

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 03-Mar-2022
Data Lock Date: 02-Mar-2022 20:03:58

MedDRA Version: MedDRA 24.1

COVID-19 mRNA Pfizer- BioNTech vaccine analysis print: All UK spontaneous reports received between 9/12/2020 and 02/03/2022 for mRNA Pfizer/BioNTech vaccine analysis print.

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

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Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia folate deficiency	1	0
Anaemia vitamin B12 deficiency	5	0
Deficiency anaemia	1	0
Iron deficiency anaemia	8	0
Pernicious anaemia	2	0
<i>Anaemias NEC</i>		
Anaemia	142	0
Anaemia macrocytic	2	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	3	0
Blood loss anaemia	1	0
Microcytic anaemia	1	0
Normocytic anaemia	1	0
<i>Anaemias haemolytic NEC</i>		
Coombs negative haemolytic anaemia	1	0
Haemolytic anaemia	7	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	19	0
Cold type haemolytic anaemia	1	0
Evans syndrome	1	0
Warm type haemolytic anaemia	1	0
<i>Anaemias haemolytic mechanical factor</i>		
Microangiopathic haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	54	0
Spontaneous haematoma	2	0
<i>Coagulation factor deficiencies</i>		
Acquired factor VIII deficiency	1	0
Acquired haemophilia	4	0
<i>Coagulopathies</i>		
Abnormal clotting factor	4	0
Antiphospholipid syndrome	6	0
Coagulopathy	28	1
Disseminated intravascular coagulation	3	0
Hypercoagulation	3	0
Thrombotic microangiopathy	4	0
<i>Eosinophilic disorders</i>		
Eosinophilia	13	0
<i>Haematological disorders</i>		
Blood disorder	7	0
Bone marrow disorder	1	0
Bone marrow oedema	1	0
Hypergammaglobulinaemia	1	0
Hyperviscosity syndrome	1	0
Mast cell activation syndrome	10	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	6	0
Intravascular haemolysis	1	0
Jaundice acholuric	1	0
<i>Leukocytoses NEC</i>		

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Leukocytosis	3	0
Lymphocytic infiltration	1	0
Lymphocytosis	6	0
Neutrophilia	12	0
Leukopenias NEC		
Leukopenia	4	1
Lymphopenia	4	0
Lymphatic system disorders NEC		
Abdominal lymphadenopathy	4	0
Hilar lymphadenopathy	3	0
Lymph node pain	2261	0
Lymph node ulcer	1	0
Lymphadenitis	182	0
Lymphadenopathy	13601	0
Lymphadenopathy mediastinal	1	0
Lymphatic disorder	3	0
Lymphatic insufficiency	1	0
Necrotic lymphadenopathy	4	0
Pseudolymphoma	12	0
Retroperitoneal lymphadenopathy	1	0
Marrow depression and hypoplastic anaemias		
Aplasia pure red cell	2	0
Aplastic anaemia	1	1
Hypoplastic anaemia	2	0
Myelosuppression	1	0
Pancytopenia	8	0
Neutropenias		
Autoimmune neutropenia	2	0
Neutropenia	42	0
Platelet disorders NEC		
Platelet anisocytosis	1	0
Platelet disorder	3	0
Polycythaemia (excl rubra vera)		
Polycythaemia	3	0
Purpuras (excl thrombocytopenic)		
Purpura non-thrombocytopenic	1	0
Red blood cell abnormal findings NEC		
Macrocytosis	2	0
Polychromasia	2	0
Red blood cell abnormality	2	0
Spleen disorders		
Spleen atrophy	1	0
Splenic infarction	3	0
Splenic lesion	1	0
Splenic thrombosis	2	0
Splenic vein thrombosis	2	0
Splenomegaly	12	0
Thrombocytopenias		
Acquired amegakaryocytic thrombocytopenia	1	0
Immune thrombocytopenia	83	0
Thrombocytopenia	236	1
Thrombocytopenic purpura	8	0
Thrombotic thrombocytopenic purpura	7	0

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
<i>Thrombocytoses</i>		
Thrombocytosis	7	0
Blood disorders SOC TOTAL	16891	4

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Aortic valvular disorders</i>		
Aortic valve incompetence	2	0
<i>Cardiac conduction disorders</i>		
Atrioventricular block	32	1
Atrioventricular block complete	3	1
Atrioventricular block first degree	2	0
Atrioventricular block second degree	4	0
Bundle branch block	2	0
Bundle branch block left	4	0
Bundle branch block right	4	0
Trifascicular block	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	7	0
Cardiac disorder	94	2
Cardiac dysfunction	2	0
Cardiac ventricular thrombosis	2	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	8	0
Intracardiac thrombus	6	0
<i>Cardiac hypertensive complications</i>		
Hypertensive heart disease	2	1
<i>Cardiac infections and inflammations NEC</i>		
Carditis	9	0
<i>Cardiac neoplasms NEC</i>		
Pericardial cyst	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	37	0
Cardiovascular symptom	3	0
Palpitations	5973	1
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	2	0
Heart valve incompetence	3	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	16	1
Congestive cardiomyopathy	8	0
Stress cardiomyopathy	3	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	1	0
Coronary artery disease	9	3
Coronary artery dissection	1	0
Coronary artery occlusion	4	0
Coronary artery thrombosis	7	2
<i>Endocarditis NEC</i>		
Endocarditis noninfective	1	1
<i>Heart failures NEC</i>		
Cardiac failure	84	10
Cardiac failure acute	6	1
Cardiac failure chronic	2	0
Cardiac failure congestive	6	3
Cardiogenic shock	5	2
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	9	1

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Acute myocardial infarction	28	2
Angina pectoris	323	1
Angina unstable	4	0
Arteriospasm coronary	4	0
Microvascular coronary artery disease	3	0
Myocardial infarction	288	40
Myocardial ischaemia	11	7
Left ventricular failures		
Acute left ventricular failure	1	1
Left ventricular failure	7	2
Mitral valvular disorders		
Mitral valve incompetence	8	0
Mitral valve prolapse	1	0
Myocardial disorders NEC		
Cardiac amyloidosis	1	0
Cardiac aneurysm	1	1
Cardiac ventricular scarring	1	0
Cardiomegaly	51	3
Dilatation ventricular	1	0
Left atrial dilatation	1	0
Left ventricular dysfunction	15	0
Left ventricular enlargement	2	0
Left ventricular hypertrophy	2	0
Myocardial fibrosis	7	0
Myocardial haemorrhage	1	0
Myocardial injury	23	0
Myocardial necrosis	1	0
Myocardial oedema	7	0
Myocardial rupture	1	0
Right atrial enlargement	1	0
Right ventricular dilatation	1	0
Right ventricular dysfunction	2	0
Right ventricular enlargement	1	0
Ventricular dysfunction	2	0
Ventricular hypertrophy	1	0
Ventricular hypokinesia	4	0
Noninfectious myocarditis		
Eosinophilic myocarditis	1	0
Hypersensitivity myocarditis	1	0
Myocarditis	739	1
Myocarditis post infection	1	0
Noninfectious pericarditis		
Pericarditis	507	2
Pericarditis constrictive	1	0
Pericarditis lupus	1	0
Pleuropericarditis	1	0
Pericardial disorders NEC		
Cardiac tamponade	2	1
Pericardial effusion	44	2
Pericardial fibrosis	1	0
Pericardial haemorrhage	4	3
Pericardial rub	2	0
Rate and rhythm disorders NEC		

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Arrhythmia	183	1
Arrhythmia neonatal	1	0
Bradycardia	74	0
Bradycardia foetal	2	0
Cardiac flutter	608	0
Extrasystoles	216	0
Heart alternation	3	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	35	0
Tachyarrhythmia	10	0
Tachycardia	2351	0
Tachycardia foetal	1	0
Tachycardia paroxysmal	1	0
Right ventricular failures		
Cor pulmonale	1	0
Right ventricular failure	1	0
Supraventricular arrhythmias		
Arrhythmia supraventricular	16	0
Atrial fibrillation	280	1
Atrial flutter	45	0
Atrial tachycardia	12	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	8	0
Sinus bradycardia	13	0
Sinus node dysfunction	1	0
Sinus tachycardia	78	0
Supraventricular extrasystoles	6	0
Supraventricular tachycardia	48	0
Tricuspid valvular disorders		
Tricuspid valve incompetence	6	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	126	44
Cardio-respiratory arrest	1	1
Pulseless electrical activity	7	0
Ventricular arrhythmia	5	0
Ventricular extrasystoles	31	0
Ventricular fibrillation	10	1
Ventricular tachycardia	17	0
Cardiac disorders SOC TOTAL	12677	145

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Autosomal chromosomal abnormalities</i>		
Trisomy 8	1	0
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	19	0
<i>Cardiac hypoplasias congenital</i>		
Ventricular hypoplasia	1	0
<i>Cardiac septal defects congenital</i>		
Atrial septal defect	2	0
Hypertrophic cardiomyopathy	1	0
Ventricular septal defect	1	0
<i>Cardiac valve disorders congenital</i>		
Bicuspid aortic valve	1	0
<i>Central nervous system disorders congenital NEC</i>		
Spina bifida	2	1
Syringomyelia	1	0
<i>Cerebellar disorders congenital</i>		
Arnold-Chiari malformation	1	0
Hereditary ataxia	1	0
<i>Cerebral disorders congenital</i>		
Anencephaly	2	0
Cerebral palsy	4	0
Congenital hydrocephalus	1	0
<i>Chromosomal abnormalities NEC</i>		
Cytogenetic abnormality	1	0
<i>Coagulation disorders congenital</i>		
Factor IX deficiency	1	0
Haemophilia	2	0
<i>Congenital disorders NEC</i>		
Congenital anomaly	1	0
Foetal malformation	1	0
Heterotaxia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	5	0
<i>Gastrointestinal tract disorders congenital NEC</i>		
Gastroschisis	3	0
<i>Genetic polymorphisms</i>		
Genetic polymorphism	1	0
<i>Great vessel disorders congenital</i>		
Congenital great vessel anomaly	1	0
Transposition of the great vessels	1	0
<i>Haematological disorders congenital NEC</i>		
Amegakaryocytic thrombocytopenia	1	0
Neonatal alloimmune thrombocytopenia	1	0
<i>Haemoglobinopathies congenital</i>		
Congenital methaemoglobinaemia	1	0
<i>Immune system abnormalities congenital</i>		
Combined immunodeficiency	1	0
<i>Inborn errors of lipid metabolism</i>		
Short-chain acyl-coenzyme A dehydrogenase deficiency	1	0
<i>Inborn errors of metabolism NEC</i>		
Alpha-1 antitrypsin deficiency	1	0
<i>Inborn errors of porphyrin metabolism</i>		
Porphyria	1	0

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Congenital disorders Congenital disorders cont'd		
<i>Laryngeal and tracheal disorders congenital</i>		
Laryngomalacia	1	0
<i>Lymphatic system disorders congenital</i>		
Cystic lymphangioma	3	0
<i>Male reproductive tract disorders congenital</i>		
Cryptorchism	1	0
Micropenis	4	0
Penoscrotal fusion	1	0
Phimosis	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Developmental hip dysplasia	1	0
Limb malformation	1	0
<i>Musculoskeletal and connective tissue disorders of skull congenital</i>		
Platybasia	1	0
<i>Musculoskeletal and connective tissue disorders of spine congenital</i>		
Block vertebra	1	0
Brachyolmia	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Dysmorphism	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	2	0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
Neurofibromatosis	1	0
Tourette's disorder	4	0
<i>Ocular disorders congenital NEC</i>		
Colour blindness	4	0
Congenital eye disorder	1	0
<i>Palate disorders congenital</i>		
Cleft lip and palate	2	0
<i>Peripheral nervous system disorders congenital NEC</i>		
Hereditary neuropathy with liability to pressure palsies	1	0
Paroxysmal extreme pain disorder	1	0
<i>Pulmonary and bronchial disorders congenital</i>		
Congenital cystic lung	1	0
<i>Retinal disorders congenital</i>		
Retinitis pigmentosa	1	0
<i>Sex chromosomal abnormalities</i>		
Turner's syndrome	1	0
<i>Skin and subcutaneous tissue disorders congenital NEC</i>		
Acral peeling skin syndrome	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
<i>Vascular anomalies congenital NEC</i>		
Congenital LUMBAR syndrome	1	0
<i>Venous disorders congenital</i>		
Anomalous pulmonary venous connection	1	0
Congenital disorders SOC TOTAL	105	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	39	0
Ear discomfort	104	0
Ear disorder	23	0
Ear haemorrhage	15	0
Ear inflammation	2	0
Ear pain	1158	0
Ear pruritus	12	0
Ear swelling	39	0
Otorrhoea	8	0
Paraesthesia ear	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	5	0
Eustachian tube dysfunction	10	0
Eustachian tube obstruction	6	0
<i>External ear disorders NEC</i>		
Auricular swelling	2	0
Excessive cerumen production	12	0
External ear pain	6	0
Red ear syndrome	2	0
<i>External ear infections and inflammations</i>		
External ear inflammation	2	0
<i>Hearing disorders NEC</i>		
Auditory disorder	6	0
Diplacusis	2	0
<i>Hearing losses</i>		
Conductive deafness	1	0
Deafness	294	0
Deafness bilateral	11	0
Deafness neurosensory	26	0
Deafness transitory	9	0
Deafness unilateral	39	0
Hypoacusis	226	0
Mixed deafness	1	0
Sudden hearing loss	52	0
<i>Hyperacusia</i>		
Hyperacusis	74	0
Misophonia	3	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	2	0
Inner ear disorder	13	0
Meniere's disease	14	0
Vestibular disorder	15	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	11	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	70	0
Phobic postural vertigo	1	0
Tinnitus	2409	0
Vertigo	1637	0
Vertigo labyrinthine	13	0
Vertigo positional	85	0

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Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
<i>Mastoid disorders</i>		
Mastoid effusion	1	0
<i>Middle ear disorders NEC</i>		
Middle ear disorder	3	0
Middle ear effusion	1	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	3	0
Ear disorders SOC TOTAL	6470	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	4	0
Thyroiditis	24	0
Thyroiditis acute	4	0
Thyroiditis subacute	8	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	2	0
Adrenal insufficiency	3	0
Adrenocortical insufficiency acute	16	0
<i>Adrenal gland disorders NEC</i>		
Adrenal disorder	3	0
Adrenal haemorrhage	3	0
<i>Anterior pituitary hyperfunction</i>		
Pituitary-dependent Cushing's syndrome	1	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	1	0
Luteal phase deficiency	1	0
<i>Endocrine abnormalities of gonadal function NEC</i>		
Oestrogen deficiency	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	4	0
Premature menarche	21	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	65	0
Ovulation delayed	35	0
<i>Male gonadal function disorders</i>		
Androgen deficiency	1	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0
Goitre	16	0
Thyroid disorder	11	0
Thyroid mass	2	0
Thyroid pain	11	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	13	0
Hyperthyroidism	53	0
Primary hyperthyroidism	1	0
Thyrotoxic crisis	5	0
<i>Thyroid hypofunction disorders</i>		
Autoimmune hypothyroidism	1	0
Hypothyroidic goitre	1	0
Hypothyroidism	42	0
Immune-mediated hypothyroidism	1	0
Myxoedema	1	0
Endocrine disorders SOC TOTAL	356	0

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Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	7	0
<i>Anterior chamber bleeding and vascular disorders</i>		
Spontaneous hyphaema	1	0
<i>Cataract conditions</i>		
Cataract	15	0
<i>Choroid and vitreous haemorrhages and vascular disorders</i>		
Choroidal haemorrhage	1	0
Choroidal neovascularisation	1	0
Vitreous haemorrhage	4	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Chorioretinopathy	8	0
Vitreous detachment	21	0
Vitreous floaters	119	0
<i>Colour blindness (incl acquired)</i>		
Colour blindness acquired	1	0
Dyschromatopsia	11	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	51	0
Scleral haemorrhage	1	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	3	0
Conjunctival ulcer	1	0
Conjunctivitis allergic	2	0
<i>Corneal infections, oedemas and inflammations</i>		
Corneal oedema	3	0
Keratitis	7	0
Ulcerative keratitis	5	0
<i>Corneal structural change, deposit and degeneration</i>		
Corneal scar	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	167	0
Excessive eye blinking	6	0
Eyelid function disorder	3	0
Eyelid myokymia	4	0
Eyelid ptosis	50	0
Paralytic lagophthalmos	2	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	2	0
Glaucoma	8	0
Ocular hypertension	1	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	3	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	3	0
Iridocyclitis	20	0
Iritis	13	0
Uveitis	55	0
Vogt-Koyanagi-Harada disease	1	0
<i>Lacrimation disorders</i>		
Dry eye	174	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Lacrimation increased	165	0
Lid bleeding and vascular disorders		
Eyelid bleeding	1	0
Lid, lash and lacrimal infections, irritations and inflammations		
Blepharitis	20	0
Blepharitis allergic	1	0
Chalazion	7	0
Eczema eyelids	10	0
Erythema of eyelid	11	0
Eyelid cyst	7	0
Eyelid irritation	4	0
Eyelid margin crusting	5	0
Eyelid oedema	14	0
Eyelid rash	20	0
Meibomian gland dysfunction	1	0
Swelling of eyelid	146	0
Swollen tear duct	2	0
Lid, lash and lacrimal structural disorders		
Dacryostenosis acquired	2	0
Dermatochalasis	1	0
Ectropion	1	0
Eyelash changes	1	0
Eyelid exfoliation	3	0
Eyelid skin dryness	2	0
Eyelid thickening	1	0
Floppy eyelid syndrome	1	0
Growth of eyelashes	3	0
Lacrimal gland enlargement	1	0
Lagophthalmos	4	0
Ocular bleeding and vascular disorders NEC		
Eye haematoma	4	0
Eye haemorrhage	38	0
Ocular vascular disorder	2	0
Ophthalmic vein thrombosis	1	0
Ocular disorders NEC		
Chorioretinal disorder	1	0
Dark circles under eyes	10	0
Eye disorder	42	0
Eye oedema	19	0
Eye pain	1289	0
Eye swelling	645	0
Eye symptom	9	0
Eye ulcer	6	0
Eyelid disorder	17	0
Eyelid pain	15	0
Eyelids pruritus	8	0
Ocular discomfort	34	0
Periorbital oedema	20	0
Periorbital pain	3	0
Periorbital swelling	130	0
Retinal disorder	2	0
Vitreous disorder	1	0
Ocular infections, inflammations and associated manifestations		

