

COVID-19 Vaccine Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Data Lock Date: 23-Nov-2022 18:30:06

All UK spontaneous reports received up to and including 23/11/22 for COVID-19 Vaccine Pfizer/BioNTech.

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

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

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	10	0
Pernicious anaemia	2	0
<i>Anaemias NEC</i>		
Anaemia	155	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	8	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	19	0
Cold type haemolytic anaemia	2	0
Evans syndrome	1	0
Warm autoimmune haemolytic anaemia	2	0
<i>Anaemias haemolytic mechanical factor</i>		
Microangiopathic haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	58	0
Spontaneous haematoma	2	0
<i>Coagulation factor deficiencies</i>		
Acquired antithrombin III deficiency	1	0
Acquired factor VIII deficiency	1	0
Acquired haemophilia	6	0
<i>Coagulopathies</i>		
Abnormal clotting factor	4	0
Antiphospholipid syndrome	8	0
Coagulopathy	35	1
Disseminated intravascular coagulation	3	0
Hypercoagulation	4	0
Thrombotic microangiopathy	5	0
<i>Eosinophilic disorders</i>		
Eosinophilia	13	0
<i>Haematological disorders</i>		
Blood disorder	7	0
Bone marrow disorder	1	0
Bone marrow oedema	1	0
Hypergammaglobulinaemia	1	0
Hyperviscosity syndrome	1	0
Mast cell activation syndrome	16	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	6	0
Intravascular haemolysis	1	0
Jaundice acholuric	1	0

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
<i>Leukocytoses NEC</i>		
Leukocytosis	3	0
Lymphocytic infiltration	1	0
Lymphocytosis	6	0
Neutrophilia	12	0
<i>Leukopenias NEC</i>		
Leukopenia	4	1
Lymphopenia	4	0
<i>Lymphatic system disorders NEC</i>		
Abdominal lymphadenopathy	4	0
Hilar lymphadenopathy	3	0
Lymph node pain	2341	0
Lymph node ulcer	1	0
Lymphadenitis	204	0
Lymphadenopathy	14201	0
Lymphadenopathy mediastinal	1	0
Lymphatic disorder	3	0
Lymphatic insufficiency	1	0
Lymphoid tissue hyperplasia	1	0
Necrotic lymphadenopathy	4	0
Pseudolymphoma	9	0
Retroperitoneal lymphadenopathy	2	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplasia pure red cell	2	0
Aplastic anaemia	1	1
Hypoplastic anaemia	2	0
Myelosuppression	1	0
Pancytopenia	10	0
<i>Neutropenias</i>		
Autoimmune neutropenia	2	0
Neutropenia	46	0
<i>Platelet disorders NEC</i>		
Platelet anisocytosis	1	0
Platelet disorder	5	0
<i>Polycythaemia (excl rubra vera)</i>		
Polycythaemia	3	0
<i>Purpuras (excl thrombocytopenic)</i>		
Purpura non-thrombocytopenic	1	0
<i>Red blood cell abnormal findings NEC</i>		
Macrocytosis	2	0
Polychromasia	2	0
Red blood cell abnormality	3	0
<i>Spleen disorders</i>		
Spleen atrophy	1	0
Spleen disorder	1	0
Splenic haemorrhage	1	0
Splenic infarction	5	0
Splenic lesion	1	0
Splenic thrombosis	2	0
Splenic vein thrombosis	2	0
Splenomegaly	13	0
<i>Thrombocytopenias</i>		
Acquired amegakaryocytic thrombocytopenia	1	0

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Immune thrombocytopenia	93	0
Thrombocytopenia	247	2
Thrombocytopenic purpura	9	0
Thrombosis with thrombocytopenia syndrome	2	0
Thrombotic thrombocytopenic purpura	8	0
<i>Thrombocytoses</i>		
Thrombocytosis	7	0
<i>Thymus disorders</i>		
Thymus enlargement	1	0
<i>White blood cell abnormal findings NEC</i>		
White blood cell disorder	1	0
Blood disorders SOC TOTAL	17677	5

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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	4	1
Atrioventricular block first degree	3	0
Atrioventricular block second degree	5	0
Bifascicular block	1	0
Bundle branch block	2	0
Bundle branch block left	7	0
Bundle branch block right	8	0
Trifascicular block	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	7	0
Atrial thrombosis	1	0
Cardiac disorder	116	3
Cardiac dysfunction	2	0
Cardiac ventricular thrombosis	3	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	10	0
Intracardiac thrombus	8	1
<i>Cardiac hypertensive complications</i>		
Hypertensive heart disease	3	2
<i>Cardiac infections and inflammations NEC</i>		
Cauditis	10	0
<i>Cardiac neoplasms NEC</i>		
Pericardial cyst	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	41	0
Cardiovascular symptom	4	0
Palpitations	6642	1
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	5	0
Heart valve incompetence	4	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	20	2
Congestive cardiomyopathy	9	0
Stress cardiomyopathy	7	0
<i>Coronary artery disorders NEC</i>		
Arteriosclerosis coronary artery	4	0
Coronary artery disease	10	3
Coronary artery dissection	2	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	97	13
Cardiac failure acute	11	2
Cardiac failure chronic	2	0
Cardiac failure congestive	7	4
Cardiogenic shock	6	2
Cardiopulmonary failure	2	1

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Cardiac disorders Cardiac disorders cont'd		
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	11	1
Acute myocardial infarction	33	5
Angina pectoris	366	1
Angina unstable	5	0
Arteriospasm coronary	4	0
Microvascular coronary artery disease	3	0
Myocardial infarction	333	50
Myocardial ischaemia	16	9
Prinzmetal angina	1	0
<i>Left ventricular failures</i>		
Acute left ventricular failure	2	2
Left ventricular failure	7	2
<i>Mitral valvular disorders</i>		
Mitral valve disease	1	0
Mitral valve incompetence	9	0
Mitral valve prolapse	3	0
<i>Myocardial disorders NEC</i>		
Cardiac amyloidosis	1	0
Cardiac aneurysm	1	1
Cardiac ventricular scarring	2	0
Cardiomegaly	64	4
Diastolic dysfunction	1	0
Dilatation ventricular	1	0
Left atrial dilatation	1	0
Left ventricular dysfunction	19	0
Left ventricular enlargement	3	0
Left ventricular hypertrophy	4	0
Myocardial fibrosis	13	0
Myocardial haemorrhage	1	0
Myocardial injury	30	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	3	0
Ventricular hypokinesia	4	0
<i>Noninfectious myocarditis</i>		
Eosinophilic myocarditis	1	0
Hypersensitivity myocarditis	1	0
Myocarditis	753	4
Myocarditis post infection	2	0
Myopericarditis	98	0
<i>Noninfectious pericarditis</i>		
Pericarditis	579	2
Pericarditis constrictive	1	0
Pericarditis lupus	1	0
Pleuropericarditis	1	0

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Cardiac disorders Cardiac disorders cont'd		
<i>Pericardial disorders NEC</i>		
Cardiac tamponade	3	1
Pericardial effusion	56	2
Pericardial fibrosis	1	0
Pericardial haemorrhage	5	3
Pericardial rub	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	209	2
Arrhythmia neonatal	1	0
Bradycardia	83	0
Bradycardia foetal	2	0
Cardiac fibrillation	1	0
Cardiac flutter	660	0
Extrasystoles	235	0
Heart alternation	4	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	62	0
Tachycardia	2686	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	18	0
Atrial fibrillation	340	1
Atrial flutter	50	0
Atrial tachycardia	14	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	10	0
Sinus bradycardia	16	0
Sinus node dysfunction	2	0
Sinus tachycardia	96	0
Supraventricular extrasystoles	6	0
Supraventricular tachycardia	53	0
<i>Tricuspid valvular disorders</i>		
Tricuspid valve incompetence	6	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	143	49
Cardio-respiratory arrest	4	3
Pulseless electrical activity	8	0
Ventricular arrhythmia	6	0
Ventricular extrasystoles	32	0
Ventricular fibrillation	10	1
Ventricular tachycardia	20	0
Cardiac disorders SOC TOTAL	14375	182

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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	20	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	2	0
<i>Cardiac valve disorders congenital</i>		
Bicuspid aortic valve	2	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	3	0
<i>Congenital disorders NEC</i>		
Congenital anomaly	2	0
Foetal malformation	1	0
Heterotaxia	1	0
Multiple congenital abnormalities	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	5	0
Hypermobility syndrome	1	0
<i>Diaphragmatic disorders congenital</i>		
Congenital diaphragmatic hernia	1	0
<i>Gastrointestinal tract disorders congenital NEC</i>		
Gastroschisis	3	0
<i>Gene mutations and other alterations NEC</i>		
PRPF8 gene mutation	1	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

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Congenital disorders Congenital disorders cont'd		
<i>Inborn errors of bilirubin metabolism</i>		
Gilbert's syndrome	1	0
<i>Inborn errors of metabolism NEC</i>		
Acetylcholinesterase deficiency	1	0
Alpha-1 antitrypsin deficiency	1	0
<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 face, neck and jaw congenital</i>		
Hypertelorism	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>		
Craniosynostosis	1	0
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
Sjogren-Larsson syndrome	1	0
Tourette's disorder	5	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	2	0
<i>Pulmonary and bronchial disorders congenital</i>		
Congenital pulmonary airway malformation	1	0
Cystic fibrosis	1	0
Pulmonary hypoplasia	1	0
<i>Renal disorders congenital</i>		
Congenital cystic kidney disease	1	0
Renal dysplasia	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>		

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Congenital disorders Congenital disorders cont'd		
Acral peeling skin syndrome	1	0
<i>Thyroid disorders congenital</i>		
Congenital hypothyroidism	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	124	1

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	40	0
Ear discomfort	113	0
Ear disorder	27	0
Ear haemorrhage	16	0
Ear inflammation	3	0
Ear pain	1227	0
Ear pruritus	12	0
Ear swelling	41	0
Otorrhoea	8	0
Ototoxicity	1	0
Paraesthesia ear	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	6	0
Eustachian tube dysfunction	14	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	331	0
Deafness bilateral	15	0
Deafness neurosensory	28	0
Deafness transitory	10	0
Deafness unilateral	42	0
Hypoacusis	240	0
Mixed deafness	1	0
Sudden hearing loss	56	0
<i>Hyperacusia</i>		
Hyperacusis	87	0
Misophonia	3	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	2	0
Inner ear disorder	15	0
Meniere's disease	17	0
Vestibular disorder	17	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	73	0
Phobic postural vertigo	1	0

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Ear disorders Ear disorders cont'd		
Tinnitus	2684	0
Vertigo	1742	0
Vertigo labyrinthine	14	0
Vertigo positional	92	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	6	0
Ear disorders SOC TOTAL	7046	0

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Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	7	0
Thyroiditis	24	0
Thyroiditis acute	4	0
Thyroiditis subacute	10	0
<i>Adrenal cortical hyperfunctions</i>		
Cushingoid	1	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	4	0
Adrenal insufficiency	3	0
Adrenocortical insufficiency acute	19	0
<i>Adrenal gland disorders NEC</i>		
Adrenal disorder	4	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>Endocrine disorders NEC</i>		
Endocrine disorder	1	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	68	0
Ovulation delayed	35	0
<i>Hyperparathyroid disorders</i>		
Hyperparathyroidism	1	0
<i>Hypoparathyroid disorders</i>		
Hypoparathyroidism	1	0
<i>Male gonadal function disorders</i>		
Androgen deficiency	1	0
<i>Posterior pituitary disorders</i>		
Inappropriate antidiuretic hormone secretion	1	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0
Goitre	18	0
Thyroid disorder	15	0
Thyroid mass	4	0
Thyroid pain	14	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	17	0
Hyperthyroidism	62	0
Primary hyperthyroidism	1	0
Thyrotoxic crisis	6	0
<i>Thyroid hypofunction disorders</i>		
Autoimmune hypothyroidism	1	0
Hypothyroidic goitre	1	0
Hypothyroidism	52	0

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Endocrine disorders Endocrine disorders cont'd		
Immune-mediated hypothyroidism	1	0
Myxoedema	1	0
Thyroid neoplasms		
Thyroid cyst	1	0
Endocrine disorders SOC TOTAL	414	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	9	0
<i>Anterior chamber bleeding and vascular disorders</i>		
Spontaneous hyphaema	1	0
<i>Cataract conditions</i>		
Cataract	18	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	24	0
Vitreous floaters	131	0
<i>Colour blindness (incl acquired)</i>		
Colour blindness acquired	2	0
Dyschromatopsia	16	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	56	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	6	0
<i>Corneal structural change, deposit and degeneration</i>		
Corneal scar	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	174	0
Excessive eye blinking	7	0
Eyelid function disorder	3	0
Eyelid myokymia	5	0
Eyelid ptosis	55	0
Paralytic lagophthalmos	2	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	2	0
Glaucoma	10	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	61	0
Vogt-Koyanagi-Harada disease	1	0
<i>Lacrimation disorders</i>		
Dry eye	186	0
Lacrimation decreased	1	0

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Lacrimation increased	175	0
<i>Lid bleeding and vascular disorders</i>		
Eyelid bleeding	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	21	0
Blepharitis allergic	1	0
Chalazion	8	0
Eczema eyelids	11	0
Erythema of eyelid	12	0
Eyelid cyst	7	0
Eyelid irritation	4	0
Eyelid margin crusting	6	0
Eyelid oedema	16	0
Eyelid rash	20	0
Meibomian gland dysfunction	1	0
Swelling of eyelid	157	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	5	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	4	0
Eye haemorrhage	42	0
Ocular vascular disorder	2	0
Ophthalmic vein thrombosis	1	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	10	0
Eye disorder	45	0
Eye oedema	20	0
Eye pain	1361	0
Eye swelling	680	0
Eye symptom	10	0
Eye ulcer	6	0
Eyelid disorder	17	0
Eyelid pain	16	0
Eyelids pruritus	8	0
Ocular discomfort	37	0
Periorbital oedema	22	0
Periorbital pain	5	0
Periorbital swelling	140	0
Retinal disorder	2	0
Vitreous disorder	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	22	0

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Eye discharge	36	0
Eye inflammation	43	0
Eye irritation	112	0
Eye pruritus	298	0
Limbal swelling	4	0
Ocular hyperaemia	280	0
Ocular vasculitis	1	0
Ocular nerve and muscle disorders		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Eye movement disorder	48	0
Gaze palsy	3	0
Ocular myasthenia	1	0
Ophthalmoplegia	11	0
Strabismus	10	0
Ocular sensation disorders		
Abnormal sensation in eye	26	0
Asthenopia	179	0
Eye paraesthesia	2	0
Eyelid sensory disorder	3	0
Foreign body sensation in eyes	19	0
Hypoaesthesia eye	20	0
Photophobia	542	0
Optic disc abnormalities NEC		
Optic disc disorder	1	0
Optic discs blurred	1	0
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	5	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Papillophlebitis	1	0
Retinal artery occlusion	18	0
Retinal artery thrombosis	2	0
Retinal haemorrhage	13	0
Retinal ischaemia	1	0
Retinal vascular thrombosis	1	0

