

COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

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All UK spontaneous reports received between 09/12/2020 and 04/05/2022 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.

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia folate deficiency	1	0
Anaemia vitamin B12 deficiency	7	0
Deficiency anaemia	1	0
Iron deficiency anaemia	8	0
Pernicious anaemia	2	0
<i>Anaemias NEC</i>		
Anaemia	147	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 autoimmune 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	55	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	31	1
Disseminated intravascular coagulation	3	0
Hypercoagulation	4	0
Thrombotic microangiopathy	4	0
<i>Eosinophilic disorders</i>		
Eosinophilia	12	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	13	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	2280	0
Lymph node ulcer	1	0
Lymphadenitis	191	0
Lymphadenopathy	13749	0
Lymphadenopathy mediastinal	1	0
Lymphatic disorder	3	0
Lymphatic insufficiency	1	0
Lymphoid tissue hyperplasia	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	9	0
Neutropenias		
Autoimmune neutropenia	2	0
Neutropenia	44	0
Platelet disorders NEC		
Platelet anisocytosis	1	0
Platelet disorder	4	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	4	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	86	0
Thrombocytopenia	241	1
Thrombocytopenic purpura	10	0

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Thrombotic thrombocytopenic purpura	7	0
Thrombocytoses		
Thrombocytosis	7	0
Blood disorders SOC TOTAL	17097	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	35	1
Atrioventricular block complete	3	1
Atrioventricular block first degree	2	0
Atrioventricular block second degree	5	0
Bundle branch block	2	0
Bundle branch block left	6	0
Bundle branch block right	5	0
Trifascicular block	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	7	0
Atrial thrombosis	1	0
Cardiac disorder	103	3
Cardiac dysfunction	2	0
Cardiac ventricular thrombosis	2	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	9	0
Intracardiac thrombus	6	0
<i>Cardiac hypertensive complications</i>		
Hypertensive heart disease	2	1
<i>Cardiac infections and inflammations NEC</i>		
Carditis	10	0
<i>Cardiac neoplasms NEC</i>		
Pericardial cyst	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	39	0
Cardiovascular symptom	4	0
Palpitations	6211	1
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	4	0
Heart valve incompetence	3	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	17	1
Congestive cardiomyopathy	8	0
Stress cardiomyopathy	3	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	2	0
Coronary artery disease	10	3
Coronary artery dissection	1	0
Coronary artery occlusion	4	0
Coronary artery thrombosis	8	2
<i>Endocarditis NEC</i>		
Endocarditis noninfective	1	1
<i>Heart failures NEC</i>		
Cardiac failure	86	10
Cardiac failure acute	6	1
Cardiac failure chronic	2	0
Cardiac failure congestive	7	4
Cardiogenic shock	6	2
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Acute coronary syndrome	10	1
Acute myocardial infarction	29	3
Angina pectoris	339	1
Angina unstable	5	0
Arteriospasm coronary	4	0
Microvascular coronary artery disease	3	0
Myocardial infarction	301	44
Myocardial ischaemia	11	7
Left ventricular failures		
Acute left ventricular failure	2	2
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	56	3
Dilatation ventricular	1	0
Left atrial dilatation	1	0
Left ventricular dysfunction	18	0
Left ventricular enlargement	3	0
Left ventricular hypertrophy	2	0
Myocardial fibrosis	8	0
Myocardial haemorrhage	1	0
Myocardial injury	24	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
Systolic dysfunction	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	694	2
Myocarditis post infection	1	0
Myopericarditis	92	0
Noninfectious pericarditis		
Pericarditis	532	2
Pericarditis constrictive	1	0
Pericarditis lupus	1	0
Pleuropericarditis	1	0
Pericardial disorders NEC		
Cardiac tamponade	2	1
Pericardial effusion	51	2
Pericardial fibrosis	1	0

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Cardiac disorders Cardiac disorders cont'd		
Pericardial haemorrhage	4	3
Pericardial rub	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	189	1
Arrhythmia neonatal	1	0
Bradycardia	79	0
Bradycardia foetal	2	0
Cardiac flutter	623	0
Extrasystoles	220	0
Heart alternation	3	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	43	0
Tachyarrhythmia	11	0
Tachycardia	2475	0
Tachycardia foetal	1	0
Tachycardia paroxysmal	1	0
<i>Right ventricular failures</i>		
Cor pulmonale	1	0
Right ventricular failure	1	0
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	16	0
Atrial fibrillation	292	1
Atrial flutter	46	0
Atrial tachycardia	12	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	9	0
Sinus bradycardia	15	0
Sinus node dysfunction	1	0
Sinus tachycardia	86	0
Supraventricular extrasystoles	6	0
Supraventricular tachycardia	51	0
<i>Tricuspid valvular disorders</i>		
Tricuspid valve incompetence	6	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	129	45
Cardio-respiratory arrest	1	1
Pulseless electrical activity	7	0
Ventricular arrhythmia	6	0
Ventricular extrasystoles	32	0
Ventricular fibrillation	10	1
Ventricular tachycardia	17	0
Cardiac disorders SOC TOTAL	13266	155

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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	3	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	2	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>Diaphragmatic disorders congenital</i>		
Congenital diaphragmatic hernia	1	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

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Congenital disorders Congenital disorders cont'd		
<i>Inborn errors of porphyrin metabolism</i>		
Porphyria	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>		
Congenital musculoskeletal disorder of limbs	1	0
Developmental hip dysplasia	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>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	107	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	107	0
Ear disorder	23	0
Ear haemorrhage	15	0
Ear inflammation	2	0
Ear pain	1181	0
Ear pruritus	12	0
Ear swelling	39	0
Otorrhoea	8	0
Ototoxicity	1	0
Paraesthesia ear	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	5	0
Eustachian tube dysfunction	11	0
Eustachian tube obstruction	7	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>		
Chondrodermatitis nodularis chronica heliis	1	0
External ear inflammation	2	0
<i>Hearing disorders NEC</i>		
Auditory disorder	6	0
Diplacusis	2	0
Dysacusis	1	0
<i>Hearing losses</i>		
Conductive deafness	1	0
Deafness	306	0
Deafness bilateral	12	0
Deafness neurosensory	27	0
Deafness transitory	10	0
Deafness unilateral	40	0
Hypoacusis	231	0
Mixed deafness	1	0
Sudden hearing loss	52	0
<i>Hyperacusia</i>		
Hyperacusis	79	0
Misophonia	3	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	2	0
Inner ear disorder	13	0
Meniere's disease	16	0
Vestibular disorder	15	0
<i>Inner ear infections and inflammations</i>		
Autoimmune inner ear disease	1	0
Inner ear inflammation	11	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	70	0
Phobic postural vertigo	1	0

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Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
Tinnitus	2527	0
Vertigo	1674	0
Vertigo labyrinthine	13	0
Vertigo positional	88	0
<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	4	0
Ear disorders SOC TOTAL	6689	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	9	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	3	0
Adrenal insufficiency	3	0
Adrenocortical insufficiency acute	16	0
<i>Adrenal gland disorders NEC</i>		
Adrenal disorder	3	0
Adrenal haemorrhage	3	0
Adrenal mass	1	0
<i>Anterior pituitary hyperfunction</i>		
Pituitary-dependent Cushing's syndrome	1	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	2	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	5	0
Premature menarche	21	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	68	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	17	0
Thyroid disorder	15	0
Thyroid mass	2	0
Thyroid pain	12	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	14	0
Hyperthyroidism	57	0
Primary hyperthyroidism	1	0
Thyrotoxic crisis	6	0
<i>Thyroid hypofunction disorders</i>		
Autoimmune hypothyroidism	1	0
Hypothyroidic goitre	1	0
Hypothyroidism	47	0
Immune-mediated hypothyroidism	1	0
Myxoedema	1	0
<i>Thyroid neoplasms</i>		
Thyroid cyst	1	0
Endocrine disorders SOC TOTAL	382	0

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Reaction Name	Total	Fatal
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	17	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>		
Vitreous detachment	21	0
Vitreous floaters	122	0
<i>Colour blindness (incl acquired)</i>		
Colour blindness acquired	1	0
Dyschromatopsia	15	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	52	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	172	0
Excessive eye blinking	6	0
Eyelid function disorder	3	0
Eyelid myokymia	4	0
Eyelid ptosis	52	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	21	0
Iritis	13	0
Uveitis	57	0
Vogt-Koyanagi-Harada disease	1	0
<i>Lacrimation disorders</i>		
Dry eye	179	0
Lacrimation increased	169	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
<i>Lid bleeding and vascular disorders</i>		
Eyelid bleeding	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	20	0
Blepharitis allergic	1	0
Chalazion	7	0
Eczema eyelids	11	0
Erythema of eyelid	11	0
Eyelid cyst	7	0
Eyelid irritation	4	0
Eyelid margin crusting	5	0
Eyelid oedema	15	0
Eyelid rash	20	0
Meibomian gland dysfunction	1	0
Swelling of eyelid	146	0
Swollen tear duct	2	0
<i>Lid, lash and lacrimal structural disorders</i>		
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
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	4	0
Eye haemorrhage	39	0
Ocular vascular disorder	2	0
Ophthalmic vein thrombosis	1	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	10	0
Eye disorder	44	0
Eye oedema	19	0
Eye pain	1310	0
Eye swelling	661	0
Eye symptom	10	0
Eye ulcer	6	0
Eyelid disorder	17	0
Eyelid pain	16	0
Eyelids pruritus	8	0
Ocular discomfort	35	0
Periorbital oedema	21	0
Periorbital pain	5	0
Periorbital swelling	133	0
Retinal disorder	2	0
Vitreous disorder	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	22	0
Eye discharge	34	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Eye inflammation	40	0
Eye irritation	107	0
Eye pruritus	286	0
Limbal swelling	4	0
Ocular hyperaemia	269	0
Ocular nerve and muscle disorders		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Eye movement disorder	44	0
Gaze palsy	3	0
Ocular myasthenia	1	0
Ophthalmoplegia	8	0
Strabismus	10	0
Ocular sensation disorders		
Abnormal sensation in eye	24	0
Asthenopia	174	0
Eye paraesthesia	2	0
Eyelid sensory disorder	3	0
Foreign body sensation in eyes	19	0
Hypoaesthesia eye	18	0
Photophobia	529	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		
Anisocoria	15	0
Miosis	2	0
Mydriasis	24	0
Pupil fixed	4	0
Pupillary disorder	1	0
Refractive and accommodative disorders		
Accommodation disorder	1	0
Altered visual depth perception	5	0
Astigmatism	3	0
Hypermetropia	4	0
Myopia	4	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Papillophlebitis	1	0
Retinal artery occlusion	18	0
Retinal artery thrombosis	2	0
Retinal haemorrhage	12	0
Retinal ischaemia	1	0
Retinal vascular thrombosis	1	0
Retinal vein occlusion	48	0
Retinal vein thrombosis	2	0
Retinal structural change, deposit and degeneration		
Age-related macular degeneration	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Chorioretinal disorder	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	7	0
Retinal oedema	2	0
Retinal vasculitis	3	0
<i>Retinopathies NEC</i>		
Acute macular neuroretinopathy	3	0
Central serous chorioretinopathy	8	0
Retinal exudates	3	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	5	0
Erythropsia	2	0
Xanthopsia	1	0
<i>Visual disorders NEC</i>		
Charles Bonnet syndrome	2	0
Diplopia	190	0
Dysmetropsia	1	0
Glare	1	0
Halo vision	10	0
Heteronymous diplopia	1	0
Metamorphopsia	25	0
Oscillopsia	3	0
Photopsia	168	0
Scintillating scotoma	4	0
Vision blurred	1460	0
Visual brightness	3	0
Visual snow syndrome	8	0
<i>Visual field disorders</i>		
Visual field defect	41	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
<i>Visual impairment and blindness (excl colour blindness)</i>		
Amaurosis fugax	4	0
Blindness	166	0
Blindness cortical	1	0
Blindness transient	21	0
Blindness unilateral	20	0
Central vision loss	6	0
Sudden visual loss	5	0
Visual acuity reduced	30	0
Visual acuity reduced transiently	1	0
Visual impairment	472	0
<i>Visual pathway disorders</i>		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	8084	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