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Eye disorders Eye disorders cont'd		
Eye allergy	22	0
Eye discharge	34	0
Eye inflammation	39	0
Eye irritation	107	0
Eye pruritus	281	0
Limbal swelling	4	0
Ocular hyperaemia	263	0
Ocular nerve and muscle disorders		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Extraocular muscle paresis	3	0
Eye movement disorder	42	0
Gaze palsy	3	0
Ocular myasthenia	1	0
Ophthalmoplegia	5	0
Strabismus	10	0
Ocular sensation disorders		
Abnormal sensation in eye	22	0
Asthenopia	172	0
Eye paraesthesia	2	0
Eyelid sensory disorder	3	0
Foreign body sensation in eyes	19	0
Hypoaesthesia eye	18	0
Photophobia	523	0
Optic disc abnormalities NEC		
Papilloedema	8	0
Optic nerve bleeding and vascular disorders		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	4	0
Orbital infections, inflammations and irritations		
Parophthalmia	1	0
Orbital structural change, deposit and degeneration		
Orbital oedema	2	0
Pupil disorders		
Miosis	2	0
Mydriasis	24	0
Pupil fixed	4	0
Pupillary disorder	1	0
Pupils unequal	14	0
Refractive and accommodative disorders		
Accommodation disorder	1	0
Altered visual depth perception	5	0
Astigmatism	3	0
Hypermetropia	4	0
Myopia	3	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Papillophlebitis	1	0
Retinal artery occlusion	18	0
Retinal artery thrombosis	2	0
Retinal haemorrhage	11	0
Retinal vascular thrombosis	1	0
Retinal vein occlusion	45	0
Retinal vein thrombosis	2	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 03-Mar-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
<i>Retinal structural change, deposit and degeneration</i>		
Age-related macular degeneration	1	0
Epiretinal membrane	1	0
Macular degeneration	4	0
Macular hole	3	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	3	0
Retinal degeneration	1	0
Retinal detachment	8	0
Retinal tear	3	0
Retinal toxicity	3	0
<i>Retinal, choroid and vitreous infections and inflammations</i>		
Birdshot chorioretinopathy	2	0
Choroiditis	1	0
Cystoid macular oedema	1	0
Macular oedema	6	0
Retinal oedema	2	0
Retinal vasculitis	3	0
<i>Retinopathies NEC</i>		
Acute macular neuroretinopathy	3	0
Retinal exudates	2	0
Retinopathy	4	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	9	0
Scleritis	6	0
<i>Scleral structural change, deposit and degeneration</i>		
Scleral discolouration	2	0
<i>Structural change, deposit and degeneration of eye NEC</i>		
Endocrine ophthalmopathy	2	0
Exophthalmos	4	0
<i>Visual colour distortions</i>		
Chloropsia	2	0
Chromatopsia	1	0
Cyanopsia	4	0
Erythropsia	2	0
Xanthopsia	1	0
<i>Visual disorders NEC</i>		
Charles Bonnet syndrome	2	0
Diplopia	183	0
Dysmetropsia	1	0
Glare	1	0
Halo vision	9	0
Heteronymous diplopia	1	0
Metamorphopsia	24	0
Oscillopsia	3	0
Photopsia	162	0
Scintillating scotoma	4	0
Vision blurred	1428	0
Visual brightness	3	0
Visual snow syndrome	8	0
<i>Visual field disorders</i>		
Visual field defect	40	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
<i>Visual impairment and blindness (excl colour blindness)</i>		
Amaurosis fugax	4	0
Blindness	157	0
Blindness cortical	1	0
Blindness transient	20	0
Blindness unilateral	20	0
Central vision loss	6	0
Sudden visual loss	4	0
Visual acuity reduced	30	0
Visual acuity reduced transiently	1	0
Visual impairment	461	0
<i>Visual pathway disorders</i>		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	7900	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	2	0
Gastrointestinal sounds abnormal	18	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	2	0
<i>Abdominal wall conditions NEC</i>		
Abdominal wall haematoma	2	0
<i>Acute and chronic pancreatitis</i>		
Alcoholic pancreatitis	1	0
Autoimmune pancreatitis	1	0
Obstructive pancreatitis	1	0
Pancreatitis	19	0
Pancreatitis acute	17	1
Pancreatitis chronic	1	0
Pancreatitis necrotising	2	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	2	0
Anal sphincter atony	1	0
Rectal prolapse	1	0
<i>Anal and rectal pains</i>		
Proctalgia	15	0
<i>Anal and rectal signs and symptoms</i>		
Anal blister	1	0
Anal erythema	1	0
Anal hypoaesthesia	1	0
Anal pruritus	2	0
Anal spasm	1	0
Anorectal discomfort	5	0
Anorectal swelling	1	0
Rectal discharge	2	0
Rectal tenesmus	1	0
<i>Anal and rectal ulcers and perforation</i>		
Anal ulcer	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	6	0
Tongue cyst	4	0
Tongue polyp	2	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	2	0
Colitis	59	1
Colitis ischaemic	1	0
Colitis microscopic	2	0
Colitis ulcerative	79	0
Crohn's disease	51	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	12	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	2	0
Periodontal inflammation	1	0
<i>Dental developmental disorders and anomalies</i>		
Tooth impacted	1	0
<i>Dental disorders NEC</i>		
Loose tooth	5	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Malpositioned teeth	2	0
Periodontal disease	1	0
Teeth brittle	3	0
Teething	9	0
Tooth disorder	2	0
Tooth erosion	1	0
Tooth socket haemorrhage	1	0
Dental pain and sensation disorders		
Dental discomfort	7	0
Dental paraesthesia	14	0
Hyperaesthesia teeth	38	0
Toothache	195	0
Dental surface disorders		
Tooth discolouration	10	0
Diaphragmatic hernias		
Hiatus hernia	8	0
Diarrhoea (excl infective)		
Diarrhoea	6061	0
Diarrhoea haemorrhagic	27	0
Diverticula		
Diverticulum	6	0
Diverticulum intestinal	1	0
Duodenal and small intestinal stenosis and obstruction		
Small intestinal obstruction	3	0
Duodenal ulcers and perforation		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	3	0
Dyspeptic signs and symptoms		
Dyspepsia	533	0
Epigastric discomfort	15	0
Eructation	62	0
Faecal abnormalities NEC		
Abnormal faeces	23	0
Faecaloma	7	0
Faeces discoloured	63	0
Faeces hard	2	0
Faeces pale	5	0
Faeces soft	12	0
Mucous stools	12	0
Flatulence, bloating and distension		
Abdominal distension	590	0
Aerophagia	3	0
Flatulence	198	0
Gastric and oesophageal haemorrhages		
Gastric haemorrhage	5	1
Mallory-Weiss syndrome	1	0
Oesophageal varices haemorrhage	1	0
Gastric ulcers and perforation		
Gastric ulcer	7	0
Gastritis (excl infective)		
Chronic gastritis	4	0
Gastritis	72	0
Reflux gastritis	8	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	2	0
Abdominal pain	1676	0
Abdominal pain lower	149	0
Abdominal pain upper	2779	0
Abdominal rigidity	25	0
Abdominal tenderness	15	0
Gastrointestinal pain	166	0
Oesophageal pain	13	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	276	0
Duodenogastric reflux	4	0
Gastric dilatation	7	0
Gastrooesophageal reflux disease	191	0
Impaired gastric emptying	10	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Intestinal pseudo-obstruction	2	0
<i>Gastrointestinal disorders NEC</i>		
Appendicolith	1	0
Appendix disorder	2	0
Food poisoning	7	0
Functional gastrointestinal disorder	11	0
Gastric disorder	10	0
Gastrointestinal disorder	30	0
Stomach mass	4	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	9	0
Change of bowel habit	13	0
Dyschezia	4	0
Gastrointestinal motility disorder	4	0
Oesophageal achalasia	1	0
<i>Gastrointestinal fistulae</i>		
Diverticular fistula	2	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Appendicitis noninfective	1	0
Duodenitis	1	0
Enteritis	6	0
Eiploic appendagitis	2	0
Gastrointestinal inflammation	5	0
Gastrointestinal tract irritation	1	0
Intestinal angioedema	2	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Barrett's oesophagus	2	0
Hyperchlorhydria	4	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	701	0
Abdominal symptom	2	0
Acute abdomen	8	0
Anal incontinence	22	0
Breath odour	22	0
Dysphagia	238	2
Gastrointestinal wall thickening	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Malignant dysphagia	1	0
Odynophagia	45	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Cardiospasm	1	0
Defaecation urgency	12	0
Frequent bowel movements	32	0
Gastrointestinal hypermotility	1	0
Irritable bowel syndrome	102	0
Oesophageal spasm	5	0
Pylorospasm	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Ileus	1	0
Intestinal obstruction	7	0
Neonatal intestinal obstruction	1	0
Volvulus	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	11	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	8	2
Mesenteric vein thrombosis	10	0
Omental infarction	1	0
Thrombosis mesenteric vessel	2	0
Visceral venous thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	13	0
Gingival discomfort	8	0
Gingival disorder	5	0
Gingival erythema	2	0
Gingival hypertrophy	1	0
Gingival oedema	1	0
Gingival pain	135	0
Gingival pruritus	2	0
Gingival recession	1	0
Gingival swelling	43	0
Gingival ulceration	2	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	12	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	82	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Gastric varices	1	0
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	35	1
Haemorrhoids thrombosed	1	0
<i>Inguinal hernias</i>		
Inguinal hernia	1	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	23	1
Intestinal haemorrhage	1	0
Rectal haemorrhage	81	0
Small intestinal haemorrhage	5	0
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	5	2

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Large intestinal ulcer	1	0
Large intestinal ulcer haemorrhage	1	0
Large intestine perforation	1	0
Large intestinal stenosis and obstruction		
Large intestinal obstruction	1	1
Malabsorption syndromes		
Bile acid malabsorption	4	0
Coeliac disease	14	0
Malabsorption	1	0
Steatorrhoea	4	0
Nausea and vomiting symptoms		
Cyclic vomiting syndrome	1	0
Discoloured vomit	13	0
Infantile vomiting	7	0
Nausea	15206	0
Regurgitation	1	0
Retching	116	0
Vomiting	5119	1
Vomiting projectile	70	0
Non-mechanical ileus		
Ileus paralytic	2	0
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	19	1
Haematemesis	39	2
Haematochezia	60	0
Melaena	9	0
Upper gastrointestinal haemorrhage	14	1
Oesophageal stenosis and obstruction		
Oesophageal stenosis	3	0
Oesophagitis (excl infective)		
Eosinophilic oesophagitis	1	0
Oesophagitis	6	0
Oral dryness and saliva altered		
Aptyalism	5	0
Dry mouth	540	0
Lip dry	48	0
Saliva altered	8	0
Salivary hypersecretion	53	0
Oral soft tissue disorders NEC		
Angina bullosa haemorrhagica	1	0
Chapped lips	27	0
Cheilitis	29	0
Enlarged uvula	15	0
Leukoplakia oral	2	0
Lip blister	35	0
Lip disorder	5	0
Oral disorder	21	0
Oral lichen planus	15	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	7	0
Oral soft tissue haemorrhages		
Lip haemorrhage	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Mouth haemorrhage	19	0
Oral blood blister	18	0
Oral purpura	2	0
Oral soft tissue infections		
Angular cheilitis	4	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	3	0
Burning mouth syndrome	7	0
Coating in mouth	1	0
Hypoaesthesia oral	517	0
Lip discolouration	9	0
Lip erythema	4	0
Lip exfoliation	6	0
Lip pain	66	0
Lip pruritus	18	0
Lip scab	1	0
Oral discomfort	88	0
Oral dysaesthesia	1	0
Oral mucosal blistering	17	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	21	0
Oral mucosal erythema	8	0
Oral mucosal exfoliation	10	0
Oral mucosal roughening	3	0
Oral mucosal scab	1	0
Oral pain	183	0
Oral pruritus	24	0
Paraesthesia oral	954	0
Pigmentation lip	1	0
Oral soft tissue swelling and oedema		
Lip oedema	4	0
Lip swelling	888	0
Mouth swelling	117	0
Oedema mouth	4	0
Palatal oedema	4	0
Palatal swelling	4	0
Pancreatic disorders NEC		
Pancreatic disorder	1	0
Pancreatic failure	1	0
Pancreatic mass	1	0
Peptic ulcers and perforation		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	14	0
Peritoneal and retroperitoneal disorders		
Ascites	2	0
Peritoneal and retroperitoneal fibrosis and adhesions		
Abdominal adhesions	2	0
Peritoneal and retroperitoneal haemorrhages		
Haemoperitoneum	1	0
Retroperitoneal haematoma	1	0
Retroperitoneal haemorrhage	2	1
Rectal inflammations NEC		
Proctitis	3	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<small>Gastrointestinal disorders cont'd</small>		
Proctitis ulcerative	1	0
Salivary gland disorders NEC		
Salivary gland disorder	1	0
Salivary gland mucocoele	1	0
Salivary gland pain	13	0
Salivary gland enlargements		
Parotid gland enlargement	11	0
Salivary gland enlargement	5	0
Submaxillary gland enlargement	8	0
Salivary gland infections and inflammations		
Noninfective sialoadenitis	2	0
Stomatitis and ulceration		
Aphthous ulcer	58	0
Lip ulceration	22	0
Mouth ulceration	480	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	68	0
Tongue disorders		
Glossitis	23	0
Hypertrophy of tongue papillae	2	0
Plicated tongue	4	0
Tongue disorder	44	0
Tongue geographic	7	0
Tongue haemorrhage	3	0
Tongue ulceration	34	0
Trichoglossia	4	0
Tongue signs and symptoms		
Glossodynia	229	0
Scalloped tongue	5	0
Stiff tongue	4	0
Swollen tongue	550	0
Tongue blistering	19	0
Tongue coated	20	0
Tongue discolouration	39	0
Tongue discomfort	45	0
Tongue dry	16	0
Tongue eruption	11	0
Tongue erythema	13	0
Tongue exfoliation	2	0
Tongue movement disturbance	7	0
Tongue oedema	24	0
Tongue pruritus	2	0
Tongue rough	5	0
Tongue spasm	12	0
Tooth missing		
Tooth loss	6	0
Gastrointestinal disorders SOC TOTAL	41851	18

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	9	0
Administration site erythema	4	0
Administration site extravasation	3	0
Administration site haematoma	3	0
Administration site inflammation	1	0
Administration site irritation	1	0
Administration site joint discomfort	1	0
Administration site joint movement impairment	2	0
Administration site joint pain	1	0
Administration site nerve damage	1	0
Administration site pain	20	0
Administration site rash	5	0
Administration site reaction	1	0
Administration site swelling	4	0
Administration site urticaria	2	0
Administration site warmth	2	0
Puncture site bruise	42	0
Puncture site pain	9	0
Puncture site reaction	1	0
Puncture site swelling	2	0
Vessel puncture site bruise	2	0
Vessel puncture site erythema	1	0
Vessel puncture site pain	1	0
<i>Adverse effect absent</i>		
No adverse event	10	0
<i>Application and instillation site reactions</i>		
Application site acne	2	0
Application site bruise	12	0
Application site burn	1	0
Application site dryness	2	0
Application site erythema	18	0
Application site haemorrhage	1	0
Application site hypoaesthesia	2	0
Application site irritation	1	0
Application site joint erythema	1	0
Application site joint pain	1	0
Application site mass	1	0
Application site odour	2	0
Application site pain	12	0
Application site pruritus	4	0
Application site rash	2	0
Application site reaction	1	0
Application site swelling	2	0
Application site vesicles	7	0
Application site warmth	1	0
Instillation site warmth	9	0
<i>Asthenic conditions</i>		
Asthenia	2343	0
Chronic fatigue syndrome	82	0
Decreased activity	10	0
Fatigue	25812	1
Malaise	5814	1

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Sluggishness	19	0
Body temperature altered		
Hyperthermia	7	0
Hyperthermia malignant	1	0
Hypothermia	26	0
Temperature regulation disorder	14	0
Breast complications associated with device		
Breast implant palpable	1	0
Capsular contracture associated with breast implant	2	0
Cardiac complications associated with device		
Prosthetic cardiac valve thrombosis	2	0
Complications associated with device NEC		
Capsular contracture associated with implant	1	0
Complication of device removal	3	0
Injury associated with device	5	0
Medical device pain	1	0
Medical device site swelling	1	0
Phantom shocks	2	0
Death and sudden death		
Brain death	3	0
Cardiac death	3	0
Clinical death	1	1
Death	187	187
Sudden cardiac death	1	1
Sudden death	28	28
Febrile disorders		
Hyperpyrexia	10	0
Pyrexia	16749	0
Feelings and sensations NEC		
Chills	10439	0
Feeling abnormal	1806	0
Feeling cold	1359	0
Feeling drunk	82	0
Feeling hot	1288	0
Feeling jittery	34	0
Feeling of body temperature change	364	0
Feeling of relaxation	3	0
Hangover	84	0
Hunger	51	0
Sensation of blood flow	5	0
Sensation of foreign body	62	0
Sense of oppression	1	0
Temperature intolerance	51	0
Thirst	380	0
Thirst decreased	2	0
Fibrosis NEC		
Fibrosis	1	0
Gait disturbances		
Gait deviation	1	0
Gait disturbance	282	0
Gait inability	109	0
Loss of control of legs	28	0
General signs and symptoms NEC		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Adhesion	1	0
Chronic disease	1	0
Concomitant disease progression	1	1
Condition aggravated	326	0
Crepitations	5	0
Crying	167	0
Deformity	2	0
Developmental delay	1	0
Discharge	13	0
Disease progression	2	0
Disease recurrence	32	0
Effusion	3	0
Energy increased	27	0
Exercise tolerance decreased	34	0
Exercise tolerance increased	1	0
Fat tissue increased	1	0
Foaming at mouth	3	0
General physical health deterioration	17	2
General symptom	3	0
Glassy eyes	7	0
High-pitched crying	3	0
Illness	2226	0
Induration	17	0
Influenza like illness	2662	0
Irritability postvaccinal	2	0
Local reaction	92	0
Moaning	4	0
Multiple organ dysfunction syndrome	12	4
Nonspecific reaction	2	0
Organ failure	3	1
Perforation	2	0
Peripheral swelling	4400	0
Physical deconditioning	2	0
Pre-existing condition improved	9	0
Prolapse	1	0
Screaming	24	0
Secretion discharge	24	0
Swelling	3550	0
Swelling face	972	0
Symptom recurrence	1	0
Terminal state	1	0
Tissue irritation	1	0
Tissue rupture	1	0
Healing abnormal NEC		
Impaired healing	6	0
Implant and catheter site reactions		
Implant site discolouration	2	0
Implant site pain	3	0
Implant site rash	1	0
Implant site reaction	1	0
Implant site swelling	2	0
Implant site urticaria	1	0
Implant site warmth	3	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Inflamations</i>		
Foreign body reaction	1	0
Granuloma	1	0
Inflammation	626	0
Papillitis	1	0
Scar inflammation	3	0
Serositis	1	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	6	0
<i>Infusion site reactions</i>		
Infusion site coldness	1	0
Infusion site discolouration	1	0
Infusion site joint effusion	1	0
Infusion site joint pain	2	0
Infusion site mass	1	0
Infusion site nerve damage	1	0
Infusion site pain	5	0
Infusion site pruritus	3	0
Infusion site swelling	2	0
Infusion site urticaria	1	0
Infusion site warmth	2	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	38	0
Injection site bruising	72	0
Injection site coldness	1	0
Injection site cyst	3	0
Injection site discolouration	5	0
Injection site discomfort	10	0
Injection site eczema	1	0
Injection site erythema	435	0
Injection site extravasation	1	0
Injection site haematoma	1	0
Injection site haemorrhage	10	0
Injection site hypersensitivity	2	0
Injection site hypoaesthesia	16	0
Injection site indentation	10	0
Injection site induration	4	0
Injection site inflammation	50	0
Injection site injury	2	0
Injection site irritation	2	0
Injection site joint discomfort	2	0
Injection site joint erythema	4	0
Injection site joint movement impairment	1	0
Injection site joint pain	15	0
Injection site lymphadenopathy	1	0
Injection site macule	1	0
Injection site mass	637	0
Injection site movement impairment	1	0
Injection site muscle weakness	1	0
Injection site necrosis	4	0
Injection site nerve damage	1	0
Injection site nodule	1	0
Injection site oedema	19	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 03-Mar-2022

Data Lock Date: 02-Mar-2022 20:03:58

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site pain	3187	0
Injection site pallor	1	0
Injection site paraesthesia	14	0
Injection site pruritus	244	0
Injection site rash	204	0
Injection site reaction	57	0
Injection site scab	4	0
Injection site scar	4	0
Injection site swelling	348	0
Injection site urticaria	36	0
Injection site vesicles	10	0
Injection site warmth	208	0
Interactions		
Alcohol interaction	5	0
Drug interaction	31	0
Inhibitory drug interaction	3	0
Mass conditions NEC		
Cyst	56	0
Mass	85	0
Nodule	44	0
Mucosal findings abnormal		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	10	0
Mucosal inflammation	3	0
Oedema mucosal	2	0
Polyp	6	0
Necrosis NEC		
Fat necrosis	4	0
Necrosis	5	0
Oedema NEC		
Face oedema	35	0
Generalised oedema	6	0
Localised oedema	21	0
Oedema	94	0
Oedema peripheral	100	0
Pain and discomfort NEC		
Axillary pain	4019	0
Breakthrough pain	1	0
Chest discomfort	2039	0
Chest pain	6611	0
Discomfort	559	0
Facial discomfort	21	0
Facial pain	234	0
Inflammatory pain	21	0
Non-cardiac chest pain	34	0
Pain	9953	0
Suprapubic pain	1	0
Tenderness	736	0
Visceral pain	2	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	43	0
Adverse food reaction	3	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 03-Mar-2022

