

COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 03-Jun-2021
Data Lock Date: 02-Jun-2021 18:30:03

All UK spontaneous reports received between 09/12/20 and 02/06/21 for mRNA Pfizer/BioNTech vaccine.

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

Case Series Drug Analysis Print

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

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia vitamin B12 deficiency	2	0
Deficiency anaemia	1	0
Iron deficiency anaemia	2	0
<i>Anaemias NEC</i>		
Anaemia	40	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	2	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	3	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	7	1
<i>Anaemias haemolytic mechanical factor</i>		
Microangiopathic haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	19	0
Spontaneous haematoma	1	0
<i>Coagulation factor deficiencies</i>		
Acquired haemophilia	2	0
<i>Coagulopathies</i>		
Abnormal clotting factor	2	0
Antiphospholipid syndrome	3	0
Coagulopathy	5	0
Disseminated intravascular coagulation	1	0
Hypercoagulation	3	0
Thrombotic microangiopathy	2	0
<i>Eosinophilic disorders</i>		
Eosinophilia	9	0
<i>Haematological disorders</i>		
Mast cell activation syndrome	3	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	7	0
Intravascular haemolysis	1	0
<i>Leukocytoses NEC</i>		
Leukocytosis	1	0
Lymphocytosis	4	0
Neutrophilia	2	0
<i>Leukopenias NEC</i>		
Leukopenia	2	0
Lymphopenia	2	0
<i>Lymphatic system disorders NEC</i>		
Abdominal lymphadenopathy	2	0
Hilar lymphadenopathy	1	0
Lymph node pain	797	0
Lymphadenitis	96	0
Lymphadenopathy	5449	0
Lymphatic disorder	1	0
Necrotic lymphadenopathy	1	0
Pseudolymphoma	5	0
Retroperitoneal lymphadenopathy	1	0
<i>Marrow depression and hypoplastic anaemias</i>		

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Aplasia pure red cell	2	0
Myelosuppression	1	0
Pancytopenia	3	0
Neutropenias		
Autoimmune neutropenia	2	0
Neutropenia	29	0
Platelet disorders NEC		
Platelet anisocytosis	1	0
Purpuras (excl thrombocytopenic)		
Purpura non-thrombocytopenic	1	0
Red blood cell abnormal findings NEC		
Polychromasia	1	0
Red blood cell abnormality	2	0
Spleen disorders		
Spleen atrophy	1	0
Splenic infarction	1	0
Splenic vein thrombosis	1	0
Splenomegaly	7	0
Thrombocytopenias		
Immune thrombocytopenia	51	0
Thrombocytopenia	118	1
Thrombocytopenic purpura	2	0
Thrombotic thrombocytopenic purpura	6	0
Thrombocytoses		
Thrombocytosis	3	0
Blood disorders SOC TOTAL	6715	2

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	4	0
Atrioventricular block complete	1	0
Atrioventricular block second degree	1	0
Bundle branch block	2	0
Bundle branch block right	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	3	0
Cardiac disorder	20	0
Cardiac dysfunction	1	0
Cardiovascular disorder	1	0
Intracardiac thrombus	1	0
<i>Cardiac hypertensive complications</i>		
Hypertensive heart disease	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	3	0
Palpitations	1156	0
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	1	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	2	0
Congestive cardiomyopathy	1	0
Stress cardiomyopathy	2	0
<i>Coronary artery disorders NEC</i>		
Coronary artery disease	4	2
Coronary artery occlusion	1	0
Coronary artery thrombosis	1	0
<i>Heart failures NEC</i>		
Cardiac failure	25	3
Cardiac failure acute	2	0
Cardiac failure chronic	1	0
Cardiac failure congestive	2	1
Cardiogenic shock	4	0
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	3	0
Acute myocardial infarction	16	1
Angina pectoris	47	0
Angina unstable	1	0
Arteriospasm coronary	1	0
Microvascular coronary artery disease	2	0
Myocardial infarction	107	21
Myocardial ischaemia	6	2
<i>Left ventricular failures</i>		
Acute left ventricular failure	1	0
Left ventricular failure	2	1
<i>Mitral valvular disorders</i>		
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
<i>Myocardial disorders NEC</i>		
Cardiac amyloidosis	1	0
Cardiomegaly	2	0
Left ventricular dysfunction	3	0