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MedDRA Version: MedDRA 25.0

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 eczema	1	0
Anal erythema	1	0
Anal hypoaesthesia	2	0
Anal pruritus	2	0
Anal rash	1	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	60	1
Colitis ischaemic	1	0
Colitis microscopic	3	0
Colitis ulcerative	82	0
Crohn's disease	52	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

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Dental disorders NEC</i>		
Loose tooth	5	0
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
<i>Dental pain and sensation disorders</i>		
Dental discomfort	7	0
Dental paraesthesia	14	0
Hyperaesthesia teeth	39	0
Toothache	196	0
<i>Dental surface disorders</i>		
Tooth discolouration	10	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	8	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	6137	0
Diarrhoea haemorrhagic	27	0
<i>Diverticula</i>		
Diverticulum	7	0
Diverticulum intestinal	1	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	4	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	3	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	547	0
Epigastric discomfort	15	0
Eructation	64	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	23	0
Faecaloma	7	0
Faeces discoloured	63	0
Faeces hard	2	0
Faeces pale	5	0
Faeces soft	13	0
Mucous stools	12	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	604	0
Aerophagia	3	0
Flatulence	202	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	5	1
Mallory-Weiss syndrome	1	0
Oesophageal varices haemorrhage	1	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	7	0
<i>Gastritis (excl infective)</i>		
Chronic gastritis	4	0

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Gastritis	72	0
Reflux gastritis	8	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	2	0
Abdominal pain	1708	0
Abdominal pain lower	154	0
Abdominal pain upper	2827	0
Abdominal rigidity	27	0
Abdominal tenderness	15	0
Gastrointestinal pain	168	0
Oesophageal pain	14	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	280	0
Duodenogastric reflux	4	0
Gastric dilatation	8	0
Gastrooesophageal reflux disease	197	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	31	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
Epiploic 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	711	0
Abdominal symptom	2	0
Acute abdomen	8	0
Anal incontinence	23	0
Breath odour	22	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Dysphagia	246	2
Gastrointestinal wall thickening	1	0
Malignant dysphagia	1	0
Odynophagia	48	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Cardiospasm	1	0
Defaecation urgency	12	0
Frequent bowel movements	34	0
Gastrointestinal hypermotility	1	0
Irritable bowel syndrome	106	0
Oesophageal spasm	5	0
Pylorospasm	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Ileus	2	0
Intestinal obstruction	8	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	9	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	2	0
Gingival pain	138	0
Gingival pruritus	2	0
Gingival recession	1	0
Gingival swelling	43	0
Gingival ulceration	3	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	14	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	85	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	84	0
Small intestinal haemorrhage	5	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	6	2
Large intestinal ulcer	1	0
Large intestinal ulcer haemorrhage	1	0
Large intestine perforation	1	0
<i>Large intestinal stenosis and obstruction</i>		
Large intestinal obstruction	2	2
<i>Malabsorption syndromes</i>		
Bile acid malabsorption	5	0
Celiac disease	14	0
Malabsorption	1	0
Steatorrhoea	4	0
<i>Nausea and vomiting symptoms</i>		
Cyclic vomiting syndrome	1	0
Discoloured vomit	13	0
Infantile vomiting	7	0
Nausea	15397	0
Regurgitation	1	0
Retching	116	0
Vomiting	5251	1
Vomiting projectile	76	0
<i>Non-mechanical ileus</i>		
Ileus paralytic	2	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	19	1
Haematemesis	41	2
Haematochezia	61	0
Melaena	11	0
Upper gastrointestinal haemorrhage	14	1
<i>Oesophageal disorders NEC</i>		
Oesophageal disorder	1	0
<i>Oesophageal stenosis and obstruction</i>		
Oesophageal stenosis	3	0
<i>Oesophagitis (excl infective)</i>		
Eosinophilic oesophagitis	2	0
Oesophagitis	6	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	5	0
Dry mouth	547	0
Lip dry	49	0
Saliva altered	8	0
Salivary hypersecretion	55	0
<i>Oral soft tissue disorders NEC</i>		
Angina bullosa haemorrhagica	1	0
Chapped lips	28	0
Cheilitis	31	0
Enlarged uvula	15	0
Leukoplakia oral	2	0
Lip blister	36	0
Lip disorder	7	0
Oral disorder	22	0
Oral lichen planus	16	0
Oral mucosal hypertrophy	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Oral papule	1	0
Uvulitis	7	0
Oral soft tissue haemorrhages		
Lip haemorrhage	2	0
Mouth haemorrhage	23	0
Oral blood blister	19	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	521	0
Lip discolouration	10	0
Lip erythema	4	0
Lip exfoliation	6	0
Lip pain	67	0
Lip pruritus	18	0
Lip scab	1	0
Oral discomfort	91	0
Oral dysaesthesia	1	0
Oral mucosal blistering	18	0
Oral mucosal discolouration	2	0
Oral mucosal eruption	21	0
Oral mucosal erythema	9	0
Oral mucosal exfoliation	10	0
Oral mucosal roughening	3	0
Oral mucosal scab	2	0
Oral pain	191	0
Oral pruritus	24	0
Paraesthesia oral	975	0
Pigmentation lip	1	0
Oral soft tissue swelling and oedema		
Lip oedema	4	0
Lip swelling	902	0
Mouth swelling	120	0
Oedema mouth	4	0
Palatal oedema	4	0
Palatal swelling	5	0
Pancreatic disorders NEC		
Pancreatic disorder	2	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	3	0
Peritoneal disorder	1	0
Peritoneal and retroperitoneal fibrosis and adhesions		
Abdominal adhesions	2	0
Peritoneal and retroperitoneal haemorrhages		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Haemoperitoneum	1	0
Retroperitoneal haematoma	1	0
Retroperitoneal haemorrhage	2	1
<i>Rectal inflammations NEC</i>		
Proctitis	4	0
Proctitis ulcerative	1	0
<i>Salivary gland disorders NEC</i>		
Salivary gland disorder	1	0
Salivary gland mucocoele	1	0
Salivary gland pain	13	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	12	0
Salivary gland enlargement	5	0
Submaxillary gland enlargement	7	0
<i>Salivary gland infections and inflammations</i>		
Noninfective sialoadenitis	2	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	60	0
Lip ulceration	23	0
Mouth ulceration	492	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	69	0
<i>Tongue disorders</i>		
Glossitis	23	0
Hypertrophy of tongue papillae	2	0
Plicated tongue	4	0
Tongue disorder	45	0
Tongue geographic	8	0
Tongue haemorrhage	3	0
Tongue ulceration	34	0
Trichoglossia	4	0
<i>Tongue signs and symptoms</i>		
Glossodynia	233	0
Scalloped tongue	5	0
Stiff tongue	4	0
Swollen tongue	559	0
Tongue blistering	19	0
Tongue coated	20	0
Tongue discolouration	40	0
Tongue discomfort	46	0
Tongue dry	16	0
Tongue eruption	11	0
Tongue erythema	13	0
Tongue exfoliation	2	0
Tongue movement disturbance	8	0
Tongue oedema	24	0
Tongue pruritus	2	0
Tongue rough	5	0
Tongue spasm	12	0
<i>Tooth missing</i>		
Tooth loss	6	0
Gastrointestinal disorders SOC TOTAL	42582	19

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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	2	0
Administration site joint movement impairment	2	0
Administration site joint pain	1	0
Administration site nerve damage	1	0
Administration site pain	21	0
Administration site rash	5	0
Administration site reaction	1	0
Administration site swelling	5	0
Administration site urticaria	2	0
Administration site warmth	2	0
Puncture site bruise	43	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	9	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	2427	0
Chronic fatigue syndrome	87	0
Decreased activity	10	0
Fatigue	26235	1
Malaise	5940	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	27	0
Temperature regulation disorder	15	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	H
Cardiac death	3	H
Clinical death	1	1
Death	195	19
Sudden cardiac death	1	1
Sudden death	28	28
Febrile disorders		
Hyperpyrexia	10	0
Pyrexia	16979	0
Feelings and sensations NEC		
Chills	10552	0
Feeling abnormal	1853	0
Feeling cold	1381	0
Feeling drunk	83	0
Feeling hot	1312	0
Feeling jittery	34	0
Feeling of body temperature change	370	0
Feeling of relaxation	3	0
Hangover	85	0
Hunger	51	0
Sensation of blood flow	5	0
Sensation of foreign body	64	0
Sense of oppression	1	0
Temperature intolerance	55	0
Thirst	383	0
Thirst decreased	2	0
Fibrosis NEC		
Fibrosis	1	0
Gait disturbances		
Gait deviation	1	0
Gait disturbance	294	0
Gait inability	117	0
Loss of control of legs	29	0
General signs and symptoms NEC		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Adhesion	2	0
Chronic disease	1	0
Concomitant disease progression	1	1
Condition aggravated	360	0
Crepitations	5	0
Crying	169	0
Deformity	2	0
Developmental delay	1	0
Discharge	12	0
Disease progression	2	0
Disease recurrence	32	0
Effusion	3	0
Energy increased	27	0
Exercise tolerance decreased	44	0
Exercise tolerance increased	2	0
Fat tissue increased	1	0
Foaming at mouth	3	0
General physical health deterioration	17	2
General symptom	3	0
Glassy eyes	8	0
High-pitched crying	3	0
Illness	2282	0
Induration	18	0
Influenza like illness	2699	0
Irritability postvaccinal	2	0
Local reaction	93	0
Moaning	4	0
Multiple organ dysfunction syndrome	13	5
Nonspecific reaction	2	0
Organ failure	4	2
Perforation	2	0
Peripheral swelling	4459	0
Physical deconditioning	2	0
Pre-existing condition improved	9	0
Prolapse	1	0
Screaming	24	0
Secretion discharge	26	0
Stenosis	1	0
Swelling	3598	0
Swelling face	987	0
Symptom recurrence	1	0
Terminal state	1	0
Tissue irritation	1	0
Tissue rupture	1	0
Healing abnormal NEC		
Impaired healing	7	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

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Implant site warmth	3	0
Inflammations		
Chronic inflammatory response syndrome	1	0
Foreign body reaction	1	0
Granuloma	1	0
Inflammation	661	0
Papillitis	1	0
Scar inflammation	3	0
Serositis	1	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	6	0
Infusion site reactions		
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
Injection site reactions		
Injected limb mobility decreased	38	0
Injection site bruising	73	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	443	0
Injection site extravasation	1	0
Injection site haematoma	2	0
Injection site haemorrhage	10	0
Injection site hypersensitivity	3	0
Injection site hypoaesthesia	17	0
Injection site indentation	10	0
Injection site induration	4	0
Injection site inflammation	50	0
Injection site injury	2	0
Injection site irritation	3	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	643	0
Injection site movement impairment	1	0
Injection site muscle weakness	1	0
Injection site necrosis	4	0
Injection site nerve damage	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site nodule	1	0
Injection site oedema	19	0
Injection site pain	3219	0
Injection site pallor	1	0
Injection site paraesthesia	15	0
Injection site pruritus	248	0
Injection site rash	205	0
Injection site reaction	58	0
Injection site scab	4	0
Injection site scar	4	0
Injection site swelling	352	0
Injection site urticaria	36	0
Injection site vesicles	10	0
Injection site warmth	210	0
Interactions		
Alcohol interaction	5	0
Drug interaction	32	0
Inhibitory drug interaction	3	0
Mass conditions NEC		
Cyst	59	0
Mass	90	0
Nodule	45	0
Mucosal findings abnormal		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	10	0
Mucosal inflammation	3	0
Mucosal ulceration	1	0
Oedema mucosal	2	0
Polyp	5	0
Necrosis NEC		
Fat necrosis	4	0
Necrosis	5	0
Oedema NEC		
Face oedema	36	0
Generalised oedema	6	0
Localised oedema	21	0
Oedema	95	0
Oedema peripheral	104	0
Pain and discomfort NEC		
Axillary pain	4073	0
Breakthrough pain	1	0
Chest discomfort	2089	0
Chest pain	6864	0
Discomfort	587	0
Facial discomfort	21	0
Facial pain	239	0
First bite syndrome	1	0
Inflammatory pain	21	0
Non-cardiac chest pain	36	0
Pain	10159	0
Suprapubic pain	1	0
Tenderness	744	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Visceral pain	2	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	22	0
Adverse food reaction	3	0
Adverse reaction	2	0
Drug ineffective	553	0
Drug intolerance	4	0
Drug resistance	1	0
Immediate post-injection reaction	5	0
Inadequate analgesia	9	0
No reaction on previous exposure to drug	26	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	99	0
Therapy non-responder	1	0
Treatment failure	12	0
Vaccination failure	113	0
Trophic disorders		
Abnormal organ growth	1	0
Atrophy	3	0
Calcinosis	2	0
Hyperplasia	1	0
Hypertrophy	1	0
Ulcers NEC		
Ulcer	39	0
Ulcer haemorrhage	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	25	0
Shoulder injury related to vaccine administration	69	0
Vaccination site anaesthesia	1	0
Vaccination site bruising	144	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	685	0
Vaccination site granuloma	5	0
Vaccination site haematoma	2	0
Vaccination site haemorrhage	34	0
Vaccination site hypersensitivity	5	0
Vaccination site hypoaesthesia	20	0
Vaccination site induration	82	0
Vaccination site inflammation	66	0
Vaccination site injury	1	0
Vaccination site irritation	16	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site joint discomfort	3	0
Vaccination site joint erythema	12	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	22	0
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	340	0
Vaccination site movement impairment	97	0
Vaccination site necrosis	1	0
Vaccination site nerve damage	1	0
Vaccination site nodule	6	0
Vaccination site oedema	3	0
Vaccination site pain	2421	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	190	0
Vaccination site rash	155	0
Vaccination site reaction	37	0
Vaccination site scab	3	0
Vaccination site scar	3	0
Vaccination site swelling	659	0
Vaccination site thrombosis	1	0
Vaccination site ulcer	3	0
Vaccination site urticaria	11	0
Vaccination site vesicles	13	0
Vaccination site warmth	305	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	122192	21