Data Lock Date: 02-Mar-2022 20:03:58

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Adverse reaction	6	0
Drug ineffective	444	0
Drug intolerance	4	0
Drug resistance	1	0
Immediate post-injection reaction	4	0
Inadequate analgesia	9	0
No reaction on previous exposure to drug	25	0
Product intolerance	1	0
Therapeutic product effect decreased	2	0
Therapeutic product effect delayed	2	0
Therapeutic product effect increased	1	0
Therapeutic product ineffective	3	0
Therapeutic response decreased	2	0
Therapeutic response unexpected	90	0
Therapy non-responder	1	0
Treatment failure	12	0
Vaccination failure	80	0
Trophic disorders		
Abnormal organ growth	1	0
Atrophy	2	0
Calcinosis	2	0
Hyperplasia	1	0
Hypertrophy	1	0
Ulcers NEC		
Ulcer	37	0
Ulcer haemorrhage	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	25	0
Shoulder injury related to vaccine administration	64	0
Vaccination site anaesthesia	1	0
Vaccination site bruising	145	0
Vaccination site coldness	4	0
Vaccination site cyst	7	0
Vaccination site dermatitis	2	0
Vaccination site discharge	1	0
Vaccination site discolouration	17	0
Vaccination site discomfort	54	0
Vaccination site dryness	2	0
Vaccination site eczema	1	0
Vaccination site erythema	681	0
Vaccination site granuloma	5	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	30	0
Vaccination site hypersensitivity	5	0
Vaccination site hypoaesthesia	20	0
Vaccination site induration	81	0
Vaccination site inflammation	66	0
Vaccination site injury	1	0
Vaccination site irritation	16	0
Vaccination site joint discomfort	3	0
Vaccination site joint erythema	12	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	20	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 03-Mar-2022

Data Lock Date: 02-Mar-2022 20:03:58

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site joint pain	35	0
Vaccination site joint swelling	4	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	8	0
Vaccination site macule	1	0
Vaccination site mass	332	0
Vaccination site movement impairment	96	0
Vaccination site necrosis	1	0
Vaccination site nerve damage	1	0
Vaccination site nodule	5	0
Vaccination site oedema	3	0
Vaccination site pain	2378	0
Vaccination site papule	2	0
Vaccination site paraesthesia	10	0
Vaccination site phlebitis	1	0
Vaccination site photosensitivity reaction	1	0
Vaccination site pruritus	187	0
Vaccination site rash	153	0
Vaccination site reaction	36	0
Vaccination site scab	3	0
Vaccination site scar	3	0
Vaccination site swelling	651	0
Vaccination site thrombosis	1	0
Vaccination site ulcer	2	0
Vaccination site urticaria	11	0
Vaccination site vesicles	13	0
Vaccination site warmth	301	0
<i>Vascular complications associated with device</i>		
Vascular stent thrombosis	1	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	4	0
Withdrawal syndrome	48	0
General disorders SOC TOTAL	119855	23H

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 03-Mar-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	19	0
Cholangitis	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	4	0
Cholecystitis acute	2	0
Cholelithiasis	12	0
<i>Cholestasis and jaundice</i>		
Cholestasis	2	0
Jaundice	27	0
Jaundice cholestatic	10	0
Ocular icterus	2	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	3	0
Gallbladder enlargement	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Hepatic cyst	1	0
Hepatic lesion	1	0
Liver disorder	16	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	8	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	2	0
Hepatic failure	2	1
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	1	0
<i>Hepatic vascular disorders</i>		
Congestive hepatopathy	2	0
Hepatic artery embolism	1	0
Hepatic haemorrhage	2	0
Hepatic vein thrombosis	5	0
Portal vein thrombosis	8	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	33	0
Hepatomegaly	7	0
Liver tenderness	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	15	0
Drug-induced liver injury	3	0
Hepatic steatosis	5	0
Hepatitis	17	0
Hepatitis acute	3	0
Hepatitis toxic	1	0
Hepatotoxicity	1	0
Immune-mediated hepatic disorder	1	0
Liver injury	27	0
Hepatic disorders SOC TOTAL	248	1

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 03-Mar-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Loefgren syndrome	1	0
Sarcoidosis	20	0
<i>Allergic conditions NEC</i>		
Allergic oedema	19	0
Allergy to animal	2	0
Allergy to arthropod bite	7	0
Allergy to arthropod sting	2	0
Allergy to metals	3	0
Allergy to sting	1	0
Hypersensitivity	1150	0
Infusion related hypersensitivity reaction	3	0
Mite allergy	2	0
Multiple allergies	16	0
Serum sickness	3	0
Serum sickness-like reaction	6	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	4	0
Type IV hypersensitivity reaction	6	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	7	0
Allergy to chemicals	6	0
Allergy to vaccine	48	0
Contrast media reaction	2	0
Drug hypersensitivity	42	0
Food allergy	45	0
Milk allergy	3	0
Oral allergy syndrome	3	0
Polymers allergy	1	0
Reaction to colouring	1	0
Reaction to excipient	11	0
Reaction to preservatives	5	0
Rubber sensitivity	1	0
Smoke sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	560	1
Anaphylactic shock	65	0
Anaphylactoid reaction	25	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	3	0
Seasonal allergy	114	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	56	0
<i>Autoinflammatory diseases</i>		
Autoinflammatory disease	1	0
<i>Immune and associated conditions NEC</i>		
Anamnestic reaction	1	0
Bacille Calmette-Guerin scar reactivation	67	0
Cytokine release syndrome	1	0
Cytokine storm	1	0
Decreased immune responsiveness	3	0
Graft versus host disease	2	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Immune system disorders cont'd</i>		
Haemophagocytic lymphohistiocytosis	3	0
Immune reconstitution inflammatory syndrome	1	0
Immune system disorder	33	0
Immune-mediated adverse reaction	7	0
Immunisation reaction	2	0
Multisystem inflammatory syndrome in children	4	0
Sensitisation	9	0
Systemic immune activation	2	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	6	0
Immunosuppression	4	0
<i>Transplant rejections</i>		
Corneal graft rejection	10	0
Kidney transplant rejection	1	0
Solid organ transplant rejection	1	0
Transplant rejection	2	0
Immune system disorders SOC TOTAL	2411	1

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Abdominal abscess	2	0
Abdominal infection	2	0
Anal abscess	3	0
Anorectal infection	1	0
Appendicitis	47	0
Appendicitis perforated	7	0
Complicated appendicitis	1	0
Diarrhoea infectious	1	0
Diverticulitis	17	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	33	0
Gastrointestinal infection	1	0
Mesenteric abscess	1	0
Peritonitis	3	1
Rectal abscess	1	0
<i>Adenoviral infections</i>		
Adenoviral conjunctivitis	1	0
Adenovirus infection	1	0
<i>Aspergillus infections</i>		
Bronchopulmonary aspergillosis	1	0
<i>Bacterial infections NEC</i>		
Abscess bacterial	2	0
Administration site cellulitis	2	0
Arthritis bacterial	4	0
Bacterial colitis	1	0
Bacterial diarrhoea	1	0
Bacterial infection	17	0
Bacterial sepsis	1	0
Bacterial vaginosis	2	0
Cellulitis	203	0
Cellulitis orbital	1	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
External ear cellulitis	1	0
Folliculitis	20	0
Gangrene	1	0
Gastrointestinal bacterial overgrowth	1	0
Injection site cellulitis	2	0
Meningitis bacterial	3	0
Myocarditis bacterial	1	0
Paronychia	3	0
Perichondritis	3	0
Periorbital cellulitis	3	0
Pneumonia bacterial	2	0
Sinusitis bacterial	2	0
Skin bacterial infection	4	0
Small intestine gangrene	1	0
Tonsillitis bacterial	3	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	21	0
Zoonotic bacterial infection	1	1

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Bartonella infections</i>		
Cat scratch disease	1	0
<i>Bone and joint infections</i>		
Abscess jaw	1	0
Arthritis infective	2	0
Osteomyelitis	3	0
<i>Bordetella infections</i>		
Pertussis	1	0
<i>Borrelial infections</i>		
Lyme disease	4	0
Relapsing fever	1	0
<i>Breast infections</i>		
Breast abscess	3	0
Mastitis	87	0
<i>Caliciviral infections</i>		
Gastroenteritis norovirus	3	0
<i>Campylobacter infections</i>		
Campylobacter gastroenteritis	1	0
Campylobacter infection	1	0
<i>Candida infections</i>		
Anal candidiasis	3	0
Balanitis candida	1	0
Candida infection	72	0
Oral candidiasis	41	0
Respiratory moniliasis	1	0
Skin candida	2	0
Systemic candida	1	0
Urinary tract candidiasis	1	0
Vulvovaginal candidiasis	55	0
<i>Cardiac infections</i>		
Cardiac infection	1	0
Cardiac valve vegetation	1	0
Endocarditis	2	0
Myocarditis infectious	1	0
Pericarditis infective	2	0
<i>Central nervous system and spinal infections</i>		
Brain abscess	2	0
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	21	0
Encephalomyelitis	1	0
Meningitis	11	0
Meningitis aseptic	3	0
Myelitis	13	0
Subdural abscess	1	0
<i>Clostridia infections</i>		
Clostridium difficile infection	2	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	21	0
COVID-19	2496	42
COVID-19 pneumonia	51	14
Coronavirus infection	7	0
Post-acute COVID-19 syndrome	8	0

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Severe acute respiratory syndrome	4	0
Suspected COVID-19	85	4
<i>Corynebacteria infections</i>		
Diphtheria	2	0
<i>Coxiella infections</i>		
Q fever	14	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus colitis	1	0
Cytomegalovirus infection	2	0
Cytomegalovirus syndrome	1	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	6	0
Gingival abscess	1	0
Gingivitis	14	0
Oral infection	1	0
Parotitis	13	0
Pericoronitis	3	0
Periodontitis	1	0
Pulpitis dental	2	0
Sialoadenitis	3	0
Tongue abscess	1	0
Tooth abscess	8	0
Tooth infection	10	0
<i>Ear infections</i>		
Ear infection	103	0
Labyrinthitis	113	0
Mastoiditis	3	0
Otitis externa	5	0
Otitis media	3	0
Otitis media acute	1	0
Otitis media chronic	5	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	6	0
Bed bug infestation	1	0
Demodicidosis	1	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	5	0
Epstein-Barr virus infection reactivation	2	0
Infectious mononucleosis	29	0
<i>Escherichia infections</i>		
Escherichia bacteraemia	1	0
Escherichia infection	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	85	0
Eye abscess	1	0
Eye infection	29	0
Eye infection intraocular	1	0
Eyelid boil	2	0
Eyelid infection	2	0
Hordeolum	30	0
Keratouveitis	1	0
Periorbital infection	2	0
<i>Female reproductive tract infections</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Bartholin's abscess	1	0
Bartholinitis	1	0
Endometritis	3	0
Funisitis	1	0
Pelvic inflammatory disease	2	0
Vaginal infection	3	0
Vulval abscess	1	0
Vulvitis	1	0
Fungal infections NEC		
Fungal infection	20	0
Fungal skin infection	5	0
Mycotoxicosis	1	0
Myocarditis mycotic	2	0
Onychomycosis	2	0
Oral fungal infection	2	0
Pneumonia fungal	2	0
Severe asthma with fungal sensitisation	2	0
Vulvovaginal mycotic infection	8	0
Hepatitis virus infections		
Hepatitis A	2	0
Hepatitis E	1	0
Hepatobiliary and spleen infections		
Biliary sepsis	3	0
Cholecystitis infective	2	0
Hepatic infection	1	0
Herpes viral infections		
Eczema herpeticum	4	0
Genital herpes	96	0
Genital herpes simplex	6	0
Genital herpes zoster	1	0
Herpes ophthalmic	3	0
Herpes simplex	34	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	3	0
Herpes virus infection	13	0
Herpes zoster	1613	0
Herpes zoster disseminated	1	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	17	0
Herpes zoster reactivation	4	0
Meningitis herpes	1	0
Nasal herpes	5	0
Ophthalmic herpes simplex	3	0
Ophthalmic herpes zoster	5	0
Oral herpes	336	0
Varicella	32	0
Varicella zoster virus infection	5	0
Infections NEC		
Abscess	40	0
Abscess limb	9	0
Abscess soft tissue	1	0
Catheter site infection	1	0
Genital abscess	2	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Groin abscess	2	0
Groin infection	1	0
Infected bite	3	0
Infected cyst	2	0
Infection	279	0
Infection susceptibility increased	2	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	39	0
Lymph gland infection	18	0
Lymph node abscess	7	0
Opportunistic infection	1	0
Pathogen resistance	1	0
Purulent discharge	1	0
Respiratory tract infection	14	0
Superinfection	1	0
Vaccination site abscess	11	0
Vaccination site infection	13	0
Vaccine breakthrough infection	23	0
Vestibulitis	2	0
Wound infection	2	0
<i>Infectious transmissions</i>		
Nosocomial infection	1	0
Secondary transmission	8	0
Vaccine virus shedding	1	0
<i>Influenza viral infections</i>		
H1N1 influenza	1	0
Influenza	1792	0
<i>Klebsiella infections</i>		
Klebsiella infection	1	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	28	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	292	9
Pneumonia	172	16
Pneumonia aspiration	11	7
Sputum purulent	1	0
<i>Male reproductive tract infections</i>		
Epididymitis	10	0
Orchitis	6	0
Prostate infection	2	0
<i>Molluscum contagiosum viral infections</i>		
Molluscum contagiosum	1	0
<i>Mumps viral infections</i>		
Mumps	8	0
<i>Muscle and soft tissue infections</i>		
Abscess neck	1	0
Infective tenosynovitis	1	0
Necrotising fasciitis	2	0
Psoas abscess	1	0
Soft tissue infection	2	0
<i>Neisseria infections</i>		
Gonorrhoea	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Meningococcal bacteraemia	1	0
Meningococcal infection	1	0
Orthopox viral infections		
Smallpox	1	0
Vaccinia virus infection	2	0
Plasmodia infections		
Malaria	2	0
Pneumocystis infections		
Pneumocystis jirovecii pneumonia	2	0
Pseudomonal infections		
Pseudomonas infection	1	0
Retroviral infections		
Acquired immunodeficiency syndrome	1	0
HIV infection	2	0
Persistent generalised lymphadenopathy	1	0
Rhinoviral infections		
Rhinovirus infection	1	0
Rotaviral infections		
Gastroenteritis rotavirus	1	0
Rubeola viral infections		
Measles	5	0
Salmonella infections		
Typhoid fever	1	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Neutropenic sepsis	4	1
Sepsis	68	11
Sepsis syndrome	2	0
Septic rash	2	0
Septic shock	6	1
Urosepsis	5	0
Skin structures and soft tissue infections		
Abscess sweat gland	1	0
Acne pustular	1	0
Blister infected	1	0
Dermatitis infected	3	0
Impetigo	11	0
Infected skin ulcer	4	0
Injection site pustule	3	0
Nail infection	2	0
Pustule	19	0
Pyoderma	1	0
Rash pustular	12	0
Skin infection	32	0
Subcutaneous abscess	12	0
Sweat gland infection	1	0
Vaccination site pustule	4	0
Staphylococcal infections		
Furuncle	44	1
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	5	0
Staphylococcal sepsis	1	0
Streptococcal infections		

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	8	0
Pneumonia pneumococcal	1	0
Scarlet fever	1	0
Streptococcal abscess	1	0
Streptococcal endocarditis	1	0
Streptococcal infection	1	0
Streptococcal sepsis	1	0
<i>Tinea infections</i>		
Body tinea	6	0
Tinea capitis	1	0
Tinea infection	1	0
Tinea pedis	3	0
Tinea versicolour	4	0
<i>Toxoplasma infections</i>		
Toxoplasmosis	1	0
<i>Treponema infections</i>		
Syphilis	2	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	4	0
<i>Tuberculous infections</i>		
Disseminated Bacillus Calmette-Guerin infection	1	0
Lymph node tuberculosis	1	0
Pulmonary tuberculosis	1	0
Tuberculosis	1	0
Tuberculosis of central nervous system	1	0
<i>Upper respiratory tract infections</i>		
Acute sinusitis	5	0
Chronic sinusitis	3	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	34	0
Nasopharyngitis	1167	1
Peritonsillar abscess	6	0
Pharyngitis	37	0
Rhinitis	55	0
Sinusitis	203	0
Tonsillitis	142	0
Tracheitis	5	0
Tracheostomy infection	1	0
Upper respiratory tract infection	12	0
<i>Urinary tract infections</i>		
Cystitis	85	0
Kidney infection	55	0
Pyelonephritis	3	0
Urethritis	1	0
Urinary tract infection	218	0
<i>Vascular infections</i>		
Haematoma infection	1	0
Infected lymphocele	2	0
Infusion site infection	1	0
Lymphangitis	14	0
<i>Viral infections NEC</i>		

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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Ear infection viral	1	0
Encephalitis viral	6	1
Eye infection viral	2	0
Gastroenteritis viral	33	0
Hepatitis viral	3	0
Meningitis viral	9	0
Meningoencephalitis viral	1	0
Oral viral infection	1	0
Pleurisy viral	2	0
Pneumonia viral	4	2
Post viral fatigue syndrome	57	0
Sweating fever	125	0
Vestibular neuronitis	35	0
Viral diarrhoea	2	0
Viral infection	65	0
Viral labyrinthitis	4	0
Viral myocarditis	4	0
Viral pericarditis	3	0
Viral pharyngitis	24	0
Viral rash	69	0
Viral sinusitis	1	0
Viral tonsillitis	2	0
Infections SOC TOTAL	11863	113

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 03-Mar-2022

Data Lock Date: 02-Mar-2022 20:03:58

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Gallbladder injury	1	0
Liver contusion	1	0
Mouth injury	3	0
Oral contusion	5	0
Oral mucosal scar	1	0
Palate injury	1	0
Rectal injury	1	0
Splenic rupture	7	0
Tongue injury	2	0
Tooth fracture	1	0
Tooth injury	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	21	0
<i>Anaesthetic and allied procedural complications</i>		
Airway complication of anaesthesia	2	0
Delayed recovery from anaesthesia	3	0
Sedation complication	1	0
<i>Atmospheric pressure injuries</i>		
Barotitis media	1	0
Barotrauma	2	0
Hypobarism	2	0
<i>Bone and joint injuries NEC</i>		
Bursa injury	3	0
Joint injury	12	0
Meniscus injury	2	0
<i>Cardiac and vascular procedural complications</i>		
Ischaemic contracture of the left ventricle	1	0
Shunt blood flow excessive	1	0
Vascular pseudoaneurysm	1	0
<i>Cardiovascular injuries</i>		
Vascular injury	9	0
<i>Cerebral injuries NEC</i>		
Brain contusion	4	0
Brain herniation	2	0
Concussion	4	0
Craniocerebral injury	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	6	0
Subdural haemorrhage	7	0
Traumatic intracranial haemorrhage	1	1
<i>Chemical injuries</i>		
Chemical burn	1	0
Chemical burn of skin	9	0
Chemical cystitis	2	0
<i>Chest and respiratory tract injuries NEC</i>		
Bronchial injury	1	0
Chest crushing	15	0
Foreign body in throat	1	0
Traumatic lung injury	1	0
<i>Conditions caused by cold</i>		
Chillblains	73	0
Cold shock response	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 03-Mar-2022

Data Lock Date: 02-Mar-2022 20:03:58

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Frostbite	1	0
Cranial nerve injuries		
IIIrd nerve injury	1	0
Vth nerve injury	1	0
Ear injuries NEC		
Deafness traumatic	1	0
Ear injury	1	0
Exposures associated with pregnancy, delivery and lactation		
Exposure during pregnancy	10	0
Exposure via breast milk	157	0
Foetal exposure during pregnancy	69	0
Foetal exposure timing unspecified	1	0
Maternal exposure before pregnancy	28	0
Maternal exposure during breast feeding	1989	0
Maternal exposure during delivery	1	0
Maternal exposure during pregnancy	1073	0
Maternal exposure timing unspecified	14	0
Paternal exposure before pregnancy	3	0
Exposures to agents or circumstances NEC		
Exposure to SARS-CoV-2	3	0
Exposure to vaccinated person	4	0
Eye and ear procedural complications		
Toxic anterior segment syndrome	1	0
Eye injuries NEC		
Corneal abrasion	1	0
Eye contusion	18	0
Eye injury	31	0
Foreign body in eye	4	0
Injury corneal	1	0
Periorbital haematoma	1	0
Retinal injury	2	0
Superficial injury of eye	1	0
Foetal and neonatal conditions associated with product exposure		
Intoxication by breast feeding	1	0
Fractures and dislocations NEC		
Fracture	3	0
Joint dislocation	4	0
Multiple fractures	1	0
Gastrointestinal and hepatobiliary procedural complications		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	11	0
Procedural vomiting	2	0
Heat injuries (excl thermal burns)		
Heat cramps	2	0
Heat exhaustion	3	0
Heat illness	2	0
Heat oedema	14	0
Heat stroke	3	0
Intentional product use issues		
Intentional dose omission	1	0
Intentional product use issue	1	0
Limb fractures and dislocations		