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Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Myocardial fibrosis	1	0
Myocardial haemorrhage	1	0
Myocardial oedema	2	0
Myocardial rupture	1	0
Right ventricular enlargement	1	0
Ventricular hypertrophy	2	0
Noninfectious myocarditis		
Myocarditis	34	0
Noninfectious pericarditis		
Pericarditis	26	1
Pericardial disorders NEC		
Pericardial effusion	7	0
Pericardial haemorrhage	2	2
Rate and rhythm disorders NEC		
Arrhythmia	41	0
Bradycardia	36	0
Cardiac flutter	70	0
Extrasystoles	44	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	6	0
Tachyarrhythmia	1	0
Tachycardia	482	0
Right ventricular failures		
Cor pulmonale	1	0
Supraventricular arrhythmias		
Arrhythmia supraventricular	8	0
Atrial fibrillation	109	0
Atrial flutter	9	0
Atrial tachycardia	3	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus bradycardia	3	0
Sinus tachycardia	32	0
Supraventricular tachycardia	21	0
Tricuspid valvular disorders		
Tricuspid valve incompetence	1	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	66	26
Cardio-respiratory arrest	1	1
Pulseless electrical activity	3	0
Ventricular arrhythmia	4	0
Ventricular extrasystoles	11	0
Ventricular fibrillation	5	1
Ventricular tachycardia	6	0
Cardiac disorders SOC TOTAL	2479	63

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	4	0
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	1	0
<i>Central nervous system disorders congenital NEC</i>		
Spina bifida	1	0
<i>Cerebellar disorders congenital</i>		
Hereditary ataxia	1	0
<i>Cerebral disorders congenital</i>		
Cerebral palsy	1	0
<i>Coagulation disorders congenital</i>		
Haemophilia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	1	0
<i>Gastrointestinal tract disorders congenital NEC</i>		
Gastroschisis	1	0
<i>Great vessel disorders congenital</i>		
Transposition of the great vessels	1	0
<i>Haematological disorders congenital NEC</i>		
Amegakaryocytic thrombocytopenia	1	0
<i>Haemoglobinopathies congenital</i>		
Congenital methaemoglobinaemia	1	0
<i>Lymphatic system disorders congenital</i>		
Cystic lymphangioma	1	0
<i>Musculoskeletal and connective tissue disorders of skull congenital</i>		
Craniosynostosis	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital multiplex arthrogyposis	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
<i>Peripheral nervous system disorders congenital NEC</i>		
Hereditary neuropathy with liability to pressure palsies	1	0
<i>Pulmonary and bronchial disorders congenital</i>		
Congenital cystic lung	1	0
<i>Retinal disorders congenital</i>		
Retinitis pigmentosa	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
Congenital disorders SOC TOTAL	24	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	11	0
Ear discomfort	41	0
Ear disorder	10	0
Ear haemorrhage	5	0
Ear pain	484	0
Ear pruritus	6	0
Ear swelling	17	0
Otorrhoea	2	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	1	0
Eustachian tube dysfunction	5	0
Eustachian tube obstruction	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	1	0
External ear pain	2	0
Red ear syndrome	2	0
<i>External ear infections and inflammations</i>		
External ear inflammation	2	0
<i>Hearing disorders NEC</i>		
Auditory disorder	4	0
<i>Hearing losses</i>		
Conductive deafness	1	0
Deafness	109	0
Deafness bilateral	5	0
Deafness neurosensory	11	0
Deafness transitory	3	0
Deafness unilateral	21	0
Hypoacusis	84	0
Sudden hearing loss	20	0
<i>Hyperacusia</i>		
Hyperacusis	22	0
Misophonia	3	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	1	0
Inner ear disorder	6	0
Meniere's disease	6	0
Vestibular disorder	3	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	3	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	27	0
Tinnitus	915	0
Vertigo	696	0
Vertigo labyrinthine	8	0
Vertigo positional	46	0
<i>Mastoid disorders</i>		
Mastoid effusion	1	0
<i>Middle ear disorders NEC</i>		
Middle ear disorder	2	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0