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

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	13	0
<i>Cholestasis and jaundice</i>		
Cholestasis	2	0
Cholestasis of pregnancy	1	0
Jaundice	29	0
Jaundice cholestatic	10	0
Ocular icterus	2	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	4	0
Gallbladder enlargement	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Hepatic cyst	1	0
Hepatic lesion	1	0
Liver disorder	17	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	9	0
Hypertransaminasaemia	5	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	2	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
Portosplenomesenteric venous thrombosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	36	0
Hepatomegaly	7	0
Liver tenderness	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	16	0
Drug-induced liver injury	3	0
Hepatic steatosis	5	0
Hepatitis	17	0
Hepatitis acute	3	0
Hepatitis toxic	2	0
Hepatotoxicity	1	0
Immune-mediated hepatic disorder	1	0
Liver injury	28	0
<i>Obstructive bile duct disorders (excl neoplasms)</i>		
Bile duct stenosis	1	0
Hepatic disorders SOC TOTAL	269	1

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

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	1175	0
Infusion related hypersensitivity reaction	3	0
Mite allergy	2	0
Multiple allergies	17	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	7	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	7	0
Allergy to chemicals	7	0
Allergy to vaccine	49	0
Contrast media reaction	2	0
Drug hypersensitivity	43	0
Food allergy	46	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	567	2
Anaphylactic shock	66	0
Anaphylactoid reaction	25	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	3	0
Seasonal allergy	115	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	58	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	4	0
Graft versus host disease	2	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Immune system disorders		
<i>Immune system disorders cont'd</i>		
Haemophagocytic lymphohistiocytosis	4	0
Immune reconstitution inflammatory syndrome	1	0
Immune system disorder	39	0
Immune-mediated adverse reaction	7	0
Immunisation reaction	57	0
Multisystem inflammatory syndrome in children	6	0
Sensitisation	9	0
Systemic immune activation	2	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	7	0
Immunosuppression	4	0
<i>Transplant rejections</i>		
Corneal graft rejection	10	0
Kidney transplant rejection	2	0
Solid organ transplant rejection	1	0
Transplant rejection	2	0
Immune system disorders SOC TOTAL	2520	2

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Abdominal abscess	3	0
Abdominal infection	2	0
Anal abscess	3	0
Anorectal infection	1	0
Appendicitis	50	0
Appendicitis perforated	7	0
Complicated appendicitis	1	0
Diarrhoea infectious	1	0
Diverticulitis	18	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	34	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	205	0
Cellulitis orbital	2	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
External ear cellulitis	1	0
Folliculitis	20	0
Gangrene	2	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	3	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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

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	3	0
Intervertebral discitis	1	0
Osteomyelitis	3	0
Osteomyelitis acute	2	0
Osteomyelitis chronic	1	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	75	0
Oral candidiasis	42	0
Respiratory moniliasis	1	0
Skin candida	2	0
Systemic candida	1	0
Urinary tract candidiasis	1	0
Vulvovaginal candidiasis	56	0
<i>Cardiac infections</i>		
Cardiac infection	1	0
Cardiac valve vegetation	1	0
Endocarditis	2	0
Myocarditis infectious	1	0
Myocarditis septic	1	0
Pericarditis infective	3	0
<i>Central nervous system and spinal infections</i>		
Brain abscess	2	0
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	23	0
Encephalomyelitis	1	0
Meningitis	11	0
Meningitis aseptic	3	0
Myelitis	14	0
Subdural abscess	1	0
<i>Clostridia infections</i>		
Clostridium difficile infection	2	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	21	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
COVID-19	2845	42
COVID-19 pneumonia	53	15
Coronavirus infection	7	0
Post-acute COVID-19 syndrome	12	0
Severe acute respiratory syndrome	4	0
Suspected COVID-19	102	4
<i>Corynebacteria infections</i>		
Diphtheria	2	0
<i>Coxiella infections</i>		
Q fever	13	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	15	0
Oral infection	1	0
Parotitis	15	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	104	0
Labyrinthitis	116	0
Mastoiditis	3	0
Otitis externa	7	0
Otitis media	4	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	31	0
<i>Escherichia infections</i>		
Escherichia bacteraemia	1	0
Escherichia infection	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	88	0
Eye abscess	1	0
Eye infection	30	0
Eye infection intraocular	1	0
Eyelid boil	2	0
Eyelid infection	2	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Hordeolum	30	0
Keratouveitis	1	0
Orbital infection	1	0
Periorbital infection	2	0
Female reproductive tract infections		
Bartholin's abscess	1	0
Bartholinitis	1	0
Endometritis	3	0
Fallopian tube abscess	1	0
Funisitis	1	0
Ovarian abscess	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	3	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	97	0
Genital herpes simplex	6	0
Genital herpes zoster	1	0
Herpes ophthalmic	3	0
Herpes simplex	35	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	3	0
Herpes virus infection	13	0
Herpes zoster	1653	0
Herpes zoster disseminated	1	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	17	0
Herpes zoster reactivation	5	0
Meningitis herpes	1	0
Nasal herpes	5	0
Ophthalmic herpes simplex	3	0
Ophthalmic herpes zoster	5	0
Oral herpes	342	0
Varicella	37	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Varicella zoster virus infection	5	0
<i>Infections NEC</i>		
Abscess	40	0
Abscess limb	9	0
Abscess soft tissue	1	0
Catheter site infection	1	0
Genital abscess	2	0
Groin abscess	2	0
Groin infection	1	0
Infected bite	3	0
Infected cyst	2	0
Infection	289	0
Infection susceptibility increased	2	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	41	0
Lymph gland infection	19	0
Lymph node abscess	7	0
Opportunistic infection	1	0
Pathogen resistance	1	0
Purulent discharge	1	0
Respiratory tract infection	15	0
Superinfection	1	0
Vaccination site abscess	12	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	1811	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	307	10
Pneumonia	180	17
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	9	0
<i>Muscle and soft tissue infections</i>		

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
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
Meningococcal bacteraemia	1	0
Meningococcal infection	1	0
<i>Orthopox viral infections</i>		
Smallpox	1	0
Vaccinia virus infection	2	0
<i>Plasmodia infections</i>		
Malaria	2	0
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	2	0
<i>Pseudomonal infections</i>		
Pseudomonas infection	1	0
<i>Retroviral infections</i>		
Acquired immunodeficiency syndrome	1	0
HIV infection	2	0
Persistent generalised lymphadenopathy	1	0
<i>Rhinoviral infections</i>		
Rhinovirus infection	1	0
<i>Rotaviral infections</i>		
Gastroenteritis rotavirus	1	0
<i>Rubeola viral infections</i>		
Measles	5	0
<i>Salmonella infections</i>		
Typhoid fever	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Neutropenic sepsis	4	1
Sepsis	73	11
Sepsis syndrome	2	0
Septic rash	3	0
Septic shock	6	1
Urosepsis	6	0
<i>Skin structures and soft tissue infections</i>		
Abscess sweat gland	1	0
Acne pustular	1	0
Blister infected	1	0
Dermatitis infected	3	0
Eczema infected	1	0
Impetigo	11	0
Infected skin ulcer	4	0
Injection site pustule	3	0
Nail infection	2	0
Pustule	21	0
Pyoderma	1	0
Rash pustular	12	0
Skin infection	34	0
Subcutaneous abscess	12	0
Sweat gland infection	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Vaccination site pustule	4	0
<i>Staphylococcal infections</i>		
Furuncle	46	1
Pneumonia staphylococcal	1	0
Septic arthritis staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	5	0
Staphylococcal sepsis	1	0
<i>Streptococcal infections</i>		
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	2	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	6	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	35	0
Nasopharyngitis	1186	1
Peritonsillar abscess	6	0
Pharyngitis	39	0
Rhinitis	57	0
Sinusitis	209	0
Tonsillitis	145	0
Tracheitis	5	0
Tracheostomy infection	1	0
Upper respiratory tract infection	12	0
<i>Urinary tract infections</i>		
Cystitis	86	0
Kidney infection	56	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Pyelonephritis	3	0
Urethritis	2	0
Urinary tract infection	223	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>		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Ear infection viral	1	0
Encephalitis viral	6	1
Eye infection viral	2	0
Gastroenteritis viral	34	0
Hepatitis viral	3	0
Meningitis viral	9	0
Meningoencephalitis viral	1	0
Oral viral infection	1	0
Pleurisy viral	2	0
Pneumonia viral	5	2
Post viral fatigue syndrome	61	0
Sweating fever	127	0
Vestibular neuronitis	35	0
Viral diarrhoea	2	0
Viral infection	67	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	12462	116

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

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
<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	5	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	2	0
Traumatic lung injury	1	0
<i>Conditions caused by cold</i>		
Chillblains	75	0
Cold shock response	1	0
Frostbite	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Cranial nerve injuries</i>		
IIIrd nerve injury	1	0
Vth nerve injury	1	0
<i>Ear injuries NEC</i>		
Deafness traumatic	1	0
Ear injury	2	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	10	0
Exposure via breast milk	155	0
Foetal exposure during pregnancy	72	0
Foetal exposure timing unspecified	1	0
Maternal exposure before pregnancy	30	0
Maternal exposure during breast feeding	2021	0
Maternal exposure during pregnancy	1094	0
Maternal exposure timing unspecified	15	0
Paternal exposure before pregnancy	3	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	3	0
Exposure to vaccinated person	4	0
<i>Eye and ear procedural complications</i>		
Toxic anterior segment syndrome	1	0
<i>Eye injuries NEC</i>		
Corneal abrasion	1	0
Eye contusion	18	0
Eye injury	33	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
<i>Foetal and neonatal conditions associated with product exposure</i>		
Intoxication by breast feeding	1	0
<i>Fractures and dislocations NEC</i>		
Fracture	3	0
Joint dislocation	4	0
Multiple fractures	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	11	0
Procedural vomiting	2	0
<i>Heat injuries (excl thermal burns)</i>		
Heat cramps	2	0
Heat exhaustion	3	0
Heat illness	2	0
Heat oedema	14	0
Heat stroke	3	0
<i>Intentional product use issues</i>		
Intentional dose omission	1	0
Intentional product use issue	1	0
<i>Limb fractures and dislocations</i>		
Ankle fracture	1	0
Atypical femur fracture	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Clavicle fracture	27	0
Femoral neck fracture	1	0
Femur fracture	1	0
Fibula fracture	1	0
Hip fracture	2	0
Lower limb fracture	1	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
Device difficult to use	1	0
Dose calculation error	1	0
Inadequate aseptic technique in use of product	1	0
Medication error	75	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	25	0
Ligament injury	2	0
Ligament sprain	11	0
Mallet finger	1	0
Muscle hernia	1	0
Muscle injury	43	0
Muscle rupture	10	0
Muscle strain	38	0
Post-traumatic neck syndrome	3	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	119	0
Neurological and psychiatric procedural complications		
Post lumbar puncture syndrome	1	0
Post procedural stroke	1	0
Procedural dizziness	13	0
Non-occupational environmental exposures		
Exposure to extreme temperature	2	0
Non-site specific injuries NEC		
Accident	2	0
Animal scratch	1	0
Arthropod bite	11	0
Arthropod sting	6	0
Bite	1	0
Bone contusion	2	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Crush injury	1	0
Electric shock	20	0
Fall	219	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	7	0
Non-site specific procedural complications		
Administration related reaction	1	0
Anastomotic leak	1	0
Incision site pain	3	0
Infusion related reaction	8	0
Injection related reaction	68	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	496	0
Overdoses NEC		
Intentional overdose	1	0
Overdose	56	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	6	0
Poisoning and toxicity		
Alcohol poisoning	1	0
Poisoning	14	0
Toxicity to various agents	5	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: 05-May-2022