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Retinal vein occlusion	54	0
Retinal vein thrombosis	3	0
<i>Retinal structural change, deposit and degeneration</i>		
Age-related macular degeneration	1	0
Chorioretinal disorder	1	0
Dry age-related macular degeneration	1	0
Epiretinal membrane	1	0
Macular cherry-red spots	1	0
Macular degeneration	6	0
Macular hole	4	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	4	0
Retinal degeneration	1	0
Retinal detachment	9	0
Retinal tear	4	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
Diabetic retinal oedema	1	0
Macular oedema	8	0
Retinal oedema	3	0
Retinal vasculitis	3	0
<i>Retinopathies NEC</i>		
Acute macular neuroretinopathy	3	0
Central serous chorioretinopathy	11	0
Diabetic retinopathy	1	0
Retinal exudates	3	0
Retinopathy	5	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	200	0
Dysmetropsia	1	0
Glare	1	0
Halo vision	12	0
Heteronymous diplopia	1	0
Metamorphopsia	26	0

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Oscillopsia	3	0
Photopsia	175	0
Scintillating scotoma	4	0
Vision blurred	1522	0
Visual brightness	3	0
Visual snow syndrome	8	0
Visual field disorders		
Visual field defect	43	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	5	0
Blindness	180	0
Blindness cortical	1	0
Blindness transient	23	0
Blindness unilateral	21	0
Central vision loss	6	0
Sudden visual loss	7	0
Visual acuity reduced	31	0
Visual acuity reduced transiently	1	0
Visual impairment	503	0
Visual pathway disorders		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	8461	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

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	21	0
Pancreatitis acute	19	1
Pancreatitis chronic	1	0
Pancreatitis necrotising	3	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	16	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 spasm	1	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	62	1
Colitis ischaemic	1	0
Colitis microscopic	4	0
Colitis ulcerative	86	0
Crohn's disease	54	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	13	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	2	0
Periodontal inflammation	1	0
<i>Dental developmental disorders and anomalies</i>		

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022
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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Tooth impacted	1	0
Dental disorders NEC		
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
Dental pain and sensation disorders		
Dental discomfort	8	0
Dental paraesthesia	16	0
Hyperaesthesia teeth	39	0
Toothache	206	0
Dental surface disorders		
Tooth discolouration	10	0
Diaphragmatic hernias		
Hiatus hernia	9	0
Diarrhoea (excl infective)		
Diarrhoea	6420	0
Diarrhoea haemorrhagic	29	0
Diverticula		
Diverticulum	7	0
Diverticulum intestinal	1	0
Duodenal and small intestinal stenosis and obstruction		
Small intestinal obstruction	4	0
Duodenal ulcers and perforation		
Duodenal ulcer	1	0
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	3	0
Dyspeptic signs and symptoms		
Dyspepsia	576	0
Epigastric discomfort	15	0
Eructation	69	0
Faecal abnormalities NEC		
Abnormal faeces	23	0
Faecaloma	7	0
Faeces discoloured	63	0
Faeces hard	3	0
Faeces pale	5	0
Faeces soft	13	0
Mucous stools	12	0
Flatulence, bloating and distension		
Abdominal distension	625	0
Aerophagia	3	0
Flatulence	213	0
Gastric and oesophageal haemorrhages		
Gastric haemorrhage	5	1
Mallory-Weiss syndrome	1	0
Oesophageal varices haemorrhage	1	0
Gastric ulcers and perforation		
Gastric perforation	1	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastric ulcer	7	0
Gastritis (excl infective)		
Chronic gastritis	4	0
Gastritis	76	0
Reflux gastritis	9	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal migraine	2	0
Abdominal pain	1757	0
Abdominal pain lower	161	0
Abdominal pain upper	2923	0
Abdominal rigidity	27	0
Abdominal tenderness	15	0
Gastrointestinal pain	181	0
Oesophageal pain	14	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	297	0
Duodenogastric reflux	5	0
Gastric dilatation	8	0
Gastrooesophageal reflux disease	213	0
Impaired gastric emptying	10	0
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Intestinal pseudo-obstruction	2	0
Gastrointestinal disorders NEC		
Appendicolith	1	0
Appendix disorder	2	0
Food poisoning	7	0
Functional gastrointestinal disorder	11	0
Gastric disorder	11	0
Gastrointestinal disorder	35	0
Stomach mass	4	0
Gastrointestinal dyskinetic disorders		
Bowel movement irregularity	9	0
Change of bowel habit	15	0
Dyschezia	4	0
Gastrointestinal motility disorder	6	0
Oesophageal achalasia	1	0
Gastrointestinal fistulae		
Diverticular fistula	2	0
Gastrointestinal inflammatory disorders NEC		
Appendicitis noninfective	1	0
Duodenitis	1	0
Enteritis	6	0
Epiploic appendagitis	2	0
Gastrointestinal inflammation	6	0
Gastrointestinal toxicity	1	0
Gastrointestinal tract irritation	1	0
Intestinal angioedema	2	0
Gastrointestinal mucosal dystrophies and secretion disorders		
Barrett's oesophagus	2	0
Hyperchlorhydria	4	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	734	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Abdominal symptom	3	0
Acute abdomen	8	0
Anal incontinence	28	0
Breath odour	23	0
Dysphagia	262	1
Gastrointestinal wall thickening	1	0
Odynophagia	48	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Cardiospasm	1	0
Defaecation urgency	14	0
Frequent bowel movements	36	0
Gastrointestinal hypermotility	1	0
Irritable bowel syndrome	110	0
Oesophageal spasm	6	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 infarction	1	0
Intestinal ischaemia	11	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	14	0
Gingival discomfort	8	0
Gingival disorder	6	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	45	0
Gingival ulceration	3	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	15	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	89	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>		

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Report Run Date: 24-Nov-2022
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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Anal haemorrhage	24	1
Intestinal haemorrhage	1	0
Rectal haemorrhage	88	0
Small intestinal haemorrhage	5	0
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	7	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
Coeliac disease	17	0
Malabsorption	3	0
Steatorrhoea	4	0
<i>Nausea and vomiting symptoms</i>		
Cyclic vomiting syndrome	1	0
Discoloured vomit	13	0
Faecal vomiting	1	0
Infantile vomiting	7	0
Nausea	15873	0
Regurgitation	2	0
Retching	121	0
Vomiting	5554	1
Vomiting projectile	81	0
<i>Non-mechanical ileus</i>		
Ileus paralytic	2	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	20	1
Haematemesis	44	2
Haematochezia	64	0
Melaena	11	0
Upper gastrointestinal haemorrhage	15	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	7	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	7	0
Dry mouth	563	0
Lip dry	52	0
Saliva altered	9	0
Salivary hypersecretion	55	0
<i>Oral soft tissue disorders NEC</i>		
Angina bullosa haemorrhagica	1	0
Chapped lips	30	0
Cheilitis	35	0
Enlarged uvula	15	0
Leukoplakia oral	2	0

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022
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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Lip blister	36	0
Lip disorder	7	0
Oral disorder	25	0
Oral lichen planus	20	0
Oral lichenoid reaction	1	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	7	0
Oral soft tissue haemorrhages		
Lip haemorrhage	2	0
Mouth haemorrhage	25	0
Oral blood blister	20	0
Oral purpura	2	0
Oral soft tissue infections		
Angular cheilitis	5	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	3	0
Burning mouth syndrome	7	0
Coating in mouth	1	0
Hypoaesthesia oral	534	0
Lip discolouration	12	0
Lip erythema	4	0
Lip exfoliation	6	0
Lip pain	68	0
Lip pruritus	19	0
Lip scab	1	0
Oral discomfort	93	0
Oral dysaesthesia	1	0
Oral mucosal blistering	19	0
Oral mucosal discolouration	2	0
Oral mucosal eruption	23	0
Oral mucosal erythema	10	0
Oral mucosal exfoliation	10	0
Oral mucosal roughening	3	0
Oral mucosal scab	2	0
Oral pain	199	0
Oral pruritus	24	0
Paraesthesia oral	1003	0
Pigmentation lip	1	0
Oral soft tissue swelling and oedema		
Lip oedema	5	0
Lip swelling	933	0
Mouth swelling	123	0
Oedema mouth	4	0
Palatal oedema	4	0
Palatal swelling	5	0
Pancreatic disorders NEC		
Pancreatic disorder	5	0
Pancreatic failure	1	0
Pancreatic mass	1	0
Peptic ulcers and perforation		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	14	0

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Earliest Reaction Date: 13-Apr-1968

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	3	0
Peritoneal disorder	1	0
<i>Peritoneal and retroperitoneal fibrosis and adhesions</i>		
Abdominal adhesions	2	0
<i>Peritoneal and retroperitoneal haemorrhages</i>		
Haemoperitoneum	1	0
Retroperitoneal haematoma	1	0
Retroperitoneal haemorrhage	2	1
<i>Rectal inflammations NEC</i>		
Proctitis	4	0
Proctitis ulcerative	2	0
<i>Salivary gland disorders NEC</i>		
Salivary gland disorder	1	0
Salivary gland mucocoele	1	0
Salivary gland pain	14	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	12	0
Salivary gland enlargement	6	0
Submaxillary gland enlargement	7	0
<i>Salivary gland infections and inflammations</i>		
Noninfective sialoadenitis	2	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	62	0
Lip ulceration	23	0
Mouth ulceration	506	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	72	0
<i>Tongue disorders</i>		
Glossitis	24	0
Hypertrophy of tongue papillae	2	0
Plicated tongue	4	0
Tongue disorder	45	0
Tongue geographic	8	0
Tongue haemorrhage	4	0
Tongue ulceration	34	0
Trichoglossia	4	0
<i>Tongue signs and symptoms</i>		
Glossodynia	239	0
Scalloped tongue	5	0
Stiff tongue	4	0
Swollen tongue	569	0
Tongue blistering	19	0
Tongue coated	21	0
Tongue discolouration	42	0
Tongue discomfort	50	0
Tongue dry	17	0
Tongue eruption	12	0
Tongue erythema	14	0
Tongue exfoliation	2	0
Tongue movement disturbance	8	0
Tongue oedema	24	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Tongue pruritus	4	0
Tongue rough	5	0
Tongue spasm	12	0
Tooth missing		
Tooth loss	6	0
Gastrointestinal disorders SOC TOTAL	44248	18

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	9	0
Administration site erythema	4	0
Administration site extravasation	3	0
Administration site haematoma	3	0
Administration site inflammation	1	0
Administration site irritation	1	0
Administration site joint discomfort	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	44	0
Puncture site pain	10	0
Puncture site reaction	1	0
Puncture site swelling	2	0
Vessel puncture site bruise	2	0
Vessel puncture site erythema	1	0
Vessel puncture site pain	1	0
<i>Adverse effect absent</i>		
No adverse event	10	0
<i>Application and instillation site reactions</i>		
Application site acne	2	0
Application site bruise	12	0
Application site burn	1	0
Application site dryness	2	0
Application site erythema	18	0
Application site haemorrhage	1	0
Application site hypoaesthesia	2	0
Application site irritation	1	0
Application site joint erythema	1	0
Application site joint pain	1	0
Application site mass	1	0
Application site odour	2	0
Application site pain	13	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	2578	0
Chronic fatigue syndrome	93	0
Decreased activity	10	0
Fatigue	27251	1
Malaise	6181	2

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Sluggishness	20	0
Body temperature altered		
Hyperthermia	8	0
Hyperthermia malignant	1	0
Hypothermia	29	0
Poikilothermia	1	0
Temperature regulation disorder	17	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 pain	1	0
Medical device site swelling	1	0
Phantom shocks	2	0
Death and sudden death		
Brain death	4	3
Cardiac death	3	2
Clinical death	1	1
Death	212	212
Death neonatal	1	1
Sudden cardiac death	2	2
Sudden death	32	32
Febrile disorders		
Hyperpyrexia	11	0
Pyrexia	17644	0
Feelings and sensations NEC		
Chills	10897	0
Feeling abnormal	1947	0
Feeling cold	1449	0
Feeling drunk	85	0
Feeling hot	1346	0
Feeling jittery	39	0
Feeling of body temperature change	382	0
Feeling of relaxation	3	0
Hangover	88	0
Hunger	52	0
Sensation of blood flow	5	0
Sensation of foreign body	67	0
Sense of oppression	1	0
Temperature intolerance	60	0
Thirst	397	0
Thirst decreased	2	0
Fibrosis NEC		
Fibrosis	3	0
Gait disturbances		
Gait deviation	1	0
Gait disturbance	324	0

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Gait inability	138	0
Loss of control of legs	29	0
General signs and symptoms NEC		
Adhesion	2	0
Chronic disease	1	0
Concomitant disease progression	1	1
Condition aggravated	382	0
Crepitations	5	0
Crying	174	0
Deformity	2	0
Developmental delay	1	0
Discharge	14	0
Disease progression	2	0
Disease recurrence	35	0
Effusion	3	0
Energy increased	27	0
Exercise tolerance decreased	48	0
Exercise tolerance increased	2	0
Fat tissue increased	1	0
Foaming at mouth	3	0
General physical health deterioration	21	3
General symptom	3	0
Glassy eyes	8	0
High-pitched crying	3	0
Illness	2393	0
Induration	18	0
Influenza like illness	2789	0
Irritability postvaccinal	2	0
Local reaction	95	0
Moaning	4	0
Multiple organ dysfunction syndrome	16	6
Nonspecific reaction	2	0
Organ failure	5	2
Perforation	2	0
Peripheral swelling	4638	0
Physical deconditioning	2	0
Pre-existing condition improved	9	0
Prolapse	1	0
Screaming	24	0
Secretion discharge	29	0
Stenosis	1	0
Swelling	3713	0
Swelling face	1035	0
Symptom recurrence	1	0
Terminal state	1	0
Tissue irritation	1	0
Tissue rupture	1	0
Unevaluable event	1	0
Xerosis	1	0
Healing abnormal NEC		
Impaired healing	7	0
Implant and catheter site reactions		
Catheter site pain	1	0

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Implant site discolouration	2	0
Implant site pain	3	0
Implant site rash	1	0
Implant site reaction	1	0
Implant site swelling	2	0
Implant site urticaria	1	0
Implant site warmth	3	0
Inflammations		
Chronic inflammatory response syndrome	1	0
Foreign body reaction	1	0
Granuloma	2	0
Inflammation	706	0
Papillitis	1	0
Scar inflammation	3	0
Serositis	1	0
Soft tissue inflammation	1	0
Systemic inflammatory response syndrome	7	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	37	0
Injection site bruising	74	0
Injection site coldness	1	0
Injection site cyst	3	0
Injection site discharge	1	0
Injection site discolouration	6	0
Injection site discomfort	10	0
Injection site eczema	1	0
Injection site erythema	458	0
Injection site haematoma	2	0
Injection site haemorrhage	11	0
Injection site hypersensitivity	3	0
Injection site hypoaesthesia	17	0
Injection site indentation	10	0
Injection site induration	4	0
Injection site inflammation	52	0
Injection site injury	2	0
Injection site irritation	3	0
Injection site joint discomfort	2	0
Injection site joint erythema	5	0
Injection site joint movement impairment	1	0
Injection site joint pain	15	0
Injection site lymphadenopathy	1	0