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Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
Ear disorders SOC TOTAL	2589	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	6	0
Thyroiditis subacute	2	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	1	0
Adrenocortical insufficiency acute	8	0
<i>Adrenal gland disorders NEC</i>		
Adrenal haemorrhage	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	1	0
Premature menarche	8	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	7	0
Ovulation delayed	1	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0
Goitre	7	0
Thyroid disorder	1	0
Thyroid pain	1	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	1	0
Hyperthyroidism	14	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	12	0
Endocrine disorders SOC TOTAL	72	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	5	0
<i>Cataract conditions</i>		
Cataract	5	0
<i>Choroid and vitreous haemorrhages and vascular disorders</i>		
Choroidal haemorrhage	1	0
Choroidal neovascularisation	1	0
Vitreous haemorrhage	3	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Chorioretinopathy	2	0
Vitreous detachment	15	0
Vitreous floaters	39	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	1	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	25	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	2	0
<i>Corneal infections, oedemas and inflammations</i>		
Keratitis	4	0
Ulcerative keratitis	4	0
<i>Eyelid movement disorders</i>		
Blepharospasm	59	0
Excessive eye blinking	1	0
Eyelid function disorder	2	0
Eyelid myokymia	2	0
Eyelid ptosis	24	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	2	0
Glaucoma	5	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	1	0
Iridocyclitis	7	0
Iritis	3	0
Uveitis	18	0
<i>Lacrimation disorders</i>		
Dry eye	80	0
Lacrimation increased	78	0
<i>Lid bleeding and vascular disorders</i>		
Eyelid bleeding	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	7	0
Chalazion	3	0
Eczema eyelids	2	0
Erythema of eyelid	3	0
Eyelid cyst	2	0
Eyelid irritation	2	0
Eyelid margin crusting	3	0
Eyelid oedema	3	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Eyelid rash	9	0
Swelling of eyelid	66	0
<i>Lid, lash and lacrimal structural disorders</i>		
Dermatochalasis	1	0
Eyelash changes	1	0
Eyelid exfoliation	2	0
Eyelid skin dryness	1	0
Growth of eyelashes	1	0
Lagophthalmos	2	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	3	0
Eye haemorrhage	12	0
Ocular vascular disorder	1	0
Ophthalmic vein thrombosis	1	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	5	0
Eye disorder	15	0
Eye oedema	7	0
Eye pain	548	0
Eye swelling	268	0
Eye symptom	2	0
Eye ulcer	2	0
Eyelid disorder	3	0
Eyelid pain	8	0
Eyelids pruritus	3	0
Ocular discomfort	18	0
Periorbital oedema	14	0
Periorbital pain	1	0
Periorbital swelling	66	0
Retinal disorder	1	0
Vitreous disorder	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	4	0
Eye discharge	14	0
Eye inflammation	13	0
Eye irritation	60	0
Eye pruritus	143	0
Limbal swelling	2	0
Ocular hyperaemia	122	0
<i>Ocular nerve and muscle disorders</i>		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Extraocular muscle paresis	1	0
Eye movement disorder	14	0
Ocular myasthenia	1	0
Ophthalmoplegia	2	0
Strabismus	2	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	9	0
Asthenopia	82	0
Eye paraesthesia	1	0
Foreign body sensation in eyes	14	0
Hypoaesthesia eye	7	0

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Eye disorders Eye disorders cont'd		
Photophobia	206	0
Optic disc abnormalities NEC		
Papilloedema	3	0
Optic nerve bleeding and vascular disorders		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	2	0
Orbital infections, inflammations and irritations		
Parophthalmia	1	0
Orbital structural change, deposit and degeneration		
Orbital oedema	2	0
Pupil disorders		
Miosis	2	0
Mydriasis	10	0
Pupil fixed	1	0
Pupils unequal	5	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal artery occlusion	4	0
Retinal artery thrombosis	1	0
Retinal haemorrhage	2	0
Retinal vein occlusion	13	0
Retinal vein thrombosis	2	0
Retinal structural change, deposit and degeneration		
Macular degeneration	1	0
Macular hole	1	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	1	0
Retinal detachment	3	0
Retinal tear	1	0
Retinal toxicity	1	0
Retinal, choroid and vitreous infections and inflammations		
Macular oedema	2	0
Retinal vasculitis	1	0
Retinopathies NEC		
Retinal exudates	2	0
Retinopathy	1	0
Scleral infections, irritations and inflammations		
Episcleritis	5	0
Scleritis	2	0
Scleral structural change, deposit and degeneration		
Scleral discolouration	2	0
Visual colour distortions		
Chloropsia	2	0
Cyanopsia	1	0
Erythropsia	2	0
Xanthopsia	1	0
Visual disorders NEC		
Diplopia	86	0
Glare	1	0
Halo vision	6	0
Metamorphopsia	9	0
Oscillopsia	2	0
Photopsia	69	0

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Eye disorders Eye disorders cont'd		
Scintillating scotoma	3	0
Vision blurred	558	0
Visual brightness	2	0
Visual snow syndrome	2	0
Visual field disorders		
Visual field defect	9	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	1	0
Blindness	41	0
Blindness transient	6	0
Blindness unilateral	8	0
Central vision loss	2	0
Sudden visual loss	2	0
Visual acuity reduced	10	0
Visual impairment	166	0
Visual pathway disorders		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	3244	0

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Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
Gastrointestinal sounds abnormal	10	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	1	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	0
Pancreatitis	4	0
Pancreatitis acute	6	0
Pancreatitis necrotising	1	0
<i>Anal and rectal disorders NEC</i>		
Anal sphincter atony	1	0
<i>Anal and rectal pains</i>		
Proctalgia	7	0
<i>Anal and rectal signs and symptoms</i>		
Anal hypoaesthesia	1	0
Anal spasm	1	0
Anorectal discomfort	3	0
Anorectal swelling	1	0
Rectal discharge	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	3	0
Tongue cyst	2	0
<i>Colitis (excl infective)</i>		
Colitis	21	1
Colitis ischaemic	1	0
Colitis microscopic	1	0
Colitis ulcerative	37	0
Crohn's disease	19	0
Eosinophilic colitis	1	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Teething	3	0
Tooth disorder	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	3	0
Dental paraesthesia	6	0
Hyperaesthesia teeth	17	0
Toothache	67	0
<i>Dental surface disorders</i>		
Tooth discolouration	1	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	3	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	2823	2
Diarrhoea haemorrhagic	14	0
<i>Diverticula</i>		
Diverticulum	2	0
Diverticulum intestinal	1	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	1	0
<i>Duodenal ulcers and perforation</i>		