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Expired product administered	14	0
Inappropriate schedule of product administration	741	0
Incomplete course of vaccination	2	0
Incorrect dose administered	63	0
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	12	0
Lack of vaccination site rotation	1	0
Poor quality product administered	5	0
Product administered at inappropriate site	24	0
Product administered to patient of inappropriate age	3	0
Product administration error	22	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	6	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	24	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	204	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: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

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	1395	0
Hair injury	2	0
Nail avulsion	1	0
Scar	37	0
Scratch	9	0
Skin abrasion	7	0
Skin injury	5	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	28	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
Injuries SOC TOTAL	8045	1

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Cortisol decreased	5	0
<i>Adrenal medulla tests</i>		
Epinephrine	1	0
Epinephrine abnormal	1	0
Epinephrine increased	1	0
<i>Auditory and vestibular diagnostic procedures</i>		
Acoustic stimulation tests	5	0
Audiogram abnormal	1	0
Weber tuning fork test abnormal	1	0
<i>Autoimmunity analyses</i>		
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
<i>Bacteria identification and serology (excl mycobacteria)</i>		
Bacterial test positive	1	0
<i>Blood counts NEC</i>		
Full blood count	7	0
Full blood count abnormal	3	0
<i>Blood gas and acid base analyses</i>		
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	12	0
Oxygen saturation abnormal	2	0
Oxygen saturation decreased	101	0
PCO2 increased	1	0
PO2 decreased	1	0
Venous oxygen saturation decreased	1	0
<i>Blood grouping and cross-matching analyses</i>		
Rhesus antigen positive	1	0
<i>Bone marrow and immune tissue histopathology procedures</i>		
Aspiration bone marrow	1	0
Biopsy lymph gland	2	0
<i>Bone marrow and immune tissue imaging procedures</i>		
Lymph nodes scan abnormal	1	0
Scan lymph nodes	4	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	12	0
Blood glucose abnormal	15	0
Blood glucose decreased	38	0

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood glucose fluctuation	17	0
Blood glucose increased	115	0
Blood glucose normal	1	0
Glycosylated haemoglobin increased	1	0
Cardiac auscultatory investigations		
Cardiac murmur	50	0
Heart sounds	10	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		
Carbohydrate antigen 15-3 increased	1	0
Carcinoembryonic antigen increased	1	0
HLA-B*27 positive	1	0
Prostatic specific antigen increased	4	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		
ADAMTS13 activity decreased	1	0
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

Case Series Drug Analysis Print

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Report Run Date: 05-May-2022

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	9	0
Coagulation time shortened	4	0
Fibrin D dimer increased	26	0
International normalised ratio abnormal	9	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	25	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	86	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		

Case Series Drug Analysis Print

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Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
EGFR status assay	1	0
<i>Haematological analyses NEC</i>		
Blood viscosity abnormal	1	0
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	2	0
Carotid pulse abnormal	1	0
Heart rate	597	0
Heart rate abnormal	80	0
Heart rate decreased	107	0
Heart rate increased	1209	0
Heart rate irregular	298	0
Heart rate normal	1	0
Heart rate variability decreased	1	0
Heart rate variability increased	1	0
Maximum heart rate	5	0
Maximum heart rate increased	2	0
Pulse abnormal	24	0
Pulse absent	1	0
Pulse pressure increased	3	0
Radial pulse abnormal	1	0
Sinus rhythm	8	0
<i>Hepatobiliary function diagnostic procedures</i>		
Alanine aminotransferase increased	28	0
Aspartate aminotransferase	1	0
Aspartate aminotransferase abnormal	1	0
Aspartate aminotransferase increased	2	0
Blood bilirubin increased	7	0
Gamma-glutamyltransferase	1	0
Gamma-glutamyltransferase increased	5	0
Hepatic enzyme	1	0
Hepatic enzyme increased	10	0
Liver function test	1	0
Liver function test abnormal	36	0
Liver function test increased	30	0
<i>Hepatobiliary imaging procedures</i>		
Computerised tomogram liver	1	0
Liver scan	1	0
<i>Imaging procedures NEC</i>		
Computerised tomogram	4	0
Magnetic resonance imaging	6	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

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
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	2	0
Allergy alert test positive	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>Metabolism tests NEC</i>		
Blood ketone body	3	0
Blood ketone body increased	1	0
Blood ketone body present	1	0
Blood uric acid increased	3	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
<i>Microbiology and serology tests NEC</i>		
Culture negative	1	0
Culture urine	1	0
Nasopharyngeal swab	1	0
Vaccine induced antibody absent	1	0
<i>Mineral and electrolyte analyses</i>		
Blood calcium increased	1	0
Blood copper increased	1	0
Blood iron	4	0
Blood iron decreased	13	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	2	0
Sweat test	2	0
Urine copper	2	0
<i>Musculoskeletal and soft tissue histopathology procedures</i>		

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Biopsy bone	1	0
<i>Musculoskeletal and soft tissue imaging procedures</i>		
Skull X-ray	6	0
<i>Musculoskeletal and soft tissue tests NEC</i>		
Swollen joint count	1	0
Swollen joint count increased	1	0
<i>Mycobacteria identification and serology</i>		
Tuberculin test positive	1	0
<i>Neurologic diagnostic procedures</i>		
Balance test	1	0
Coma scale abnormal	5	0
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
<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	299	0
Body temperature abnormal	55	0
Body temperature decreased	47	0
Body temperature fluctuation	69	0
Body temperature increased	535	0
Body temperature normal	1	0
Breath sounds abnormal	2	0
General physical condition abnormal	1	0
Grip strength	3	0
Grip strength decreased	27	0
Gynaecological examination	1	0
Head lag	9	0
Intelligence test	1	0
Lymph node palpable	45	0
Male genital examination abnormal	1	0
Menstruation normal	4	0
Muscle strength abnormal	5	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	28	0
Respiratory rate increased	49	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Skin temperature	48	0
Temperature difference of extremities	13	0
Weight	1	0
Weight abnormal	1	0
Weight decreased	138	0
Weight increased	53	0
<i>Pituitary analyses anterior</i>		
Blood corticotrophin	1	0
Blood follicle stimulating hormone increased	3	0
Blood growth hormone	3	0
Blood prolactin	3	0
Blood prolactin increased	4	0
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	11	0
<i>Platelet analyses</i>		
Mean platelet volume decreased	1	0
Mean platelet volume increased	1	0
Platelet count	3	0
Platelet count abnormal	1	0
Platelet count decreased	88	0
Platelet count increased	6	0
<i>Protein analyses NEC</i>		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	32	0
<i>Red blood cell analyses</i>		
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
<i>Renal function analyses</i>		
Blood creatine decreased	1	0
Blood creatinine	2	0
Blood creatinine decreased	1	0
Blood creatinine increased	5	0
Glomerular filtration rate decreased	4	0
Glomerular filtration rate increased	1	0
<i>Reproductive hormone analyses</i>		
Blood oestrogen	2	0
Blood oestrogen decreased	2	0
Blood testosterone decreased	2	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

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
<i>Reproductive organ and breast histopathology procedures</i>		
Biopsy breast	2	0
Biopsy endometrium	1	0
Smear cervix	3	0
<i>Reproductive organ and breast imaging procedures</i>		
Breast scan	1	0
Hysteroscopy	2	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Airway peak pressure increased	1	0
Forced expiratory volume	1	0
Forced expiratory volume increased	3	0
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	2	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	29	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	1	0
Thyroxine	1	0
Thyroxine decreased	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

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood lactate dehydrogenase	1	0
Blood lactate dehydrogenase increased	1	0
Enzyme level increased	1	0
Toxicology laboratory analyses		
Blood caffeine decreased	1	0
Blood lead	1	0
Drug screen positive	2	0
Opiates	1	0
Toxicologic test abnormal	1	0
Urinalysis NEC		
Blood urine	19	0
Blood urine present	80	0
Cells in urine	1	0
Glucose urine present	1	0
Protein urine	1	0
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	13	0
Blood pressure ambulatory increased	1	0
Blood pressure decreased	92	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	307	0
Blood pressure measurement	49	0
Blood pressure normal	2	0
Blood pressure orthostatic	1	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

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
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	36	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	113	0
Viral load	2	0
Viral test	4	0
Viral test positive	1	0
Vitamin analyses		
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	4	0
Water and electrolyte analyses NEC		
Urine osmolarity	1	0
Volume blood	1	0
White blood cell analyses		
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	12	0
Neutrophil count increased	4	0
White blood cell count	5	0
White blood cell count decreased	16	0
White blood cell count increased	13	0
Investigations SOC TOTAL	6463	3

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	23	0
Decreased appetite	1537	0
Diet refusal	1	0
Eating disorder symptom	3	0
Food craving	13	0
Food refusal	16	0
Hyperphagia	15	0
Hypophagia	20	0
Increased appetite	38	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	3	0
Tetany	5	0
<i>Copper metabolism disorders</i>		
Copper deficiency	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	62	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	109	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	1	0
Fluid imbalance	2	0
<i>Elevated cholesterol</i>		
Hypercholesterolaemia	1	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	11	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	23	0
Gluten sensitivity	7	0
Histamine intolerance	7	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	42	0
Abnormal weight gain	21	0
Cachexia	1	0
Feeding disorder	112	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Food aversion	14	0
Malnutrition	3	0
Neonatal insufficient breast milk syndrome	7	0
Obesity	1	0
Overweight	1	0
Poor feeding infant	17	0
Weight loss poor	3	0
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	2	0
Hyperglycaemia	69	0
Insulin resistance	5	0
Hyperlipidaemias NEC		
Hyperlipidaemia	1	0
Hypoglycaemic conditions NEC		
Glycopenia	1	0
Hypoglycaemia	84	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	3	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	7	1
Lactic acidosis	3	0
Metabolic acidosis	4	0
Metabolic disorders NEC		
Hypercarotinaemia	1	0
Hypercatabolism	1	0
Hypometabolism	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		

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Dehydration	245	0
Total fluid volume increased		
Fluid retention	67	0
Hypervolaemia	5	0
Vitamin deficiencies NEC		
Hypovitaminosis	6	0
Water soluble vitamin deficiencies		
Folate deficiency	11	0
Vitamin B complex deficiency	1	0
Vitamin B12 deficiency	8	0
Metabolic disorders SOC TOTAL	2787	2

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	410	0
Arthropathy	35	0
Autoimmune arthritis	10	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	3	0
Polyarthritis	17	0
Rheumatic fever	2	0
Sacroiliitis	6	0
Seronegative arthritis	3	0
<i>Bone disorders NEC</i>		
Bone cyst	2	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	458	0
Bone swelling	10	0
Coccydynia	4	0
Metatarsalgia	1	0
Pain in jaw	435	0
Pubic pain	2	0
Spinal pain	102	0
<i>Bursal disorders</i>		
Bursitis	105	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	147	0
Osteochondritis	1	0
Polychondritis	3	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	3	0
Polymyalgia rheumatica	91	0
Reynold's syndrome	2	0
Scleroderma	1	0
Sjogren's syndrome	8	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	3	0
Foot deformity	4	0
Hand deformity	4	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Knee deformity	1	0
Limb deformity	6	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
Greater trochanteric pain syndrome	2	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	275	0
Rotator cuff syndrome	44	0
Temporomandibular joint syndrome	16	0
Joint related signs and symptoms		
Arthralgia	10605	0
Jaw clicking	7	0
Joint effusion	16	0
Joint noise	44	0
Joint range of motion decreased	39	0
Joint stiffness	307	0
Joint swelling	692	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	30	0
Metabolic bone disorders		
Osteopenia	4	0
Osteoporosis	7	0
Muscle infections and inflammations		
Antisynthetase syndrome	3	0
Immune-mediated myositis	2	0
Myositis	53	0
Polymyositis	9	0
Muscle pains		
Fibromyalgia	145	0
Myalgia	11894	0
Myalgia intercostal	2	0