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site macule	1	0
Injection site mass	667	0
Injection site movement impairment	1	0
Injection site muscle atrophy	1	0
Injection site muscle weakness	1	0
Injection site necrosis	4	0
Injection site nerve damage	1	0
Injection site nodule	1	0
Injection site oedema	21	0
Injection site pain	3307	0
Injection site pallor	1	0
Injection site paraesthesia	15	0
Injection site pruritus	264	0
Injection site rash	213	0
Injection site reaction	59	0
Injection site scab	4	0
Injection site scar	4	0
Injection site swelling	366	0
Injection site urticaria	38	0
Injection site vesicles	11	0
Injection site warmth	213	0
Interactions		
Alcohol interaction	5	0
Drug interaction	33	0
Drug-device interaction	2	0
Inhibitory drug interaction	3	0
Mass conditions NEC		
Cyst	62	0
Mass	96	0
Nodule	47	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	6	0
Necrosis NEC		
Fat necrosis	4	0
Necrosis	5	0
Oedema NEC		
Face oedema	41	0
Generalised oedema	7	0
Localised oedema	21	0
Oedema	102	0
Oedema peripheral	111	0
Pain and discomfort NEC		
Axillary pain	4184	0
Breakthrough pain	1	0
Chest discomfort	2161	0
Chest pain	7290	0
Discomfort	603	0

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Facial discomfort	23	0
Facial pain	251	0
First bite syndrome	1	0
Inflammatory pain	24	0
Non-cardiac chest pain	36	0
Pain	10445	0
Suprapubic pain	1	0
Tenderness	758	0
Visceral pain	2	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	375	2
Adverse food reaction	5	0
Adverse reaction	2	0
Drug ineffective	701	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	31	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	106	0
Therapy non-responder	1	0
Treatment failure	12	0
Vaccination failure	161	0
Trophic disorders		
Abnormal organ growth	1	0
Atrophy	3	0
Calcinosis	2	0
Hyperplasia	1	0
Hypertrophy	2	0
Ulcers NEC		
Ulcer	39	0
Ulcer haemorrhage	2	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	25	0
Shoulder injury related to vaccine administration	78	0
Vaccination site anaesthesia	1	0
Vaccination site bruising	146	0
Vaccination site coldness	4	0
Vaccination site cyst	7	0
Vaccination site dermatitis	2	0
Vaccination site discharge	1	0
Vaccination site discolouration	18	0
Vaccination site discomfort	54	0
Vaccination site dryness	2	0
Vaccination site eczema	1	0
Vaccination site erythema	697	0
Vaccination site granuloma	5	0

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site haematoma	2	0
Vaccination site haemorrhage	36	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	17	0
Vaccination site joint discomfort	3	0
Vaccination site joint erythema	12	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	23	0
Vaccination site joint pain	38	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	345	0
Vaccination site movement impairment	100	0
Vaccination site necrosis	1	0
Vaccination site nerve damage	1	0
Vaccination site nodule	6	0
Vaccination site oedema	4	0
Vaccination site pain	2465	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	196	0
Vaccination site rash	158	0
Vaccination site reaction	37	0
Vaccination site scab	4	0
Vaccination site scar	3	0
Vaccination site swelling	667	0
Vaccination site thrombosis	1	0
Vaccination site ulcer	3	0
Vaccination site urticaria	11	0
Vaccination site vesicles	14	0
Vaccination site warmth	310	0
<i>Vascular complications associated with device</i>		
Vascular stent thrombosis	1	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	4	0
Rebound effect	2	0
Withdrawal syndrome	48	0
General disorders SOC TOTAL	127421	270

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	20	0
Cholangitis	2	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	4	0
Cholecystitis acute	4	0
Cholelithiasis	15	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	2	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Hepatic cyst	1	0
Hepatic lesion	1	0
Liver disorder	18	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	11	0
Hypertransaminasaemia	5	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	2	0
Hepatic failure	3	1
<i>Hepatic fibrosis and cirrhosis</i>		
Cirrhosis alcoholic	1	0
Hepatic cirrhosis	3	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	11	0
Portosplenomesenteric venous thrombosis	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	40	0
Hepatomegaly	7	0
Hepatosplenomegaly	1	0
Liver tenderness	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	16	0
Drug-induced liver injury	3	0
Hepatic steatosis	7	0
Hepatitis	19	0
Hepatitis acute	5	0
Hepatitis toxic	2	0
Hepatotoxicity	1	0
Immune-mediated hepatic disorder	1	0
Liver injury	31	0
<i>Obstructive bile duct disorders (excl neoplasms)</i>		
Bile duct stenosis	1	0

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Hepatic disorders Hepatic disorders cont'd		
Hepatic disorders SOC TOTAL	299	1

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Loefgren syndrome	1	0
Sarcoidosis	22	0
<i>Allergic conditions NEC</i>		
Allergic oedema	20	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
Dust allergy	1	0
Hypersensitivity	1215	0
Infusion related hypersensitivity reaction	3	0
Mite allergy	2	0
Multiple allergies	20	0
Serum sickness	3	0
Serum sickness-like reaction	8	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	8	0
Allergy to vaccine	51	0
Caffeine allergy	1	0
Contrast media reaction	2	0
Drug hypersensitivity	45	0
Food allergy	50	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	6	0
Rubber sensitivity	1	0
Smoke sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	586	1
Anaphylactic shock	70	0
Anaphylactoid reaction	27	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	3	0
Seasonal allergy	119	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	72	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	68	0
Cytokine release syndrome	1	0
Cytokine storm	2	0

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Immune system disorders		
Immune system disorders cont'd		
Decreased immune responsiveness	4	0
Graft versus host disease	2	0
Haemophagocytic lymphohistiocytosis	4	0
Immune reconstitution inflammatory syndrome	1	0
Immune system disorder	44	0
Immune-mediated adverse reaction	7	0
Immunisation reaction	63	0
Multisystem inflammatory syndrome in children	6	0
Sensitisation	10	0
Systemic immune activation	2	0
Immunodeficiency disorders NEC		
Hypogammaglobulinaemia	1	0
Immunodeficiency	8	0
Immunosuppression	5	0
Transplant rejections		
Corneal graft rejection	10	0
Kidney transplant rejection	2	0
Solid organ transplant rejection	1	0
Transplant rejection	2	0
Vasculitides		
Anti-neutrophil cytoplasmic antibody positive vasculitis	2	0
Immune system disorders SOC TOTAL	2641	1

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Abdominal abscess	3	0
Abdominal infection	2	0
Anal abscess	4	0
Anorectal infection	1	0
Appendicitis	52	0
Appendicitis perforated	7	0
Complicated appendicitis	1	0
Diarrhoea infectious	1	0
Diverticulitis	22	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	37	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	18	0
Bacterial sepsis	1	0
Bacterial vaginosis	2	0
Cellulitis	217	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	5	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 Vaccine Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Bartonella infections</i>		
Cat scratch disease	1	0
<i>Bone and joint infections</i>		
Abscess jaw	1	0
Arthritis infective	3	0
Intervertebral discitis	1	0
Joint abscess	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	6	0
Relapsing fever	1	0
<i>Breast infections</i>		
Breast abscess	4	0
Mastitis	91	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	2	0
Candida infection	77	0
Oral candidiasis	46	0
Respiratory moniliasis	1	0
Skin candida	2	0
Systemic candida	1	0
Urinary tract candidiasis	1	0
Vulvovaginal candidiasis	59	0
<i>Cardiac infections</i>		
Cardiac infection	2	0
Cardiac valve vegetation	1	0
Endocarditis	5	0
Myocarditis infectious	1	0
Myocarditis septic	1	0
Pericarditis infective	4	0
<i>Central nervous system and spinal infections</i>		
Brain abscess	2	0
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	24	0
Encephalomyelitis	1	0
Extradural abscess	1	0
Meningitis	11	0
Meningitis aseptic	4	0
Myelitis	15	0
Subdural abscess	1	0
<i>Clostridia infections</i>		
Clostridium difficile infection	2	0

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Tetanus	1	0
Coronavirus infections		
Asymptomatic COVID-19	22	0
COVID-19	3461	42
COVID-19 pneumonia	57	18
Coronavirus infection	8	0
Coronavirus pneumonia	1	0
Post-acute COVID-19 syndrome	23	0
Severe acute respiratory syndrome	4	0
Suspected COVID-19	123	4
Corynebacteria infections		
Diphtheria	2	0
Coxiella infections		
Q fever	13	0
Cytomegaloviral infections		
Cytomegalovirus colitis	1	0
Cytomegalovirus hepatitis	1	0
Cytomegalovirus infection	3	0
Cytomegalovirus syndrome	1	0
Dental and oral soft tissue infections		
Abscess oral	6	0
Gingival abscess	2	0
Gingivitis	17	0
Ludwig angina	1	0
Oral infection	1	0
Oral pustule	1	0
Parotitis	16	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
Ear infections		
Ear infection	106	0
Labyrinthitis	120	0
Mastoiditis	3	0
Otitis externa	8	0
Otitis media	4	0
Otitis media acute	1	0
Otitis media chronic	5	0
Ectoparasitic infestations		
Acarodermatitis	7	0
Bed bug infestation	1	0
Demodicidosis	1	0
Lice infestation	1	0
Enteroviral infections NEC		
Enterovirus infection	1	0
Epstein-Barr viral infections		
Epstein-Barr virus infection	6	0
Epstein-Barr virus infection reactivation	3	0
Infectious mononucleosis	31	0

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Escherichia infections</i>		
Escherichia bacteraemia	1	0
Escherichia infection	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	90	0
Eye abscess	1	0
Eye infection	31	0
Eye infection intraocular	1	0
Eyelid boil	2	0
Eyelid infection	2	0
Hordeolum	31	0
Keratouveitis	1	0
Orbital infection	1	0
Periorbital infection	2	0
<i>Female reproductive tract infections</i>		
Bartholin's abscess	1	0
Bartholinitis	1	0
Endometritis	3	0
Fallopian tube abscess	1	0
Funisitis	1	0
Ovarian abscess	1	0
Parametritis	1	0
Pelvic inflammatory disease	2	0
Vaginal infection	3	0
Vulval abscess	1	0
Vulvitis	1	0
<i>Fungal infections NEC</i>		
Fungal infection	23	0
Fungal skin infection	8	0
Mycotoxicosis	1	0
Myocarditis mycotic	2	0
Onychomycosis	4	0
Oral fungal infection	2	0
Pneumonia fungal	4	0
Severe asthma with fungal sensitisation	2	0
Vulvovaginal mycotic infection	8	0
<i>Helicobacter infections</i>		
Helicobacter infection	1	0
<i>Helminthic infections NEC</i>		
Helminthic infection	1	0
<i>Hepatitis virus infections</i>		
Hepatitis A	2	0
Hepatitis E	1	0
<i>Hepatobiliary and spleen infections</i>		
Biliary sepsis	3	0
Cholecystitis infective	3	0
Hepatic infection	1	0
Liver abscess	1	0
<i>Herpes viral infections</i>		
Eczema herpeticum	4	0
Genital herpes	99	0
Genital herpes simplex	6	0
Genital herpes zoster	1	0

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Herpes ophthalmic	3	0
Herpes simplex	38	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	3	0
Herpes virus infection	13	0
Herpes zoster	1722	0
Herpes zoster disseminated	1	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	18	0
Herpes zoster reactivation	5	0
Meningitis herpes	1	0
Nasal herpes	5	0
Ophthalmic herpes simplex	3	0
Ophthalmic herpes zoster	7	0
Oral herpes	362	0
Varicella	41	0
Varicella zoster virus infection	7	0
Infections NEC		
Abscess	41	0
Abscess limb	9	0
Abscess soft tissue	1	0
Catheter site infection	1	0
Device related infection	1	0
Genital abscess	2	0
Groin abscess	2	0
Groin infection	1	0
Infected bite	3	0
Infected cyst	2	0
Infection	300	0
Infection susceptibility increased	3	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	43	0
Lymph gland infection	19	0
Lymph node abscess	7	0
Opportunistic infection	1	0
Pathogen resistance	1	0
Purulent discharge	1	0
Pyuria	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	4	0
Wound infection	2	0
Infectious transmissions		
Nosocomial infection	1	0
Secondary transmission	8	0
Vaccine virus shedding	1	0
Influenza viral infections		
H1N1 influenza	1	0
Influenza	1874	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
<i>Klebsiella infections</i>		
Klebsiella infection	1	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	31	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	336	10
Lung abscess	1	0
Pneumonia	203	17
Pneumonia aspiration	11	7
Sputum purulent	1	0
<i>Male reproductive tract infections</i>		
Epididymitis	11	0
Orchitis	7	0
Prostate infection	2	0
<i>Molluscum contagiosum viral infections</i>		
Molluscum contagiosum	2	0
<i>Mumps viral infections</i>		
Mumps	9	0
<i>Muscle and soft tissue infections</i>		
Abscess neck	1	0
Infective tenosynovitis	1	0
Necrotising fasciitis	2	0
Psoas abscess	1	0
Soft tissue infection	3	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	3	0
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	2	0
<i>Pseudomonas 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	2	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	84	12
Sepsis syndrome	2	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Septic rash	4	0
Septic shock	9	3
Urosepsis	6	0
Skin structures and soft tissue infections		
Abscess sweat gland	1	0
Acne pustular	1	0
Blister infected	1	0
Dermatitis infected	3	0
Eczema infected	2	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	13	0
Skin infection	36	0
Subcutaneous abscess	12	0
Sweat gland infection	1	0
Vaccination site pustule	4	0
Staphylococcal infections		
Furuncle	48	1
Pneumonia staphylococcal	1	0
Septic arthritis staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	6	0
Staphylococcal sepsis	1	0
Streptococcal infections		
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
Tinea infections		
Body tinea	6	0
Tinea capitis	1	0
Tinea infection	1	0
Tinea pedis	4	0
Tinea versicolour	6	0
Toxoplasma infections		
Toxoplasmosis	1	0
Treponema infections		
Syphilis	2	0
Trypanosomal infections		
African trypanosomiasis	5	0
Tuberculous infections		
Disseminated Bacillus Calmette-Guerin infection	1	0
Lymph node tuberculosis	1	0
Pulmonary tuberculosis	1	0
Tuberculosis	1	0

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022
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Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Tuberculosis of central nervous system	1	0
Upper respiratory tract infections		
Acute sinusitis	5	0
Chronic sinusitis	7	0
Croup infectious	1	0
Epiglottitis	3	0
Laryngitis	37	0
Nasopharyngitis	1230	1
Peritonsillar abscess	6	0
Pharyngitis	41	0
Rhinitis	59	0
Sinusitis	219	0
Tonsillitis	147	0
Tracheitis	5	0
Tracheostomy infection	1	0
Upper respiratory tract infection	12	0
Urinary tract infections		
Cystitis	92	0
Kidney infection	58	0
Pyelonephritis	3	0
Urethritis	3	0
Urinary tract infection	232	0
Vascular infections		
Haematoma infection	1	0
Infected lymphocele	2	0
Infusion site infection	1	0
Lymphangitis	15	0
Viral infections NEC		
Arthritis viral	2	0
Conjunctivitis viral	3	0
Ear infection viral	1	0
Encephalitis viral	6	1
Eye infection viral	2	0
Gastroenteritis viral	35	0
Gianotti-Crosti syndrome	1	0
Hepatitis viral	4	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	69	0
Sweating fever	137	0
Vestibular neuronitis	37	0
Viral diarrhoea	2	0
Viral infection	72	0
Viral labyrinthitis	4	0
Viral myocarditis	5	0
Viral pericarditis	4	0
Viral pharyngitis	25	0
Viral rash	71	0
Viral sinusitis	1	0
Viral tonsillitis	2	0