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	2	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	176	0
Epigastric discomfort	9	0
Eructation	29	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	9	0
Faecaloma	1	0
Faeces discoloured	24	0
Faeces hard	1	0
Faeces pale	3	0
Faeces soft	8	0
Mucous stools	3	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	149	0
Aerophagia	3	0
Flatulence	93	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	4	1
Mallory-Weiss syndrome	1	0
Oesophageal varices haemorrhage	1	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	3	0
<i>Gastritis (excl infective)</i>		
Chronic gastritis	1	0
Gastritis	26	0
Reflux gastritis	4	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	2	0
Abdominal pain	648	0
Abdominal pain lower	42	0
Abdominal pain upper	1062	0
Abdominal rigidity	7	0
Abdominal tenderness	5	0
Gastrointestinal pain	68	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	126	0
Duodenogastric reflux	2	0
Gastric dilatation	3	0
Gastrooesophageal reflux disease	57	0
Impaired gastric emptying	4	0
Infrequent bowel movements	2	0
Intestinal pseudo-obstruction	2	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	1	0
Functional gastrointestinal disorder	5	0
Gastric disorder	4	0
Gastrointestinal disorder	7	0
Stomach mass	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	3	0

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Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Dyschezia	1	0
Gastrointestinal motility disorder	1	0
<i>Gastrointestinal fistulae</i>		
Diverticular fistula	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Duodenitis	1	0
Enteritis	3	0
Epiplonic appendagitis	1	0
Intestinal angioedema	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	3	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	331	0
Abdominal symptom	1	0
Acute abdomen	3	0
Anal incontinence	9	0
Breath odour	9	0
Dysphagia	104	1
Odynophagia	10	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	5	0
Frequent bowel movements	13	0
Irritable bowel syndrome	39	0
Oesophageal spasm	2	0
Pylorospasm	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	2	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	6	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	3	2
Mesenteric vein thrombosis	4	0
Visceral venous thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	8	0
Gingival discomfort	2	0
Gingival disorder	2	0
Gingival erythema	1	0
Gingival pain	55	0
Gingival pruritus	1	0
Gingival swelling	17	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	4	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	27	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Gastric varices	1	0
Haemorrhoids	17	0
Haemorrhoids thrombosed	1	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	8	0
Rectal haemorrhage	38	0
Small intestinal haemorrhage	5	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	4	2
Large intestine perforation	1	0
<i>Malabsorption syndromes</i>		
Bile acid malabsorption	1	0
Coeliac disease	7	0
Steatorrhoea	3	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	7	0
Nausea	7828	1
Regurgitation	1	0
Retching	51	0
Vomiting	2203	2
Vomiting projectile	35	0
<i>Non-mechanical ileus</i>		
Ileus paralytic	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	10	0
Haematemesis	21	2
Haematochezia	20	0
Melaena	7	0
Upper gastrointestinal haemorrhage	2	0
<i>Oesophageal stenosis and obstruction</i>		
Oesophageal stenosis	1	0
<i>Oesophagitis (excl infective)</i>		
Eosinophilic oesophagitis	1	0
Oesophagitis	1	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	1	0
Dry mouth	314	0
Lip dry	27	0
Saliva altered	2	0
Salivary hypersecretion	25	0
<i>Oral soft tissue disorders NEC</i>		
Angina bullosa haemorrhagica	1	0
Chapped lips	13	0
Cheilitis	17	0
Enlarged uvula	9	0
Lip blister	15	0
Lip disorder	4	0
Oral disorder	7	0
Oral lichen planus	3	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	2	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	6	0
Oral blood blister	8	0
Oral purpura	1	0
<i>Oral soft tissue infections</i>		
Angular cheilitis	1	0
<i>Oral soft tissue signs and symptoms</i>		
Anaesthesia oral	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Burning mouth syndrome	4	0
Coating in mouth	1	0
Hypoaesthesia oral	276	0
Lip discolouration	2	0
Lip erythema	1	0
Lip exfoliation	5	0
Lip pain	35	0
Lip pruritus	6	0
Lip scab	1	0
Oral discomfort	48	0
Oral dysaesthesia	1	0
Oral mucosal blistering	9	0
Oral mucosal eruption	10	0
Oral mucosal erythema	3	0
Oral mucosal exfoliation	6	0
Oral mucosal roughening	3	0
Oral pain	104	0
Oral pruritus	15	0
Paraesthesia oral	642	0
Pigmentation lip	1	0
Oral soft tissue swelling and oedema		
Lip oedema	3	0
Lip swelling	415	0
Mouth swelling	54	0
Oedema mouth	4	0
Palatal oedema	2	0
Palatal swelling	1	0
Peptic ulcers and perforation		
Peptic ulcer haemorrhage	6	0
Peritoneal and retroperitoneal disorders		
Ascites	1	0
Peritoneal and retroperitoneal fibrosis and adhesions		
Abdominal adhesions	1	0
Peritoneal and retroperitoneal haemorrhages		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	1
Rectal inflammations NEC		
Proctitis	1	0
Proctitis ulcerative	1	0
Salivary gland disorders NEC		
Salivary gland pain	8	0
Salivary gland enlargements		
Parotid gland enlargement	6	0
Salivary gland enlargement	3	0
Submaxillary gland enlargement	6	0
Salivary gland infections and inflammations		
Noninfective sialoadenitis	1	0
Stomatitis and ulceration		
Aphthous ulcer	26	0
Lip ulceration	9	0
Mouth ulceration	235	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Stomatitis	35	0
<i>Tongue disorders</i>		
Glossitis	10	0
Plicated tongue	2	0
Tongue disorder	22	0
Tongue haemorrhage	1	0
Tongue ulceration	17	0
Trichoglossia	2	0
<i>Tongue signs and symptoms</i>		
Glossodynia	123	0
Scalloped tongue	4	0
Stiff tongue	2	0
Swollen tongue	307	0
Tongue blistering	10	0
Tongue coated	11	0
Tongue discolouration	18	0
Tongue discomfort	28	0
Tongue dry	10	0
Tongue eruption	7	0
Tongue erythema	4	0
Tongue exfoliation	1	0
Tongue movement disturbance	3	0
Tongue oedema	17	0
Tongue rough	2	0
Tongue spasm	6	0
Gastrointestinal disorders SOC TOTAL	19679	15