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 03-Mar-2022

Data Lock Date: 02-Mar-2022 20:03:58

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Ankle fracture	1	0
Atypical femur fracture	1	0
Clavicle fracture	28	0
Femoral neck fracture	1	0
Femur fracture	1	0
Fibula fracture	1	0
Hip fracture	2	0
Tibia fracture	1	0
Upper limb fracture	1	0
Wrist fracture	1	0
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	2	0
Dose calculation error	1	0
Inadequate aseptic technique in use of product	1	0
Medication error	47	0
Prescription drug used without a prescription	3	0
Product use complaint	2	0
Product use issue	34	0
Vaccination error	6	0
Wrong dose	4	0
Wrong drug	11	0
Wrong schedule	1	0
Wrong technique in product usage process	10	0
Muscle, tendon and ligament injuries		
Epicondylitis	24	0
Ligament injury	2	0
Ligament sprain	10	0
Mallet finger	1	0
Muscle hernia	1	0
Muscle injury	38	0
Muscle rupture	10	0
Muscle strain	37	0
Post-traumatic neck syndrome	2	0
Tendon injury	7	0
Tendon rupture	26	0
Musculoskeletal procedural complications		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
Nerve injuries NEC		
Nerve injury	114	0
Neurological and psychiatric procedural complications		
Post lumbar puncture syndrome	1	0
Post procedural stroke	1	0
Procedural dizziness	12	0
Non-occupational environmental exposures		
Exposure to extreme temperature	2	0
Non-site specific injuries NEC		
Accident	1	0
Animal scratch	1	0
Arthropod bite	10	0
Arthropod sting	6	0
Bite	1	0
Bone contusion	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 03-Mar-2022

Data Lock Date: 02-Mar-2022 20:03:58

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Crush injury	1	0
Electric shock	20	0
Fall	209	0
Foreign body	6	0
Injury	14	0
Multiple injuries	2	0
Nervous system injury	2	0
Post concussion syndrome	2	0
Traumatic haematoma	1	0
Wound	7	0
Wound complication	12	0
Wound haematoma	1	0
Wound haemorrhage	3	0
Wound secretion	6	0
Non-site specific procedural complications		
Administration related reaction	2	0
Anastomotic leak	1	0
Incision site pain	3	0
Infusion related reaction	8	0
Injection related reaction	67	0
Post procedural complication	5	0
Post procedural erythema	1	0
Post procedural inflammation	1	0
Post procedural pruritus	1	0
Procedural pain	4	0
Seroma	1	0
Occupational exposures		
Occupational exposure to SARS-CoV-2	1	0
Occupational exposure to product	1	0
Off label uses		
Off label use	448	0
Overdoses NEC		
Intentional overdose	1	0
Overdose	52	0
Pathways and sources of exposure		
Exposure via contaminated device	1	0
Exposure via unknown route	1	0
Pelvic fractures and dislocations		
Pelvic fracture	1	0
Peripheral nerve injuries		
Axillary nerve injury	1	0
Brachial plexus injury	1	0
Radial nerve injury	2	0
Sciatic nerve injury	2	0
Ulnar nerve injury	5	0
Poisoning and toxicity		
Alcohol poisoning	1	0
Poisoning	14	0
Toxicity to various agents	4	0
Product administration errors and issues		
Accidental overdose	8	0
Contraindicated product administered	3	0
Duplicate therapy error	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 03-Mar-2022

Data Lock Date: 02-Mar-2022 20:03:58

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Expired product administered	14	0
Inappropriate schedule of product administration	708	0
Incomplete course of vaccination	2	0
Incorrect dose administered	59	0
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	9	0
Lack of vaccination site rotation	1	0
Poor quality product administered	3	0
Product administered at inappropriate site	23	0
Product administered to patient of inappropriate age	1	0
Product administration error	13	0
Product dose omission issue	6	0
Wrong product administered	20	0
Product confusion errors and issues		
Product dosage form confusion	1	0
Product label confusion	5	0
Product packaging confusion	2	0
Product dispensing errors and issues		
Product dispensing error	4	0
Product monitoring errors and issues		
Drug monitoring procedure incorrectly performed	1	0
Product preparation errors and issues		
Product preparation error	3	0
Product preparation issue	6	0
Product prescribing errors and issues		
Contraindicated product prescribed	2	0
Product prescribing error	2	0
Product selection errors and issues		
Product selection error	2	0
Radiation injuries		
Sunburn	23	0
Renal and urinary tract injuries NEC		
Bladder injury	1	0
Foreign body in urogenital tract	1	0
Reproductive system and breast injuries		
Breast injury	1	0
Cervix injury	1	0
Penile contusion	1	0
Penis injury	2	0
Uterine rupture	1	0
Reproductive tract and breast procedural complications		
Failed in vitro fertilisation	1	0
Site specific injuries NEC		
Back injury	4	0
Face crushing	3	0
Face injury	1	0
Head injury	36	0
Limb crushing injury	4	0
Limb injury	196	0
Nasal injury	2	0
Neck crushing	1	0
Neck injury	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 03-Mar-2022

Data Lock Date: 02-Mar-2022 20:03:58

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Pharyngeal contusion	1	0
Site specific procedural complications NEC		
Axillary web syndrome	3	0
Skin injuries NEC		
Contusion	1375	0
Hair injury	1	0
Nail avulsion	1	0
Scar	34	0
Scratch	7	0
Skin abrasion	7	0
Skin injury	4	0
Skin laceration	4	0
Skin wound	3	0
Splinter	1	0
Subcutaneous haematoma	2	0
Skin procedural complications		
Dermal filler overcorrection	1	0
Recall phenomenon	1	0
Skull fractures, facial bone fractures and dislocations		
Facial bones fracture	1	0
Fractured skull depressed	1	0
Spinal cord injuries NEC		
Spinal cord injury cervical	1	0
Spinal fractures and dislocations		
Spinal compression fracture	1	0
Spinal fracture	4	0
Stoma complications		
Gastrointestinal stoma complication	2	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
Thermal burns		
Airway burns	1	0
Burn oesophageal	4	0
Burn of internal organs	4	0
Burn oral cavity	5	0
Burns second degree	3	0
Burns third degree	1	0
Cold burn	1	0
Thermal burn	27	0
Thermal burns of eye	17	0
Underdoses NEC		
Underdose	6	0
Vaccination related complications		
Adverse event following immunisation	1	0
Post vaccination syndrome	1	0
Vaccination complication	54	0
Injuries SOC TOTAL	7833	1

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 03-Mar-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations		
Adrenal cortex tests		
Cortisol decreased	5	0
Adrenal medulla tests		
Epinephrine	1	0
Epinephrine abnormal	1	0
Epinephrine increased	1	0
Auditory and vestibular diagnostic procedures		
Acoustic stimulation tests	5	0
Audiogram abnormal	1	0
Weber tuning fork test abnormal	1	0
Autoimmunity analyses		
Antineutrophil cytoplasmic antibody positive	1	0
Antinuclear antibody	3	0
Antinuclear antibody increased	1	0
Antinuclear antibody positive	1	0
Beta-2 glycoprotein antibody positive	1	0
Cardiolipin antibody positive	1	0
Rheumatoid factor	3	0
Rheumatoid factor increased	2	0
Rheumatoid factor positive	1	0
Bacteria identification and serology (excl mycobacteria)		
Bacterial test positive	1	0
Blood counts NEC		
Full blood count	7	0
Full blood count abnormal	2	0
Blood gas and acid base analyses		
Acid base balance abnormal	1	0
Blood lactic acid	4	0
Blood lactic acid decreased	1	0
Blood lactic acid increased	5	0
Blood pH	7	0
Blood pH abnormal	1	0
Blood pH increased	12	0
Oxygen consumption	1	0
Oxygen consumption decreased	2	0
Oxygen saturation	11	0
Oxygen saturation abnormal	2	0
Oxygen saturation decreased	96	0
PO2 decreased	1	0
Venous oxygen saturation decreased	1	0
Blood grouping and cross-matching analyses		
Rhesus antigen positive	1	0
Bone marrow and immune tissue histopathology procedures		
Aspiration bone marrow	1	0
Biopsy lymph gland	1	0
Bone marrow and immune tissue imaging procedures		
Lymph nodes scan abnormal	1	0
Scan lymph nodes	4	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose	12	0
Blood glucose abnormal	15	0
Blood glucose decreased	38	0
Blood glucose fluctuation	17	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 03-Mar-2022

Data Lock Date: 02-Mar-2022 20:03:58

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood glucose increased	110	0
Blood glucose normal	1	0
Glycosylated haemoglobin increased	1	0
Cardiac auscultatory investigations		
Cardiac murmur	46	0
Heart sounds	9	0
Heart sounds abnormal	6	0
Cardiac function diagnostic procedures		
Cardiac monitoring	1	0
Cardiac output	1	0
Central venous pressure	1	0
Echocardiogram	1	0
Ejection fraction decreased	3	0
Myocardial strain imaging	2	0
Right atrial volume abnormal	1	0
Stroke volume decreased	1	0
Cardiac imaging procedures		
Catheterisation cardiac	1	0
Magnetic resonance imaging heart	1	0
Scan myocardial perfusion abnormal	1	0
Cell marker analyses		
Carcinoembryonic antigen increased	1	0
HLA-B*27 positive	1	0
Prostatic specific antigen increased	3	0
Central nervous system imaging procedures		
Computerised tomogram head	10	0
Magnetic resonance imaging head	12	0
Magnetic resonance imaging head abnormal	2	0
Cerebrospinal fluid tests (excl microbiology)		
CSF pressure	1	0
CSF protein increased	1	0
Chemistry analyses NEC		
Histamine abnormal	1	0
Histamine level	1	0
Histamine level increased	2	0
Inflammatory marker decreased	1	0
Inflammatory marker increased	5	0
Inflammatory marker test	1	0
Renin	1	0
Cholesterol analyses		
Blood cholesterol increased	13	0
Remnant-like lipoprotein particles	4	0
Coagulation and bleeding analyses		
Activated partial thromboplastin time prolonged	15	0
Activated partial thromboplastin time shortened	1	0
Bleeding time	1	0
Bleeding time abnormal	2	0
Bleeding time prolonged	11	0
Blood thromboplastin	1	0
Clot retraction	1	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	9	0
Coagulation time shortened	4	0

Case Series Drug Analysis Print

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Report Run Date: 03-Mar-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Fibrin D dimer increased	25	0
International normalised ratio abnormal	8	0
International normalised ratio decreased	22	0
International normalised ratio fluctuation	3	0
International normalised ratio increased	53	0
Platelet factor 4	1	0
Prothrombin time prolonged	1	0
Prothrombin time shortened	1	0
Digestive enzymes		
Amylase increased	1	0
ECG investigations		
Electrocardiogram	5	0
Electrocardiogram QRS complex prolonged	1	0
Electrocardiogram QT prolonged	11	0
Electrocardiogram ST segment depression	2	0
Electrocardiogram ST segment elevation	12	0
Electrocardiogram ST-T segment abnormal	2	0
Electrocardiogram T wave inversion	6	0
Electrocardiogram abnormal	24	0
Electrocardiogram change	1	0
Electrocardiogram normal	3	0
Electrocardiogram repolarisation abnormality	1	0
QRS axis abnormal	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	84	0
Faecal analyses NEC		
Faecal calprotectin	2	0
Faecal calprotectin increased	4	0
Fertility analyses		
Infertility tests	1	0
Semen analysis abnormal	1	0
Semen volume increased	1	0
Sperm concentration	2	0
Sperm concentration decreased	2	0
Spermatozoa abnormal	1	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate abnormal	5	2
Foetal heart rate increased	1	0
Foetal monitoring	1	0
Foetal non-stress test	1	0
Gastrointestinal and abdominal imaging procedures		
Computerised tomogram abdomen	1	0
Sigmoidoscopy abnormal	1	0
X-ray with contrast upper gastrointestinal tract	1	0
Gastrointestinal function diagnostic procedures		
Gastric pH decreased	4	0
Gastrointestinal, pancreatic and APUD hormone analyses		
Blood insulin	2	0
Blood insulin decreased	1	0
Gene analyses		
EGFR status assay	1	0
Haematological analyses NEC		
Blood viscosity abnormal	1	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 03-Mar-2022

Data Lock Date: 02-Mar-2022 20:03:58

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood viscosity decreased	1	0
Blood viscosity increased	2	0
Plasma viscosity	1	0
Plasma viscosity abnormal	1	0
Red blood cell sedimentation rate increased	8	0
<i>Heart rate and pulse investigations</i>		
Carotid pulse	1	0
Heart rate	580	0
Heart rate abnormal	75	0
Heart rate decreased	103	0
Heart rate increased	1177	0
Heart rate irregular	287	0
Heart rate normal	1	0
Heart rate variability decreased	1	0
Maximum heart rate	3	0
Maximum heart rate increased	2	0
Pulse abnormal	23	0
Pulse absent	1	0
Pulse pressure increased	3	0
Radial pulse abnormal	1	0
Sinus rhythm	8	0
<i>Hepatobiliary imaging procedures</i>		
Liver scan	1	0
<i>Imaging procedures NEC</i>		
Computerised tomogram	4	0
Magnetic resonance imaging	5	0
Magnetic resonance imaging abnormal	1	0
Scan	2	0
X-ray	2	0
<i>Immune response protein analyses NEC</i>		
Cytokine test	1	0
<i>Immunoglobulin analyses</i>		
Blood immunoglobulin E increased	2	0
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	2	0
<i>Immunology analyses NEC</i>		
Antibody test	4	0
Antibody test positive	1	0
Immunology test	13	0
<i>Immunology skin tests NEC</i>		
Allergy alert test	1	0
Skin test positive	2	0
<i>Investigations NEC</i>		
Blood test	27	0
Blood test abnormal	48	0
False positive investigation result	1	0
Laboratory test	1	0
Polymerase chain reaction	1	0
Polymerase chain reaction positive	33	0
Quality of life decreased	1	0
Systemic lupus erythematosus disease activity index increased	1	0
<i>Liver function analyses</i>		

Case Series Drug Analysis Print

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Report Run Date: 03-Mar-2022

Data Lock Date: 02-Mar-2022 20:03:58

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Alanine aminotransferase increased	28	0
Aspartate aminotransferase	1	0
Aspartate aminotransferase abnormal	1	0
Aspartate aminotransferase increased	2	0
Blood bilirubin increased	6	0
Gamma-glutamyltransferase increased	5	0
Hepatic enzyme increased	10	0
Liver function test	1	0
Liver function test abnormal	34	0
Liver function test increased	30	0
Transaminases increased	5	0
Metabolism tests NEC		
Blood ketone body	3	0
Blood ketone body increased	1	0
Blood ketone body present	1	0
Blood uric acid increased	2	0
Brain natriuretic peptide increased	1	0
N-terminal prohormone brain natriuretic peptide increased	1	0
Ubiquinone	1	0
Urine ketone body	1	0
Urine ketone body present	1	0
Microbiology and serology tests NEC		
Culture negative	1	0
Culture throat	1	0
Culture urine	1	0
Vaccine induced antibody absent	1	0
Mineral and electrolyte analyses		
Blood calcium increased	1	0
Blood copper increased	1	0
Blood iron	2	0
Blood iron decreased	11	0
Blood iron increased	1	0
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0
Blood phosphorus increased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	5	0
Blood potassium increased	3	0
Blood sodium decreased	11	0
Serum ferritin	1	0
Serum ferritin decreased	5	0
Serum ferritin increased	1	0
Sweat test	2	0
Urine copper	2	0
Musculoskeletal and soft tissue imaging procedures		
Skull X-ray	6	0
Musculoskeletal and soft tissue tests NEC		
Swollen joint count	1	0
Swollen joint count increased	1	0
Mycobacteria identification and serology		
Tuberculin test positive	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	5	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 03-Mar-2022

Data Lock Date: 02-Mar-2022 20:03:58

MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Hoover's sign of leg paresis	1	0
Joint position sense decreased	1	0
Lumbar puncture	6	0
Magnetic resonance neurography	1	0
Nerve conduction studies	1	0
Pain threshold decreased	1	0
Sensory level	2	0
Temperature perception test abnormal	1	0
Temperature perception test increased	1	0
Total neuropathy score	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Corneal reflex decreased	1	0
Intraocular pressure increased	9	0
Intraocular pressure test	3	0
Pupil dilation procedure	1	0
Visual acuity tests	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	291	0
Body temperature abnormal	54	0
Body temperature decreased	45	0
Body temperature fluctuation	66	0
Body temperature increased	510	0
Body temperature normal	1	0
Breath sounds abnormal	2	0
General physical condition abnormal	1	0
Grip strength	3	0
Grip strength decreased	26	0
Gynaecological examination	1	0
Head lag	8	0
Intelligence test	1	0
Lymph node palpable	45	0
Male genital examination abnormal	1	0
Menstruation normal	4	0
Muscle strength abnormal	4	0
Ophthalmological examination	3	0
Orthopaedic examination	1	0
Palpatory finding abnormal	2	0
Product residue present	2	0
Psoriasis area severity index decreased	2	0
Psoriasis area severity index increased	1	0
Respiratory rate	9	0
Respiratory rate decreased	27	0
Respiratory rate increased	46	0
Skin temperature	45	0
Temperature difference of extremities	13	0
Weight	1	0
Weight abnormal	1	0
Weight decreased	130	0
Weight increased	51	0
<i>Pituitary analyses anterior</i>		
Blood corticotrophin	1	0
Blood follicle stimulating hormone increased	3	0
Blood growth hormone	3	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 03-Mar-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood prolactin	3	0
Blood prolactin increased	4	0
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	10	0
Platelet analyses		
Mean platelet volume decreased	1	0
Mean platelet volume increased	1	0
Platelet count	3	0
Platelet count abnormal	1	0
Platelet count decreased	83	0
Platelet count increased	6	0
Protein analyses NEC		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	30	0
Red blood cell analyses		
Haematocrit	1	0
Haematocrit decreased	1	0
Haematocrit increased	1	0
Haemoglobin decreased	16	0
Haemoglobin increased	2	0
Red blood cell count decreased	1	0
Red blood cell count increased	1	0
Red blood cell rouleaux formation present	1	0
Renal function analyses		
Blood creatinine	1	0
Blood creatinine decreased	1	0
Blood creatinine increased	5	0
Glomerular filtration rate decreased	4	0
Glomerular filtration rate increased	1	0
Reproductive hormone analyses		
Blood oestrogen	2	0
Blood oestrogen decreased	2	0
Blood testosterone decreased	1	0
Blood testosterone increased	2	0
False negative pregnancy test	9	0
Female sex hormone level	3	0
Human chorionic gonadotropin increased	1	0
Pregnancy test	18	0
Pregnancy test false positive	1	0
Pregnancy test positive	1	0
Progesterone decreased	1	0
Reproductive organ and breast histopathology procedures		
Biopsy breast	2	0
Biopsy endometrium	1	0
Smear cervix	3	0
Reproductive organ and breast imaging procedures		
Breast scan	1	0
Hysteroscopy	2	0
Respiratory and pulmonary function diagnostic procedures		
Airway peak pressure increased	1	0
Forced expiratory volume	1	0
Forced expiratory volume increased	3	0