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Myofascial pain syndrome	13	0
Muscle related signs and symptoms NEC		
Haematoma muscle	1	0
Muscle atrophy	33	0
Muscle discomfort	8	0
Muscle disorder	12	0
Muscle fatigue	405	0
Muscle haemorrhage	1	0
Muscle mass	5	0
Muscle oedema	5	0
Muscle spasms	2368	0
Muscle swelling	45	0
Muscle tightness	112	0
Muscle twitching	568	0
Myofascial spasm	1	0
Muscle tone abnormalities		
Muscle rigidity	25	0
Nuchal rigidity	13	0
Torticollis	7	0
Trismus	42	0
Muscle weakness conditions		
Muscular weakness	1191	0
Musculoskeletal and connective tissue conditions NEC		
Back disorder	5	0
Chest wall mass	1	0
Growth disorder	2	0
Limb mass	24	0
Mandibular mass	3	0
Mastication disorder	8	0
Mobility decreased	158	0
Muscle contracture	1	0
Musculoskeletal disorder	13	0
Musculoskeletal stiffness	1521	0
Pelvic misalignment	1	0
Posture abnormal	2	0
Sacroiliac joint dysfunction	1	0
Weight bearing difficulty	5	0
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		
Facial asymmetry	1	0
Head deformity	2	0
Nose deformity	1	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Connective tissue inflammation	1	0
Dactylitis	3	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	17	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	2899	0
Flank pain	87	0
Growing pains	1	0
Limb discomfort	1682	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Musculoskeletal chest pain	314	0
Musculoskeletal discomfort	130	0
Musculoskeletal pain	145	0
Neck pain	2254	0
Pain in extremity	14711	1
Rheumatic disorder	17	0
Sacral pain	4	0
Myopathies		
Mitochondrial myopathy acquired	1	0
Myopathy	9	0
Rhabdomyolysis	14	0
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	67	0
Spinal osteoarthritis	2	0
Psoriatic arthropathies		
Psoriatic arthropathy	27	0
Rheumatoid arthropathies		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	150	0
Rheumatoid nodule	1	0
Still's disease	2	0
Soft tissue disorders NEC		
Axillary mass	322	0
Fistula	1	0
Fistula discharge	1	0
Fluctuance	1	0
Groin pain	128	0
Neck mass	47	0
Purple glove syndrome	1	0
Soft tissue disorder	3	0
Soft tissue necrosis	1	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	79	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	65	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Tenosynovitis	4	0
Tenosynovitis stenosaurs	2	0
Trigger finger	34	0
<i>Trunk deformities</i>		
Deformity thorax	1	0
Drooping shoulder syndrome	3	0
Shoulder deformity	4	0
Muscle & tissue disorders SOC TOTAL	56150	1

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

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MedDRA Version: MedDRA 25.0

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>Bile duct neoplasms malignant</i>		
Bile duct cancer	1	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	45	0
Breast cancer female	1	0
Breast cancer male	2	0
Breast cancer stage I	1	0
Breast cancer stage III	3	0
HER2 positive breast cancer	1	0
Inflammatory carcinoma of the breast	1	0
Invasive ductal breast carcinoma	1	0
Triple negative breast cancer	4	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	3	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	2	0
Colorectal cancer	2	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	4	0
<i>Hepatic neoplasms malignant</i>		
Hepatocellular carcinoma	1	0
<i>Hepatobiliary neoplasms benign</i>		

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Haemangioma of liver	1	0
Hepatobiliary neoplasms malignancy unspecified		
Hepatic neoplasm	1	0
Hodgkin's disease NEC		
Hodgkin's disease	4	0
Islet cell neoplasms and APUDoma NEC		
Pancreatic neuroendocrine tumour	1	0
Kaposi's sarcomas		
Kaposi's sarcoma	1	0
Leukaemias NEC		
Leukaemia	6	1
Leukaemias acute NEC		
Acute leukaemia	2	0
Leukaemias chronic NEC		
Chronic leukaemia	1	0
Leukaemias chronic lymphocytic		
Chronic lymphocytic leukaemia	3	0
Leukaemias chronic myeloid		
Chronic myeloid leukaemia	1	0
Lip and oral cavity neoplasms malignant		
Lip and/or oral cavity cancer recurrent	1	0
Lymphomas unspecified NEC		
Lymphoma	47	1
Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)		
Histiocytic necrotising lymphadenitis	1	0
Mantle cell lymphomas		
Mantle cell lymphoma	2	0
Metastases to specified sites		
Metastases to bone	1	0
Metastases to liver	1	0
Metastases to lymph nodes	5	0
Metastases to unknown and unspecified sites		
Metastasis	1	0
Myelodysplastic syndromes		
Myelodysplastic syndrome	4	0
Myeloproliferative disorders (excl leukaemias)		
Essential thrombocythaemia	2	0
Neoplasms malignant site unspecified NEC		
Adenocarcinoma metastatic	1	0
Metastatic neoplasm	2	0
Neoplasm malignant	14	3
Second primary malignancy	1	0
Squamous cell carcinoma	5	0
Neoplasms unspecified malignancy and site unspecified NEC		
Neoplasm	2	0
Neoplasm recurrence	1	0
Nervous system neoplasms benign NEC		
Cranial nerve neoplasm benign	1	0
Neurilemmoma benign	1	0
Nervous system neoplasms unspecified malignancy NEC		
Brain neoplasm	5	0
Meningioma	1	0
Spinal cord neoplasm	1	1

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Neuromas		
Acoustic neuroma	3	0
Neuroma	1	0
Non-Hodgkin's lymphomas NEC		
Non-Hodgkin's lymphoma	3	0
Ocular neoplasms benign		
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
Paraneoplastic syndromes NEC		
Paraneoplastic syndrome	2	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

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Seborrhoeic keratosis	2	0
Skin papilloma	22	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
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
<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	18	0
Neoplasms SOC TOTAL	388	11

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	10	0
Extensor plantar response	2	0
Hoffmann's sign	1	0
Hyperreflexia	5	0
Hyporeflexia	11	0
Reflexes abnormal	2	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	32	0
<i>Absence seizures</i>		
Petit mal epilepsy	32	0
<i>Acute polyneuropathies</i>		
Acute motor axonal neuropathy	1	0
Acute motor-sensory axonal neuropathy	1	0
Guillain-Barre syndrome	102	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	15	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	3	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	8	1
Cerebral artery embolism	3	1
Cerebral artery occlusion	2	0
Cerebral artery thrombosis	5	0
Cerebral haemorrhage	65	15
Cerebral infarction	32	3
Cerebral ischaemia	1	0
Cerebral thrombosis	15	0
Cerebrovascular accident	499	20
Embolic stroke	8	0
Haemorrhage intracranial	16	4
Haemorrhagic cerebral infarction	1	0

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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	2	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	64	3
Lacunar infarction	4	0
Lacunar stroke	6	0
Lateral medullary syndrome	2	0
Pseudostroke	3	0
Ruptured cerebral aneurysm	1	0
Spinal cord infarction	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	2	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	4	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	58	5
Cerebral venous thrombosis	9	0
Superior sagittal sinus thrombosis	6	0
Transverse sinus thrombosis	3	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	2	0
Diabetic neuropathy	1	0
Coma states		
Coma	18	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
Coordination and balance disturbances		
Ataxia	21	0
Balance disorder	514	0
Cerebellar ataxia	1	0
Cerebellar syndrome	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Coordination abnormal	76	0
Dysdiadochokinesis	1	0
Dysstasia	77	0
Nystagmus	17	0
Cortical dysfunction NEC		
Alexia	2	0
Aphasia	105	0
Apraxia	1	0
Dysgraphia	4	0
Dyslexia	1	0
Dyspraxia	2	0
Neurologic neglect syndrome	1	0
Sensory processing disorder	3	0
Visuospatial deficit	1	0
Cranial nerve disorders NEC		
Cranial nerve disorder	3	0
Cranial nerve paralysis	1	0
Dementia (excl Alzheimer's type)		
Dementia	19	0
Dementia with Lewy bodies	2	0
Senile dementia	1	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	7	0
Clinically isolated syndrome	1	0
Demyelination	13	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	56	0
Infant sedation	1	0
Lethargy	2568	0
Loss of consciousness	823	1
Postictal state	6	0
Sedation	9	0
Sedation complication	1	0
Somnolence	1222	0
Stupor	5	0
Syncope	2839	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	26	0
Clumsiness	23	0
Dyskinesia	86	0
Extrapyramidal disorder	3	0
Fine motor skill dysfunction	13	0
Foetal movement disorder	7	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Hyperkinesia	4	0
Hypokinesia	113	0
Micrographia	1	0
Motor dysfunction	6	0
Movement disorder	73	0
Psychomotor hyperactivity	30	0
Synkinesis	2	0
Tardive dyskinesia	2	0
Dystonias		
Dystonia	17	0
Writer's cramp	1	0
Encephalitis NEC		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	7	0
Encephalopathies NEC		
Autoimmune encephalopathy	2	1
Encephalopathy	6	0
Hashimoto's encephalopathy	2	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	13	0
Facial cranial nerve disorders		
Bell's palsy	646	0
Facial nerve disorder	9	0
Facial paralysis	487	0
Facial paresis	107	0
Facial spasm	56	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	82	0
Glossopharyngeal nerve disorders		
Glossopharyngeal neuralgia	1	0
Headaches NEC		
Cervicogenic headache	3	0
Cluster headache	295	0
Cold-stimulus headache	37	0
Drug withdrawal headache	3	0
Exertional headache	9	0
External compression headache	2	0
Headache	30414	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	403	0
Tension headache	635	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Thunderclap headache	25	0
Vascular headache	22	0
<i>Hydrocephalic conditions</i>		
Hydrocephalus	5	0
<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>		
Cauda equina syndrome	1	0
Sciatica	139	0
<i>Memory loss (excl dementia)</i>		
Amnesia	236	0
Memory impairment	258	0
Retrograde amnesia	1	0
Transient global amnesia	10	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	110	0
Cognitive linguistic deficit	1	0
Disturbance in attention	404	0
Mental impairment	62	0
<i>Migraine headaches</i>		
Basilar migraine	1	0
Hemiplegic migraine	44	0
Migraine	3566	0
Migraine with aura	235	0
Migraine without aura	22	0
Ophthalmic migraine	7	0
Retinal migraine	39	0
Typical aura without headache	9	0
Vestibular migraine	30	0
<i>Mixed cranial nerve disorders</i>		
Bulbar palsy	2	0
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	36	0
Cubital tunnel syndrome	4	0
Meralgia paraesthetica	2	0
Mononeuritis	2	0
Mononeuropathy	4	0
Nerve compression	32	0
Peripheral nerve lesion	2	0
Peroneal nerve palsy	21	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