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	4	0
Administration site erythema	2	0
Administration site extravasation	2	0
Administration site haematoma	3	0
Administration site inflammation	1	0
Administration site irritation	1	0
Administration site joint discomfort	1	0
Administration site joint movement impairment	1	0
Administration site pain	10	0
Administration site rash	1	0
Administration site swelling	2	0
Administration site warmth	1	0
Puncture site bruise	15	0
Puncture site pain	4	0
Puncture site reaction	1	0
Puncture site swelling	2	0
Vessel puncture site bruise	1	0
Vessel puncture site erythema	1	0
Vessel puncture site pain	1	0
<i>Adverse effect absent</i>		
No adverse event	14	0
<i>Application and instillation site reactions</i>		
Application site acne	2	0
Application site bruise	4	0
Application site burn	1	0
Application site erythema	7	0
Application site haemorrhage	1	0
Application site hypoaesthesia	1	0
Application site joint erythema	1	0
Application site joint pain	1	0
Application site mass	1	0
Application site odour	1	0
Application site pain	7	0
Application site pruritus	4	0
Application site rash	2	0
Application site reaction	1	0
Application site swelling	2	0
Application site vesicles	3	0
Instillation site warmth	2	0
<i>Asthenic conditions</i>		
Asthenia	860	1
Chronic fatigue syndrome	34	0
Decreased activity	2	0
Fatigue	12197	0
Malaise	2843	0
Sluggishness	5	0
<i>Body temperature altered</i>		
Hyperthermia	5	0
Hypothermia	18	0
Temperature regulation disorder	5	0
<i>Breast complications associated with device</i>		
Capsular contracture associated with breast implant	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Complications associated with device NEC</i>		
Capsular contracture associated with implant	1	0
Injury associated with device	2	0
Medical device pain	1	0
Medical device site swelling	1	0
<i>Death and sudden death</i>		
Clinical death	1	1
Death	126	126
Sudden death	23	23
<i>Febrile disorders</i>		
Hyperpyrexia	6	0
Pyrexia	8378	0
<i>Feelings and sensations NEC</i>		
Chills	5712	0
Feeling abnormal	688	0
Feeling cold	686	0
Feeling drunk	43	0
Feeling hot	625	0
Feeling jittery	12	0
Feeling of body temperature change	176	0
Hangover	34	0
Hunger	13	0
Sensation of foreign body	30	0
Temperature intolerance	19	0
Thirst	178	0
<i>Gait disturbances</i>		
Gait disturbance	84	0
Gait inability	34	0
Loss of control of legs	9	0
<i>General signs and symptoms NEC</i>		
Adhesion	1	0
Condition aggravated	80	0
Crepitations	1	0
Crying	51	0
Deformity	2	0
Developmental delay	1	0
Discharge	2	0
Disease progression	2	0
Disease recurrence	14	0
Effusion	2	0
Energy increased	8	0
Exercise tolerance decreased	4	0
Foaming at mouth	1	0
General physical health deterioration	11	1
General symptom	1	0
Glassy eyes	2	0
High-pitched crying	2	0
Illness	873	0
Induration	2	0
Influenza like illness	1399	0
Irritability postvaccinal	2	0
Local reaction	64	0
Moaning	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Multiple organ dysfunction syndrome	3	1
Nonspecific reaction	1	0
Peripheral swelling	1817	0
Pre-existing condition improved	8	0
Prolapse	1	0
Screaming	8	0
Secretion discharge	6	0
Swelling	1378	0
Swelling face	466	0
Symptom recurrence	1	0
Implant and catheter site reactions		
Implant site discolouration	1	0
Implant site pain	1	0
Implant site rash	1	0
Implant site swelling	1	0
Implant site warmth	1	0
Inflamations		
Granuloma	1	0
Inflammation	164	0
Papillitis	1	0
Serositis	1	0
Systemic inflammatory response syndrome	1	0
Infusion site reactions		
Infusion site coldness	1	0
Infusion site joint pain	2	0
Infusion site mass	1	0
Infusion site pain	1	0
Infusion site swelling	1	0
Infusion site urticaria	1	0
Infusion site warmth	1	0
Injection site reactions		
Injected limb mobility decreased	20	0
Injection site bruising	35	0
Injection site coldness	1	0
Injection site cyst	2	0
Injection site discolouration	3	0
Injection site discomfort	8	0
Injection site erythema	219	0
Injection site haemorrhage	4	0
Injection site hypoaesthesia	8	0
Injection site indentation	2	0
Injection site induration	2	0
Injection site inflammation	22	0
Injection site joint discomfort	1	0
Injection site joint movement impairment	1	0
Injection site joint pain	11	0
Injection site lymphadenopathy	1	0
Injection site macule	1	0
Injection site mass	277	0
Injection site necrosis	3	0
Injection site oedema	11	0
Injection site pain	1811	0
Injection site paraesthesia	9	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site pruritus	103	0
Injection site rash	80	0
Injection site reaction	20	0
Injection site scab	2	0
Injection site scar	3	0
Injection site swelling	190	0
Injection site urticaria	16	0
Injection site vesicles	7	0
Injection site warmth	99	0
Interactions		
Alcohol interaction	2	0
Drug interaction	15	0
Mass conditions NEC		
Cyst	10	0
Mass	21	0
Nodule	17	0
Mucosal findings abnormal		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	5	0
Mucosal inflammation	1	0
Oedema mucosal	1	0
Polyp	1	0
Necrosis NEC		
Fat necrosis	1	0
Necrosis	1	0
Oedema NEC		
Face oedema	20	0
Generalised oedema	1	0
Localised oedema	14	0
Oedema	31	0
Oedema peripheral	47	0
Pain and discomfort NEC		
Axillary pain	1245	0
Chest discomfort	683	0
Chest pain	1170	0
Discomfort	151	0
Facial discomfort	11	0
Facial pain	116	0
Inflammatory pain	3	0
Non-cardiac chest pain	16	0
Pain	4008	0
Suprapubic pain	1	0
Tenderness	385	0
Visceral pain	1	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	21	0
Adverse event	3	0
Adverse reaction	7	0
Drug ineffective	135	1
Immediate post-injection reaction	2	0
Inadequate analgesia	4	0
No reaction on previous exposure to drug	33	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Product intolerance	1	0
Therapeutic product effect delayed	2	0
Therapeutic product effect increased	1	0
Therapeutic product ineffective	2	0
Therapeutic response decreased	2	0
Therapeutic response unexpected	35	0
Treatment failure	5	0
Vaccination failure	5	0
Trophic disorders		
Calcinosis	1	0
Ulcers NEC		
Ulcer	10	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	8	0
Shoulder injury related to vaccine administration	9	0
Vaccination site bruising	67	0
Vaccination site coldness	1	0
Vaccination site cyst	2	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	9	0
Vaccination site discomfort	35	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	373	0
Vaccination site granuloma	1	0
Vaccination site haematoma	1	0
Vaccination site haemorrhage	9	0
Vaccination site hypersensitivity	2	0
Vaccination site hypoaesthesia	9	0
Vaccination site induration	57	0
Vaccination site inflammation	36	0
Vaccination site irritation	7	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	6	0
Vaccination site joint movement impairment	12	0
Vaccination site joint pain	22	0
Vaccination site joint swelling	2	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	3	0
Vaccination site macule	1	0
Vaccination site mass	135	0
Vaccination site movement impairment	47	0
Vaccination site nerve damage	1	0
Vaccination site nodule	1	0
Vaccination site oedema	3	0
Vaccination site pain	1337	0
Vaccination site paraesthesia	4	0
Vaccination site pruritus	86	0
Vaccination site rash	66	0
Vaccination site reaction	22	0
Vaccination site scab	1	0
Vaccination site swelling	365	0
Vaccination site ulcer	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site urticaria	8	0
Vaccination site vesicles	2	0
Vaccination site warmth	183	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	4	0
Withdrawal syndrome	12	0
General disorders SOC TOTAL	53534	154

