disorders							
Number of Cases	50	31	295	246	444	2,489	102
Number of Events	80	54	436	375	721	3,861	124
Rales			2	1	2	27	
Respiration abnormal			1	1	3	15	
Respiratory acidosis			1	1	1	22	
Respiratory alkalosis					1	5	
Respiratory arrest	3	2	18	11	26	154	1
Respiratory depression		2	2			4	
Respiratory disorder		2	3	2	5	72	2
Respiratory distress			5	8	15	104	1
Respiratory failure	7	2	18	14	44	292	4
Respiratory fatigue					1	3	
Respiratory gas exchange disorder		1					
Respiratory muscle weakness			1			1	
Respiratory paralysis						3	
Respiratory symptom						2	
Respiratory tract congestion			1			1	
Respiratory tract haemorrhage						1	1
Respiratory tract inflammation						1	
Respiratory tract oedema						1	
Rhinorrhoea	1		1	3	4	6	
Rhonchi						7	
Sinus disorder						1	
Sleep apnoea syndrome						2	
Sneezing				1	1	3	
Snoring				1		5	
Sputum discoloured						5	
Sputum increased			1			3	
Sputum retention						3	
Status asthmaticus			1				
Stertor			1	1		2	
Stridor						6	
Suffocation feeling				1		2	
Tachypnoea	2		4	3	12	95	
Thoracic haemorrhage	1					2	
Throat irritation			1		2	1	
Throat tightness						3	
Tonsillar hypertrophy			1				
Tonsillar inflammation				1			
Tracheal dilatation	1						
Upper airway obstruction					1	1	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Respiratory, thoracic and mediastinal disorders							
Number of Cases	50	31	295	246	444	2,489	102
Number of Events	80	54	436	375	721	3,861	124
Upper respiratory tract congestion						2	
Upper respiratory tract inflammation						1	
Use of accessory respiratory muscles					1	5	
Wheezing				2	5	57	1
Yawning						1	
Skin and subcutaneous tissue disorders							
Number of Cases	8	2	39	34	61	315	23
Number of Events	12	2	46	39	78	422	31
Acantholysis						1	
Acute generalised exanthematous pustulosis						1	
Alopecia			1				
Angioedema		1			2	2	
Blister			1		1	5	1
Bullous haemorrhagic dermatosis						2	
Cold sweat	1		3	3	6	26	2
Cutaneous vasculitis						4	
Decubitus ulcer				2	1	8	
Dermal cyst						1	
Dermatitis					1	2	
Dermatitis allergic						2	
Dermatitis bullous					1	3	
Dermatitis exfoliative generalised						1	
Dermatomyositis					3	2	
Dermatosis						1	
Drug eruption						1	
Drug reaction with eosinophilia and systemic symptoms						3	
Dry skin			1			3	
Ecchymosis						6	
Eczema				1		2	
Erythema			5	4	2	26	
Erythema multiforme					1	1	
Erythrodermic psoriasis							1
Haemorrhage subcutaneous				2		13	
Henoch-Schonlein purpura				1		2	
Hirsutism							1
Hyperhidrosis	2		12	9	23	62	4
Ichthyosis acquired						1	
Livedo reticularis			1	2	3	17	
Lividity					1	4	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Skin and subcutaneous tissue disorders							
Number of Cases	8	2	39	34	61	315	23
Number of Events	12	2	46	39	78	422	31
Nail discolouration						2	
Nail disorder						1	
Night sweats			3		1		2
Nikolsky's sign						1	
Pain of skin						2	
Peau d'orange						1	
Pemphigoid						10	
Pemphigus							1
Petechiae			4	3	3	22	2
Pigmentation disorder						2	
Pruritus	1		3	1	5	15	2
Psoriasis					1	3	
Purpura	1			1		16	2
Rash	4	1	4	3	11	35	4
Rash erythematous			1	1		3	
Rash macular			1			12	1
Rash maculo-papular						2	
Rash pruritic	1				1	3	
Rash vesicular						1	
Scab					1		1
Sensitive skin				1		1	
Skin burning sensation						2	
Skin discolouration			2		4	14	2
Skin disorder						7	
Skin erosion						1	
Skin exfoliation						4	
Skin haemorrhage						5	
Skin hypertrophy						1	
Skin lesion					3	6	
Skin necrosis						1	
Skin plaque			1			1	
Skin reaction				1			
Skin striae							1
Skin ulcer					1	12	2
Skin warm						2	
Skin weeping						2	
Solar dermatitis						1	
Stevens-Johnson syndrome			1		1	5	1
Subcutaneous emphysema	1					2	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Skin and subcutaneous tissue disorders							
Number of Cases	8	2	39	34	61	315	23
Number of Events	12	2	46	39	78	422	31
Target skin lesion						1	
Toxic epidermal necrolysis						6	1
Toxic skin eruption				1			
Urticaria	1		1	2	1	10	
Vascular purpura						1	
Vitiligo				1			
Xeroderma						1	
Yellow skin			1			3	
Social circumstances							
Number of Cases				6	8	70	2
Number of Events				7	8	74	2
Alcohol use				1			
Anal sex							1
Bedridden				2	3	23	
Blood product transfusion dependent				1			
Dependence on oxygen therapy						1	
Disability						2	
Disease risk factor						1	
Immobile				1	1	8	
Impaired quality of life						4	
Loss of personal independence in daily activities				1	2	20	1
Patient uncooperative						1	
Physical disability						1	
Refusal of treatment by patient						4	
Sitting disability						1	
Social problem						1	
Walking disability				1	2	6	
Wheelchair user						1	
Surgical and medical procedures							
Number of Cases	3	3	59	57	116	480	40
Number of Events	3	4	65	66	132	532	49
Aneurysm repair						1	
Aortic surgery			1				
Bed rest						1	
Bladder catheter permanent						1	
Cardiac operation						1	
Cataract operation						1	
Chemotherapy				1			
COVID-19 immunisation					3	3	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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MedDRA System Organ Class (SOC) and MedDRA Preferred Terms (PTs)	less or equal to 17 years	18 - 24 years	25 - 49 years	50 - 59 years	60 - 69 years	70+ years	Unknown
Surgical and medical procedures							
Number of Cases	3	3	59	57	116	480	40
Number of Events	3	4	65	66	132	532	49
Cranial nerve decompression						1	
Craniectomy			1	1			
Dermabrasion						1	
Dialysis							1
Endotracheal intubation					1	3	1
General anaesthesia					1		
Haemodialysis						1	
Hand amputation						1	
Heart valve operation						1	
Hospitalisation						1	
Immunisation	2	2	24	29	68	379	27
Intensive care						1	
Interchange of vaccine products	1	2	30	29	51	119	16
Leg amputation			1			1	
Mechanical ventilation					1		
Medical induction of coma			1	1	1	2	1
Palliative care						3	
Pericardial drainage						1	
Platelet transfusion							1
Resuscitation			7	4	2	6	
Surgery					1		
Thrombectomy					1	1	
Tracheostomy						1	
Transfusion							2
Vascular anastomosis				1			
Vascular graft						1	
Venous operation					1		
Withdrawal of life support					1		
Vascular disorders							
Number of Cases	23	10	146	139	252	1,138	69
Number of Events	30	12	179	183	309	1,450	75
Acute aortic syndrome				1		2	
Air embolism					1		
Aneurysm	1		1	2		8	2
Aneurysm ruptured	1		4	2	3	6	1
Angiodysplasia						1	
Angiopathy			2		1	4	
Aortic aneurysm					1	14	
Aortic aneurysm rupture				1	3	25	1