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Motor neurone diseases		
Amyotrophic lateral sclerosis	1	0
Lower motor neurone lesion	2	0
Motor neurone disease	7	3
Progressive bulbar palsy	1	0
Upper motor neurone lesion	1	0
Multiple sclerosis acute and progressive		
Band sensation	1	0
Multiple sclerosis	39	0
Multiple sclerosis relapse	26	0
Relapsing-remitting multiple sclerosis	1	0
Tumefactive multiple sclerosis	1	1
Muscle tone abnormal		
Drop attacks	2	0
Hypertonia	2	0
Hypotonia	40	0
Morvan syndrome	1	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
Myelitis (incl infective)		
Myelitis transverse	38	0
Narcolepsy and hypersomnia		
Cataplexy	3	0
Hypersomnia	126	0
Narcolepsy	7	0
Nervous system disorders NEC		
Central nervous system lesion	3	0
Cerebral disorder	3	0
Nervous system disorder	29	0
Neurotoxicity	4	0
Psychomotor skills impaired	1	0
Neurologic visual problems NEC		
Hemianopia	1	0
Hemianopia homonymous	2	0
Quadrantanopia	2	0
Tunnel vision	24	0
Neurological signs and symptoms NEC		
Agitation neonatal	1	0
Cerebrospinal fluid leakage	1	0
Clonus	5	0
Decerebrate posture	1	0
Decorticate posture	1	0
Dizziness	11453	0
Dizziness exertional	53	0
Dizziness postural	856	0
Drooling	26	0
Fontanelle bulging	2	0
Head discomfort	411	0
Hyporesponsive to stimuli	2	0
Inability to crawl	3	0
Infant irritability	10	0
Meningism	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Myoclonus	35	0
Neurological symptom	75	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	18	0
Presyncope	722	0
Sensory overload	5	0
Slow response to stimuli	4	0
Tongue biting	8	0
Unresponsive to stimuli	66	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	32	0
Muscle spasticity	21	0
Neuromuscular pain	3	0
Neuromuscular junction dysfunction		
Myasthenia gravis	17	0
Myasthenia gravis crisis	2	0
Myasthenic syndrome	1	0
Olfactory nerve disorders		
Anosmia	335	0
Hyposmia	19	0
Parosmia	339	0
Optic nerve disorders NEC		
Optic neuritis	44	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	14	0
Burning sensation	680	0
Burning sensation mucosal	2	0
Dysaesthesia	8	0
Formication	46	0
Hemianaesthesia	1	0
Hemihypoaesthesia	3	0
Hemiparaesthesia	5	0
Hyperaesthesia	125	0
Hypoaesthesia	3565	0
Lhermitte's sign	1	0
Paraesthesia	4868	0
Reversed hot-cold sensation	4	0
Synaesthesia	2	0
Vibration syndrome	3	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	22	0
Hemiparesis	71	0
Hemiplegia	50	0
Locked-in syndrome	1	0
Monoparesis	94	0
Monoplegia	103	0
Paralysis	158	0
Paraparesis	4	0
Paraplegia	4	0
Paresis	10	0
Quadriparesis	1	0
Quadriplegia	1	0
Parkinson's disease and parkinsonism		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
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
Partial complex seizures		
Dreamy state	6	0
Focal dyscognitive seizures	6	0
Temporal lobe epilepsy	2	0
Partial simple seizures NEC		
Autonomic seizure	1	0
Peripheral neuropathies NEC		
Axonal neuropathy	2	0
Brachial plexopathy	2	0
Neuralgic amyotrophy	11	0
Neuritis	12	0
Neuropathy peripheral	162	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	13	0
Polyneuropathy	5	0
Small fibre neuropathy	4	0
Thoracic outlet syndrome	2	0
Seizures and seizure disorders NEC		
Atonic seizures	9	0
Change in seizure presentation	2	0
Clonic convulsion	6	0
Convulsions local	1	0
Convulsive threshold lowered	1	0
Epilepsy	176	0
Epileptic aura	2	0
Epileptic encephalopathy	2	0
Febrile convulsion	21	0
Idiopathic generalised epilepsy	1	0
Neonatal epileptic seizure	1	0
Partial seizures	30	0
Partial seizures with secondary generalisation	1	0
Post stroke seizure	1	0
Psychogenic seizure	11	0
Seizure	769	2
Seizure anoxic	3	0
Seizure cluster	7	0
Seizure like phenomena	4	0
Status epilepticus	41	0
Tonic clonic movements	7	0
Tonic convulsion	38	0
Tonic posturing	1	0
Sensory abnormalities NEC		
Ageusia	611	0
Allodynia	33	0
Aura	29	0
Central pain syndrome	1	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Complex regional pain syndrome	6	0
Dysgeusia	1334	0
Electric shock sensation	58	0
Hypergeusia	1	0
Hypogeusia	9	0
Intercostal neuralgia	2	0
Loss of proprioception	3	0
Morton's neuralgia	4	0
Neuralgia	739	0
Persistent genital arousal disorder	2	0
Phantom limb syndrome	8	0
Post herpetic neuralgia	17	0
Restless arm syndrome	4	0
Restless legs syndrome	165	0
Sensory disturbance	132	0
Sensory loss	116	0
Taste disorder	320	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	247	0
Incoherent	15	0
Language disorder	2	0
Repetitive speech	5	0
Slow speech	24	0
Speech disorder	86	0
Speech disorder developmental	2	0
Spinal cord and nerve root disorders NEC		
Acquired syringomyelia	1	0
Myelopathy	1	0
Radiculitis brachial	18	0
Radiculopathy	8	0
Structural brain disorders NEC		
Brain injury	12	2
Cerebral ventricle dilatation	2	0
Hyperintensity in brain deep nuclei	1	0
Intracranial mass	1	0
White matter lesion	2	0
Transient cerebrovascular events		
Transient ischaemic attack	200	3
Tremor (excl congenital)		
Essential tremor	6	0
Head titubation	15	0
Resting tremor	4	0
Tremor	2181	0
Trigeminal disorders		
Numb chin syndrome	2	0
Trigeminal nerve disorder	3	0
Trigeminal neuralgia	87	0
Trigeminal neuritis	3	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
<i>Vagus nerve disorders</i>		
Vagus nerve disorder	1	0
Vocal cord paralysis	4	0
<i>Vertigos NEC</i>		
Cervicogenic vertigo	1	0
Vertigo CNS origin	3	0
Nervous system disorders SOC TOTAL	81422	91

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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	490	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	13	0
<i>Foetal conditions due to maternal conditions</i>		
Maternal condition affecting foetus	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	8	1
<i>Gestational age and weight conditions</i>		
Low birth weight baby	1	0
Premature baby	8	1
Small for dates baby	1	0
<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	4	0
<i>Labour onset and length abnormalities</i>		
Induced labour	1	0
Premature delivery	1	0
Premature labour	9	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	8	0
<i>Maternal complications of pregnancy NEC</i>		
Biochemical pregnancy	4	0
Complication of pregnancy	1	0
Decidual cast	8	0
Ectopic pregnancy	15	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>		

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Reaction Name	Total	Fatal
Pregnancy conditions <small>Pregnancy conditions cont'd</small>		
Jaundice neonatal	1	0
Normal newborn status		
Normal newborn	2	0
Normal pregnancy, labour and delivery		
Labour pain	1	0
Live birth	8	0
Pregnancy	35	0
Term birth	2	0
Uterine contractions during pregnancy	6	0
Placental abnormalities (excl neoplasms)		
Foetal vascular malperfusion	2	0
Placental calcification	1	0
Placental disorder	2	0
Placental insufficiency	1	0
Small size placenta	2	0
Postpartum complications NEC		
Postpartum haemorrhage	5	0
Pregnancy complicated by maternal disorders		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0
Stillbirth and foetal death		
Foetal death	2	2
Stillbirth	10	10
Umbilical cord complications		
Umbilical cord abnormality	1	0
Umbilical cord thrombosis	1	0
Unintended pregnancies		
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	733	14

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

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	3	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	16	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	131	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

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	5	0
<i>Affect alterations NEC</i>		
Affect lability	16	0
Constricted affect	8	0
Flat affect	12	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	98	0
Anxiety	1120	0
Immunisation stress-related response	4	0
Nervousness	218	0
Stress	144	0
Tension	47	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	6	0
Social avoidant behaviour	6	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	252	0
<i>Communications disorders</i>		
Communication disorder	7	0
Mutism	4	0
Speech sound disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	1072	0
Disorientation	331	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

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	151	0
<i>Delusional symptoms</i>		
Delusion	19	0
<i>Depressive disorders</i>		
Agitated depression	6	0
Depression	433	0
Depression suicidal	20	0
Major depression	15	0
Mixed anxiety and depressive disorder	4	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	13	0
Dissociation	40	0
Dissociative amnesia	4	0
Dissociative disorder	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	30	0
Insomnia	1999	0
Middle insomnia	34	0
Terminal insomnia	35	0
<i>Dyssomnias</i>		
Breathing-related sleep disorder	1	0
Dyssomnia	1	0
Poor quality sleep	271	0
<i>Eating disorders NEC</i>		
Bulimia nervosa	1	0
Eating disorder	16	0
Selective eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	48	0
Dysphoria	3	0
Emotional disorder	76	0
Emotional distress	65	0
Emotional poverty	2	0
Euphoric mood	51	0
Frustration tolerance decreased	2	0
Irritability	239	0
Mood altered	67	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	34	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

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

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	174	0
Hallucinations (excl sleep-related)		
Hallucination	261	0
Hallucination, auditory	23	0
Hallucination, olfactory	15	0
Hallucination, tactile	1	0
Hallucination, visual	33	0
Hallucinations, mixed	4	0
Increased physical activity levels		
Restlessness	178	0
Infancy, childhood and adolescence psychiatric disorders NEC		
Social (pragmatic) communication disorder	1	0
Learning disorders		
Learning disability	1	0
Learning disorder	1	0
Reading disorder	1	0
Mental disorders NEC		
Mental disorder	24	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	461	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	50	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

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Orgasmic disorders and disturbances</i>		
Anorgasmia	5	0
Female orgasmic disorder	2	0
Orgasm abnormal	4	0
Orgasmic sensation decreased	1	0
Premature ejaculation	1	0
<i>Panic attacks and disorders</i>		
Limited symptom panic attack	1	0
Panic attack	270	0
Panic disorder	10	0
Panic reaction	32	0
<i>Paraphilias and paraphilic disorders</i>		
Transvestism	1	0
<i>Parasomnias</i>		
Abnormal dreams	213	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	2	0
Nightmare	239	0
Parasomnia	5	0
Sleep inertia	1	0
Sleep talking	6	0
Sleep terror	29	0
Somnambulism	10	0
<i>Perception disturbances NEC</i>		
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
<i>Personality disorders NEC</i>		
Personality disorder	1	0
Self esteem decreased	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	5	0
<i>Psychiatric elimination disorders</i>		
Enuresis	31	0
<i>Psychiatric symptoms NEC</i>		
Helplessness	1	0
Hypervigilance	9	0
Psychiatric symptom	13	0
Psychological trauma	4	0
Trance	1	0
<i>Psychotic disorder NEC</i>		
Acute psychosis	1	0
Psychotic behaviour	1	0
Psychotic disorder	34	0
<i>Schizophrenia NEC</i>		
Schizophrenia	2	0
<i>Sexual and gender identity disorders NEC</i>		
Gender dysphoria	1	0

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Sexual arousal disorders</i>		
Disturbance in sexual arousal	4	0
Sexual inhibition	1	0
<i>Sexual desire disorders</i>		
Hypersexuality	1	0
Libido decreased	20	0
Libido disorder	2	0
Libido increased	8	0
Loss of libido	22	0
<i>Sexual dysfunction NEC</i>		
Genito-pelvic pain/penetration disorder	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	290	0
Sleep disorder due to general medical condition, insomnia type	5	0
<i>Somatic symptom disorders</i>		
Conversion disorder	33	0
Habit cough	22	0
Somatic symptom disorder	2	0
Vomiting psychogenic	1	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	10	0
Logorrhoea	2	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	27	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
<i>Stereotypies and automatisms</i>		
Automatism	1	0
Bruxism	16	0
Head banging	12	0
Stereotypy	1	0
<i>Stress disorders</i>		
Burnout syndrome	2	0
Post-traumatic stress disorder	6	0
<i>Substance related and addictive disorders</i>		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	5	0
Dependence	1	0
Nicotine dependence	2	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	3	H
Intentional self-injury	6	0
Self-injurious ideation	2	0
Suicidal ideation	53	0
Suicide attempt	9	0
Suicide threat	2	0
<i>Thinking disturbances</i>		
Bradyphrenia	45	0
Flight of ideas	1	0
Intrusive thoughts	8	0
Morbid thoughts	1	0
Tachyphrenia	8	0

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Thinking abnormal	22	0
Thought blocking	3	0
<i>Tic disorders</i>		
Tic	20	0
Psychiatric disorders SOC TOTAL	10270	H