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Infections SOC TOTAL	13600	122

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Name: COVID-19 Vaccine Pfizer/BioNTech Vaccine Analysis Print

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Gallbladder injury	1	0
Gingival injury	1	0
Liver contusion	1	0
Mouth injury	4	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
Anaesthetic complication neurological	1	0
Delayed recovery from anaesthesia	3	0
Sedation complication	1	0
<i>Atmospheric pressure injuries</i>		
Barotitis media	1	0
Barotrauma	2	0
Hypobarism	3	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>		
Aortic injury	1	0
Vascular injury	9	0
<i>Cerebral injuries NEC</i>		
Brain contusion	4	0
Brain herniation	3	0
Concussion	5	0
Craniocerebral injury	2	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

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Conditions caused by cold</i>		
Chillblains	76	0
Cold shock response	1	0
Frostbite	1	0
<i>Cranial nerve injuries</i>		
IIIrd nerve injury	1	0
Optic 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	11	0
Exposure via breast milk	155	0
Foetal exposure during pregnancy	81	0
Foetal exposure timing unspecified	1	0
Maternal exposure before pregnancy	33	0
Maternal exposure during breast feeding	2053	0
Maternal exposure during pregnancy	1124	0
Maternal exposure timing unspecified	16	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	19	0
Eye injury	33	0
Foreign body in eye	5	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>		
Diversion colitis	1	0
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	15	0
Heat stroke	4	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Intentional product use issues</i>		
Intentional product use issue	1	0
<i>Limb fractures and dislocations</i>		
Ankle fracture	1	0
Atypical femur fracture	1	0
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
Osteochondral fracture	1	0
Tibia fracture	1	0
Upper limb fracture	1	0
Wrist fracture	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Circumstance or information capable of leading to medication error	2	0
Dose calculation error	1	0
Inadequate aseptic technique in use of product	1	0
Medication error	177	0
Prescription drug used without a prescription	3	0
Product use complaint	2	0
Product use in unapproved indication	1	0
Product use issue	44	0
Vaccination error	6	0
Wrong dose	4	0
Wrong drug	11	0
Wrong schedule	1	0
Wrong technique in product usage process	12	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	25	0
Ligament injury	2	0
Ligament sprain	12	0
Mallet finger	1	0
Muscle hernia	1	0
Muscle injury	47	0
Muscle rupture	11	0
Muscle strain	40	0
Post-traumatic neck syndrome	3	0
Tendon injury	7	0
Tendon rupture	26	0
<i>Musculoskeletal procedural complications</i>		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	133	0
<i>Neurological and psychiatric procedural complications</i>		
Post lumbar puncture syndrome	2	0
Post procedural stroke	1	0
Procedural dizziness	14	0
<i>Non-occupational environmental exposures</i>		
Exposure to extreme temperature	2	0
<i>Non-site specific injuries NEC</i>		

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Accident	2	0
Animal scratch	1	0
Arthropod bite	11	0
Arthropod sting	6	0
Bite	1	0
Bone contusion	2	0
Crush injury	1	0
Electric shock	25	0
Fall	237	0
Foreign body	6	0
Injury	15	0
Multiple injuries	2	0
Musculoskeletal injury	1	0
Nervous system injury	3	0
Post concussion syndrome	2	0
Traumatic haematoma	1	0
Wound	10	0
Wound complication	12	0
Wound haematoma	1	0
Wound haemorrhage	5	0
Wound necrosis	1	1
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	77	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	565	0
Overdoses NEC		
Intentional overdose	1	0
Overdose	57	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
Peripheral nerve injury	1	0
Radial nerve injury	2	0
Sciatic nerve injury	2	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Ulnar nerve injury	6	0
Poisoning and toxicity		
Alcohol poisoning	1	0
Poisoning	14	0
Toxicity to various agents	7	0
Product administration errors and issues		
Accidental overdose	8	0
Contraindicated product administered	3	0
Duplicate therapy error	1	0
Expired product administered	15	0
Inappropriate schedule of product administration	756	0
Incomplete course of vaccination	2	0
Incorrect dose administered	76	0
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	13	0
Lack of vaccination site rotation	1	0
Poor quality product administered	5	0
Product administered at inappropriate site	28	0
Product administered to patient of inappropriate age	4	0
Product administration error	22	0
Product dose omission issue	6	0
Wrong product administered	24	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	5	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
Product storage errors and issues in the product use system		
Product storage error	1	0
Radiation injuries		
Sunburn	25	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		

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
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	220	0
Nasal injury	2	0
Neck crushing	1	0
Neck injury	1	0
Pharyngeal contusion	1	0
Site specific procedural complications NEC		
Axillary web syndrome	3	0
Skin injuries NEC		
Contusion	1439	0
Hair injury	3	0
Nail avulsion	1	0
Scar	40	0
Scratch	9	0
Skin abrasion	7	0
Skin injury	6	0
Skin laceration	4	0
Skin pressure mark	1	0
Skin wound	4	0
Splinter	1	0
Subcutaneous haematoma	2	0
Skin procedural complications		
Dermal filler overcorrection	1	0
Recall phenomenon	1	0
Skin procedural complication	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	1	0
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	2	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	6	0
Burns second degree	3	0
Burns third degree	1	0
Cold burn	1	0
Thermal burn	29	0

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Thermal burns of eye	17	0
<i>Underdoses NEC</i>		
Underdose	6	0
<i>Vaccination related complications</i>		
Adverse event following immunisation	2	0
Post vaccination syndrome	1	0
Vaccination complication	1	0
Injuries SOC TOTAL	8504	2

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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	4	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	3	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	13	0
Oxygen consumption	1	0
Oxygen consumption decreased	2	0
Oxygen saturation	12	0
Oxygen saturation abnormal	2	0
Oxygen saturation decreased	109	0
Oxygen saturation increased	1	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

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood glucose decreased	39	0
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	55	0
Heart sounds	10	0
Heart sounds abnormal	6	0
Cardiac function diagnostic procedures		
Cardiac monitoring	1	0
Cardiac output	2	0
Central venous pressure	1	0
Echocardiogram	1	0
Ejection fraction decreased	4	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	5	0
Central nervous system imaging procedures		
Computerised tomogram head	11	0
Magnetic resonance imaging head	13	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	2	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 abnormal	1	0
Blood cholesterol increased	17	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	12	0

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 24-Nov-2022
Earliest Reaction Date: 13-Apr-1968

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Bleeding time shortened	1	0
Blood thromboplastin	1	0
Clot retraction	1	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	9	0
Coagulation time shortened	4	0
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	54	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	13	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	90	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		
Amniocentesis abnormal	1	0
Amniotic fluid volume decreased	1	0
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		

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Gastric pH decreased	4	0
<i>Gastrointestinal, pancreatic and APUD hormone analyses</i>		
Blood insulin	2	0
Blood insulin decreased	1	0
<i>Gene analyses</i>		
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	637	0
Heart rate abnormal	87	0
Heart rate decreased	113	0
Heart rate increased	1272	0
Heart rate irregular	322	0
Heart rate normal	1	0
Heart rate variability decreased	2	0
Heart rate variability increased	1	0
Maximum heart rate	6	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	1	0
Alanine aminotransferase increased	29	0
Aspartate aminotransferase	1	0
Aspartate aminotransferase abnormal	1	0
Aspartate aminotransferase increased	2	0
Blood bilirubin decreased	1	0
Blood bilirubin increased	7	0
Gamma-glutamyltransferase	2	0
Gamma-glutamyltransferase increased	5	0
Hepatic enzyme	2	0
Hepatic enzyme increased	10	0
Liver function test	1	0
Liver function test abnormal	39	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

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Positron emission tomogram abnormal	1	0
Scan	2	0
X-ray	2	0
<i>Immune response protein analyses NEC</i>		
Cytokine increased	1	0
Cytokine test	1	0
<i>Immunoglobulin analyses</i>		
Blood immunoglobulin E increased	2	0
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	2	0
<i>Immunology analyses NEC</i>		
Antibody test	4	0
Antibody test positive	1	0
Immunology test	16	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	49	0
Blood test normal	1	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	5	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	16	0
Blood iron increased	2	0
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0
Blood phosphorus increased	1	0

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood potassium abnormal	1	0
Blood potassium decreased	5	0
Blood potassium increased	3	0
Blood sodium decreased	11	0
Serum ferritin	2	0
Serum ferritin abnormal	2	0
Serum ferritin decreased	5	0
Serum ferritin increased	3	0
Sweat test	2	0
Urine copper	2	0
<i>Musculoskeletal and soft tissue histopathology procedures</i>		
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
NIH stroke scale score increased	1	0
Nerve conduction studies	1	0
Pain threshold decreased	1	0
Romberg test positive	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	318	0
Body temperature abnormal	57	0
Body temperature decreased	50	0
Body temperature fluctuation	76	0
Body temperature increased	564	0
Body temperature normal	1	0
Breath sounds abnormal	2	0
General physical condition abnormal	1	0
Grip strength	3	0
Grip strength decreased	29	0
Gynaecological examination	1	0
Head lag	9	0
Intelligence test	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Lymph node palpable	46	0
Male genital examination abnormal	1	0
Menstruation normal	4	0
Muscle strength abnormal	6	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	2	0
Respiratory rate	9	0
Respiratory rate decreased	29	0
Respiratory rate increased	51	0
Skin temperature	51	0
Temperature difference of extremities	13	0
Weight	1	0
Weight abnormal	1	0
Weight decreased	156	0
Weight increased	58	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	92	0
Platelet count increased	7	0
<i>Protein analyses NEC</i>		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	33	0
Protein total	1	0
Protein total abnormal	1	0
<i>Red blood cell analyses</i>		
Haematocrit	1	0
Haematocrit decreased	2	0
Haematocrit increased	1	0
Haemoglobin decreased	17	0
Haemoglobin increased	2	0
Red blood cell count decreased	2	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	2	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood creatinine increased	5	0
Glomerular filtration rate decreased	5	0
Glomerular filtration rate increased	1	0
Reproductive hormone analyses		
Blood oestrogen	2	0
Blood oestrogen decreased	2	0
Blood testosterone decreased	4	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	2	0
Reproductive organ and breast histopathology procedures		
Biopsy breast	2	0
Biopsy endometrium	1	0
Smear cervix	3	0
Reproductive organ and breast imaging procedures		
Breast scan	1	0
Hysteroscopy	2	0
Respiratory and pulmonary function diagnostic procedures		
Airway peak pressure increased	1	0
Forced expiratory volume	1	0
Forced expiratory volume increased	3	0
Fractional exhaled nitric oxide normal	1	0
Maximal voluntary ventilation	2	0
Peak expiratory flow rate	2	0
Peak expiratory flow rate decreased	7	0
Pulmonary function test	3	0
Spirometry abnormal	1	0
Total lung capacity decreased	4	0
Vital capacity	1	0
Respiratory tract and thoracic histopathology procedures		
Sputum abnormal	3	0
Respiratory tract and thoracic imaging procedures		
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
Skeletal and cardiac muscle analyses		
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 abnormal	1	0
Troponin increased	33	0
Therapeutic drug monitoring analyses		

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
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
Thyroid analyses		
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
Tri-iodothyronine free decreased	1	0
Tissue enzyme analyses NEC		
Blood alkaline phosphatase abnormal	1	0
Blood alkaline phosphatase increased	6	0
Blood lactate dehydrogenase	1	0
Blood lactate dehydrogenase increased	1	0
Enzyme level increased	1	0
Toxicology laboratory analyses		
Blood antimony	1	0
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	21	0
Blood urine present	86	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
White blood cells urine	1	0
pH urine	7	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		
Biopsy kidney	1	0
Urine cytology	1	0
Urinary tract imaging procedures		
Bladder scan	1	0
Cystoscopy	2	0
Ultrasound kidney normal	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Vascular imaging procedures NEC</i>		
Venogram	3	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	14	0
Blood pressure ambulatory increased	1	0
Blood pressure decreased	94	0
Blood pressure diastolic	2	0
Blood pressure diastolic decreased	2	0
Blood pressure diastolic increased	4	0
Blood pressure difference of extremities	1	0
Blood pressure increased	317	0
Blood pressure measurement	50	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
<i>Virus identification and serology</i>		
Coronavirus test	11	0
Coronavirus test positive	4	0
Cytomegalovirus test positive	1	0
HIV antibody positive	1	0
HIV test	1	0
Respiratory syncytial virus test positive	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	16	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	112	0
Viral load	2	0
Viral test	4	0
Viral test positive	1	0
<i>Vitamin analyses</i>		
Blood folate decreased	10	0
Vitamin B12	2	0
Vitamin B12 abnormal	2	0
Vitamin B12 decreased	5	0
Vitamin D	4	0
Vitamin D decreased	7	0
<i>Water and electrolyte analyses NEC</i>		
Urine osmolarity	1	0
Volume blood	1	0
Volume blood decreased	1	0
<i>White blood cell analyses</i>		
Eosinophil count	1	0
Eosinophil count decreased	1	0
Eosinophil count increased	3	0
Lymphocyte count	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Lymphocyte count decreased	3	0
Lymphocyte count increased	1	0
Monocyte count increased	2	0
Neutrophil count	4	0
Neutrophil count decreased	15	0
Neutrophil count increased	4	0
White blood cell count	5	0
White blood cell count decreased	17	0
White blood cell count increased	14	0
Investigations SOC TOTAL	6834	3

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	25	0
Decreased appetite	1660	0
Diet refusal	1	0
Eating disorder symptom	4	0
Food craving	14	0
Food refusal	17	0
Hyperphagia	15	0
Hypophagia	21	0
Increased appetite	38	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Hypercalcaemia	1	0
Hypocalcaemia	3	0
Tetany	5	0
<i>Copper metabolism disorders</i>		
Copper deficiency	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	70	0
Diabetes mellitus inadequate control	18	1
Fulminant type 1 diabetes mellitus	1	0
Increased insulin requirement	2	0
Insulin resistant diabetes	2	0
Latent autoimmune diabetes in adults	2	0
Type 1 diabetes mellitus	19	0
Type 2 diabetes mellitus	7	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	115	0
<i>Electrolyte imbalance NEC</i>		
Electrolyte imbalance	1	0
Fluid imbalance	2	0
Tumour lysis syndrome	1	0
<i>Elevated cholesterol</i>		
Hypercholesterolaemia	2	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	12	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	10	0
Breast milk substitute intolerance	1	0
Dairy intolerance	4	0
Food intolerance	27	0
Gluten sensitivity	7	0
Histamine intolerance	8	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	51	0