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

*Only post birth cases included

MedDRA System Organ Class (SOC) and MedDRA Preferred Terms (PTs)	less or equal to 17 years	18 - 24 years	25 - 49 years	50 - 59 years	60 - 69 years	70+ years	Unknown
Vascular disorders							
Number of Cases	23	10	146	139	252	1,138	69
Number of Events	30	12	179	183	309	1,450	75
Aortic arteriosclerosis				2	1	12	
Aortic dilatation						2	
Aortic dissection			5	7	13	53	2
Aortic dissection rupture			1	1	2	3	
Aortic embolus						1	
Aortic intramural haematoma						1	
Aortic occlusion						1	
Aortic perforation					1		
Aortic rupture			1		4	5	
Aortic stenosis				2		10	
Aortic thrombosis					1	6	
Aortitis					1	2	
Arterial disorder					1		
Arterial haemorrhage			1			2	
Arterial occlusive disease			3		1	6	
Arterial rupture				1	3	4	1
Arterial stenosis						1	
Arterial thrombosis			1	2	1	7	
Arteriosclerosis			6	9	9	45	3
Arteriovenous fistula						1	
Artery dissection					1	1	
Atherosclerotic plaque rupture				1	1	2	
Axillary vein thrombosis				1		1	
Blood pressure fluctuation					1	10	1
Blood pressure inadequately controlled						2	
Bloody discharge						2	
Blue toe syndrome							1
Brachiocephalic artery stenosis						1	
Brachiocephalic vein thrombosis				1			
Capillary fragility						1	
Capillary leak syndrome			1	2	1	4	
Circulatory collapse	2	2	28	27	41	132	4
Cryoglobulinaemia						1	
Cyanosis	9		13	11	12	80	1
Deep vein thrombosis	1		10	17	25	58	3
Dependent rubor						1	
Embolism			3	3	9	32	2
Embolism arterial					1	3	
Embolism venous					1	2	