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	4	0
Bladder irritation	14	0
Bladder pain	36	0
Bladder spasm	2	0
Dysuria	61	0
Incontinence	45	0
Lower urinary tract symptoms	3	0
Micturition disorder	2	0
Micturition urgency	55	0
Mixed incontinence	1	0
Pollakiuria	164	0
Stress urinary incontinence	2	0
Urethral pain	8	0
Urge incontinence	3	0
Urinary hesitation	3	0
Urinary incontinence	78	0
Urinary retention	56	0
Urine flow decreased	19	0
<i>Bladder disorders NEC</i>		
Bladder dilatation	1	0
Bladder disorder	13	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	2	0
Urinary tract disorder	4	0
Urinary tract obstruction	1	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Focal segmental glomerulosclerosis	1	0
Glomerulonephritis membranous	1	0
Glomerulonephritis minimal lesion	8	0
Glomerulonephritis rapidly progressive	2	0
IgA nephropathy	4	0
Nephrotic syndrome	21	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	8	0
Hypertonic bladder	6	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	3	0
<i>Nephropathies and tubular disorders NEC</i>		

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Nephropathy	1	0
Renal disorders NEC		
Kidney fibrosis	1	0
Renal disorder	11	1
Renal haemorrhage	1	0
Renal mass	1	0
Renal failure and impairment		
Acute kidney injury	59	4
Anuria	3	0
Chronic kidney disease	6	0
Oliguria	1	0
Renal failure	26	1
Renal impairment	35	0
Renal injury	3	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	69	0
Haematuria	54	0
Ketonuria	1	0
Myoglobinuria	1	0
Proteinuria	13	0
Urine abnormality	13	0
Urine odour abnormal	11	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	31	1
Nocturia	3	0
Polyuria	9	0
Renal colic	5	0

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Renal pain	367	0
Urinary tract discomfort	2	0
Urinary tract pain	6	0
Renal & urinary disorders SOC TOTAL	1424	8

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	18	0
<i>Breast disorders NEC</i>		
Breast atrophy	1	0
Breast disorder	4	0
Breast enlargement	32	0
Breast mass	152	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	3	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	878	0
Breast swelling	196	0
Breast tenderness	107	0
Nipple pain	47	1
Nipple swelling	4	0
<i>Cervix disorders NEC</i>		
Cervical dysplasia	3	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	2	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation disorder	3	0
Ejaculation failure	3	0
Erectile dysfunction	78	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	4	0
Breast milk odour abnormal	2	0
Galactorrhoea	5	0
Galactostasis	1	0
Lactation disorder	11	0
Lactation puerperal increased	6	0
Suppressed lactation	50	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

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	47	0
Menopause delayed	1	0
Premature menopause	25	0
<i>Menopausal effects on the genitourinary tract</i>		
Atrophic vulvovaginitis	2	0
Postmenopausal haemorrhage	117	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	8	0
Abnormal withdrawal bleeding	3	0
Bleeding anovulatory	1	0
Dysmenorrhoea	3346	0
Intermenstrual bleeding	1326	0
Menstrual discomfort	36	0
Menstrual disorder	2318	0
Menstruation irregular	4107	0
Premenstrual dysphoric disorder	14	0
Premenstrual headache	13	0
Premenstrual pain	151	0
Premenstrual syndrome	141	0
Retrograde menstruation	2	0
Withdrawal bleed	16	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	733	0
Hypomenorrhoea	760	0
Menstruation delayed	5768	0
Oligomenorrhoea	234	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	6380	0
Menometrorrhagia	21	0
Polymenorrhoea	1048	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Haemorrhagic ovarian cyst	3	0
Ovarian cyst	32	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	85	0
Premature ovulation	4	0
Superovulation	1	0
<i>Pelvic prolapse conditions</i>		
Vaginal prolapse	1	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.0

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	72	0
Pelvic congestion	1	0
Pelvic floor muscle weakness	1	0
Pelvic fluid collection	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	2	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	2	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 discolouration	1	0
Genital erythema	1	0
Genital pain	7	0
Genital rash	6	0
Genital swelling	5	0
Pelvic discomfort	6	0
Pelvic pain	132	0
Perineal pain	3	0
Perineal rash	1	0
Pruritus genital	8	0
<i>Scrotal disorders NEC</i>		
Acquired hydrocele	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Scrotal angiokeratoma	1	0
Scrotal discomfort	1	0
Scrotal erythema	2	0
Scrotal exfoliation	2	0
Scrotal pain	22	0
Scrotal swelling	6	0
Scrotum erosion	1	0
Varicocele	2	0
<i>Sexual function and fertility disorders NEC</i>		
Dyspareunia	7	0
Infertility	18	0
Infertility female	5	0
Sexual dysfunction	10	0
<i>Spermatogenesis and semen disorders</i>		
Aspermia	1	0
Haemospermia	8	0
Semen discolouration	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular atrophy	1	0
Testicular disorder	4	0
Testicular oedema	1	0
Testicular pain	74	0
Testicular swelling	14	0
Testicular torsion	1	0
Testis discomfort	3	0
<i>Testicular and epididymal neoplasms</i>		
Testicular cyst	1	0
<i>Uterine disorders NEC</i>		
Adenomyosis	11	0
Endometrial thickening	4	0
Endometriosis	98	0
Uterine haemorrhage	49	0
Uterine pain	19	0
<i>Uterine infections and inflammations (excl cervix)</i>		
Uterine inflammation	1	0
<i>Uterine neoplasms</i>		
Uterine polyp	6	0
<i>Uterine tone disorders</i>		
Uterine spasm	42	0
<i>Vaginal and vulval infections and inflammations</i>		
Vulvovaginal inflammation	2	0
<i>Vulvovaginal cysts and neoplasms</i>		
Bartholin's cyst	2	0
Vaginal cyst	8	0
Vaginal polyp	1	0
Vulva cyst	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	1819	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	4	0
Vulval disorder	2	0
Vulval haemorrhage	34	0
Vulval ulceration	8	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Vulvovaginal ulceration	6	0
<i>Vulvovaginal signs and symptoms</i>		
Clitoral engorgement	1	0
Coital bleeding	8	0
Labia enlarged	2	0
Vaginal discharge	89	0
Vaginal lesion	1	0
Vaginal odour	4	0
Vaginal oedema	1	0
Vulval eczema	1	0
Vulval oedema	2	0
Vulvovaginal burning sensation	9	0
Vulvovaginal discomfort	2	0
Vulvovaginal dryness	6	0
Vulvovaginal erythema	3	0
Vulvovaginal pain	33	0
Vulvovaginal pruritus	11	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	5	0
Reproductive & breast disorders SOC TOTAL	31372	1

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	7	0
Apnoeic attack	1	0
Dyspnoea	7002	5
Dyspnoea at rest	11	0
Dyspnoea exertional	48	1
Grunting	1	0
Hyperventilation	67	0
Hypopnoea	132	0
Hypoventilation	1	0
Irregular breathing	29	0
Mouth breathing	7	0
Nocturnal dyspnoea	2	0
Obstructive sleep apnoea syndrome	1	0
Orthopnoea	4	0
Respiration abnormal	74	0
Respiratory arrest	23	0
Respiratory depression	1	0
Respiratory distress	20	0
Sleep apnoea syndrome	17	0
Tachypnoea	33	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	4	0
Bronchiectasis	16	0
<i>Bronchospasm and obstruction</i>		
Asthma	437	0
Asthma late onset	3	0
Bronchospasm	19	0
Chronic obstructive pulmonary disease	29	1
Cough variant asthma	7	0
Obstructive airways disorder	14	0
Reversible airways obstruction	1	0
Wheezing	487	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	2	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	36	2
Respiratory acidosis	2	0
<i>Coughing and associated symptoms</i>		
Allergic cough	9	0
Atopic cough	1	0
Cough	3021	1
Cough decreased	2	0
Haemoptysis	75	0
Productive cough	198	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

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Laryngeal disorder	1	0
Reflux laryngitis	3	0
Vocal cord disorder	2	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	3	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	27	0
Pulmonary haemorrhage	1	0
Pulmonary pain	121	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	342	0
Nasal inflammation	5	0
Rhinitis allergic	28	0
<i>Nasal disorders NEC</i>		
Epistaxis	1101	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	7	0
Nasal oedema	8	0
Nasal polyps	2	0
Nasal pruritus	13	0
Nasal ulcer	3	0
<i>Neonatal hypoxic conditions</i>		
Dry lung syndrome	1	0
Gasping syndrome	1	0

Case Series Drug Analysis Print

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

Report Run Date: 05-May-2022

Data Lock Date: 04-May-2022 18:30:04

MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Infantile apnoea	2	0
Paranasal sinus disorders (excl infections and neoplasms)		
Allergic sinusitis	3	0
Paranasal sinus inflammation	5	0
Sinonasal obstruction	15	0
Sinus congestion	73	0
Sinus disorder	8	0
Parenchymal lung disorders NEC		
Atelectasis	5	0
Combined pulmonary fibrosis and emphysema	1	0
Emphysema	3	0
Interstitial lung disease	11	0
Lung consolidation	6	0
Lung infiltration	2	1
Organising pneumonia	2	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	11	0
Pulmonary toxicity	1	0
Pharyngeal disorders (excl infections and neoplasms)		
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	15	0
Pharyngeal paraesthesia	57	0
Pharyngeal swelling	303	0
Pharyngeal ulceration	19	0
Tonsillar erythema	14	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	99	0
Tonsillar inflammation	4	0
Tonsillar ulcer	1	0
Tonsillolith	1	0
Pleural infections and inflammations		
Pleurisy	41	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	42	0
Pneumothorax	14	0
Pneumothorax spontaneous	5	0
Pulmonary hypertensions		
Pulmonary hypertension	3	0
Pulmonary oedemas		
Acute respiratory distress syndrome	3	1
Pulmonary congestion	20	0
Pulmonary oedema	25	2
Pulmonary thrombotic and embolic conditions		
Pulmonary artery thrombosis	2	0
Pulmonary embolism	557	41

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Report Run Date: 05-May-2022

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Pulmonary infarction	7	0
Pulmonary thrombosis	13	1
Respiratory failures (excl neonatal)		
Acute respiratory failure	3	1
Respiratory failure	15	2
Respiratory signs and symptoms NEC		
Allergic respiratory symptom	6	0
Diaphragmalgia	10	0
Nasal flaring	1	0
Painful respiration	19	1
Pleural rub	1	0
Respiratory symptom	21	0
Suffocation feeling	2	0
Use of accessory respiratory muscles	2	0
Respiratory tract disorders NEC		
Allergic respiratory disease	1	0
Aspiration	4	0
Lung disorder	12	0
Pulmonary mass	6	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
Thoracic musculoskeletal disorders		
Respiratory muscle weakness	2	0
Tracheal disorders (excl infections and neoplasms)		
Tracheal disorder	1	0
Tracheal pain	2	0
Upper respiratory tract neoplasms		
Tonsillar cyst	1	0
Upper respiratory tract signs and symptoms		
Aphonia	148	0
Catarrh	34	0
Choking	20	0
Choking sensation	7	0
Dry throat	188	0
Dysphonia	189	0
Increased upper airway secretion	6	0
Increased viscosity of upper respiratory secretion	36	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	3306	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	55	0
Rhinalgia	15	0
Rhinorrhoea	1090	0

Case Series Drug Analysis Print

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Report Run Date: 05-May-2022

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Sinus pain	252	0
Sneezing	469	0
Snoring	8	0
Throat clearing	8	0
Throat irritation	270	0
Throat lesion	1	0
Throat tightness	294	0
Upper airway obstruction	3	0
Upper respiratory tract congestion	2	0
Upper respiratory tract irritation	1	0
Upper-airway cough syndrome	16	0
Yawning	31	0
<i>Vascular pulmonary disorders NEC</i>		
Acute chest syndrome	1	0
Respiratory disorders SOC TOTAL	21919	63

Case Series Drug Analysis Print

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Report Run Date: 05-May-2022