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	3	0
Cholangitis	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholelithiasis	5	0
<i>Cholestasis and jaundice</i>		
Cholestasis	2	0
Cholestasis of pregnancy	1	0
Jaundice	13	0
Jaundice cholestatic	2	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	4	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	1	0
Hepatic failure	1	0
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	1	0
<i>Hepatic vascular disorders</i>		
Congestive hepatopathy	1	0
Hepatic artery embolism	1	0
Hepatic haemorrhage	1	0
Hepatic vein thrombosis	5	0
Portal vein thrombosis	2	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	10	0
Liver tenderness	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	3	0
Drug-induced liver injury	3	0
Hepatitis	7	0
Immune-mediated hepatic disorder	1	0
Liver injury	7	0
Hepatic disorders SOC TOTAL	80	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	9	0
<i>Allergic conditions NEC</i>		
Allergic oedema	10	0
Allergy to arthropod bite	1	0
Allergy to arthropod sting	1	0
Allergy to metals	1	0
Hypersensitivity	507	0
Mite allergy	1	0
Multiple allergies	5	0
Serum sickness	2	0
Serum sickness-like reaction	3	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	1	0
Type IV hypersensitivity reaction	5	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	4	0
Allergy to chemicals	2	0
Allergy to vaccine	27	0
Contrast media allergy	1	0
Contrast media reaction	1	0
Drug hypersensitivity	15	0
Food allergy	10	0
Oral allergy syndrome	2	0
Reaction to colouring	1	0
Reaction to excipient	5	0
Reaction to preservatives	3	0
Rubber sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	309	2
Anaphylactic shock	26	0
Anaphylactoid reaction	18	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	1	0
Seasonal allergy	23	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	18	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	17	0
Graft versus host disease	1	0
Immune system disorder	13	0
Immune-mediated adverse reaction	4	0
Immunisation reaction	1	0
Sensitisation	2	0
Systemic immune activation	2	0
<i>Immunodeficiency disorders NEC</i>		
Immunodeficiency	1	0
<i>Transplant rejections</i>		
Corneal graft rejection	4	0
Kidney transplant rejection	1	0
Immune system disorders SOC TOTAL	1064	2