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Abnormal weight gain	23	0
Cachexia	1	0
Feeding disorder	117	0
Food aversion	15	0
Malnutrition	3	0
Neonatal insufficient breast milk syndrome	7	0
Obesity	2	0
Overweight	1	0
Poor feeding infant	17	0
Weight loss poor	3	0
Hyperglycaemic conditions NEC		
Glucose tolerance impaired	2	0
Hyperglycaemia	72	0
Insulin resistance	6	0
Hyperlipidaemias NEC		
Hyperlipidaemia	1	0
Hypoglycaemic conditions NEC		
Glycopenia	1	0
Hypoglycaemia	87	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	3	0
Iron deficiencies		
Iron deficiency	14	0
Iron excess		
Haemochromatosis	3	0
Iron overload	1	0
Lipid metabolism and deposit disorders NEC		
Body fat disorder	1	0
Magnesium metabolism disorders		
Hypomagnesaemia	2	0
Magnesium deficiency	1	0
Metabolic acidoses (excl diabetic acidoses)		
Ketoacidosis	8	1
Lactic acidosis	3	0
Metabolic acidosis	5	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	15	0
Hyponatraemic syndrome	3	0
Salt intoxication	1	0

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	6	0
<i>Total fluid volume decreased</i>		
Dehydration	251	0
<i>Total fluid volume increased</i>		
Fluid retention	74	0
Hypervolaemia	7	0
<i>Vitamin deficiencies NEC</i>		
Hypovitaminosis	6	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	11	0
Vitamin B complex deficiency	1	0
Vitamin B12 deficiency	10	0
Metabolic disorders SOC TOTAL	3000	2

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	445	0
Arthropathy	37	0
Autoimmune arthritis	11	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Oligoarthritis	1	0
Palindromic rheumatism	3	0
Polyarthritis	18	0
Rheumatic fever	2	0
Sacroiliitis	6	0
Seronegative arthritis	5	0
<i>Bone disorders NEC</i>		
Bone cyst	2	0
Bone disorder	2	0
Bone loss	1	0
Exostosis	1	0
Jaw disorder	4	0
Medial tibial stress syndrome	9	0
Osteitis	10	0
Osteonecrosis	1	0
Osteonecrosis of jaw	3	0
Spinal disorder	4	0
<i>Bone related signs and symptoms</i>		
Bone pain	475	0
Bone swelling	10	0
Coccydynia	5	0
Metatarsalgia	1	0
Pain in jaw	448	0
Pubic pain	2	0
Spinal pain	109	0
<i>Bursal disorders</i>		
Bursitis	117	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Chondropathy	1	0
Costochondritis	151	0
Osteochondritis	1	0
Polychondritis	3	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	4	0
Polymyalgia rheumatica	110	0
Reynold's syndrome	3	0
Scleroderma	4	0
Sjogren's syndrome	10	0
Systemic scleroderma	1	0
<i>Crystal arthropathic disorders</i>		
Chondrocalcinosis	3	0
Crystal arthropathy	2	0
Gouty arthritis	2	0
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Bone deformity	1	0
Elbow deformity	1	0
Finger deformity	4	0
Foot deformity	4	0
Hand deformity	6	0
Knee deformity	1	0
Limb deformity	6	0
Musculoskeletal deformity	1	0
Fractures NEC		
Osteoporotic fracture	2	0
Intervertebral disc disorders NEC		
Intervertebral disc compression	1	0
Intervertebral disc protrusion	3	0
Joint related disorders NEC		
Carpal collapse	1	0
Chondromalacia	1	0
Greater trochanteric pain syndrome	2	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	3	0
Periarthritis	310	0
Rotator cuff syndrome	48	0
Temporomandibular joint syndrome	17	0
Joint related signs and symptoms		
Arthralgia	11059	0
Jaw clicking	7	0
Joint effusion	17	0
Joint noise	46	0
Joint range of motion decreased	40	0
Joint stiffness	334	0
Joint swelling	723	0
Joint vibration	4	0
Joint warmth	18	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	32	0
Metabolic bone disorders		
Osteopenia	4	0
Osteoporosis	9	0
Muscle infections and inflammations		
Antisynthetase syndrome	3	0
Autoimmune myositis	1	0
Immune-mediated myositis	2	0

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Myositis	57	1
Polymyositis	9	0
Muscle pains		
Fibromyalgia	156	0
Myalgia	12282	0
Myalgia intercostal	2	0
Myofascial pain syndrome	13	0
Muscle related signs and symptoms NEC		
Haematoma muscle	1	0
Muscle atrophy	39	0
Muscle discomfort	9	0
Muscle disorder	12	0
Muscle fatigue	421	0
Muscle haemorrhage	1	0
Muscle mass	5	0
Muscle oedema	5	0
Muscle spasms	2425	0
Muscle swelling	45	0
Muscle tightness	121	0
Muscle twitching	587	0
Myofascial spasm	1	0
Trigger points	1	0
Muscle tone abnormalities		
Muscle rigidity	28	0
Nuchal rigidity	14	0
Torticollis	7	0
Trismus	43	0
Muscle weakness conditions		
Muscular weakness	1261	0
Musculoskeletal and connective tissue conditions NEC		
Back disorder	5	0
Chest wall mass	1	0
Dupuytren's contracture	1	0
Growth disorder	2	0
Limb mass	24	0
Mandibular mass	3	0
Mastication disorder	8	0
Mobility decreased	182	0
Muscle contracture	1	0
Musculoskeletal disorder	13	0
Musculoskeletal stiffness	1581	0
Pelvic misalignment	1	0
Posture abnormal	2	0
Sacroiliac joint dysfunction	1	0
Weight bearing difficulty	6	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	2	0
Dactylitis	3	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Fasciitis	1	0
Plantar fasciitis	18	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	3018	0
Flank pain	87	0
Growing pains	1	0
Limb discomfort	1727	0
Musculoskeletal chest pain	328	0
Musculoskeletal discomfort	135	0
Musculoskeletal pain	151	0
Neck pain	2344	0
Pain in extremity	15175	1
Rheumatic disorder	18	0
Sacral pain	4	0
<i>Myopathies</i>		
Compartment syndrome	1	0
Mitochondrial myopathy acquired	1	0
Myopathy	9	0
Rhabdomyolysis	14	0
<i>Osteoarthropathies</i>		
Nodal osteoarthritis	1	0
Osteoarthritis	70	0
Spinal osteoarthritis	2	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	33	0
<i>Rheumatoid arthropathies</i>		
Juvenile idiopathic arthritis	1	0
Rheumatoid arthritis	165	0
Rheumatoid nodule	1	0
Still's disease	2	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	337	0
Fistula	1	0
Fistula discharge	1	0
Fluctuance	1	0
Groin pain	131	0
Neck mass	48	0
Purple glove syndrome	1	0
Soft tissue disorder	3	0
Soft tissue necrosis	1	0
Soft tissue swelling	9	0
<i>Spine and neck deformities</i>		
Cervical spinal stenosis	1	0
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
Spinal stenosis	3	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	11	0
Arthritis reactive	82	0
Axial spondyloarthritis	1	0
Diffuse idiopathic skeletal hyperostosis	1	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Spondylitis	4	0
Spondyloarthropathy	2	0
Synovial disorders		
Synovial cyst	23	0
Synovitis	16	0
Tendon disorders		
Enthesopathy	3	0
Posterior tibial tendon dysfunction	1	0
Tendon disorder	7	0
Tendon pain	32	0
Tendonitis	73	0
Tenosynovitis	4	0
Tenosynovitis stenosaurs	2	0
Trigger finger	35	0
Trunk deformities		
Deformity thorax	1	0
Drooping shoulder syndrome	3	0
Shoulder deformity	4	0
Muscle & tissue disorders SOC TOTAL	58340	2

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

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>Bladder neoplasms malignant</i>		
Bladder cancer	3	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	46	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	3	0
Pericardial lipoma	1	0
<i>Cardiovascular neoplasms malignant and unspecified</i>		
Angiosarcoma	1	0
Cardiac neoplasm unspecified	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	4	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	2	0
Colorectal cancer	2	0
Rectal cancer	2	0
<i>Endocrine neoplasms benign NEC</i>		
Pituitary tumour benign	1	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

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Gastric neoplasms malignant</i>		
Gastric cancer	1	1
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	7	0
<i>Glial tumours malignant</i>		
Glioblastoma	1	0
<i>Hepatic neoplasms malignant</i>		
Hepatic cancer	2	1
Hepatocellular carcinoma	1	0
<i>Hepatobiliary neoplasms benign</i>		
Haemangioma of liver	2	0
<i>Hepatobiliary neoplasms malignancy unspecified</i>		
Hepatic neoplasm	2	0
<i>Hodgkin's disease NEC</i>		
Hodgkin's disease	4	0
<i>Islet cell neoplasms and APUDoma NEC</i>		
Pancreatic neuroendocrine tumour	1	0
<i>Kaposi's sarcomas</i>		
Kaposi's sarcoma	2	0
<i>Leukaemias NEC</i>		
Leukaemia	7	1
<i>Leukaemias acute NEC</i>		
Acute leukaemia	2	0
<i>Leukaemias acute myeloid</i>		
Acute myeloid leukaemia	1	1
<i>Leukaemias chronic NEC</i>		
Chronic leukaemia	1	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	3	0
<i>Leukaemias chronic myeloid</i>		
Chronic myeloid leukaemia	1	0
<i>Lip and oral cavity neoplasms malignant</i>		
Lip and/or oral cavity cancer recurrent	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	54	1
<i>Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)</i>		
Histiocytic necrotising lymphadenitis	1	0
<i>Mantle cell lymphomas</i>		
Mantle cell lymphoma	2	0
<i>Metastases to specified sites</i>		
Metastases to bone	1	0
Metastases to liver	1	0
Metastases to lymph nodes	5	0
<i>Metastases to unknown and unspecified sites</i>		
Metastasis	1	0
<i>Myelodysplastic syndromes</i>		
Myelodysplastic syndrome	4	0
<i>Myeloproliferative disorders (excl leukaemias)</i>		
Essential thrombocythaemia	3	0
<i>Neoplasms benign site unspecified NEC</i>		
Papilloma	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Adenocarcinoma metastatic	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Metastatic neoplasm	2	0
Neoplasm malignant	18	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
Neuromas		
Acoustic neuroma	3	0
Neuroma	1	0
Non-Hodgkin's lymphomas NEC		
Non-Hodgkin's lymphoma	3	0
Ocular neoplasms benign		
Benign neoplasm of eye	1	0
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	1	0
Plasma cell myelomas		
POEMS syndrome	1	0
Plasma cell myeloma	2	0
Plasma cell myeloma refractory	1	0
Plasma cell neoplasms NEC		
Hypergammaglobulinaemia benign monoclonal	1	0
TEMPI syndrome	2	0
Prostatic neoplasms malignant		
Prostate cancer	5	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

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Bronchial carcinoma	1	0
Lung cancer metastatic	2	2
Lung neoplasm malignant	16	1
Throat cancer	1	1
<i>Salivary gland neoplasms unspecified malignancy</i>		
Salivary gland neoplasm	2	0
<i>Skin melanomas (excl ocular)</i>		
Malignant melanoma	3	0
Metastatic malignant melanoma	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	8	0
Anogenital warts	7	0
Fibrous histiocytoma	1	0
Haemangioma of skin	7	0
Melanocytic naevus	10	0
Pyogenic granuloma	1	0
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	2	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>Testicular neoplasms malignant</i>		
Testis cancer	1	0
<i>Thyroid neoplasms malignant</i>		
Anaplastic thyroid cancer	1	0
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	430	15

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

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	33	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	116	2
Miller Fisher syndrome	7	0
Subacute inflammatory demyelinating polyneuropathy	1	0
<i>Alzheimer's disease (incl subtypes)</i>		
Dementia Alzheimer's type	3	2
<i>Auditory nerve disorders</i>		
Auditory nerve disorder	1	0
<i>Autonomic nervous system disorders</i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	22	0
Autonomic neuropathy	3	0
Horner's syndrome	2	0
Orthostatic intolerance	3	0
<i>Central nervous system aneurysms and dissections</i>		
Carotid artery dissection	2	0
Intracranial aneurysm	2	1
Vertebrobasilar 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	4	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	4	0
Cerebellar ischaemia	1	0
Cerebellar stroke	8	1
Cerebral artery embolism	3	1
Cerebral artery occlusion	2	0
Cerebral artery thrombosis	6	0
Cerebral haematoma	2	0
Cerebral haemorrhage	74	21
Cerebral infarction	34	3
Cerebral ischaemia	2	0
Cerebral thrombosis	16	0
Cerebrovascular accident	546	23