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	222	0
Acne cystic	28	0
Dermatitis acneiform	13	0
Oil acne	1	0
<i>Alopecias</i>		
Alopecia	475	0
Alopecia areata	78	0
Alopecia totalis	4	0
Alopecia universalis	2	0
Androgenetic alopecia	2	0
Diffuse alopecia	4	0
Hypotrichosis	3	0
Lichen planopilaris	2	0
Madarosis	9	0
<i>Angioedemas</i>		
Angioedema	285	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	889	0
Hidradenitis	5	0
Hyperhidrosis	2735	0
Hypohidrosis	2	0
Milia	2	0
Miliaria	119	0
Night sweats	965	0
Sweat discolouration	1	0
<i>Bullous conditions</i>		
Autoimmune blistering disease	1	0
Blister	555	0
Blister rupture	1	0
Blood blister	37	0
Dermatitis bullous	19	0
Erythema multiforme	45	0
Fracture blisters	1	0
Herpes gestationis	1	0
Mucous membrane pemphigoid	1	0
Pemphigoid	33	0
Pemphigus	9	0
Stevens-Johnson syndrome	7	0
Toxic epidermal necrolysis	2	1
<i>Connective tissue disorders</i>		
Chronic cutaneous lupus erythematosus	3	0
Dermatomyositis	12	0
Subacute cutaneous lupus erythematosus	3	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	2	0
Dry skin	305	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Koebner phenomenon	1	0
Macule	5	0
Neutrophilic dermatosis	1	0
Pain of skin	349	0
Papule	120	0
Pathergy reaction	1	0
Scab	28	0
Scar discomfort	1	0
Scar pain	20	0
Sensitive skin	238	0
Shagreen skin	1	0
Skin burning sensation	274	0
Skin degenerative disorder	1	0
Skin discolouration	168	0
Skin discomfort	6	0
Skin disorder	36	0
Skin fissures	11	0
Skin indentation	3	0
Skin induration	5	0
Skin lesion	53	0
Skin lesion inflammation	1	0
Skin necrosis	3	0
Skin odour abnormal	27	0
Skin plaque	4	0
Skin reaction	175	0
Skin sensitisation	45	0
Skin swelling	116	0
Skin texture abnormal	2	0
Skin tightness	30	0
Skin warm	371	0
Skin weeping	18	0
Sticky skin	3	0
Target skin lesion	3	0
Transient acantholytic dermatosis	1	0
Yellow skin	29	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	2	0
Dermatitis	170	0
Dermatitis allergic	308	0
Dermatitis atopic	65	0
Dermatitis contact	26	0
Dermatitis diaper	4	0
Dyshidrotic eczema	32	0
Eczema	439	0
Eczema asteatotic	17	0
Eczema infantile	1	0
Eczema nummular	7	0
Eczema vesicular	1	0
Eczema weeping	8	0
Hand dermatitis	5	0
Intertrigo	1	0
Neurodermatitis	4	0
Perioral dermatitis	3	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Seborrhoeic dermatitis	9	0
Skin irritation	160	0
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	3	0
Palmar-plantar erythrodysesthesia syndrome	3	0
Toxic skin eruption	2	0
<i>Erythemas</i>		
Erythema	2528	0
Palmar erythema	4	0
Pernio-like erythema	1	0
Vancomycin infusion reaction	2	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	2	0
Dermatitis exfoliative generalised	6	0
Exfoliative rash	26	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	152	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	2	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	5	0
Skin hypopigmentation	1	0
Vitiligo	27	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

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Onychomadesis	3	0
Splinter haemorrhages	4	0
<i>Panniculitides</i>		
Erythema nodosum	35	0
Panniculitis	3	0
<i>Papulosquamous conditions</i>		
Erythema annulare	2	0
Lichen planus	28	0
Lichen sclerosus	11	0
Parapsoriasis	9	0
Pityriasis alba	1	0
Pityriasis rosea	144	0
Pityriasis rubra pilaris	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Actinic prurigo	1	0
Photosensitivity reaction	72	0
Polymorphic light eruption	3	0
Solar dermatitis	2	0
<i>Pigmentation changes NEC</i>		
Haemosiderin stain	1	0
Pigmentation disorder	18	0
<i>Pilar disorders NEC</i>		
Hair colour changes	11	0
Hair disorder	1	0
Hair growth abnormal	13	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	6458	0
<i>Psoriatic conditions</i>		
Dermatitis psoriasiform	6	0
Guttate psoriasis	25	0
Nail psoriasis	3	0
Palmoplantar pustulosis	2	0
Psoriasis	260	0
Pustular psoriasis	3	0
Rebound psoriasis	2	0
<i>Purpura and related conditions</i>		
Ecchymosis	1	0
Henoch-Schonlein purpura	16	0
Petechiae	163	0
Purpura	62	0
<i>Pustular conditions</i>		
Acute generalised exanthematous pustulosis	2	0
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	8	0
Rash	6778	1
Rash erythematous	1472	0
Rash macular	590	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash maculo-papular	69	0
Rash morbilliform	50	0
Rash papular	409	0
Rash pruritic	1439	0
Rash scarlatiniform	1	0
Rash vesicular	91	0
Systemic lupus erythematosus rash	9	0
Rosaceas		
Erythematotelangiectatic rosacea	1	0
Papulopustular rosacea	1	0
Rosacea	40	0
Scaly conditions		
Dandruff	5	0
Pityriasis	30	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	31	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	21	0
Skin dystrophies		
Keloid scar	3	0
Skin wrinkling	4	0
Skin haemorrhages		
Haemorrhage subcutaneous	15	0
Skin haemorrhage	24	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	2	0
Skin oedema	5	0
Skin vasculitides		
Capillaritis	4	0
Cutaneous vasculitis	16	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Hypersensitivity vasculitis	1	0
Vasculitic rash	22	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	30	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	1	0
Telangiectasia	1	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	14	0
Cold urticaria	10	0
Idiopathic urticaria	3	0
Mechanical urticaria	17	0
Solar urticaria	3	0
Urticaria	2350	0
Urticaria cholinergic	2	0
Urticaria chronic	42	0
Urticaria contact	1	0
Urticaria papular	6	0
Urticaria thermal	11	0
Urticularial vasculitis	7	0
Skin disorders SOC TOTAL	34354	2

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Infant	2	0
Menarche	3	0
Menopause	50	0
Postmenopause	5	0
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Dependents</i>		
Sick relative	7	0
<i>Dietary and nutritional issues</i>		
Feeding tube user	1	0
<i>Disability issues</i>		
Bedridden	37	0
Breast prosthesis user	3	0
Disability	4	0
Hearing disability	4	0
Housebound	1	0
Immobile	13	0
Impaired driving ability	5	0
Impaired work ability	21	0
Loss of personal independence in daily activities	62	0
Mental disability	1	0
Physical disability	6	0
Sight disability	13	0
Sitting disability	4	0
Walking disability	4	0
Wheelchair user	2	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
Family stress	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	4	0
Patient dissatisfaction with treatment	1	0

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Reaction Name	Total	Fatal
Social circumstances Social circumstances cont'd		
<i>Tobacco use</i>		
Ex-tobacco user	1	0
Non-tobacco user	6	0
Tobacco user	1	0
Social circumstances SOC TOTAL	305	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Adrenal gland therapeutic procedures</i>		
Adrenalectomy	1	0
<i>Anaesthesia and allied procedures</i>		
Local anaesthesia	2	0
Nerve block	5	0
<i>Analgesia supportive care</i>		
Analgesic therapy	2	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 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

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
Hormone therapy	8	0
Immunisations		
COVID-19 immunisation	97	0
Immunisation	491	1
Induced abortions		
Abortion induced	1	0
Joint therapeutic procedures		
Joint injection	6	0
Joint surgery	1	0
Knee arthroplasty	1	0
Large intestine therapeutic procedures		
Appendectomy	2	0
Limb therapeutic procedures		
Arm amputation	1	0
Limb immobilisation	12	0
Limb operation	10	0
Lymphoid tissue therapeutic procedures		
Lymphadenectomy	2	0
Splenectomy	1	0
Mastectomies		
Breast conserving surgery	5	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	2	0
Renal therapeutic procedures		
Dialysis	1	0
Respiratory tract therapeutic procedures NEC		
Asthma prophylaxis	4	0
Retinal therapeutic procedures		
Retinopexy	1	0
Skin and subcutaneous tissue therapeutic procedures NEC		
Dermal filler injection	4	0
Therapeutic skin care topical	1	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
<i>Skull and brain therapeutic procedures</i>		
Cerebrovascular operation	1	0
Posterior fossa decompression	1	0
<i>Small intestine therapeutic procedures</i>		
Ileostomy	1	0
<i>Spine and spinal cord therapeutic procedures</i>		
Spinal decompression	1	0
<i>Tendon therapeutic procedures</i>		
Tenodesis	1	0
<i>Therapeutic bladder catheterisation</i>		
Bladder catheterisation	2	0
<i>Therapeutic procedures NEC</i>		
Abscess drainage	1	0
Anaphylaxis treatment	7	0
Bed rest	6	0
Fatigue management	1	0
Hospitalisation	15	0
Injection	54	0
Interchange of vaccine products	332	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	2	0
Therapy change	2	0
<i>Tracheal therapeutic procedures</i>		
Tracheostomy	1	0
<i>Uterine therapeutic procedures</i>		
Endometrial ablation	2	0
<i>Vascular therapeutic procedures NEC</i>		
Vasodilation procedure	1	0
Surgical & medical procedures SOC TOTAL	1214	1

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Accelerated hypertension	1	0
Hypertensive crisis	16	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	2	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
Aortic stenosis	1	0
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	23	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	17	0
Labile blood pressure	4	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	4	0
<i>Circulatory collapse and shock</i>		
CT hypotension complex	2	0
Circulatory collapse	94	0
Hypoperfusion	2	0
Hypovolaemic shock	2	1
Neurogenic shock	24	0
Peripheral circulatory failure	6	0
Shock	25	0
Shock symptom	4	0
<i>Haemorrhages NEC</i>		
Arterial haemorrhage	1	0
Bloody discharge	26	0
Haematoma	52	0
Haemorrhage	1414	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	249	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	4	0
Embolism	68	0
Embolism arterial	2	0
Embolism venous	8	1
Microembolism	2	0
Thrombosis	545	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 compression	1	0
Vascular occlusion	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Capillary disorder	1	0
Capillary fragility	6	0
Endothelial dysfunction	1	0
Haemodynamic instability	1	0
Superficial vein prominence	3	0
Vascular fragility	1	0
Vascular pain	44	0
Vascular wall hypertrophy	1	0
Vasodilatation	46	0
Vein discolouration	7	0
Vein disorder	9	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	36	0
Deep vein thrombosis	365	1
Femoral artery embolism	1	0
Jugular vein thrombosis	5	0
Pelvic venous thrombosis	4	0
Peripheral artery thrombosis	4	0
Peripheral embolism	4	0
Subclavian vein thrombosis	4	0
Superficial vein thrombosis	31	0
Thrombophlebitis	31	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	57	0
Erythromelalgia	2	0
Flushing	484	0
Hot flush	1279	0
Peripheral vascular disorder	3	0
Vein wall hypertrophy	1	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Claudication of jaw muscles	1	0
Extremity necrosis	3	0
Iliac artery occlusion	1	0
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	398	0
Peripheral ischaemia	13	0
Poor peripheral circulation	24	0
Raynaud's phenomenon	73	0
Subclavian vein occlusion	1	0
Vasoconstriction	2	0
<i>Phlebitis NEC</i>		
Phlebitis	37	0
Phlebitis superficial	10	0
<i>Site specific vascular disorders NEC</i>		
Aortic disorder	1	0
Aortic rupture	2	2
Inferior vena cava dilatation	1	0
Pallor	450	0
<i>Varicose veins NEC</i>		
Spider vein	7	0
Varicophlebitis	4	0
Varicose vein	42	0
Varicose vein ruptured	1	0
<i>Vascular hypertensive disorders NEC</i>		
Diastolic hypertension	6	0
Essential hypertension	6	0
Hypertension	792	0
Labile hypertension	2	0
Orthostatic hypertension	2	0
Secondary hypertension	1	0
Systolic hypertension	7	0
White coat hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Capillary leak syndrome	1	0
Diastolic hypotension	1	0
Hypotension	472	1
Orthostatic hypotension	34	0
<i>Vasculitides NEC</i>		
Behcet's syndrome	5	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	3	0
MAGIC syndrome	2	0
Thromboangiitis obliterans	1	0
Vasculitis	58	0
<i>Vena caval embolism and thrombosis</i>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Vascular disorders SOC TOTAL	7607	21
TOTAL REACTIONS FOR DRUG	490234	71 H
TOTAL REPORTS	170337	
TOTAL FATAL OUTCOME REPORTS		71 H