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Abdominal abscess	1	0
Abdominal infection	1	0
Anal abscess	1	0
Appendicitis	11	0
Appendicitis perforated	1	0
Diverticulitis	4	0
Dysentery	1	0
Gastroenteritis	21	0
Mesenteric abscess	1	0
Peritonitis	1	1
Rectal abscess	1	0
<i>Aspergillus infections</i>		
Bronchopulmonary aspergillosis	1	0
<i>Bacterial infections NEC</i>		
Arthritis bacterial	2	0
Bacterial diarrhoea	1	0
Bacterial infection	3	0
Cellulitis	116	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
Folliculitis	8	0
Injection site cellulitis	2	0
Meningitis bacterial	1	0
Paronychia	1	0
Periorbital cellulitis	1	0
Tonsillitis bacterial	2	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	13	0
<i>Bone and joint infections</i>		
Abscess jaw	1	0
Osteomyelitis	1	0
<i>Borrelial infections</i>		
Lyme disease	1	0
Relapsing fever	1	0
<i>Breast infections</i>		
Breast abscess	2	0
Mastitis	25	0
<i>Caliciviral infections</i>		
Gastroenteritis norovirus	1	0
<i>Campylobacter infections</i>		
Campylobacter gastroenteritis	1	0
<i>Candida infections</i>		
Anal candidiasis	2	0
Candida infection	18	0
Oral candidiasis	26	0
Systemic candida	1	0
Vulvovaginal candidiasis	17	0
<i>Central nervous system and spinal infections</i>		
Cavernous sinus thrombosis	1	0
Encephalitis	11	0
Meningitis	4	0
Meningitis aseptic	1	0

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Infections Infections cont'd		
Myelitis	3	0
<i>Clostridia infections</i>		
Clostridium difficile infection	2	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	10	0
COVID-19	660	32
COVID-19 pneumonia	26	12
Coronavirus infection	6	0
Severe acute respiratory syndrome	1	0
Suspected COVID-19	37	1
<i>Coxiella infections</i>		
Q fever	9	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	3	0
Gingivitis	6	0
Parotitis	7	0
Pulpitis dental	1	0
Sialoadenitis	2	0
Tooth abscess	3	0
Tooth infection	4	0
<i>Ear infections</i>		
Ear infection	44	0
Labyrinthitis	56	0
Mastoiditis	1	0
Otitis media	2	0
Otitis media acute	1	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	2	0
Bed bug infestation	1	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	1	0
Infectious mononucleosis	15	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	39	0
Eye abscess	1	0
Eye infection	11	0
Eyelid infection	1	0
Hordeolum	14	0
Periorbital infection	2	0
<i>Female reproductive tract infections</i>		
Bartholinitis	1	0
Endometritis	1	0
Vulval abscess	1	0
<i>Fungal infections NEC</i>		
Fungal infection	4	0
Fungal skin infection	1	0
Onychomycosis	1	0
Pneumonia fungal	1	0
Vulvovaginal mycotic infection	2	0
<i>Hepatitis virus infections</i>		
Hepatitis A	1	0
Hepatitis E	1	0
<i>Hepatobiliary and spleen infections</i>		