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Embolic stroke	8	0
Haemorrhage intracranial	16	4
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	13	5
Internal capsule infarction	1	0
Intracranial haematoma	3	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	70	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	21	8
Thalamic infarction	1	0
Thrombotic stroke	6	1
Vertebrobasilar stroke	1	0
Central nervous system inflammatory disorders NEC		
Arachnoiditis	1	0
Gliosis	3	0
Central nervous system vascular disorders NEC		
Brain hypoxia	5	1
Carotid arteriosclerosis	1	0
Central nervous system vasculitis	1	0
Cerebral amyloid angiopathy	3	0
Cerebral congestion	6	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	62	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	3	0
Cervicobrachial syndrome	7	0
Choreiform movements		
Chorea	3	0
Chronic polyneuropathies		
Chronic inflammatory demyelinating polyradiculoneuropathy	4	0
Demyelinating polyneuropathy	3	0
Diabetic neuropathy	1	0
Coma states		
Coma	21	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
Coordination and balance disturbances		
Ataxia	25	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Balance disorder	568	0
Cerebellar ataxia	1	0
Cerebellar syndrome	1	0
Coordination abnormal	81	0
Dysdiadochokinesis	1	0
Dysstasia	82	0
Nystagmus	19	0
Cortical dysfunction NEC		
Alexia	2	0
Anosognosia	1	0
Aphasia	117	0
Apraxia	1	0
Dysgraphia	4	0
Dyslexia	2	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	20	0
Dementia with Lewy bodies	2	0
Senile dementia	1	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	9	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	4	0
Depressed level of consciousness	59	0
Infant sedation	1	0
Lethargy	2648	0
Loss of consciousness	868	1
Postictal state	6	0
Sedation	9	0
Somnolence	1267	0
Stupor	6	0
Syncope	2993	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	26	0
Dyskinesia	92	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Extrapyramidal disorder	3	0
Fine motor skill dysfunction	14	0
Foetal movement disorder	7	0
Hyperkinesia	4	0
Hypokinesia	121	0
Micrographia	1	0
Motor dysfunction	5	0
Movement disorder	78	0
Psychomotor hyperactivity	31	0
Synkinesis	2	0
Tardive dyskinesia	2	0
Dystonias		
Dystonia	17	0
Opisthotonus	1	0
Writer's cramp	1	0
Encephalitis NEC		
Encephalitis autoimmune	2	0
Limbic encephalitis	2	0
Noninfective encephalitis	8	0
Encephalopathies NEC		
Autoimmune encephalopathy	3	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	2	0
VIth nerve paralysis	13	0
Facial cranial nerve disorders		
Bell's palsy	677	0
Facial nerve disorder	10	0
Facial paralysis	504	0
Facial paresis	113	0
Facial spasm	60	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	92	0
Glossopharyngeal nerve disorders		
Glossopharyngeal neuralgia	1	0
Headaches NEC		
Cervicogenic headache	3	0
Cluster headache	315	0
Cold-stimulus headache	37	0
Drug withdrawal headache	3	0
Exertional headache	10	0
External compression headache	2	0
Headache	31393	1
Medication overuse headache	2	0
Menstrual headache	13	0
New daily persistent headache	11	0
Occipital neuralgia	17	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Ophthalmoplegic migraine	2	0
Primary cough headache	4	0
Primary headache associated with sexual activity	10	0
Sinus headache	423	0
Tension headache	655	0
Thunderclap headache	25	0
Vascular headache	23	0
Hydrocephalic conditions		
Hydrocephalus	5	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Increased intracranial pressure disorders		
Brain compression	2	0
Brain oedema	15	2
Idiopathic intracranial hypertension	13	0
Intracranial pressure increased	6	0
Intellectual disabilities		
Intellectual disability	4	0
Lumbar spinal cord and nerve root disorders		
Cauda equina syndrome	1	0
Sciatica	147	0
Memory loss (excl dementia)		
Amnesia	263	0
Memory impairment	275	0
Retrograde amnesia	1	0
Transient global amnesia	11	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	120	0
Cognitive linguistic deficit	1	0
Disturbance in attention	424	0
Mental impairment	68	0
Migraine headaches		
Basilar migraine	1	0
Hemiplegic migraine	45	0
Migraine	3671	0
Migraine with aura	244	0
Migraine without aura	22	0
Ophthalmic migraine	8	0
Retinal migraine	40	0
Typical aura without headache	9	0
Vestibular migraine	32	0
Mixed cranial nerve disorders		
Bulbar palsy	3	0
Mononeuropathies		
Carpal tunnel syndrome	39	0
Cubital tunnel syndrome	4	0
Meralgia paraesthetica	2	0
Mononeuritis	2	0
Mononeuropathy	4	0
Nerve compression	33	0
Peripheral nerve lesion	2	0
Peroneal nerve palsy	22	0
Piriformis syndrome	2	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Pudendal canal syndrome	3	0
Radial nerve palsy	1	0
Sciatic nerve neuropathy	2	0
Ulnar nerve palsy	2	0
Ulnar neuritis	3	0
Ulnar tunnel syndrome	2	0
Motor neurone diseases		
Amyotrophic lateral sclerosis	3	0
Lower motor neurone lesion	2	0
Motor neurone disease	8	3
Progressive bulbar palsy	1	0
Upper motor neurone lesion	1	0
Multiple sclerosis acute and progressive		
Band sensation	1	0
Multiple sclerosis	43	0
Multiple sclerosis relapse	27	0
Relapsing-remitting multiple sclerosis	2	0
Tumefactive multiple sclerosis	1	1
Muscle tone abnormal		
Drop attacks	4	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	42	0
Narcolepsy and hypersomnia		
Cataplexy	4	0
Hypersomnia	129	0
Narcolepsy	8	0
Nervous system disorders NEC		
Central nervous system lesion	3	0
Cerebral disorder	3	0
Nervous system disorder	32	0
Neurotoxicity	4	0
Psychomotor skills impaired	1	0
Neurologic visual problems NEC		
Hemianopia	2	0
Hemianopia homonymous	3	0
Quadrantanopia	2	0
Tunnel vision	26	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	11835	0
Dizziness exertional	58	0
Dizziness postural	900	0
Drizzling	28	0

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 24-Nov-2022

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Fontanelle bulging	2	0
Head discomfort	431	0
Hyporesponsive to stimuli	2	0
Inability to crawl	3	0
Infant irritability	10	0
Meningism	2	0
Myoclonus	35	0
Neurological symptom	88	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	21	0
Presyncope	750	0
Slow response to stimuli	4	0
Tongue biting	9	0
Unresponsive to stimuli	70	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	35	0
Muscle spasticity	21	0
Neuromuscular pain	3	0
Neuromuscular junction dysfunction		
Myasthenia gravis	19	0
Myasthenia gravis crisis	2	0
Myasthenic syndrome	1	0
Olfactory nerve disorders		
Anosmia	350	0
Hyposmia	20	0
Parosmia	352	0
Optic nerve disorders NEC		
Optic neuritis	47	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	16	0
Burning sensation	721	0
Burning sensation mucosal	2	0
Dysaesthesia	8	0
Formication	55	0
Hemianaesthesia	1	0
Hemihypoaesthesia	4	0
Hemiparaesthesia	7	0
Hyperaesthesia	129	0
Hypoaesthesia	3689	0
Lhermitte's sign	1	0
Paraesthesia	5043	0
Reversed hot-cold sensation	4	0
Synaesthesia	2	0
Vibration syndrome	3	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	24	0
Hemiparesis	77	0
Hemiplegia	55	0
Locked-in syndrome	1	0
Monoparesis	98	0
Monoplegia	110	0
Paralysis	169	1
Paraparesis	4	0

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Report Run Date: 24-Nov-2022
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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Paraplegia	3	0
Paresis	10	0
Quadriparesis	1	0
Quadriplegia	1	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	18	0
Hypokinetic dysarthria	1	0
Parkinson's disease	4	0
Parkinsonian gait	2	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	15	0
Neuritis	12	0
Neuropathy peripheral	182	0
Peripheral sensorimotor neuropathy	2	0
Peripheral sensory neuropathy	13	0
Polyneuropathy	5	0
Small fibre neuropathy	5	0
Thoracic outlet syndrome	2	0
Seizures and seizure disorders NEC		
Atonic seizures	11	0
Change in seizure presentation	2	0
Clonic convulsion	6	0
Convulsions local	1	0
Convulsive threshold lowered	1	0
Epilepsy	188	0
Epileptic aura	3	0
Epileptic encephalopathy	2	0
Febrile convulsion	22	0
Idiopathic generalised epilepsy	1	0
Neonatal epileptic seizure	1	0
Partial seizures	34	0
Partial seizures with secondary generalisation	1	0
Post stroke seizure	1	0
Psychogenic seizure	12	0
Seizure	809	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	43	0
Tonic posturing	1	0

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Sensory abnormalities NEC</i>		
Ageusia	631	0
Allodynia	36	0
Aura	31	0
Central pain syndrome	2	0
Complex regional pain syndrome	7	0
Dysgeusia	1359	0
Electric shock sensation	68	0
Hypergeusia	1	0
Hypogeusia	9	0
Intercostal neuralgia	3	0
Loss of proprioception	3	0
Morton's neuralgia	4	0
Neuralgia	804	0
Persistent genital arousal disorder	2	0
Phantom limb syndrome	8	0
Post herpetic neuralgia	19	0
Post-traumatic neuralgia	1	0
Restless arm syndrome	4	0
Restless legs syndrome	169	0
Sensory disturbance	136	0
Sensory loss	128	0
Sensory overload	5	0
Taste disorder	329	0
Visual perseveration	3	0
<i>Sleep disturbances NEC</i>		
Microsleep	1	0
Sleep deficit	13	0
Sudden onset of sleep	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	266	0
Incoherent	17	0
Language disorder	2	0
Repetitive speech	5	0
Slow speech	26	0
Speech disorder	90	0
Speech disorder developmental	4	0
<i>Spinal cord and nerve root disorders NEC</i>		
Acquired syringomyelia	1	0
Myelopathy	2	0
Radiculitis brachial	21	0
Radiculopathy	8	0
<i>Structural brain disorders NEC</i>		
Brain injury	14	2
Cerebral ventricle dilatation	2	0
Hyperintensity in brain deep nuclei	1	0
Intracranial mass	1	0
White matter lesion	2	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	214	3
<i>Tremor (excl congenital)</i>		
Action tremor	1	0
Essential tremor	8	0

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Head titubation	15	0
Resting tremor	5	0
Tremor	2301	0
Trigeminal disorders		
Numb chin syndrome	2	0
Trigeminal nerve disorder	3	0
Trigeminal neuralgia	97	0
Trigeminal neuritis	3	0
Vagus nerve disorders		
Vagus nerve disorder	2	0
Vocal cord paralysis	4	0
Vertigos NEC		
Cervicogenic vertigo	1	0
Vertigo CNS origin	4	0
Nervous system disorders SOC TOTAL	84728	102

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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	2	0
Abortion missed	7	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	505	1
Abortion threatened	2	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Amniorrhoea	2	0
Oligohydramnios	1	0
Polyhydramnios	1	0
<i>Foetal complications NEC</i>		
Foetal cardiac disorder	1	0
Foetal distress syndrome	3	0
Foetal hypokinesia	14	0
<i>Foetal conditions due to maternal conditions</i>		
Maternal condition affecting foetus	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	8	1
<i>Gestational age and weight conditions</i>		
Low birth weight baby	1	0
Premature baby	9	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>High risk pregnancies</i>		
Risk of future pregnancy miscarriage	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	4	0
<i>Labour onset and length abnormalities</i>		
Induced labour	1	0
Obstructed 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	5	0
Complication of pregnancy	1	0
Decidual cast	8	0
Ectopic pregnancy	15	0
Hyperemesis gravidarum	1	0
Morning sickness	19	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Pregnancy conditions <small>Pregnancy conditions cont'd</small>		
Preterm premature rupture of membranes	3	0
Ruptured ectopic pregnancy	1	0
Somatic symptom disorder of pregnancy	3	0
Neonatal hepatobiliary disorders		
Jaundice neonatal	1	0
Normal newborn status		
Normal newborn	1	0
Normal pregnancy, labour and delivery		
Labour pain	1	0
Live birth	8	0
Pregnancy	35	0
Term birth	1	0
Uterine contractions during pregnancy	6	0
Placental abnormalities (excl neoplasms)		
Foetal vascular malperfusion	2	0
Placental calcification	1	0
Placental disorder	4	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	3	3
Stillbirth	13	13
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	764	19

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Reaction Name	Total	Fatal
<i>Device electrical issues</i>		
Electromagnetic interference	1	0
<i>Device issues NEC</i>		
Device connection issue	1	0
Device delivery system issue	1	0
Device expulsion	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	22	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	10	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	135	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	29	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	9	0
Flat affect	12	0
Inappropriate affect	23	0
<i>Amnesic symptoms</i>		
Paramnesia	7	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	4	0
Generalised anxiety disorder	3	0
Neurosis	1	0
<i>Anxiety symptoms</i>		
Agitation	108	0
Anxiety	1171	0
Immunisation stress-related response	4	0
Nervousness	227	0
Stress	151	0
Tension	48	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	7	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	19	0
Attention-seeking behaviour	1	0
Aversion	1	0
Disinhibition	3	0
Indifference	7	0
Paranoia	33	0
Personality change	8	0
Social avoidant behaviour	6	0
Soliloquy	2	0
Suspiciousness	1	0
<i>Bipolar disorders</i>		
Bipolar I disorder	2	0
Bipolar disorder	6	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	9	0
Distractibility	4	0
Executive dysfunction	1	0
Mental fatigue	261	0
<i>Communications disorders</i>		
Communication disorder	10	0
Mutism	4	0
Speech sound disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	1122	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Disorientation	345	0
Decreased physical activity levels		
Catatonia	1	0
Deliria		
Delirium	166	0
Delirium febrile	1	0
Delusional symptoms		
Delusion	21	0
Depressive disorders		
Agitated depression	7	0
Depression	457	0
Depression suicidal	20	0
Major depression	16	0
Mixed anxiety and depressive disorder	5	0
Dissociative states		
Depersonalisation/derealisation disorder	14	0
Dissociation	43	0
Dissociative amnesia	4	0
Dissociative disorder	2	0
Disturbances in initiating and maintaining sleep		
Initial insomnia	30	0
Insomnia	2111	0
Middle insomnia	36	0
Terminal insomnia	35	0
Dyssomnias		
Breathing-related sleep disorder	1	0
Dyssomnia	1	0
Poor quality sleep	285	0
Eating disorders NEC		
Bulimia nervosa	1	0
Eating disorder	16	0
Selective eating disorder	1	0
Emotional and mood disturbances NEC		
Anger	52	0
Dysphoria	3	0
Emotional disorder	80	0
Emotional distress	70	0
Emotional poverty	2	0
Euphoric mood	51	0
Frustration tolerance decreased	2	0
Irritability	252	0
Mood altered	69	0
Morose	1	0
Factitious disorders		
Factitious disorder	4	0
Fear symptoms and phobic disorders (incl social phobia)		
Agoraphobia	2	0
Claustrophobia	1	0
Fear	37	0
Fear of death	2	0
Fear of eating	1	0
Fear of falling	3	0
Fear of injection	7	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Osmophobia	1	0
Performance fear	1	0
Phobia	3	0
Phonophobia	3	0
Social anxiety disorder	2	0
Social fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	175	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	282	0
Hallucination, auditory	24	0
Hallucination, olfactory	16	0
Hallucination, tactile	1	0
Hallucination, visual	35	0
Hallucinations, mixed	4	0
<i>Increased physical activity levels</i>		
Restlessness	181	0
<i>Infancy, childhood and adolescence psychiatric disorders NEC</i>		
Social (pragmatic) communication disorder	1	0
<i>Learning disorders</i>		
Learning disability	1	0
Learning disorder	1	0
Reading disorder	2	0
<i>Mental disorders NEC</i>		
Mental disorder	26	0
Mental status changes	2	0
Psychological factor affecting medical condition	1	0
<i>Mood alterations with depressive symptoms</i>		
Anhedonia	3	0
Decreased interest	13	0
Depressed mood	477	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	54	0
<i>Mood alterations with manic symptoms</i>		
Hypomania	2	0
Mania	11	0
<i>Mood disorders NEC</i>		
Affective disorder	5	0
Apathy	43	0
Boredom	1	0
Laziness	3	0
Listless	27	0
Mood disorder due to a general medical condition	1	0
<i>Narcolepsy and associated conditions</i>		
Hypnagogic hallucination	4	0
Hypnopompic hallucination	2	0
Sleep attacks	3	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Obsessive-compulsive disorders and symptoms</i>		
Body dysmorphic disorder	1	0
Obsessive-compulsive symptom	1	0
<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	283	0
Panic disorder	11	0
Panic reaction	32	0
<i>Paraphilias and paraphilic disorders</i>		
Transvestism	1	0
<i>Parasomnias</i>		
Abnormal dreams	220	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	3	0
Nightmare	246	0
Parasomnia	5	0
Sleep inertia	1	0
Sleep talking	6	0
Sleep terror	33	0
Somnambulism	11	0
<i>Perception disturbances NEC</i>		
Autoscopy	21	0
Deja vu	3	0
Derealisation	15	0
Flashback	4	0
Illusion	6	0
Near death experience	2	0
Time perception altered	2	0
<i>Personality disorders NEC</i>		
Personality disorder	1	0
Self esteem decreased	2	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	5	0
<i>Psychiatric elimination disorders</i>		
Enuresis	32	0
<i>Psychiatric symptoms NEC</i>		
Helplessness	1	0
Hypervigilance	10	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	37	1
<i>Schizophrenia NEC</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Schizophrenia	2	0
Sexual and gender identity disorders NEC		
Gender dysphoria	1	0
Sexual arousal disorders		
Disturbance in sexual arousal	4	0
Sexual inhibition	1	0
Sexual desire disorders		
Hypersexuality	1	0
Libido decreased	21	0
Libido disorder	2	0
Libido increased	9	0
Loss of libido	23	0
Sexual dysfunction NEC		
Genito-pelvic pain/penetration disorder	2	0
Sleep disorders NEC		
Sleep disorder	307	0
Sleep disorder due to general medical condition, insomnia type	5	0
Somatic symptom disorders		
Conversion disorder	39	0
Habit cough	22	0
Somatic symptom disorder	2	0
Vomiting psychogenic	1	0
Speech and language usage disturbances		
Disorganised speech	10	0
Logorrhoea	2	0
Speech articulation and rhythm disturbances		
Dysphemia	29	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
Stereotypies and automatisms		
Automatism	1	0
Bruxism	16	0
Head banging	13	0
Stereotypy	1	0
Stress disorders		
Burnout syndrome	2	0
Post-traumatic stress disorder	6	0
Substance related and addictive disorders		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	5	0
Dependence	1	0
Nicotine dependence	2	0
Suicidal and self-injurious behaviour		
Completed suicide	2	2
Intentional self-injury	6	0
Self-injurious ideation	2	0
Suicidal ideation	62	0
Suicide attempt	10	0
Suicide threat	2	0
Thinking disturbances		
Bradyphrenia	46	0
Flight of ideas	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Intrusive thoughts	8	0
Morbid thoughts	1	0
Tachyphrenia	11	0
Thinking abnormal	24	0
Thought blocking	3	0
<i>Tic disorders</i>		
Tic	23	0
Psychiatric disorders SOC TOTAL	10798	3