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 03-Mar-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Fractional exhaled nitric oxide normal	1	0
Maximal voluntary ventilation	2	0
Peak expiratory flow rate	2	0
Peak expiratory flow rate decreased	6	0
Pulmonary function test	3	0
Spirometry abnormal	1	0
Total lung capacity decreased	4	0
Vital capacity	1	0
<i>Respiratory tract and thoracic histopathology procedures</i>		
Sputum abnormal	3	0
<i>Respiratory tract and thoracic imaging procedures</i>		
Chest X-ray	19	0
Chest X-ray abnormal	1	0
Chest X-ray normal	2	0
Chest scan	2	0
Computerised tomogram thorax	2	0
Ventilation/perfusion scan	1	0
<i>Skeletal and cardiac muscle analyses</i>		
Blood creatine phosphokinase increased	12	0
Muscle enzyme	1	0
Myocardial necrosis marker	1	0
Myocardial necrosis marker increased	3	0
Troponin I increased	2	0
Troponin T increased	2	0
Troponin increased	25	0
<i>Therapeutic drug monitoring analyses</i>		
Analgesic drug level	9	0
Anticoagulation drug level above therapeutic	1	0
Anticoagulation drug level below therapeutic	5	0
Anticoagulation drug level increased	1	0
Drug level decreased	1	0
<i>Thyroid analyses</i>		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	5	0
Thyroxine	1	0
Thyroxine free increased	2	0
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	5	0
<i>Tissue enzyme analyses NEC</i>		
Blood alkaline phosphatase abnormal	1	0
Blood alkaline phosphatase increased	6	0
Blood lactate dehydrogenase increased	1	0
Enzyme level increased	1	0
<i>Toxicology laboratory analyses</i>		
Blood caffeine decreased	1	0
Blood lead	1	0
Drug screen positive	2	0
Opiates	1	0
<i>Urinalysis NEC</i>		
Blood urine	18	0
Blood urine present	75	0
Cells in urine	1	0
Glucose urine present	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Protein urine absent	1	0
Protein urine present	1	0
Red blood cells urine	1	0
Urine analysis abnormal	6	0
Urine leukocyte esterase positive	1	0
Urine uric acid increased	1	0
pH urine	6	0
pH urine increased	2	0
Urinary tract function analyses NEC		
Urine output	14	0
Urine output decreased	15	0
Urine output increased	7	0
Urinary tract histopathology procedures		
Urine cytology	1	0
Urinary tract imaging procedures		
Bladder scan	1	0
Cystoscopy	2	0
Ultrasound kidney normal	1	0
Vascular imaging procedures NEC		
Venogram	2	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	11	0
Blood pressure ambulatory increased	1	0
Blood pressure decreased	88	0
Blood pressure diastolic	2	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	4	0
Blood pressure difference of extremities	1	0
Blood pressure increased	294	0
Blood pressure measurement	49	0
Blood pressure normal	2	0
Blood pressure systolic	1	0
Blood pressure systolic decreased	4	0
Blood pressure systolic increased	1	0
Virus identification and serology		
Coronavirus test	11	0
Coronavirus test positive	4	0
Cytomegalovirus test positive	1	0
HIV antibody positive	1	0
HIV test	1	0
SARS-CoV-1 test	1	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	10	0
SARS-CoV-2 antibody test negative	15	0
SARS-CoV-2 antibody test positive	6	0
SARS-CoV-2 test	35	0
SARS-CoV-2 test false negative	2	0
SARS-CoV-2 test false positive	4	0
SARS-CoV-2 test negative	10	0
SARS-CoV-2 test positive	109	0
Viral load	2	0
Viral test	4	0
Viral test positive	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Vitamin analyses</i>		
Blood folate decreased	8	0
Vitamin B12	1	0
Vitamin B12 abnormal	2	0
Vitamin B12 decreased	3	0
Vitamin D	4	0
Vitamin D decreased	3	0
<i>Water and electrolyte analyses NEC</i>		
Urine osmolarity	1	0
Volume blood	1	0
<i>White blood cell analyses</i>		
Eosinophil count	1	0
Eosinophil count decreased	1	0
Eosinophil count increased	3	0
Lymphocyte count	1	0
Lymphocyte count decreased	3	0
Lymphocyte count increased	1	0
Monocyte count increased	2	0
Neutrophil count	4	0
Neutrophil count decreased	11	0
Neutrophil count increased	4	0
White blood cell count	4	0
White blood cell count decreased	15	0
White blood cell count increased	13	0
Investigations SOC TOTAL	6240	3

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	21	0
Decreased appetite	1496	0
Diet refusal	1	0
Eating disorder symptom	3	0
Food craving	13	0
Food refusal	16	0
Hyperphagia	15	0
Hypophagia	18	0
Increased appetite	36	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	3	0
Tetany	3	0
<i>Copper metabolism disorders</i>		
Copper deficiency	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	55	0
Diabetes mellitus inadequate control	18	1
Increased insulin requirement	2	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	2	0
Type 1 diabetes mellitus	16	0
Type 2 diabetes mellitus	5	0
<i>Diabetic complications NEC</i>		
Diabetic complication	2	0
Diabetic ketoacidosis	12	0
Diabetic ketosis	1	0
<i>Disorders of purine metabolism</i>		
Gout	108	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	1	0
Fluid imbalance	2	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	9	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	2	0
<i>Fluid intake increased</i>		
Polydipsia	7	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	8	0
Breast milk substitute intolerance	1	0
Dairy intolerance	3	0
Food intolerance	21	0
Gluten sensitivity	7	0
Histamine intolerance	4	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	39	0
Abnormal weight gain	21	0
Cachexia	1	0
Feeding disorder	107	0
Food aversion	12	0
Malnutrition	3	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Metabolic disorders <small>Metabolic disorders cont'd</small>		
Neonatal insufficient breast milk syndrome	7	0
Obesity	1	0
Overweight	1	0
Poor feeding infant	16	0
Weight loss poor	3	0
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	1	0
Hyperglycaemia	68	0
Insulin resistance	5	0
Hyperlipidaemias NEC		
Hyperlipidaemia	1	0
Hypoglycaemic conditions NEC		
Glycopenia	1	0
Hypoglycaemia	81	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	2	0
Iron deficiencies		
Iron deficiency	13	0
Iron excess		
Haemochromatosis	2	0
Iron overload	1	0
Lipid metabolism and deposit disorders NEC		
Body fat disorder	1	0
Magnesium metabolism disorders		
Hypomagnesaemia	1	0
Magnesium deficiency	1	0
Metabolic acidoses (excl diabetic acidoses)		
Ketoacidosis	6	1
Lactic acidosis	3	0
Metabolic acidosis	4	0
Metabolic disorders NEC		
Hypercarotinaemia	1	0
Hypercatabolism	1	0
Metabolic disorder	1	0
Mixed acid-base disorders		
Acidosis	4	0
Phosphorus metabolism disorders		
Hypophosphataemia	1	0
Potassium imbalance		
Hyperkalaemia	6	0
Hypokalaemia	5	0
Hypokalaemic syndrome	1	0
Sodium imbalance		
Hypernatraemia	1	0
Hyponatraemia	12	0
Hyponatraemic syndrome	3	0
Salt intoxication	1	0
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	5	0
Total fluid volume decreased		
Dehydration	235	0
Total fluid volume increased		
Fluid retention	65	0

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Hypervolaemia	5	0
Vitamin deficiencies NEC		
Hypovitaminosis	6	0
Water soluble vitamin deficiencies		
Folate deficiency	8	0
Vitamin B complex deficiency	1	0
Vitamin B12 deficiency	6	0
Metabolic disorders SOC TOTAL	2686	2

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	392	0
Arthropathy	33	0
Autoimmune arthritis	9	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	2	0
Polyarthritis	16	0
Rheumatic fever	2	0
Sacroiliitis	6	0
Seronegative arthritis	3	0
<i>Bone disorders NEC</i>		
Bone cyst	1	0
Exostosis	1	0
Jaw disorder	4	0
Medial tibial stress syndrome	6	0
Osteitis	9	0
Osteonecrosis	1	0
Osteonecrosis of jaw	3	0
Spinal disorder	2	0
<i>Bone related signs and symptoms</i>		
Bone pain	450	0
Bone swelling	10	0
Coccydynia	4	0
Metatarsalgia	1	0
Pain in jaw	431	0
Pubic pain	2	0
Spinal pain	98	0
<i>Bursal disorders</i>		
Bursitis	101	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	137	0
Osteochondritis	1	0
Polychondritis	3	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	2	0
Polymyalgia rheumatica	84	0
Reynold's syndrome	2	0
Scleroderma	1	0
Sjogren's syndrome	7	0
Systemic scleroderma	1	0
<i>Crystal arthropathic disorders</i>		
Chondrocalcinosis pyrophosphate	3	0
Crystal arthropathy	2	0
Gouty arthritis	2	0
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		
Bone deformity	1	0
Finger deformity	2	0
Foot deformity	3	0
Hand deformity	4	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Knee deformity	1	0
Limb deformity	5	0
Musculoskeletal deformity	1	0
Fractures NEC		
Osteoporotic fracture	1	0
Intervertebral disc disorders NEC		
Intervertebral disc protrusion	3	0
Joint related disorders NEC		
Carpal collapse	1	0
Chondromalacia	1	0
Hypermobility syndrome	1	0
Joint ankylosis	1	0
Joint deposit	1	0
Joint destruction	1	0
Joint instability	2	0
Joint laxity	3	0
Joint lock	36	0
Ligament laxity	1	0
Patellofemoral pain syndrome	2	0
Periarthritis	253	0
Rotator cuff syndrome	42	0
Temporomandibular joint syndrome	16	0
Joint related signs and symptoms		
Arthralgia	10423	0
Jaw clicking	7	0
Joint effusion	16	0
Joint noise	44	0
Joint range of motion decreased	34	0
Joint stiffness	297	0
Joint swelling	656	0
Joint vibration	4	0
Joint warmth	17	0
Loose body in joint	1	0
Ligament disorders		
Ligament pain	4	0
Ligamentitis	3	0
Symphysiolysis	1	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	29	0
Metabolic bone disorders		
Osteopenia	4	0
Osteoporosis	7	0
Muscle infections and inflammations		
Antisynthetase syndrome	3	0
Immune-mediated myositis	2	0
Myositis	52	0
Polymyositis	9	0
Muscle pains		
Fibromyalgia	144	0
Myalgia	11743	0
Myalgia intercostal	2	0
Myofascial pain syndrome	12	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
<i>Muscle related signs and symptoms NEC</i>		
Haematoma muscle	1	0
Muscle atrophy	27	0
Muscle discomfort	8	0
Muscle disorder	10	0
Muscle fatigue	396	0
Muscle haemorrhage	1	0
Muscle mass	5	0
Muscle oedema	5	0
Muscle spasms	2333	0
Muscle swelling	43	0
Muscle tightness	102	0
Muscle twitching	553	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	21	0
Nuchal rigidity	13	0
Torticollis	7	0
Trismus	40	0
<i>Muscle weakness conditions</i>		
Muscular weakness	1142	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Back disorder	5	0
Chest wall mass	1	0
Growth disorder	2	0
Limb mass	24	0
Mandibular mass	3	0
Mastication disorder	7	0
Mobility decreased	146	0
Muscle contracture	1	0
Musculoskeletal disorder	13	0
Musculoskeletal stiffness	1495	0
Pelvic misalignment	1	0
Posture abnormal	2	0
Sacroiliac joint dysfunction	1	0
Weight bearing difficulty	5	0
<i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>		
Facial asymmetry	1	0
Head deformity	2	0
Nose deformity	1	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Connective tissue inflammation	1	0
Dactylitis	3	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	15	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	2828	0
Flank pain	87	0
Growing pains	1	0
Limb discomfort	1664	0
Musculoskeletal chest pain	308	0
Musculoskeletal discomfort	128	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Musculoskeletal pain	138	0
Neck pain	2215	0
Pain in extremity	14469	1
Rheumatic disorder	15	0
Sacral pain	4	0
Myopathies		
Mitochondrial myopathy acquired	1	0
Myopathy	9	0
Rhabdomyolysis	14	0
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	63	0
Spinal osteoarthritis	2	0
Psoriatic arthropathies		
Psoriatic arthropathy	23	0
Rheumatoid arthropathies		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	139	0
Rheumatoid nodule	1	0
Still's disease	2	0
Soft tissue disorders NEC		
Axillary mass	316	0
Fistula	1	0
Fluctuance	1	0
Groin pain	127	0
Neck mass	47	0
Purple glove syndrome	1	0
Soft tissue disorder	3	0
Soft tissue swelling	7	0
Spine and neck deformities		
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
Spinal stenosis	3	0
Spondyloarthropathies		
Ankylosing spondylitis	10	0
Arthritis reactive	75	0
Spondylitis	4	0
Spondyloarthropathy	1	0
Synovial disorders		
Synovial cyst	23	0
Synovitis	12	0
Tendon disorders		
Enthesopathy	3	0
Posterior tibial tendon dysfunction	1	0
Tendon disorder	7	0
Tendon pain	27	0
Tendonitis	61	0
Tenosynovitis	4	0
Tenosynovitis stenosaurs	2	0
Trigger finger	34	0
Trunk deformities		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Deformity thorax	1	0
Drooping shoulder syndrome	3	0
Shoulder deformity	4	0
Muscle & tissue disorders SOC TOTAL	55071	1

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Reaction Name	Total	Fatal
Neoplasms		
<i>Adrenal neoplasms malignant</i>		
Adrenal gland cancer	1	0
<i>Angioimmunoblastic T-cell lymphomas</i>		
Angioimmunoblastic T-cell lymphoma	1	0
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma	2	1
Follicular lymphoma	4	0
<i>Bone neoplasms malignant (excl sarcomas)</i>		
Bone cancer	1	1
<i>Bone neoplasms unspecified malignancy</i>		
Bone neoplasm	1	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	3	0
Fibroadenoma of breast	2	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	43	0
Breast cancer female	1	0
Breast cancer male	2	0
Breast cancer stage I	1	0
Breast cancer stage III	3	0
Invasive ductal breast carcinoma	1	0
Triple negative breast cancer	2	0
<i>Cardiovascular neoplasms benign</i>		
Haemangioma	2	0
Pericardial lipoma	1	0
<i>Cartilage sarcomas</i>		
Chondrosarcoma	1	0
<i>Central nervous system neoplasms malignant NEC</i>		
Brain cancer metastatic	1	0
<i>Cervix neoplasms malignant</i>		
Cervix carcinoma	2	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	2	0
Colorectal cancer	1	0
Rectal cancer	2	0
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Neuroendocrine tumour	1	0
Thyroid neoplasm	1	0
<i>Endometrial neoplasms malignant</i>		
Endometrial cancer	2	0
<i>Follicular lymphomas</i>		
Primary gastrointestinal follicular lymphoma	1	0
<i>Gastric neoplasms malignant</i>		
Gastric cancer	1	1
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	3	0
<i>Hepatic neoplasms malignant</i>		
Hepatocellular carcinoma	1	0
<i>Hepatobiliary neoplasms benign</i>		
Haemangioma of liver	1	0
<i>Hepatobiliary neoplasms malignancy unspecified</i>		
Hepatic neoplasm	1	0
<i>Hodgkin's disease NEC</i>		

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Reaction Name	Total	Fatal
Neoplasms <i>Neoplasms cont'd</i>		
Hodgkin's disease	4	0
<i>Islet cell neoplasms and APUDoma NEC</i>		
Pancreatic neuroendocrine tumour	1	0
<i>Kaposi's sarcomas</i>		
Kaposi's sarcoma	1	0
<i>Leukaemias NEC</i>		
Leukaemia	5	1
<i>Leukaemias acute NEC</i>		
Acute leukaemia	2	0
<i>Leukaemias chronic NEC</i>		
Chronic leukaemia	1	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	3	0
<i>Leukaemias chronic myeloid</i>		
Chronic myeloid leukaemia	1	0
<i>Lip and oral cavity neoplasms malignant</i>		
Lip and/or oral cavity cancer recurrent	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	47	1
<i>Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)</i>		
Histiocytic necrotising lymphadenitis	1	0
<i>Metastases to specified sites</i>		
Metastases to bone	1	0
Metastases to liver	1	0
Metastases to lymph nodes	5	0
<i>Metastases to unknown and unspecified sites</i>		
Metastasis	1	0
<i>Myelodysplastic syndromes</i>		
Myelodysplastic syndrome	3	0
<i>Myeloproliferative disorders (excl leukaemias)</i>		
Essential thrombocythaemia	2	0
<i>Neoplasms malignant site unspecified NEC</i>		
Adenocarcinoma metastatic	1	0
Metastatic neoplasm	2	0
Neoplasm malignant	13	3
Second primary malignancy	1	0
Squamous cell carcinoma	5	0
<i>Neoplasms unspecified malignancy and site unspecified NEC</i>		
Neoplasm	2	0
Neoplasm recurrence	1	0
<i>Nervous system neoplasms benign NEC</i>		
Cranial nerve neoplasm benign	1	0
Neurilemmoma benign	1	0
<i>Nervous system neoplasms unspecified malignancy NEC</i>		
Brain neoplasm	3	0
Meningioma	1	0
Spinal cord neoplasm	1	1
<i>Neuromas</i>		
Acoustic neuroma	3	0
Neuroma	1	0
<i>Non-Hodgkin's lymphomas NEC</i>		
Non-Hodgkin's lymphoma	3	0
<i>Ocular neoplasms benign</i>		

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Eye naevus	3	0
Ocular neoplasms malignancy unspecified		
Eyelid tumour	1	0
Oesophageal neoplasms malignant		
Oesophageal cancer metastatic	4	0
Oncologic complications and emergencies		
Cancer pain	1	0
Tumour haemorrhage	1	0
Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified		
Tonsil cancer	4	0
Ovarian neoplasms malignant (excl germ cell)		
Ovarian cancer	1	0
Pancreatic neoplasms malignant (excl islet cell and carcinoid)		
Pancreatic carcinoma	4	0
Plasma cell myelomas		
POEMS syndrome	1	0
Plasma cell myeloma	2	0
Plasma cell neoplasms NEC		
Hypergammaglobulinaemia benign monoclonal	1	0
TEMPI syndrome	2	0
Prostatic neoplasms malignant		
Prostate cancer	4	0
Renal neoplasms malignant		
Clear cell renal cell carcinoma	1	0
Renal cancer	3	0
Reproductive neoplasms female benign NEC		
Benign hydatidiform mole	5	0
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC		
Bronchial carcinoma	1	0
Lung cancer metastatic	1	1
Lung neoplasm malignant	15	1
Salivary gland neoplasms unspecified malignancy		
Salivary gland neoplasm	2	0
Skin melanomas (excl ocular)		
Malignant melanoma	3	0
Metastatic malignant melanoma	1	0
Skin neoplasms benign		
Acrochordon	7	0
Anogenital warts	7	0
Fibrous histiocytoma	1	0
Haemangioma of skin	7	0
Melanocytic naevus	10	0
Pyogenic granuloma	1	0
Seborrhoeic keratosis	1	0
Skin papilloma	21	0
Skin neoplasms malignant and unspecified (excl melanoma)		
Basal cell carcinoma	3	0
Bowen's disease	1	0
Neoplasm skin	3	0
Skin cancer	1	0
Squamous cell carcinoma of skin	1	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	7	0
Lymphangioma	1	0
<i>Soft tissue sarcomas histology unspecified</i>		
Sarcoma	1	0
<i>Thyroid neoplasms malignant</i>		
Huerthle cell carcinoma	1	0
Papillary thyroid cancer	2	0
Thyroid cancer	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	15	0
Neoplasms SOC TOTAL	364	11

Case Series Drug Analysis Print

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Report Run Date: 03-Mar-2022