090177e19b0e6be1\Approved\Approved On: 19-Aug-2022 10:22 (GMT)

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Vascular disorders							
Number of Cases	23	10	146	139	252	1,138	69
Number of Events	30	12	179	183	309	1,450	75
Essential hypertension						3	
Exsanguination						1	
Extremity necrosis						2	
False lumen dilatation of aortic dissection				1			
Femoral artery embolism					1	1	
Flushing				1		2	
Giant cell arteritis					1	2	
Granulomatosis with polyangiitis						1	
Haematoma			5	1	4	31	2
Haemodynamic instability				2	5	11	
Haemorrhage		1	5	5	7	33	3
Haemorrhagic infarction				1		2	
Hot flush			1	1	3	5	1
Hyperaemia			1			1	
Hypertension	1		14	9	20	114	5
Hypertensive crisis			3	3		18	
Hypertensive emergency						2	
Hypertensive urgency			1				
Hypoperfusion					1	4	
Hypotension	3	4	10	11	23	170	5
Hypotensive crisis						2	
Hypovolaemic shock			2	1	1	9	
Iliac artery occlusion						2	
Iliac artery rupture						1	
Infarction	2			2	5	21	3
Inferior vena cava dilatation						1	
Intermittent claudication					1		
Internal haemorrhage			2	1		15	2
Ischaemia				1	1	14	1
Jugular vein distension	1					3	
Jugular vein embolism						1	
Jugular vein thrombosis			1	1		2	
Labile blood pressure					1		
Labile hypertension						2	
Leriche syndrome						1	
Lymphoedema				1		3	
Macroangiopathy						1	
Malignant hypertension				2			
Microangiopathy						1	

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Vascular disorders							
Number of Cases	23	10	146	139	252	1,138	69
Number of Events	30	12	179	183	309	1,450	75
Neurogenic shock					1		
Obstructive shock						1	
Orthostatic hypotension						1	
Pallor	1		7	3	10	71	
Paraneoplastic thrombosis					1		
Pelvic venous thrombosis		1				3	
Peripheral arterial occlusive disease			1			6	
Peripheral artery aneurysm						1	
Peripheral artery occlusion						2	
Peripheral artery stenosis						1	
Peripheral artery thrombosis			1		1	4	
Peripheral circulatory failure					2	7	
Peripheral coldness			3	1	5	23	
Peripheral embolism						2	
Peripheral ischaemia				1	1	21	
Peripheral vascular disorder					2	7	1
Peripheral venous disease				2		6	
Phlebitis				1			
Poor peripheral circulation							1
Raynaud's phenomenon						1	
Shock	6		8	9	14	56	
Shock haemorrhagic			1	1	6	13	
Subclavian artery dissection					1		
Subclavian artery occlusion					1		
Subclavian artery thrombosis				1	1		
Subclavian vein thrombosis			1	1		2	
Superficial vein thrombosis						1	
Superior vena cava syndrome						2	
Systolic hypertension						1	
Thrombophlebitis		1				6	
Thrombosis	2	3	23	22	38	134	25
Varicose ulceration						1	
Varicose vein						1	
Vascular insufficiency						1	
Vascular occlusion						1	1
Vascular pain				1		1	1
Vascular shunt							1
Vasculitis			4	3	4	13	
Vasculitis necrotising						2	

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Vascular disorders							
Number of Cases	23	10	146	139	252	1,138	69
Number of Events	30	12	179	183	309	1,450	75
Vasodilatation			2			1	
Vasospasm					2		
Vena cava thrombosis			1			3	
Venocclusive disease						1	
Venous haemorrhage						1	1
Venous thrombosis			1		2	7	
Venous thrombosis limb					2	7	
Visceral congestion			1		1	1	
Number of Cases					1		
Number of Events					1		
						1	

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