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	6	0
Bladder irritation	15	0
Bladder pain	38	0
Bladder spasm	2	0
Dysuria	60	0
Incontinence	54	0
Lower urinary tract symptoms	3	0
Micturition disorder	2	0
Micturition urgency	59	0
Mixed incontinence	1	0
Pollakiuria	175	0
Stress urinary incontinence	2	0
Urethral pain	8	0
Urge incontinence	3	0
Urinary hesitation	4	0
Urinary incontinence	94	0
Urinary retention	60	0
Urine flow decreased	21	0
<i>Bladder disorders NEC</i>		
Bladder dilatation	1	0
Bladder disorder	15	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>		
Anti-glomerular basement membrane disease	1	0
Focal segmental glomerulosclerosis	1	0
Glomerulonephritis membranous	1	0
Glomerulonephritis minimal lesion	11	0
Glomerulonephritis rapidly progressive	2	0
Goodpasture's syndrome	1	0
IgA nephropathy	6	0
Nephrotic syndrome	26	0
<i>Myoneurogenic bladder disorders</i>		
Automatic bladder	1	0
Bladder dysfunction	8	0
Hypertonic bladder	8	0
Hypotonic urinary bladder	1	0
Loss of bladder sensation	4	0
Neurogenic bladder	2	0
<i>Nephritis NEC</i>		
Lupus nephritis	2	0

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Nephritis	3	0
Tubulointerstitial nephritis	3	0
<i>Nephropathies and tubular disorders NEC</i>		
Nephropathy	1	0
<i>Renal disorders NEC</i>		
Kidney fibrosis	1	0
Renal disorder	13	1
Renal haemorrhage	1	0
Renal mass	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	63	4
Anuria	5	0
Chronic kidney disease	9	0
End stage renal disease	1	0
Oliguria	1	0
Renal failure	34	2
Renal impairment	40	0
Renal injury	4	0
<i>Renal failure complications</i>		
Azotaemia	1	0
<i>Renal lithiasis</i>		
Nephrolithiasis	14	0
<i>Renal neoplasms</i>		
Renal cyst	2	0
<i>Renal obstructive disorders</i>		
Hydronephrosis	2	0
<i>Renal structural abnormalities and trauma</i>		
Kidney enlargement	1	0
Kidney small	2	0
<i>Renal vascular and ischaemic conditions</i>		
Renal aneurysm	1	0
Renal infarct	4	0
Renal tubular necrosis	2	0
Renal vasculitis	2	1
<i>Structural and obstructive urethral disorders (excl congenital)</i>		
Urethral stenosis	1	0
<i>Ureteric disorders NEC</i>		
Ureteric stenosis	1	0
<i>Urinary abnormalities</i>		
Albuminuria	1	0
Chromaturia	76	0
Haematuria	58	0
Ketonuria	1	0
Myoglobinuria	1	0
Proteinuria	14	0
Urine abnormality	14	0
Urine odour abnormal	11	0
<i>Urinary tract lithiasis (excl renal)</i>		
Calculus bladder	1	0
Calculus urinary	1	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Haemorrhage urinary tract	32	1
Nocturia	6	0
Polyuria	9	0
Renal colic	5	0
Renal pain	383	0
Urinary tract discomfort	2	0
Urinary tract pain	8	0
Renal & urinary disorders SOC TOTAL	1558	9

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	20	0
<i>Breast disorders NEC</i>		
Breast atrophy	1	0
Breast disorder	4	0
Breast enlargement	33	0
Breast mass	157	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	7	0
Breast discomfort	15	0
Breast engorgement	11	0
Breast haematoma	1	0
Breast oedema	10	0
Breast pain	899	0
Breast swelling	197	0
Breast tenderness	107	0
Nipple pain	48	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	85	0
Erection increased	5	0
Organic erectile dysfunction	14	0
Painful ejaculation	2	0
Painful erection	1	0
Spontaneous ejaculation	2	0
Spontaneous penile erection	2	0
<i>Fallopian tube and ovary infections and inflammations</i>		
Noninfective oophoritis	7	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

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Suppressed lactation	51	0
Menopausal effects NEC		
Artificial menopause	1	0
Menopausal disorder	1	0
Menopausal symptoms	49	0
Menopause delayed	1	0
Premature menopause	28	0
Menopausal effects on the genitourinary tract		
Atrophic vulvovaginitis	2	0
Postmenopausal haemorrhage	120	0
Menstruation and uterine bleeding NEC		
Abnormal uterine bleeding	8	0
Abnormal withdrawal bleeding	3	0
Bleeding anovulatory	1	0
Dysmenorrhoea	3377	0
Intermenstrual bleeding	1337	0
Menstrual discomfort	37	0
Menstrual disorder	2348	0
Menstruation irregular	4173	0
Premenstrual dysphoric disorder	15	0
Premenstrual pain	153	0
Premenstrual syndrome	145	0
Retrograde menstruation	2	0
Withdrawal bleed	16	0
Menstruation with decreased bleeding		
Amenorrhoea	742	0
Hypomenorrhoea	768	0
Menstruation delayed	5823	0
Oligomenorrhoea	237	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	6456	0
Menometrorrhagia	22	0
Polymenorrhoea	1065	0
Ovarian and fallopian tube cysts and neoplasms		
Haemorrhagic ovarian cyst	3	0
Ovarian cyst	36	0
Ovarian cyst ruptured	2	0
Polycystic ovaries	51	0
Ovarian and fallopian tube disorders NEC		
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	3	0
Ovarian necrosis	1	0
Ovulation disorder	4	0
Ovulation pain	85	0
Premature ovulation	4	0
Superovulation	2	0
Pelvic prolapse conditions		
Vaginal prolapse	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri mass	1	0
Adnexa uteri pain	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 dermatitis	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 size reduced	1	0
Penile swelling	6	0
Penis disorder	14	0
Peyronie's disease	1	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 blister	1	0
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	8	0
Genital rash	6	0
Genital swelling	5	0
Pelvic discomfort	6	0
Pelvic pain	137	0
Perineal pain	3	0
Perineal rash	1	0
Pruritus genital	8	0

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Scrotal disorders NEC		
Acquired hydrocele	1	0
Scrotal angiokeratoma	1	0
Scrotal discomfort	1	0
Scrotal erythema	2	0
Scrotal exfoliation	2	0
Scrotal pain	23	0
Scrotal swelling	6	0
Scrotum erosion	1	0
Varicocele	3	0
Sexual function and fertility disorders NEC		
Dyspareunia	7	0
Infertility	22	0
Infertility female	6	0
Infertility male	1	0
Sexual dysfunction	10	0
Spermatogenesis and semen disorders		
Aspermia	1	0
Haematospermia	8	0
Semen discolouration	1	0
Testicular and epididymal disorders NEC		
Testicular atrophy	1	0
Testicular disorder	4	0
Testicular oedema	1	0
Testicular pain	76	0
Testicular swelling	15	0
Testicular torsion	1	0
Testis discomfort	3	0
Testicular and epididymal neoplasms		
Testicular cyst	1	0
Uterine disorders NEC		
Adenomyosis	12	0
Endometrial thickening	4	0
Endometriosis	98	0
Uterine haemorrhage	50	0
Uterine mass	1	0
Uterine pain	19	0
Uterine infections and inflammations (excl cervix)		
Uterine inflammation	1	0
Uterine neoplasms		
Uterine polyp	6	0
Uterine tone disorders		
Uterine spasm	42	0
Vaginal and vulval infections and inflammations		
Vulvovaginal inflammation	2	0
Vulvovaginal cysts and neoplasms		
Bartholin's cyst	2	0
Vaginal cyst	8	0
Vaginal polyp	1	0
Vulva cyst	2	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	1841	0
Vaginal mucosal blistering	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Vaginal ulceration	6	0
Vulval disorder	3	0
Vulval haemorrhage	35	0
Vulval ulceration	8	0
Vulvovaginal ulceration	6	0
<i>Vulvovaginal signs and symptoms</i>		
Clitoral engorgement	1	0
Coital bleeding	8	0
Labia enlarged	2	0
Vaginal discharge	90	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	7	0
Vulvovaginal erythema	3	0
Vulvovaginal pain	33	0
Vulvovaginal pruritus	13	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	5	0
Reproductive & breast disorders SOC TOTAL	31789	1

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Agonal respiration	1	0
Apnoea	9	0
Apnoeic attack	1	0
Dyspnoea	7477	5
Dyspnoea at rest	11	0
Dyspnoea exertional	51	1
Grunting	1	0
Hyperventilation	68	0
Hypopnoea	144	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	77	0
Respiratory arrest	23	0
Respiratory depression	1	0
Respiratory distress	22	0
Sleep apnoea syndrome	22	0
Tachypnoea	34	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	5	0
Bronchiectasis	17	0
<i>Bronchospasm and obstruction</i>		
Asthma	462	3
Asthma exercise induced	1	0
Asthma late onset	3	0
Bronchospasm	19	0
Chronic obstructive pulmonary disease	32	2
Cough variant asthma	8	0
Obstructive airways disorder	14	0
Reversible airways obstruction	1	0
Wheezing	501	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	3	1
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	36	2
Respiratory acidosis	2	0
<i>Coughing and associated symptoms</i>		
Allergic cough	10	0
Atopic cough	1	0
Cough	3164	1
Cough decreased	2	0
Haemoptysis	79	0
Productive cough	209	0
Sputum discoloured	11	0
Sputum increased	4	0
<i>Diaphragmatic disorders</i>		
Acquired diaphragmatic eventration	1	0
Diaphragm muscle weakness	2	0

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MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Diaphragmatic disorder	1	0
Diaphragmatic paralysis	1	0
<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	4	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
Eosinophilic pneumonia	1	1
Hypersensitivity pneumonitis	1	0
Lower respiratory tract inflammation	1	0
Pneumonitis	37	2
Pulmonary sarcoidosis	3	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	37	0
Increased bronchial secretion	3	0
Increased viscosity of bronchial secretion	1	0
Lower respiratory tract congestion	1	0
Lung hyperinflation	2	0
Lung opacity	4	0
Pleuritic pain	28	0
Pulmonary haemorrhage	1	0
Pulmonary pain	125	0
Rales	7	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	355	0
Nasal inflammation	5	0
Rhinitis allergic	28	0
<i>Nasal disorders NEC</i>		
Epistaxis	1148	0
Intranasal hypoaesthesia	2	0
Intranasal paraesthesia	1	0
Nasal crusting	2	0
Nasal disorder	4	0
Nasal dryness	37	0
Nasal mucosal discolouration	1	0
Nasal odour	7	0
Nasal oedema	8	0
Nasal polyps	3	0
Nasal pruritus	14	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Nasal ulcer	3	0
Neonatal hypoxic conditions		
Dry lung syndrome	1	0
Gasping syndrome	1	0
Infantile apnoea	2	0
Paranasal sinus disorders (excl infections and neoplasms)		
Allergic sinusitis	3	0
Paranasal sinus inflammation	5	0
Sinonasal obstruction	17	0
Sinus congestion	79	0
Sinus disorder	12	0
Parenchymal lung disorders NEC		
Atelectasis	5	0
Combined pulmonary fibrosis and emphysema	1	0
Emphysema	3	0
Interstitial lung disease	13	1
Lung consolidation	7	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)		
Adenoidal disorder	1	0
Hyperactive pharyngeal reflex	1	0
Pharyngeal enanthema	1	0
Pharyngeal erythema	11	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	40	0
Pharyngeal inflammation	5	0
Pharyngeal lesion	1	0
Pharyngeal mass	1	0
Pharyngeal oedema	15	0
Pharyngeal paraesthesia	60	0
Pharyngeal swelling	314	0
Pharyngeal ulceration	20	0
Tonsillar erythema	14	0
Tonsillar exudate	1	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	100	0
Tonsillar inflammation	4	0
Tonsillar ulcer	1	0
Tonsillolith	1	0
Pleural infections and inflammations		
Pleurisy	43	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	44	0
Pneumothorax	15	0
Pneumothorax spontaneous	5	0
Pulmonary hypertension		
Pulmonary hypertension	4	0
Pulmonary oedemas		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Acute respiratory distress syndrome	3	1
Pulmonary congestion	23	0
Pulmonary oedema	27	2
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary artery thrombosis	2	0
Pulmonary embolism	617	42
Pulmonary infarction	8	0
Pulmonary thrombosis	13	1
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	3	1
Respiratory failure	16	2
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	6	0
Diaphragmalgia	10	0
Nasal flaring	1	0
Painful respiration	20	1
Pleural rub	1	0
Respiratory symptom	22	0
Suffocation feeling	2	0
Use of accessory respiratory muscles	2	0
<i>Respiratory tract disorders NEC</i>		
Allergic respiratory disease	1	0
Aspiration	4	0
Lung disorder	15	0
Pulmonary mass	7	0
Respiratory disorder	17	1
Respiratory tract congestion	6	0
Respiratory tract haemorrhage	2	0
Respiratory tract inflammation	2	0
Respiratory tract irritation	9	0
Respiratory tract oedema	4	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	2	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal disorder	1	0
Tracheal pain	2	0
<i>Upper respiratory tract neoplasms</i>		
Tonsillar cyst	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	155	0
Catarrh	34	0
Choking	22	0
Choking sensation	8	0
Dry throat	192	0
Dysphonia	203	0
Increased upper airway secretion	6	0
Increased viscosity of upper respiratory secretion	41	0
Laryngeal pain	1	0
Nasal discharge discolouration	4	0
Nasal discomfort	32	0
Nasal obstruction	4	0
Oropharyngeal blistering	11	0
Oropharyngeal discolouration	1	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Oropharyngeal discomfort	73	0
Oropharyngeal pain	3423	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	56	0
Rhinalgia	46	0
Rhinorrhoea	1134	0
Sinus pain	262	0
Sneezing	478	0
Snoring	8	0
Throat clearing	8	0
Throat irritation	278	0
Throat lesion	2	0
Throat tightness	305	0
Upper airway obstruction	3	0
Upper respiratory tract congestion	2	0
Upper respiratory tract irritation	1	0
Upper-airway cough syndrome	17	0
Yawning	31	0
<i>Vascular pulmonary disorders NEC</i>		
Acute chest syndrome	1	0
Respiratory disorders SOC TOTAL	23064	71