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	8	0
Extensor plantar response	2	0
Hoffmann's sign	1	0
Hyperreflexia	4	0
Hyporeflexia	10	0
Reflexes abnormal	2	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	31	0
<i>Absence seizures</i>		
Petit mal epilepsy	30	0
<i>Acute polyneuropathies</i>		
Acute motor axonal neuropathy	1	0
Acute motor-sensory axonal neuropathy	1	0
Guillain-Barre syndrome	99	2
Miller Fisher syndrome	5	0
Subacute inflammatory demyelinating polyneuropathy	1	0
<i>Alzheimer's disease (incl subtypes)</i>		
Dementia Alzheimer's type	1	1
<i>Autonomic nervous system disorders</i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	12	0
Autonomic neuropathy	3	0
Horner's syndrome	2	0
Orthostatic intolerance	2	0
<i>Central nervous system aneurysms and dissections</i>		
Carotid artery dissection	1	0
Intracranial aneurysm	2	1
Vertebral artery dissection	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Basal ganglia haemorrhage	1	0
Basal ganglia infarction	1	0
Brain stem haemorrhage	3	3
Brain stem infarction	1	1
Brain stem stroke	2	0
Carotid artery occlusion	1	0
Carotid artery thrombosis	4	0
Cerebellar artery thrombosis	1	0
Cerebellar haemorrhage	3	0
Cerebellar infarction	3	0
Cerebellar ischaemia	1	0
Cerebellar stroke	9	1
Cerebral artery embolism	3	1
Cerebral artery occlusion	2	0
Cerebral artery thrombosis	5	0
Cerebral haemorrhage	61	14
Cerebral infarction	31	3
Cerebral ischaemia	1	0
Cerebral thrombosis	15	0
Cerebrovascular accident	484	19
Embolic stroke	8	0
Haemorrhage intracranial	15	3
Haemorrhagic cerebral infarction	1	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Haemorrhagic stroke	12	5
Internal capsule infarction	1	0
Intracranial haematoma	1	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	59	3
Lacunar infarction	4	0
Lacunar stroke	6	0
Lateral medullary syndrome	2	0
Pseudostroke	2	0
Ruptured cerebral aneurysm	1	0
Spinal stroke	1	0
Stroke in evolution	1	0
Subarachnoid haemorrhage	19	8
Thalamic infarction	1	0
Thrombotic stroke	6	1
Vertebrobasilar stroke	1	0
Central nervous system inflammatory disorders NEC		
Arachnoiditis	1	0
Gliosis	1	0
Central nervous system vascular disorders NEC		
Brain hypoxia	5	1
Carotid arteriosclerosis	1	0
Central nervous system vasculitis	1	0
Cerebral amyloid angiopathy	1	0
Cerebral congestion	5	0
Cerebral small vessel ischaemic disease	3	0
Cerebrovascular disorder	3	0
Post cardiac arrest syndrome	1	0
Reversible cerebral vasoconstriction syndrome	1	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	54	5
Cerebral venous thrombosis	9	0
Superior sagittal sinus thrombosis	6	0
Transverse sinus thrombosis	2	0
Cervical spinal cord and nerve root disorders		
Cervical radiculopathy	2	0
Cervicobrachial syndrome	6	0
Choreiform movements		
Chorea	3	0
Chronic polyneuropathies		
Chronic inflammatory demyelinating polyradiculoneuropathy	2	0
Demyelinating polyneuropathy	1	0
Diabetic neuropathy	1	0
Coma states		
Coma	18	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
Coordination and balance disturbances		
Ataxia	20	0
Balance disorder	493	0
Cerebellar ataxia	1	0
Cerebellar syndrome	1	0
Coordination abnormal	72	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Dysdiadochokinesis	1	0
Dysstasia	73	0
Nystagmus	16	0
Cortical dysfunction NEC		
Alexia	2	0
Aphasia	101	0
Apraxia	1	0
Dysgraphia	3	0
Dyslexia	1	0
Dyspraxia	1	0
Neurologic neglect syndrome	1	0
Sensory processing disorder	3	0
Visuospatial deficit	1	0
Cranial nerve disorders NEC		
Cranial nerve disorder	2	0
Cranial nerve paralysis	1	0
Dementia (excl Alzheimer's type)		
Dementia	18	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	7	0
Clinically isolated syndrome	1	0
Demyelination	9	0
Neuromyelitis optica spectrum disorder	2	0
Disturbances in consciousness NEC		
Altered state of consciousness	14	0
Consciousness fluctuating	3	0
Depressed level of consciousness	53	0
Infant sedation	1	0
Lethargy	2525	0
Loss of consciousness	800	1
Postictal state	5	0
Sedation	9	0
Somnolence	1195	0
Stupor	5	0
Syncope	2745	0
Disturbances in sleep phase rhythm		
Circadian rhythm sleep disorder	2	0
Irregular sleep phase	2	0
Irregular sleep wake rhythm disorder	2	0
Non-24-hour sleep-wake disorder	1	0
Dyskinesias and movement disorders NEC		
Akathisia	7	0
Ballismus	1	0
Bradykinesia	24	0
Clumsiness	23	0
Dyskinesia	82	0
Extrapyramidal disorder	3	0
Fine motor skill dysfunction	13	0
Foetal movement disorder	7	0
Hyperkinesia	4	0
Hypokinesia	107	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Micrographia	1	0
Motor dysfunction	4	0
Movement disorder	70	0
Psychomotor hyperactivity	29	0
Synkinesis	2	0
Tardive dyskinesia	2	0
Dystonias		
Dystonia	16	0
Writer's cramp	1	0
Encephalitis NEC		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	7	0
Encephalopathies NEC		
Autoimmune encephalopathy	1	1
Encephalopathy	5	0
Hashimoto's encephalopathy	1	0
Posterior reversible encephalopathy syndrome	1	0
Eye movement disorders		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	7	0
IVth nerve paralysis	1	0
Microvascular cranial nerve palsy	2	0
VIth nerve disorder	1	0
VIth nerve paralysis	12	0
Facial cranial nerve disorders		
Bell's palsy	631	0
Facial nerve disorder	9	0
Facial paralysis	475	0
Facial paresis	104	0
Facial spasm	55	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	77	0
Headaches NEC		
Cervicogenic headache	3	0
Cluster headache	289	0
Cold-stimulus headache	36	0
Drug withdrawal headache	3	0
Exertional headache	9	0
External compression headache	2	0
Headache	30020	1
Medication overuse headache	2	0
New daily persistent headache	8	0
Occipital neuralgia	17	0
Ophthalmoplegic migraine	1	0
Primary cough headache	4	0
Primary headache associated with sexual activity	10	0
Sinus headache	396	0
Tension headache	628	0
Thunderclap headache	23	0
Vascular headache	21	0
Hydrocephalic conditions		
Hydrocephalus	5	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Hypoglossal nerve disorders</i>		
Tongue paralysis	1	0
<i>Increased intracranial pressure disorders</i>		
Brain compression	2	0
Brain oedema	13	2
Idiopathic intracranial hypertension	12	0
Intracranial pressure increased	5	0
<i>Intellectual disabilities</i>		
Intellectual disability	4	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	134	0
<i>Memory loss (excl dementia)</i>		
Amnesia	227	0
Memory impairment	247	0
Transient global amnesia	10	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	105	0
Cognitive linguistic deficit	1	0
Disturbance in attention	398	0
Mental impairment	59	0
<i>Migraine headaches</i>		
Basilar migraine	1	0
Hemiplegic migraine	44	0
Migraine	3504	0
Migraine with aura	230	0
Migraine without aura	22	0
Ophthalmic migraine	7	0
Retinal migraine	38	0
Typical aura without headache	9	0
Vestibular migraine	29	0
<i>Mixed cranial nerve disorders</i>		
Bulbar palsy	2	0
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	34	0
Cubital tunnel syndrome	4	0
Meralgia paraesthetica	2	0
Mononeuritis	2	0
Mononeuropathy	4	0
Nerve compression	31	0
Peripheral nerve lesion	2	0
Peroneal nerve palsy	20	0
Piriformis syndrome	2	0
Pudendal canal syndrome	3	0
Sciatic nerve neuropathy	2	0
Ulnar nerve palsy	2	0
Ulnar neuritis	3	0
Ulnar tunnel syndrome	2	0
<i>Motor neurone diseases</i>		
Amyotrophic lateral sclerosis	1	0
Lower motor neurone lesion	2	0
Motor neurone disease	7	2
Progressive bulbar palsy	1	0
Upper motor neurone lesion	1	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Multiple sclerosis acute and progressive</i>		
Band sensation	1	0
Multiple sclerosis	37	0
Multiple sclerosis relapse	26	0
Relapsing-remitting multiple sclerosis	1	0
Tumefactive multiple sclerosis	1	1
<i>Muscle tone abnormal</i>		
Drop attacks	2	0
Hypertonia	2	0
Hypotonia	37	0
Morvan syndrome	1	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	35	0
<i>Narcolepsy and hypersomnia</i>		
Cataplexy	3	0
Hypersomnia	124	0
Narcolepsy	7	0
<i>Nervous system disorders NEC</i>		
Central nervous system lesion	2	0
Cerebral disorder	2	0
Nervous system disorder	23	0
Neurotoxicity	4	0
Psychomotor skills impaired	1	0
<i>Neurologic visual problems NEC</i>		
Hemianopia	1	0
Hemianopia homonymous	2	0
Quadrantanopia	2	0
Tunnel vision	23	0
<i>Neurological signs and symptoms NEC</i>		
Agitation neonatal	1	0
Cerebrospinal fluid leakage	1	0
Clonus	5	0
Decerebrate posture	1	0
Decorticate posture	1	0
Dizziness	11247	0
Dizziness exertional	51	0
Dizziness postural	851	0
Drooling	25	0
Fontanelle bulging	2	0
Head discomfort	403	0
Hyporesponsive to stimuli	2	0
Inability to crawl	3	0
Infant irritability	10	0
Meningism	2	0
Myoclonus	35	0
Neurological symptom	66	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	17	0
Presyncope	711	0
Sensory overload	5	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Slow response to stimuli	4	0
Tongue biting	8	0
Unresponsive to stimuli	59	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	32	0
Muscle spasticity	20	0
Neuromuscular pain	3	0
Neuromuscular junction dysfunction		
Myasthenia gravis	12	0
Myasthenia gravis crisis	2	0
Myasthenic syndrome	1	0
Olfactory nerve disorders		
Anosmia	330	0
Hyposmia	19	0
Parosmia	325	0
Optic nerve disorders NEC		
Optic neuritis	41	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	14	0
Burning sensation	657	0
Burning sensation mucosal	2	0
Dysaesthesia	8	0
Formication	46	0
Hand-arm vibration syndrome	3	0
Hemianaesthesia	4	0
Hemiparaesthesia	5	0
Hyperaesthesia	123	0
Hypoaesthesia	3490	0
Lhermitte's sign	1	0
Paraesthesia	4770	0
Reversed hot-cold sensation	4	0
Synaesthesia	1	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	20	0
Hemiparesis	69	0
Hemiplegia	47	0
Locked-in syndrome	1	0
Monoparesis	92	0
Monoplegia	102	0
Paralysis	154	0
Paraparesis	3	0
Paraplegia	3	0
Paresis	10	0
Quadriparesis	1	0
Quadriplegia	1	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	18	0
Hypokinetic dysarthria	1	0
Parkinson's disease	4	0
Parkinsonian gait	1	0
Parkinsonian rest tremor	1	0
Parkinsonism	4	0
Reduced facial expression	11	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Partial complex seizures</i>		
Dreamy state	6	0
Focal dyscognitive seizures	6	0
Temporal lobe epilepsy	2	0
<i>Partial simple seizures NEC</i>		
Autonomic seizure	1	0
<i>Peripheral neuropathies NEC</i>		
Axonal neuropathy	2	0
Brachial plexopathy	1	0
Neuralgic amyotrophy	5	0
Neuritis	9	0
Neuropathy peripheral	156	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	12	0
Polyneuropathy	5	0
Small fibre neuropathy	4	0
Thoracic outlet syndrome	2	0
<i>Seizures and seizure disorders NEC</i>		
Atonic seizures	9	0
Change in seizure presentation	2	0
Clonic convulsion	5	0
Convulsions local	1	0
Convulsive threshold lowered	1	0
Epilepsy	171	0
Epileptic aura	2	0
Epileptic encephalopathy	2	0
Febrile convulsion	19	0
Idiopathic generalised epilepsy	1	0
Neonatal epileptic seizure	1	0
Partial seizures	29	0
Partial seizures with secondary generalisation	1	0
Post stroke seizure	1	0
Psychogenic seizure	11	0
Seizure	729	2
Seizure anoxic	3	0
Seizure cluster	7	0
Seizure like phenomena	3	0
Status epilepticus	39	0
Tonic clonic movements	5	0
Tonic convulsion	36	0
Tonic posturing	1	0
<i>Sensory abnormalities NEC</i>		
Ageusia	599	0
Allodynia	32	0
Aura	28	0
Central pain syndrome	1	0
Complex regional pain syndrome	6	0
Dysgeusia	1311	0
Electric shock sensation	52	0
Hypergeusia	1	0
Hypogeusia	9	0
Intercostal neuralgia	1	0
Loss of proprioception	3	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Morton's neuralgia	4	0
Neuralgia	709	0
Persistent genital arousal disorder	2	0
Phantom limb syndrome	8	0
Post herpetic neuralgia	16	0
Restless arm syndrome	4	0
Restless legs syndrome	159	0
Sensory disturbance	126	0
Sensory loss	109	0
Taste disorder	311	0
Visual perseveration	3	0
Sleep disturbances NEC		
Microsleep	1	0
Sleep deficit	13	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	238	0
Incoherent	14	0
Language disorder	2	0
Repetitive speech	5	0
Slow speech	23	0
Speech disorder	82	0
Speech disorder developmental	1	0
Spinal cord and nerve root disorders NEC		
Acquired syringomyelia	1	0
Cauda equina syndrome	1	0
Myelopathy	1	0
Radiculitis brachial	18	0
Radiculopathy	8	0
Structural brain disorders NEC		
Brain injury	10	2
Cerebral ventricle dilatation	2	0
Hyperintensity in brain deep nuclei	1	0
Intracranial mass	1	0
Transient cerebrovascular events		
Transient ischaemic attack	195	3
Tremor (excl congenital)		
Essential tremor	5	0
Head titubation	14	0
Resting tremor	4	0
Tremor	2118	0
Trigeminal disorders		
Numb chin syndrome	2	0
Trigeminal nerve disorder	3	0
Trigeminal neuralgia	84	0
Trigeminal neuritis	3	0
Vagus nerve disorders		
Vocal cord paralysis	4	0
Vertigos NEC		
Cervicogenic vertigo	1	0
Vertigo CNS origin	3	0
Nervous system disorders SOC TOTAL	79763	87

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortion related conditions and complications</i>		
Anembryonic gestation	3	0
<i>Abortions not specified as induced or spontaneous</i>		
Abortion	1	0
Abortion missed	7	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	482	0
Abortion threatened	2	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Amniorrhoea	2	0
Oligohydramnios	1	0
<i>Foetal complications NEC</i>		
Foetal cardiac disorder	1	0
Foetal distress syndrome	1	0
Foetal hypokinesia	14	0
<i>Foetal conditions due to maternal conditions</i>		
Maternal condition affecting foetus	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	7	0
<i>Gestational age and weight conditions</i>		
Low birth weight baby	1	0
Premature baby	7	1
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	3	0
Premature separation of placenta	3	0
Retroplacental haematoma	1	0
Subchorionic haematoma	3	0
Subchorionic haemorrhage	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	2	0
<i>Labour onset and length abnormalities</i>		
Induced labour	1	0
Premature delivery	1	0
Premature labour	8	0
Premature rupture of membranes	3	0
Threatened labour	1	0
<i>Maternal complications of delivery NEC</i>		
Retained placenta or membranes	2	0
<i>Maternal complications of labour NEC</i>		
Uterine contractions abnormal	1	0
Uterine hypertonus	9	0
<i>Maternal complications of pregnancy NEC</i>		
Biochemical pregnancy	4	0
Complication of pregnancy	1	0
Decidual cast	6	0
Ectopic pregnancy	14	0
Hyperemesis gravidarum	1	0
Morning sickness	16	0
Preterm premature rupture of membranes	3	0
Ruptured ectopic pregnancy	1	0
Somatic symptom disorder of pregnancy	3	0
<i>Neonatal hepatobiliary disorders</i>		
Jaundice neonatal	1	0

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Reaction Name	Total	Fatal
Pregnancy conditions <small>Pregnancy conditions cont'd</small>		
<i>Normal newborn status</i>		
Normal newborn	1	0
<i>Normal pregnancy, labour and delivery</i>		
Labour pain	1	0
Live birth	7	0
Pregnancy	35	0
Term birth	1	0
Uterine contractions during pregnancy	6	0
<i>Placental abnormalities (excl neoplasms)</i>		
Foetal vascular malperfusion	2	0
Placental disorder	1	0
Placental insufficiency	1	0
Small size placenta	1	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	5	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0
<i>Stillbirth and foetal death</i>		
Foetal death	3	3
Stillbirth	11	1F
<i>Umbilical cord complications</i>		
Umbilical cord abnormality	1	0
Umbilical cord thrombosis	1	0
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	2	0
Pregnancy on contraceptive	3	0
Pregnancy on oral contraceptive	2	0
Pregnancy with contraceptive device	2	0
Pregnancy with implant contraceptive	1	0
Unintended pregnancy	4	0
Unwanted pregnancy	1	0
Pregnancy conditions SOC TOTAL	714	1F

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Reaction Name	Total	Fatal
<i>Device electrical issues</i>		
Electromagnetic interference	1	0
<i>Device issues NEC</i>		
Device connection issue	1	0
Device failure	1	0
Device issue	2	0
<i>Device malfunction events NEC</i>		
Device infusion issue	1	0
Device malfunction	1	0
Device pacing issue	1	0
Device stimulation issue	1	0
Oversensing	21	0
Thrombosis in device	15	0
Undersensing	1	0
<i>Device physical property and chemical issues</i>		
Device breakage	1	0
Device defective	9	0
Device kink	1	0
Needle issue	3	0
<i>Manufacturing materials issues</i>		
Manufacturing materials contamination	1	0
<i>Product contamination and sterility issues</i>		
Product contamination	17	0
Product contamination physical	11	0
<i>Product packaging issues</i>		
Packaging design issue	1	0
Product closure issue	1	0
<i>Product physical issues</i>		
Liquid product physical issue	12	0
Product after taste	3	0
Product deposit	1	0
Product odour abnormal	3	0
Product physical issue	2	0
Product taste abnormal	9	0
<i>Product quality issues NEC</i>		
Product complaint	2	0
Product origin unknown	5	0
<i>Product supply and availability issues</i>		
Product availability issue	1	0
null SOC TOTAL	129	0