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	223	0
Acne cystic	28	0
Dermatitis acneiform	13	0
Oil acne	1	0
<i>Alopecias</i>		
Alopecia	536	0
Alopecia areata	94	0
Alopecia totalis	5	0
Alopecia universalis	3	0
Androgenetic alopecia	2	0
Diffuse alopecia	5	0
Hypotrichosis	3	0
Lichen planopilaris	4	0
Madarosis	10	0
<i>Angioedemas</i>		
Angioedema	300	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	917	0
Hidradenitis	5	0
Hyperhidrosis	2866	0
Hypohidrosis	3	0
Milia	3	0
Miliaria	122	0
Night sweats	1030	0
Sweat discolouration	1	0
<i>Bullous conditions</i>		
Autoimmune blistering disease	1	0
Blister	578	0
Blister rupture	1	0
Blood blister	38	0
Dermatitis bullous	22	0
Erythema multiforme	52	0
Fracture blisters	1	0
Herpes gestationis	2	0
Mucous membrane pemphigoid	1	0
Pemphigoid	49	1
Pemphigus	11	0
Stevens-Johnson syndrome	7	0
Toxic epidermal necrolysis	2	1
<i>Connective tissue disorders</i>		
Chronic cutaneous lupus erythematosus	3	0
Dermatomyositis	15	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	318	0

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Fingerprint loss	1	0
Koebner phenomenon	1	0
Macule	6	0
Neutrophilic dermatosis	1	0
Pain of skin	367	0
Papule	121	0
Pathergy reaction	1	0
Scab	32	0
Scar discomfort	1	0
Scar pain	20	0
Sensitive skin	245	0
Shagreen skin	1	0
Skin burning sensation	284	0
Skin degenerative disorder	2	0
Skin discolouration	174	0
Skin discomfort	6	0
Skin disorder	40	0
Skin fissures	13	0
Skin indentation	3	0
Skin induration	5	0
Skin lesion	59	0
Skin lesion inflammation	1	0
Skin necrosis	3	0
Skin odour abnormal	31	0
Skin plaque	6	0
Skin reaction	182	0
Skin sensitisation	48	0
Skin swelling	120	0
Skin texture abnormal	2	0
Skin tightness	30	0
Skin warm	391	0
Skin weeping	21	0
Sticky skin	3	0
Target skin lesion	4	0
Transient acantholytic dermatosis	2	0
Yellow skin	28	0
<i>Dermatitis and eczema</i>		
Autoimmune dermatitis	2	0
Dermatitis	175	0
Dermatitis allergic	313	0
Dermatitis atopic	70	0
Dermatitis contact	31	0
Dermatitis diaper	4	0
Dyshidrotic eczema	33	0
Eczema	469	0
Eczema asteatotic	18	0
Eczema infantile	1	0
Eczema nummular	9	0
Eczema vesicular	1	0
Eczema weeping	8	0
Hand dermatitis	5	0
Intertrigo	1	0
Neurodermatitis	8	0

Case Series Drug Analysis Print

Name: COVID-19 Vaccine Pfizer/BioNTech Vaccine Analysis Print

Report Run Date: 24-Nov-2022

Data Lock Date: 23-Nov-2022 18:30:06

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Perioral dermatitis	3	0
Seborrhoeic dermatitis	10	0
Skin irritation	164	0
Stasis dermatitis	3	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	36	0
Drug reaction with eosinophilia and systemic symptoms	2	0
Fixed eruption	4	0
Palmar-plantar erythrodysesthesia syndrome	3	0
Severe cutaneous adverse reaction	2	0
Toxic skin eruption	2	0
<i>Erythemas</i>		
Erythema	2607	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	27	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	156	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Cutaneous sarcoidosis	1	0
Granuloma annulare	9	0
Interstitial granulomatous dermatitis	1	0
Necrobiosis lipoidica diabetorum	1	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	2	0
Keratosis pilaris	3	0
Lichenoid keratosis	7	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	3	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	6	0
Skin hypopigmentation	1	0
Vitiligo	39	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 bed bleeding	1	0
Nail discolouration	13	0
Nail disorder	8	0
Nail growth abnormal	1	0

Case Series Drug Analysis Print

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Report Run Date: 24-Nov-2022

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Nail pigmentation	2	0
Nail ridging	3	0
Onychalgia	10	0
Onychoclasia	10	0
Onychomadesis	4	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	35	0
Lichen sclerosus	14	0
Parapsoriasis	9	0
Pityriasis alba	1	0
Pityriasis rosea	150	0
Pityriasis rubra pilaris	1	0
<i>Photosensitivity and photodermatosis conditions</i>		
Actinic prurigo	1	0
Photosensitivity reaction	76	0
Polymorphic light eruption	4	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	15	0
Hair growth rate abnormal	1	0
Hair texture abnormal	8	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	6656	0
<i>Psoriatic conditions</i>		
Dermatitis psoriasiform	6	0
Guttate psoriasis	27	0
Nail psoriasis	3	0
Palmoplantar pustulosis	5	0
Psoriasis	287	0
Pustular psoriasis	5	0
Rebound psoriasis	2	0
<i>Purpura and related conditions</i>		
Ecchymosis	1	0
Henoch-Schonlein purpura	20	0
Petechiae	169	0
Purpura	67	0
<i>Pustular conditions</i>		
Acute generalised exanthematous pustulosis	2	0

Case Series Drug Analysis Print

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Data Lock Date: 23-Nov-2022 18:30:06
MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Rashes, eruptions and exanthems NEC</i>		
Butterfly rash	8	0
Rash	7021	1
Rash erythematous	1564	0
Rash macular	605	0
Rash maculo-papular	71	0
Rash morbilliform	51	0
Rash papular	419	0
Rash pruritic	1497	0
Rash scarlatiniform	1	0
Rash vesicular	96	0
Systemic lupus erythematosus rash	9	0
<i>Rosaceas</i>		
Erythematotelangiectatic rosacea	1	0
Papulopustular rosacea	1	0
Rosacea	43	0
<i>Scaly conditions</i>		
Dandruff	5	0
Pityriasis	32	0
<i>Sebaceous gland disorders</i>		
Sebaceous glands overactivity	1	0
Seborrhoea	15	0
<i>Skin and subcutaneous conditions NEC</i>		
Cellulite	2	0
Cutaneous symptom	6	0
Reactive perforating collagenosis	1	0
Skin mass	35	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Ischaemic skin ulcer	1	0
Mucocutaneous ulceration	1	0
Pyoderma gangrenosum	2	0
Scleroderma associated digital ulcer	1	0
Skin erosion	33	0
Skin ulcer	25	0
<i>Skin cysts and polyps</i>		
Dermal cyst	21	0
<i>Skin dystrophies</i>		
Keloid scar	3	0
Skin wrinkling	5	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	16	0
Skin haemorrhage	25	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	3	0
<i>Skin hypoplasias and atrophies</i>		
Skin atrophy	3	0
Skin striae	8	0
<i>Skin injuries and mechanical dermatoses</i>		
Decubitus ulcer	3	0
Needle track marks	5	0
<i>Skin preneoplastic conditions NEC</i>		
Actinic keratosis	1	0
<i>Skin vascular conditions NEC</i>		

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Angiodermatitis	2	0
Skin oedema	5	0
Vascular skin disorder	1	0
<i>Skin vasculitides</i>		
Capillaritis	4	0
Cutaneous vasculitis	18	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	23	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	33	0
<i>Telangiectasia and related conditions</i>		
Spider naevus	1	0
Telangiectasia	1	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	16	0
Cold urticaria	11	0
Idiopathic urticaria	4	0
Mechanical urticaria	19	0
Solar urticaria	4	0
Urticaria	2454	0
Urticaria cholinergic	2	0
Urticaria chronic	49	0
Urticaria contact	1	0
Urticaria papular	7	0
Urticaria thermal	12	0
Urticarial vasculitis	8	0
Skin disorders SOC TOTAL	35879	3

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Infant	2	0
Menarche	3	0
Menopause	56	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	42	0
Breast prosthesis user	3	0
Disability	5	0
Hearing disability	4	0
Housebound	1	0
Immobile	14	0
Impaired driving ability	5	0
Impaired work ability	22	0
Loss of personal independence in daily activities	71	0
Mental disability	2	0
Physical disability	8	0
Sight disability	13	0
Sitting disability	6	0
Walking aid user	3	0
Walking disability	3	0
Wheelchair user	1	0
<i>Economic circumstances</i>		
High income	1	0
Low income	1	0
<i>Educational issues</i>		
Educational problem	1	0
Illiteracy	3	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

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 25.1

Reaction Name	Total	Fatal
Social circumstances <small>Social circumstances cont'd</small>		
Patient dissatisfaction with treatment	1	0
Tattoo	1	0
<i>Tobacco use</i>		
Ex-tobacco user	1	0
Non-tobacco user	6	0
Tobacco user	1	0
Social circumstances SOC TOTAL	336	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 25.1

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
Lung transplant	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Cardiac operation	1	0
<i>Contraceptive methods female</i>		
Contraception	1	0
Contraceptive implant	4	0
Oral contraception	1	0
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dental and gingival therapeutic procedures</i>		
Tooth extraction	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>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
Hernia repair	1	0
Hormonal therapeutic procedures NEC		
Hormone replacement therapy	2	0
Hormone therapy	8	0
Immunisations		
COVID-19 immunisation	103	0
Immunisation	518	1
Vaccine coadministration	1	0
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	4	0
Limb therapeutic procedures		
Amputation	1	0
Arm amputation	1	0
Limb immobilisation	13	0
Limb operation	10	0
Lymphoid tissue therapeutic procedures		
Lymphadenectomy	2	0
Splenectomy	2	0
Male genital tract therapeutic procedures NEC		
Vasoligation	1	0
Mastectomies		
Breast conserving surgery	6	0
Nail therapeutic procedures		
Nail operation	3	0
Nervous system therapeutic procedures NEC		
Medical induction of coma	1	0
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		

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Dialysis	1	0
Respiratory tract therapeutic procedures NEC		
Asthma prophylaxis	4	0
Retinal therapeutic procedures		
Retinopexy	2	0
Skin and subcutaneous tissue therapeutic procedures NEC		
Dermal filler injection	4	0
Therapeutic skin care topical	1	0
Skull and brain therapeutic procedures		
Cerebrovascular operation	1	0
Posterior fossa decompression	1	0
Small intestine therapeutic procedures		
Ileostomy	1	0
Spine and spinal cord therapeutic procedures		
Spinal decompression	1	0
Tendon therapeutic procedures		
Tenodesis	1	0
Therapeutic bladder catheterisation		
Bladder catheterisation	2	0
Therapeutic procedures NEC		
Abscess drainage	1	0
Anaphylaxis treatment	8	0
Bed rest	9	0
Fatigue management	1	0
Hospitalisation	17	0
Injection	54	0
Interchange of vaccine products	420	0
Lesion excision	1	0
Localised alternating hot and cold therapy	3	0
Magnetic therapy	1	0
Mass excision	6	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
Stress management	1	0
Therapeutic procedure	2	0
Therapy change	2	0
Traction	1	0
Tracheal therapeutic procedures		
Tracheostomy	1	0
Uterine therapeutic procedures		
Endometrial ablation	2	0
Vascular therapeutic procedures NEC		
Vasodilation procedure	1	0
Surgical & medical procedures SOC TOTAL	1359	1

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Accelerated hypertension	2	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	3	0
<i>Aortic aneurysms and dissections</i>		
Acute aortic syndrome	1	0
Aortic aneurysm	3	0
Aortic aneurysm rupture	1	1
Aortic dissection	1	0
Aortic dissection rupture	1	1
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	6	0
Aortic thrombosis	5	0
<i>Aortic infections and inflammations</i>		
Aortitis	1	0
<i>Aortic necrosis and vascular insufficiency</i>		
Aortic occlusion	1	0
Aortic stenosis	2	0
<i>Arterial infections and inflammations</i>		
Arteritis	2	0
Giant cell arteritis	27	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	23	0
Labile blood pressure	5	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	4	0
<i>Circulatory collapse and shock</i>		
CT hypotension complex	2	0
Circulatory collapse	102	0
Hypoperfusion	2	0
Hypovolaemic shock	3	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	53	0
Haemorrhage	1428	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>		

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Lymphoedema	271	0
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	5	0
Embolism	67	0
Embolism arterial	2	0
Embolism venous	9	1
Microembolism	2	0
Thrombosis	588	12
Venous thrombosis	8	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial occlusive disease	2	0
Arterial spasm	1	0
Arteriosclerosis	5	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>		
Angiopathy	1	0
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	45	0
Vascular wall hypertrophy	1	0
Vasodilatation	47	0
Vein discolouration	8	0
Vein disorder	10	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	393	1
Femoral artery embolism	1	0
Jugular vein thrombosis	5	0
Pelvic venous thrombosis	4	0
Peripheral artery thrombosis	5	0
Peripheral embolism	5	0
Subclavian artery thrombosis	1	0
Subclavian vein thrombosis	4	0
Superficial vein thrombosis	33	0
Thrombophlebitis	34	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	65	0
Erythromelalgia	2	0
Flushing	502	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Hot flush	1308	0
Peripheral vascular disorder	4	0
Vein wall hypertrophy	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Claudication of jaw muscles	1	0
Extremity necrosis	3	0
Iliac artery occlusion	1	0
Intermittent claudication	4	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	419	0
Peripheral ischaemia	14	0
Poor peripheral circulation	25	0
Raynaud's phenomenon	81	0
Subclavian vein occlusion	1	0
Vasoconstriction	2	0
Phlebitis NEC		
Phlebitis	40	0
Phlebitis superficial	10	0
Site specific embolism and thrombosis NEC		
Brachiocephalic vein thrombosis	1	0
Site specific vascular disorders NEC		
Aortic disorder	1	0
Aortic rupture	2	2
Inferior vena cava dilatation	1	0
Pallor	469	0
Varicose veins NEC		
Spider vein	8	0
Varicophlebitis	4	0
Varicose vein	43	0
Varicose vein ruptured	1	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	6	0
Essential hypertension	6	0
Hypertension	846	0
Labile hypertension	2	0
Orthostatic hypertension	2	0
Secondary hypertension	1	0
Systolic hypertension	7	0
White coat hypertension	1	0
Vascular hypotensive disorders		
Capillary leak syndrome	2	0
Diastolic hypotension	1	0
Hypotension	490	1
Orthostatic hypotension	35	0
Vasculitides NEC		
Behcet's syndrome	5	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	4	1
Lupus vasculitis	1	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
MAGIC syndrome	2	0
Thromboangiitis obliterans	1	0
Vasculitis	63	0
<i>Vena caval embolism and thrombosis</i>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	7952	24
TOTAL REACTIONS FOR DRUG	511776	857
TOTAL REPORTS	177925	
TOTAL FATAL OUTCOME REPORTS		857