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MedDRA Version: MedDRA 24.1

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	28	0
Behaviour disorder	2	0
Breath holding	7	0
Staring	8	0
<i>Adjustment disorders</i>		
Adjustment disorder	1	0
Adjustment disorder with depressed mood	4	0
<i>Affect alterations NEC</i>		
Affect lability	15	0
Constricted affect	6	0
Flat affect	13	0
Inappropriate affect	23	0
<i>Amnesic symptoms</i>		
Paramnesia	7	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	2	0
Generalised anxiety disorder	3	0
Neurosis	1	0
<i>Anxiety symptoms</i>		
Agitation	95	0
Anxiety	1080	0
Immunisation anxiety related reaction	4	0
Nervousness	209	0
Stress	137	0
Tension	44	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	7	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	17	0
Attention-seeking behaviour	1	0
Aversion	1	0
Disinhibition	3	0
Indifference	7	0
Paranoia	31	0
Personality change	5	0
Social avoidant behaviour	5	0
Soliloquy	2	0
Suspiciousness	1	0
<i>Bipolar disorders</i>		
Bipolar I disorder	2	0
Bipolar disorder	5	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	9	0
Distractibility	4	0
Mental fatigue	249	0
<i>Communications disorders</i>		
Communication disorder	5	0
Mutism	4	0
Speech sound disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	1052	0
Disorientation	327	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	150	0
<i>Delusional symptoms</i>		
Delusion	18	0
<i>Depressive disorders</i>		
Agitated depression	6	0
Depression	419	0
Depression suicidal	19	0
Major depression	15	0
Mixed anxiety and depressive disorder	4	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	12	0
Dissociation	39	0
Dissociative amnesia	4	0
Dissociative disorder	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	30	0
Insomnia	1946	0
Middle insomnia	34	0
Terminal insomnia	35	0
<i>Dyssomnias</i>		
Breathing-related sleep disorder	1	0
Dyssomnia	1	0
Poor quality sleep	269	0
<i>Eating disorders NEC</i>		
Bulimia nervosa	1	0
Eating disorder	14	0
Selective eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	45	0
Dysphoria	3	0
Emotional disorder	72	0
Emotional distress	64	0
Emotional poverty	2	0
Euphoric mood	50	0
Frustration tolerance decreased	2	0
Irritability	235	0
Mood altered	64	0
Morose	1	0
<i>Factitious disorders</i>		
Factitious disorder	4	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Agoraphobia	2	0
Claustrophobia	1	0
Fear	33	0
Fear of death	2	0
Fear of eating	1	0
Fear of falling	3	0
Fear of injection	6	0
Osmophobia	1	0
Performance fear	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Phobia	3	0
Phonophobia	3	0
Social anxiety disorder	2	0
Social fear	1	0
Fluctuating mood symptoms		
Mood swings	171	0
Hallucinations (excl sleep-related)		
Hallucination	255	0
Hallucination, auditory	22	0
Hallucination, olfactory	15	0
Hallucination, tactile	1	0
Hallucination, visual	31	0
Hallucinations, mixed	4	0
Increased physical activity levels		
Restlessness	176	0
Infancy, childhood and adolescence psychiatric disorders NEC		
Social (pragmatic) communication disorder	1	0
Learning disorders		
Learning disability	1	0
Learning disorder	1	0
Mental disorders NEC		
Mental disorder	21	0
Mental status changes	1	0
Psychological factor affecting medical condition	1	0
Mood alterations with depressive symptoms		
Anhedonia	3	0
Decreased interest	11	0
Depressed mood	454	0
Depressive symptom	2	0
Feeling guilty	1	0
Feeling of despair	5	0
Feelings of worthlessness	2	0
Negative thoughts	3	0
Psychomotor retardation	2	0
Sense of a foreshortened future	3	0
Tearfulness	49	0
Mood alterations with manic symptoms		
Hypomania	2	0
Mania	11	0
Mood disorders NEC		
Affective disorder	4	0
Apathy	38	0
Boredom	1	0
Laziness	3	0
Listless	26	0
Mood disorder due to a general medical condition	1	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	4	0
Hypnopompic hallucination	2	0
Sleep attacks	3	0
Obsessive-compulsive disorders and symptoms		
Obsessive-compulsive symptom	1	0
Orgasmic disorders and disturbances		

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Anorgasmia	5	0
Female orgasmic disorder	2	0
Orgasm abnormal	4	0
Orgasmic sensation decreased	1	0
Premature ejaculation	1	0
Panic attacks and disorders		
Limited symptom panic attack	1	0
Panic attack	264	0
Panic disorder	9	0
Panic reaction	31	0
Paraphilias and paraphilic disorders		
Transvestism	1	0
Parasomnias		
Abnormal dreams	213	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	2	0
Nightmare	234	0
Parasomnia	5	0
Sleep inertia	1	0
Sleep talking	6	0
Sleep terror	29	0
Somnambulism	10	0
Perception disturbances NEC		
Autoscopy	20	0
Deja vu	3	0
Derealisation	14	0
Flashback	4	0
Illusion	6	0
Near death experience	1	0
Time perception altered	2	0
Personality disorders NEC		
Personality disorder	1	0
Self esteem decreased	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	3	0
Psychiatric elimination disorders		
Enuresis	31	0
Psychiatric symptoms NEC		
Helplessness	1	0
Hypervigilance	9	0
Psychiatric symptom	13	0
Psychological trauma	4	0
Trance	1	0
Psychotic disorder NEC		
Acute psychosis	1	0
Psychotic behaviour	1	0
Psychotic disorder	33	0
Schizophrenia NEC		
Schizophrenia	2	0
Sexual and gender identity disorders NEC		
Gender dysphoria	1	0
Sexual arousal disorders		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Disturbance in sexual arousal	4	0
Sexual inhibition	1	0
Sexual desire disorders		
Hypersexuality	1	0
Libido decreased	20	0
Libido disorder	2	0
Libido increased	8	0
Loss of libido	22	0
Sexual dysfunction NEC		
Genito-pelvic pain/penetration disorder	2	0
Sleep disorders NEC		
Sleep disorder	283	0
Sleep disorder due to general medical condition, insomnia type	5	0
Somatic symptom disorders		
Conversion disorder	30	0
Habit cough	22	0
Somatic symptom disorder	2	0
Vomiting psychogenic	1	0
Speech and language usage disturbances		
Disorganised speech	10	0
Logorrhoea	2	0
Speech articulation and rhythm disturbances		
Dysphemia	27	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
Stereotypies and automatisms		
Automatism	1	0
Bruxism	15	0
Head banging	12	0
Stereotypy	1	0
Stress disorders		
Burnout syndrome	2	0
Post-traumatic stress disorder	5	0
Substance related and addictive disorders		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	5	0
Nicotine dependence	2	0
Suicidal and self-injurious behaviour		
Completed suicide	2	2
Intentional self-injury	6	0
Self-injurious ideation	2	0
Suicidal ideation	52	0
Suicide attempt	9	0
Suicide threat	2	0
Thinking disturbances		
Bradyphrenia	44	0
Flight of ideas	1	0
Intrusive thoughts	8	0
Morbid thoughts	1	0
Tachyphrenia	8	0
Thinking abnormal	21	0
Thought blocking	3	0

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Reaction Name	Total	Fatal
Psychiatric disorders ^P Psychiatric disorders cont'd		
<i>Tic disorders</i>		
Tic	19	0
Psychiatric disorders SOC TOTAL	10021	2

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	3	0
Bladder irritation	13	0
Bladder pain	35	0
Bladder spasm	2	0
Dysuria	57	0
Incontinence	42	0
Lower urinary tract symptoms	3	0
Micturition disorder	2	0
Micturition urgency	53	0
Mixed incontinence	1	0
Pollakiuria	162	0
Stress urinary incontinence	2	0
Urethral pain	8	0
Urge incontinence	3	0
Urinary hesitation	3	0
Urinary incontinence	71	0
Urinary retention	55	0
Urine flow decreased	19	0
<i>Bladder disorders NEC</i>		
Bladder disorder	11	0
Bladder fibrosis	1	0
Bladder prolapse	1	0
Urinary bladder haemorrhage	4	0
<i>Bladder infections and inflammations</i>		
Cystitis haemorrhagic	1	0
Cystitis interstitial	6	0
Cystitis noninfective	1	0
<i>Bladder neoplasms</i>		
Bladder cyst	1	0
<i>Genital and urinary tract disorders NEC</i>		
Genitourinary symptom	3	0
Urinary tract disorder	4	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Glomerulonephritis minimal lesion	6	0
Glomerulonephritis rapidly progressive	2	0
IgA nephropathy	4	0
Nephrotic syndrome	19	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	7	0
Hypertonic bladder	5	0
Hypotonic urinary bladder	1	0
Loss of bladder sensation	3	0
Neurogenic bladder	2	0
<i>Nephritis NEC</i>		
Lupus nephritis	2	0
Nephritis	3	0
Tubulointerstitial nephritis	2	0
<i>Nephropathies and tubular disorders NEC</i>		
Nephropathy	1	0
<i>Renal disorders NEC</i>		
Kidney fibrosis	1	0
Renal disorder	9	1

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Renal haemorrhage	1	0
Renal mass	1	0
Renal failure and impairment		
Acute kidney injury	55	4
Anuria	3	0
Chronic kidney disease	4	0
Oliguria	1	0
Renal failure	24	1
Renal impairment	31	0
Renal injury	2	0
Renal failure complications		
Azotaemia	1	0
Renal lithiasis		
Nephrolithiasis	12	0
Renal neoplasms		
Renal cyst	1	0
Renal obstructive disorders		
Hydronephrosis	2	0
Renal structural abnormalities and trauma		
Kidney enlargement	1	0
Kidney small	2	0
Renal vascular and ischaemic conditions		
Renal aneurysm	1	0
Renal infarct	4	0
Renal tubular necrosis	2	0
Renal vasculitis	1	1
Structural and obstructive urethral disorders (excl congenital)		
Urethral stenosis	1	0
Ureteric disorders NEC		
Ureteric stenosis	1	0
Urinary abnormalities		
Albuminuria	1	0
Chromaturia	68	0
Haematuria	51	0
Ketonuria	1	0
Myoglobinuria	1	0
Proteinuria	13	0
Urine abnormality	12	0
Urine odour abnormal	10	0
Urinary tract lithiasis (excl renal)		
Calculus bladder	1	0
Calculus urinary	1	0
Urinary tract signs and symptoms NEC		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	30	1
Nocturia	3	0
Polyuria	9	0
Renal colic	4	0
Renal pain	358	0
Urinary tract discomfort	2	0
Urinary tract pain	6	0
Renal & urinary disorders SOC TOTAL	1358	8

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	17	0
<i>Breast disorders NEC</i>		
Breast atrophy	1	0
Breast disorder	4	0
Breast enlargement	31	0
Breast mass	149	0
Fibrocystic breast disease	1	0
Gynaecomastia	7	0
Mastoptosis	1	0
Nipple disorder	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	6	0
Nipple inflammation	2	0
<i>Breast signs and symptoms</i>		
Breast discharge	5	0
Breast discomfort	15	0
Breast engorgement	11	0
Breast haematoma	1	0
Breast oedema	9	0
Breast pain	863	0
Breast swelling	192	0
Breast tenderness	104	0
Nipple pain	47	1
Nipple swelling	4	0
<i>Cervix disorders NEC</i>		
Cervical dysplasia	2	0
Cervix disorder	1	0
Cervix haemorrhage uterine	5	0
Ectropion of cervix	5	0
<i>Cervix infections and inflammations</i>		
Cervix inflammation	1	0
<i>Cervix neoplasms</i>		
Cervical polyp	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation disorder	3	0
Ejaculation failure	3	0
Erectile dysfunction	75	0
Erection increased	4	0
Organic erectile dysfunction	14	0
Painful ejaculation	1	0
Spontaneous ejaculation	2	0
Spontaneous penile erection	2	0
<i>Fallopian tube and ovary infections and inflammations</i>		
Noninfective oophoritis	6	0
<i>Lactation disorders</i>		
Breast milk discolouration	3	0
Breast milk odour abnormal	2	0
Galactorrhoea	5	0
Galactostasis	1	0
Lactation disorder	11	0
Lactation puerperal increased	6	0
Suppressed lactation	48	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Menopausal effects NEC</i>		
Artificial menopause	1	0
Menopausal disorder	1	0
Menopausal symptoms	46	0
Menopause delayed	1	0
Premature menopause	24	0
<i>Menopausal effects on the genitourinary tract</i>		
Atrophic vulvovaginitis	2	0
Postmenopausal haemorrhage	113	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	8	0
Abnormal withdrawal bleeding	3	0
Bleeding anovulatory	1	0
Dysmenorrhoea	3303	0
Intermenstrual bleeding	1304	0
Menstrual discomfort	36	0
Menstrual disorder	2267	0
Menstruation irregular	4013	0
Premenstrual dysphoric disorder	14	0
Premenstrual headache	13	0
Premenstrual pain	149	0
Premenstrual syndrome	137	0
Retrograde menstruation	2	0
Withdrawal bleed	16	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	710	0
Hypomenorrhoea	752	0
Menstruation delayed	5686	0
Oligomenorrhoea	231	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	6293	0
Menometrorrhagia	21	0
Polymenorrhoea	1034	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Haemorrhagic ovarian cyst	3	0
Ovarian cyst	31	0
Ovarian cyst ruptured	2	0
Polycystic ovaries	51	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Adnexal torsion	1	0
Hydrosalpinx	2	0
Ovarian enlargement	1	0
Ovarian failure	1	0
Ovarian haemorrhage	8	0
Ovarian hyperstimulation syndrome	1	0
Ovarian mass	2	0
Ovarian necrosis	1	0
Ovulation disorder	4	0
Ovulation pain	84	0
Premature ovulation	4	0
Superovulation	1	0
<i>Pelvic prolapse conditions</i>		
Vaginal prolapse	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri mass	1	0
Adnexa uteri pain	70	0
Pelvic congestion	1	0
Pelvic floor muscle weakness	1	0
Pelvic haemorrhage	22	0
<i>Penile and scrotal infections and inflammations</i>		
Balanoposthitis	5	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Foreskin oedema	1	0
Penile blister	1	0
Penile discharge	1	0
Penile discomfort	1	0
Penile erythema	1	0
Penile haemorrhage	3	0
Penile oedema	1	0
Penile pain	1	0
Penile rash	1	0
Penile size reduced	1	0
Penile swelling	6	0
Penis disorder	12	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	5	0
<i>Prostatic neoplasms and hypertrophy</i>		
Benign prostatic hyperplasia	2	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
Prostatomegaly	3	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital erosion	1	0
Genital haemorrhage	25	0
Genital hypoaesthesia	1	0
Genital lesion	2	0
Genital paraesthesia	1	0
Genital ulceration	8	0
Perineal ulceration	1	0
<i>Reproductive tract infections and inflammations NEC</i>		
Genital tract inflammation	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital burning sensation	3	0
Genital erythema	1	0
Genital pain	7	0
Genital rash	6	0
Genital swelling	5	0
Pelvic discomfort	6	0
Pelvic pain	129	0
Perineal pain	3	0
Perineal rash	1	0
Pruritus genital	6	0
<i>Scrotal disorders NEC</i>		
Acquired hydrocele	1	0
Scrotal angiokeratoma	1	0
Scrotal discomfort	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Scrotal erythema	2	0
Scrotal exfoliation	2	0
Scrotal pain	22	0
Scrotal swelling	6	0
Scrotum erosion	1	0
Varicocele	2	0
Sexual function and fertility disorders NEC		
Dyspareunia	7	0
Infertility	16	0
Infertility female	5	0
Sexual dysfunction	10	0
Spermatogenesis and semen disorders		
Aspermia	1	0
Haematospermia	8	0
Semen discolouration	1	0
Testicular and epididymal disorders NEC		
Testicular atrophy	1	0
Testicular disorder	4	0
Testicular oedema	1	0
Testicular pain	71	0
Testicular swelling	13	0
Testicular torsion	1	0
Testis discomfort	3	0
Testicular and epididymal neoplasms		
Testicular cyst	1	0
Uterine disorders NEC		
Adenomyosis	11	0
Endometrial thickening	4	0
Endometriosis	97	0
Uterine haemorrhage	48	0
Uterine pain	19	0
Uterine infections and inflammations (excl cervix)		
Uterine inflammation	1	0
Uterine neoplasms		
Uterine polyp	5	0
Uterine tone disorders		
Uterine spasm	39	0
Vaginal and vulval infections and inflammations		
Vulvovaginal inflammation	2	0
Vulvovaginal cysts and neoplasms		
Bartholin's cyst	2	0
Vaginal cyst	7	0
Vaginal polyp	1	0
Vulva cyst	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	1796	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	4	0
Vulval disorder	2	0
Vulval haemorrhage	34	0
Vulval ulceration	7	0
Vulvovaginal ulceration	6	0
Vulvovaginal signs and symptoms		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<small>Reproductive & breast disorders cont'd</small>		
Clitoral engorgement	1	0
Coital bleeding	7	0
Labia enlarged	2	0
Vaginal discharge	88	0
Vaginal lesion	1	0
Vaginal odour	4	0
Vulval oedema	2	0
Vulvovaginal burning sensation	9	0
Vulvovaginal discomfort	2	0
Vulvovaginal dryness	5	0
Vulvovaginal erythema	2	0
Vulvovaginal pain	30	0
Vulvovaginal pruritus	10	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	5	0
Reproductive & breast disorders SOC TOTAL	30837	1

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	7	0
Apnoeic attack	1	0
Dyspnoea	6760	5
Dyspnoea at rest	11	0
Dyspnoea exertional	45	1
Grunting	1	0
Hyperventilation	62	0
Hypopnoea	129	0
Hypoventilation	1	0
Irregular breathing	27	0
Mouth breathing	7	0
Nocturnal dyspnoea	2	0
Orthopnoea	3	0
Respiration abnormal	72	0
Respiratory arrest	21	0
Respiratory depression	1	0
Respiratory distress	20	0
Sleep apnoea syndrome	15	0
Tachypnoea	31	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	4	0
Bronchiectasis	15	0
<i>Bronchospasm and obstruction</i>		
Asthma	425	0
Asthma late onset	3	0
Bronchospasm	19	0
Chronic obstructive pulmonary disease	28	1
Cough variant asthma	7	0
Obstructive airways disorder	13	0
Reversible airways obstruction	1	0
Wheezing	476	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	2	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	33	2
Respiratory acidosis	2	0
<i>Coughing and associated symptoms</i>		
Allergic cough	9	0
Atopic cough	1	0
Cough	2961	1
Cough decreased	2	0
Haemoptysis	73	0
Productive cough	197	0
Sputum discoloured	11	0
Sputum increased	4	0
<i>Diaphragmatic disorders</i>		
Acquired diaphragmatic eventration	1	0
Diaphragm muscle weakness	1	0
Diaphragmatic disorder	1	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Laryngeal disorder	1	0
Reflux laryngitis	3	0
Vocal cord disorder	1	0
Vocal cord dysfunction	3	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	4	0
Laryngospasm	3	0
Stridor	28	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	1	0
Autoimmune lung disease	1	0
Hypersensitivity pneumonitis	1	0
Lower respiratory tract inflammation	1	0
Pneumonitis	36	2
Pulmonary sarcoidosis	2	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	36	0
Increased bronchial secretion	3	0
Increased viscosity of bronchial secretion	1	0
Lung hyperinflation	2	0
Lung opacity	4	0
Pleuritic pain	26	0
Pulmonary haemorrhage	1	0
Pulmonary pain	120	0
Rales	6	0
Respiratory fremitus	1	0
<i>Mediastinal disorders</i>		
Mediastinal mass	1	0
Pulmonary hilum mass	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	335	0
Nasal inflammation	5	0
Rhinitis allergic	26	0
<i>Nasal disorders NEC</i>		
Epistaxis	1075	0
Intranasal hypoaesthesia	2	0
Intranasal paraesthesia	1	0
Nasal crusting	2	0
Nasal disorder	4	0
Nasal dryness	36	0
Nasal mucosal discolouration	1	0
Nasal odour	6	0
Nasal oedema	8	0
Nasal polyps	2	0
Nasal pruritus	12	0
Nasal ulcer	2	0
<i>Neonatal hypoxic conditions</i>		
Dry lung syndrome	1	0
Gasping syndrome	1	0
Infantile apnoea	2	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		

Case Series Drug Analysis Print

Name: COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Allergic sinusitis	3	0
Paranasal sinus inflammation	4	0
Sinonasal obstruction	15	0
Sinus congestion	72	0
Sinus disorder	8	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	4	0
Combined pulmonary fibrosis and emphysema	1	0
Emphysema	3	0
Interstitial lung disease	11	0
Lung consolidation	5	0
Lung infiltration	2	1
Organising pneumonia	2	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	9	0
Pulmonary toxicity	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Hyperactive pharyngeal reflex	1	0
Pharyngeal enanthema	1	0
Pharyngeal erythema	10	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	40	0
Pharyngeal inflammation	4	0
Pharyngeal lesion	1	0
Pharyngeal mass	1	0
Pharyngeal oedema	14	0
Pharyngeal paraesthesia	57	0
Pharyngeal swelling	299	0
Pharyngeal ulceration	18	0
Tonsillar erythema	13	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	98	0
Tonsillar inflammation	4	0
Tonsillar ulcer	1	0
Tonsillolith	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	38	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	40	0
Pneumothorax	12	0
Pneumothorax spontaneous	5	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	3	0
<i>Pulmonary oedemas</i>		
Acute respiratory distress syndrome	2	1
Pulmonary congestion	19	0
Pulmonary oedema	23	2
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary artery thrombosis	2	0
Pulmonary embolism	535	38
Pulmonary infarction	6	0
Pulmonary thrombosis	12	1

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	3	1
Respiratory failure	15	2
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	6	0
Diaphragmalgia	9	0
Nasal flaring	1	0
Painful respiration	18	1
Pleural rub	1	0
Respiratory symptom	21	0
Suffocation feeling	2	0
Use of accessory respiratory muscles	2	0
<i>Respiratory tract disorders NEC</i>		
Allergic respiratory disease	1	0
Aspiration	4	0
Lung disorder	11	1
Pulmonary mass	5	0
Respiratory disorder	16	1
Respiratory tract congestion	5	0
Respiratory tract haemorrhage	2	0
Respiratory tract inflammation	2	0
Respiratory tract irritation	9	0
Respiratory tract oedema	4	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	2	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal disorder	1	0
Tracheal pain	2	0
<i>Upper respiratory tract neoplasms</i>		
Tonsillar cyst	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	140	0
Catarrh	33	0
Choking	20	0
Choking sensation	6	0
Dry throat	186	0
Dysphonia	184	0
Increased upper airway secretion	6	0
Increased viscosity of upper respiratory secretion	35	0
Laryngeal pain	1	0
Nasal discharge discolouration	4	0
Nasal discomfort	59	0
Nasal obstruction	3	0
Oropharyngeal blistering	11	0
Oropharyngeal discolouration	1	0
Oropharyngeal discomfort	71	0
Oropharyngeal pain	3240	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	54	0
Rhinalgia	14	0
Rhinorrhoea	1067	0
Sinus pain	251	0
Sneezing	455	0

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Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Snoring	8	0
Throat clearing	8	0
Throat irritation	264	0
Throat lesion	1	0
Throat tightness	286	0
Upper airway obstruction	3	0
Upper respiratory tract congestion	2	0
Upper respiratory tract irritation	1	0
Upper-airway cough syndrome	15	0
Yawning	31	0
Vascular pulmonary disorders NEC		
Acute chest syndrome	1	0
Respiratory disorders SOC TOTAL	21328	61

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	217	0
Acne cystic	28	0
Dermatitis acneiform	13	0
Oil acne	1	0
<i>Alopecias</i>		
Alopecia	438	0
Alopecia areata	71	0
Alopecia totalis	3	0
Alopecia universalis	2	0
Androgenetic alopecia	2	0
Diffuse alopecia	4	0
Hypotrichosis	3	0
Lichen planopilaris	1	0
Madarosis	9	0
<i>Angioedemas</i>		
Angioedema	278	0
Circumoral oedema	1	0
Circumoral swelling	1	0
Idiopathic angioedema	1	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	2	0
Bromhidrosis	1	0
Cold sweat	874	0
Hidradenitis	5	0
Hyperhidrosis	2684	0
Hypohidrosis	2	0
Milia	2	0
Miliaria	119	0
Night sweats	941	0
Sweat discolouration	1	0
<i>Bullous conditions</i>		
Autoimmune blistering disease	1	0
Blister	537	0
Blister rupture	1	0
Blood blister	35	0
Dermatitis bullous	17	0
Erythema multiforme	44	0
Fracture blisters	1	0
Herpes gestationis	1	0
Pemphigoid	30	0
Pemphigus	9	0
Stevens-Johnson syndrome	7	0
Toxic epidermal necrolysis	2	1
<i>Connective tissue disorders</i>		
Cutaneous lupus erythematosus	3	0
Dermatomyositis	11	0
Subacute cutaneous lupus erythematosus	3	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	290	0
Koebner phenomenon	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Macule	5	0
Neutrophilic dermatosis	1	0
Pain of skin	341	0
Papule	118	0
Pathergy reaction	1	0
Scab	27	0
Scar discomfort	1	0
Scar pain	20	0
Sensitive skin	230	0
Shagreen skin	1	0
Skin burning sensation	267	0
Skin degenerative disorder	1	0
Skin discolouration	160	0
Skin discomfort	5	0
Skin disorder	35	0
Skin fissures	9	0
Skin indentation	3	0
Skin induration	5	0
Skin lesion	51	0
Skin lesion inflammation	1	0
Skin necrosis	3	0
Skin odour abnormal	26	0
Skin plaque	4	0
Skin reaction	170	0
Skin sensitisation	45	0
Skin swelling	115	0
Skin texture abnormal	2	0
Skin tightness	29	0
Skin warm	367	0
Skin weeping	16	0
Sticky skin	3	0
Target skin lesion	3	0
Transient acantholytic dermatosis	1	0
Yellow skin	29	0
<i>Dermatitis and eczema</i>		
Dermatitis	163	0
Dermatitis allergic	300	0
Dermatitis atopic	60	0
Dermatitis contact	26	0
Dermatitis diaper	4	0
Dyshidrotic eczema	32	0
Eczema	409	0
Eczema asteatotic	16	0
Eczema infantile	1	0
Eczema nummular	7	0
Eczema vesicular	1	0
Eczema weeping	6	0
Hand dermatitis	2	0
Intertrigo	1	0
Neurodermatitis	4	0
Perioral dermatitis	3	0
Seborrhoeic dermatitis	7	0
Skin irritation	153	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Stasis dermatitis	2	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	35	0
Drug reaction with eosinophilia and systemic symptoms	1	0
Fixed eruption	2	0
Palmar-plantar erythrodysesthesia syndrome	3	0
Toxic skin eruption	2	0
<i>Erythemas</i>		
Erythema	2488	0
Palmar erythema	4	0
Pernio-like erythema	1	0
Red man syndrome	2	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	5	0
Exfoliative rash	26	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	143	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Cutaneous sarcoidosis	1	0
Granuloma annulare	8	0
Necrobiosis lipoidica diabetorum	1	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	2	0
Keratosis pilaris	3	0
Lichenoid keratosis	4	0
<i>Hyperpigmentation disorders</i>		
Argyria	1	0
Chloasma	2	0
Ephelides	1	0
Skin hyperpigmentation	7	0
Solar lentigo	4	0
<i>Hypertrichoses</i>		
Hirsutism	2	0
Hypertrichosis	1	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	4	0
Skin hypopigmentation	1	0
Vitiligo	24	0
<i>Lipodystrophies</i>		
Lipoatrophy	4	0
Lipodystrophy acquired	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Ingrowing nail	2	0
Nail discolouration	12	0
Nail disorder	7	0
Nail growth abnormal	1	0
Nail pigmentation	2	0
Nail ridging	3	0
Onychalgia	10	0
Onychoclasia	6	0
Onychomadesis	3	0
Splinter haemorrhages	3	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Panniculitides</i>		
Erythema nodosum	34	0
Panniculitis	2	0
<i>Papulosquamous conditions</i>		
Erythema annulare	2	0
Lichen planus	24	0
Lichen sclerosus	11	0
Parapsoriasis	6	0
Pityriasis alba	1	0
Pityriasis rosea	140	0
Pityriasis rubra pilaris	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	72	0
Polymorphic light eruption	3	0
Solar dermatitis	2	0
<i>Pigmentation changes NEC</i>		
Haemosiderin stain	1	0
Pigmentation disorder	15	0
<i>Pilar disorders NEC</i>		
Hair colour changes	11	0
Hair disorder	1	0
Hair growth abnormal	11	0
Hair texture abnormal	7	0
Piloerection	29	0
Pseudofolliculitis	3	0
Trichorrhexis	3	0
<i>Pruritus NEC</i>		
Itching scar	10	0
Polymorphic eruption of pregnancy	1	0
Pruritus	6348	0
<i>Psoriatic conditions</i>		
Dermatitis psoriasiform	6	0
Guttate psoriasis	25	0
Nail psoriasis	2	0
Palmoplantar pustulosis	2	0
Psoriasis	245	0
Pustular psoriasis	3	0
Rebound psoriasis	1	0
<i>Purpura and related conditions</i>		
Ecchymosis	1	0
Henoch-Schonlein purpura	12	0
Petechiae	155	0
Purpura	62	0
<i>Pustular conditions</i>		
Acute generalised exanthematous pustulosis	2	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	7	0
Rash	6633	1
Rash erythematous	1445	0
Rash macular	579	0
Rash maculo-papular	69	0
Rash morbilliform	49	0
Rash papular	404	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash pruritic	1405	0
Rash scarlatiniform	1	0
Rash vesicular	88	0
Systemic lupus erythematosus rash	8	0
Rosaceas		
Rosacea	39	0
Scaly conditions		
Dandruff	5	0
Pityriasis	29	0
Sebaceous gland disorders		
Sebaceous glands overactivity	1	0
Seborrhoea	15	0
Skin and subcutaneous conditions NEC		
Cellulite	2	0
Cutaneous symptom	6	0
Reactive perforating collagenosis	1	0
Skin mass	28	0
Skin and subcutaneous tissue ulcerations		
Ischaemic skin ulcer	1	0
Mucocutaneous ulceration	1	0
Pyoderma gangrenosum	2	0
Scleroderma associated digital ulcer	1	0
Skin erosion	31	0
Skin ulcer	23	0
Skin cysts and polyps		
Dermal cyst	18	0
Skin dystrophies		
Keloid scar	3	0
Skin wrinkling	4	0
Skin haemorrhages		
Haemorrhage subcutaneous	15	0
Skin haemorrhage	22	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	2	0
Skin hypoplasias and atrophies		
Skin atrophy	3	0
Skin striae	8	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	3	0
Needle track marks	5	0
Skin preneoplastic conditions NEC		
Actinic keratosis	1	0
Skin vascular conditions NEC		
Angiodermatitis	1	0
Skin oedema	5	0
Skin vasculitides		
Capillaritis	4	0
Cutaneous vasculitis	15	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	22	0
Skin vasomotor conditions		
Livedo reticularis	28	0
Telangiectasia and related conditions		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Spider naevus	1	0
Telangiectasia	1	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	13	0
Cold urticaria	9	0
Idiopathic urticaria	2	0
Mechanical urticaria	14	0
Solar urticaria	3	0
Urticaria	2277	0
Urticaria cholinergic	2	0
Urticaria chronic	40	0
Urticaria contact	1	0
Urticaria papular	6	0
Urticaria thermal	10	0
Urticarial vasculitis	7	0
Skin disorders SOC TOTAL	33500	2

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Infant	2	0
Menarche	3	0
Menopause	48	0
Postmenopause	5	0
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Dependents</i>		
Sick relative	6	0
<i>Dietary and nutritional issues</i>		
Feeding tube user	1	0
<i>Disability issues</i>		
Bedridden	34	0
Breast prosthesis user	3	0
Disability	2	0
Hearing disability	3	0
Housebound	1	0
Immobile	13	0
Impaired driving ability	5	0
Impaired work ability	21	0
Loss of personal independence in daily activities	46	0
Physical disability	5	0
Sight disability	13	0
Sitting disability	4	0
Walking disability	1	0
Wheelchair user	1	0
<i>Economic circumstances</i>		
High income	1	0
Low income	1	0
<i>Educational issues</i>		
Educational problem	1	0
Illiteracy	2	0
<i>Employment issues</i>		
Job dissatisfaction	1	0
Retirement	4	0
Sick leave	1	0
Stress at work	3	0
<i>Family and partner issues</i>		
Bed sharing	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Flooding	2	0
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	17	0
Multigravida	1	0
Parity	1	0
<i>Social issues NEC</i>		
Exercise adequate	2	0
Hair dye user	2	0
Impaired quality of life	3	0
<i>Tobacco use</i>		
Ex-tobacco user	1	0
Non-tobacco user	5	0

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Reaction Name	Total	Fatal
Social circumstances Social circumstances cont'd		
Tobacco user	1	0
Social circumstances SOC TOTAL	270	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Local anaesthesia	2	0
Nerve block	5	0
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Antiinfective therapies</i>		
COVID-19 prophylaxis	1	0
COVID-19 treatment	4	0
<i>Arterial therapeutic procedures (excl aortic)</i>		
Splenic artery embolisation	1	0
<i>Blood and blood product treatment</i>		
Transfusion	2	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	3	0
Mammoplasty	1	0
<i>Bronchial and pulmonary therapeutic procedures</i>		
Airway secretion clearance therapy	1	0
<i>Cardiac device therapeutic procedures</i>		
Cardiac pacemaker insertion	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Cardiac operation	1	0
<i>Contraceptive methods female</i>		
Contraception	1	0
Contraceptive implant	3	0
Oral contraception	1	0
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	8	0
Nothing by mouth order	13	0
Wheat-free diet	1	0
<i>External ear therapeutic procedures</i>		
Ear irrigation	1	0
<i>Facial therapeutic procedures</i>		
Face lift	1	0
<i>Fertility and fertilisation interventions female</i>		
Endometrial scratching	1	0
Ovulation induction	2	0
<i>Gastric therapeutic procedures</i>		
Gastric operation	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Intestinal anastomosis	1	0
Prophylaxis of nausea and vomiting	16	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	15	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	1	0
<i>Head, neck and oral cavity therapeutic procedures NEC</i>		
Neck lift	1	0
<i>Hernia repairs</i>		
Hernia repair	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	2	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
Hormone therapy	8	0
Immunisations		
COVID-19 immunisation	94	0
Immunisation	575	1
Induced abortions		
Abortion induced	1	0
Joint therapeutic procedures		
Joint injection	5	0
Joint surgery	1	0
Knee arthroplasty	1	0
Large intestine therapeutic procedures		
Appendectomy	3	0
Limb therapeutic procedures		
Arm amputation	1	0
Limb immobilisation	12	0
Limb operation	10	0
Lip therapeutic procedures		
Lip lesion excision	1	0
Lymphoid tissue therapeutic procedures		
Lymphadenectomy	2	0
Splenectomy	1	0
Mastectomies		
Breast conserving surgery	4	0
Nail therapeutic procedures		
Nail operation	3	0
Nervous system therapeutic procedures NEC		
Multiple sclerosis relapse prophylaxis	3	0
Obstetric therapeutic procedures		
Caesarean section	1	0
Labour stimulation	1	0
Orbit and globe therapeutic procedures		
Strabismus correction	1	0
Ovarian therapeutic procedures		
Ovarian operation	1	0
Peripheral nerve therapeutic procedures		
Neurolysis	1	0
Peripheral nerve neurostimulation	1	0
Phototherapies		
UV light therapy	1	0
Prophylactic procedures NEC		
Anaphylaxis prophylaxis	3	0
Immune tolerance induction	1	0
Prophylaxis against transplant rejection	1	0
Reproductive system disorder prophylaxis	1	0
Psychiatric therapies		
Electroconvulsive therapy	1	0
Renal therapeutic procedures		
Dialysis	1	0
Respiratory tract therapeutic procedures NEC		
Asthma prophylaxis	3	0
Retinal therapeutic procedures		
Retinopexy	1	0
Skin and subcutaneous tissue therapeutic procedures NEC		

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
Dermal filler injection	4	0
Therapeutic skin care topical	1	0
Skull and brain therapeutic procedures		
Cerebrovascular operation	1	0
Posterior fossa decompression	1	0
Small intestine therapeutic procedures		
Ileostomy	1	0
Spine and spinal cord therapeutic procedures		
Spinal decompression	1	0
Therapeutic bladder catheterisation		
Bladder catheterisation	2	0
Therapeutic procedures NEC		
Abscess drainage	1	0
Anaphylaxis treatment	7	0
Bed rest	5	0
Fatigue management	1	0
Hospitalisation	15	0
Injection	54	0
Interchange of vaccine products	282	0
Localised alternating hot and cold therapy	2	0
Magnetic therapy	1	0
Mass excision	5	0
Medical procedure	1	0
Medication dilution	2	0
Physical fitness training	1	0
Product used for unknown indication	2	0
Promotion of wound healing	1	0
Specialist consultation	1	0
Stent placement	1	0
Stoma care	1	0
Therapeutic procedure	1	0
Therapy change	2	0
Tracheal therapeutic procedures		
Tracheostomy	1	0
Uterine therapeutic procedures		
Endometrial ablation	2	0
Vascular therapeutic procedures NEC		
Vasodilation procedure	1	0
Surgical & medical procedures SOC TOTAL	1239	1

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	14	0
Hypertensive urgency	2	0
Malignant hypertension	4	0
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm	4	0
Aneurysm ruptured	1	0
Artery dissection	2	0
<i>Aortic aneurysms and dissections</i>		
Acute aortic syndrome	1	0
Aortic aneurysm	1	0
Aortic aneurysm rupture	1	1
Aortic dissection	1	0
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	5	0
Aortic thrombosis	4	0
<i>Aortic infections and inflammations</i>		
Aortitis	1	0
<i>Aortic necrosis and vascular insufficiency</i>		
Aortic occlusion	1	0
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	20	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	15	0
Labile blood pressure	3	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	4	0
<i>Circulatory collapse and shock</i>		
CT hypotension complex	2	0
Circulatory collapse	87	0
Hypoperfusion	2	0
Hypovolaemic shock	2	1
Neurogenic shock	24	0
Peripheral circulatory failure	6	0
Shock	24	0
Shock symptom	3	0
<i>Haemorrhages NEC</i>		
Arterial haemorrhage	1	0
Bloody discharge	25	0
Haematoma	53	0
Haemorrhage	1397	2
Internal haemorrhage	14	1
Venous haemorrhage	2	0
<i>Lymphangiopathies</i>		
Lymphangiopathy	1	0
Lymphocele	7	0
Lymphorrhoea	2	0
Lymphostasis	1	0
<i>Lymphoedemas</i>		
Lymphoedema	245	0
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	4	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Embolism	65	0
Embolism arterial	2	0
Embolism venous	8	1
Microembolism	2	0
Thrombosis	519	11
Venous thrombosis	8	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial occlusive disease	2	0
Arterial spasm	1	0
Arteriosclerosis	4	0
Haemorrhagic infarction	1	0
Infarction	3	0
Ischaemia	11	0
Peripheral venous disease	2	0
Vascular occlusion	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Capillary disorder	1	0
Capillary fragility	5	0
Endothelial dysfunction	1	0
Haemodynamic instability	1	0
Superficial vein prominence	3	0
Vascular pain	44	0
Vascular wall hypertrophy	1	0
Vasodilatation	45	0
Vein discolouration	8	0
Vein disorder	8	0
Vein rupture	7	0
<i>Peripheral aneurysms and dissections</i>		
Peripheral artery aneurysm	1	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	35	0
Deep vein thrombosis	351	1
Femoral artery embolism	1	0
Jugular vein thrombosis	4	0
Pelvic venous thrombosis	4	0
Peripheral artery thrombosis	3	0
Peripheral embolism	2	0
Subclavian vein thrombosis	4	0
Superficial vein thrombosis	30	0
Thrombophlebitis	29	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	54	0
Erythromelalgia	2	0
Flushing	476	0
Hot flush	1262	0
Peripheral vascular disorder	2	0
Vein wall hypertrophy	1	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Claudication of jaw muscles	1	0
Extremity necrosis	3	0
Iliac artery occlusion	1	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Intermittent claudication	3	0
Ischaemic limb pain	2	0
Jugular vein occlusion	2	0
May-Thurner syndrome	1	0
Peripheral arterial occlusive disease	2	0
Peripheral artery occlusion	1	0
Peripheral coldness	390	0
Peripheral ischaemia	12	0
Poor peripheral circulation	21	0
Raynaud's phenomenon	68	0
Subclavian vein occlusion	1	0
Vasoconstriction	2	0
Phlebitis NEC		
Phlebitis	37	0
Phlebitis superficial	10	0
Site specific vascular disorders NEC		
Aortic disorder	1	0
Aortic rupture	2	2
Inferior vena cava dilatation	1	0
Pallor	430	0
Varicose veins NEC		
Spider vein	7	0
Varicophlebitis	4	0
Varicose vein	39	0
Varicose vein ruptured	1	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	6	0
Essential hypertension	6	0
Hypertension	753	0
Labile hypertension	2	0
Orthostatic hypertension	2	0
Secondary hypertension	1	0
Systolic hypertension	7	0
White coat hypertension	1	0
Vascular hypotensive disorders		
Capillary leak syndrome	1	0
Diastolic hypotension	1	0
Hypotension	460	1
Orthostatic hypotension	34	0
Vasculitides NEC		
Behcet's syndrome	5	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	3	0
MAGIC syndrome	2	0
Thromboangiitis obliterans	1	0
Vasculitis	53	0
Vena caval embolism and thrombosis		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	7386	21
TOTAL REACTIONS FOR DRUG	479366	7HG
TOTAL REPORTS	166780	

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
TOTAL FATAL OUTCOME REPORTS		7HG