Case Series Drug Analysis Print

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

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Biliary sepsis	1	0
Herpes viral infections		
Disseminated varicella zoster virus infection	1	0
Eczema herpeticum	2	0
Genital herpes	37	0
Genital herpes simplex	4	0
Herpes ophthalmic	3	0
Herpes simplex	14	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	2	0
Herpes virus infection	5	0
Herpes zoster	870	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	7	0
Herpes zoster reactivation	1	0
Nasal herpes	3	0
Ophthalmic herpes zoster	1	0
Oral herpes	189	0
Varicella	17	0
Varicella zoster virus infection	1	0
Infections NEC		
Abscess	22	0
Abscess limb	2	0
Abscess soft tissue	1	0
Genital abscess	1	0
Infected bite	1	0
Infected cyst	1	0
Infection	122	0
Injection site abscess	1	0
Injection site infection	4	0
Localised infection	16	0
Lymph gland infection	5	0
Lymph node abscess	2	0
Respiratory tract infection	4	0
Vaccination site abscess	3	0
Vaccination site infection	11	0
Vaccine breakthrough infection	22	0
Vestibulitis	2	0
Infectious transmissions		
Secondary transmission	2	0
Influenza viral infections		
Influenza	857	0
Klebsiella infections		
Klebsiella infection	1	0
Lower respiratory tract and lung infections		
Bronchitis	8	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	104	7
Pneumonia	63	9
Sputum purulent	1	0
Male reproductive tract infections		
Epididymitis	2	0
Orchitis	2	0

Case Series Drug Analysis Print

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

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Prostate infection	1	0
Mumps viral infections		
Mumps	4	0
Muscle and soft tissue infections		
Infective tenosynovitis	1	0
Necrotising fasciitis	1	0
Soft tissue infection	1	0
Neisseria infections		
Gonorrhoea	1	0
Pneumocystis infections		
Pneumocystis jirovecii pneumonia	1	0
Polyomavirus infections		
Progressive multifocal leukoencephalopathy	1	0
Retroviral infections		
HIV infection	1	0
Rotaviral infections		
Gastroenteritis rotavirus	1	0
Rubeola viral infections		
Measles	2	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Bacteraemia	1	0
Neutropenic sepsis	2	0
Sepsis	28	3
Sepsis syndrome	1	0
Septic shock	4	1
Urosepsis	2	0
Skin structures and soft tissue infections		
Abscess sweat gland	1	0
Acne pustular	1	0
Dermatitis infected	1	0
Impetigo	3	0
Infected skin ulcer	1	0
Injection site pustule	1	0
Pustule	7	0
Rash pustular	8	0
Skin infection	18	0
Subcutaneous abscess	6	0
Vaccination site pustule	2	0
Staphylococcal infections		
Furuncle	24	0
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	2	0
Staphylococcal sepsis	1	0
Streptococcal infections		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	5	0
Streptococcal abscess	1	0
Streptococcal endocarditis	1	0
Streptococcal sepsis	1	0
Tinea infections		
Body tinea	1	0
Tinea versicolour	1	0

Case Series Drug Analysis Print

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

Report Run Date: 03-Jun-2021

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Treponema infections</i>		
Syphilis	1	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	1	0
<i>Tuberculous infections</i>		
Lymph node tuberculosis	1	0
Pulmonary tuberculosis	1	0
<i>Upper respiratory tract infections</i>		
Acute sinusitis	1	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	13	0
Nasopharyngitis	464	0
Pharyngitis	11	0
Rhinitis	31	0
Sinusitis	70	0
Tonsillitis	46	0
Tracheitis	4	0
Upper respiratory tract infection	3	0
<i>Urinary tract infections</i>		
Cystitis	36	0
Kidney infection	12	0
Pyelonephritis	1	0
Urinary tract infection	73	0
<i>Vascular infections</i>		
Haematoma infection	1	0
Infusion site infection	1	0
Lymphangitis	5	0
<i>Viral infections NEC</i>		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Encephalitis viral	3	0
Eye infection viral	2	0
Gastroenteritis viral	12	0
Hepatitis viral	2	0
Meningitis viral	7	0
Oral viral infection	1	0
Pneumonia viral	1	1
Post viral fatigue syndrome	25	0
Sweating fever	59	0
Vestibular neuronitis	14	0
Viral diarrhoea	1	0
Viral infection	26	0
Viral labyrinthitis	3	0
Viral pericarditis	1	0
Viral pharyngitis	8	0
Viral rash	31	0
Viral sinusitis	1	0
Viral tonsillitis	1	0
Infections SOC TOTAL	4839	68

Case Series Drug Analysis Print

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

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 13-Apr-1968

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Mouth injury	3	0
Oral contusion	1	0
Palate injury	1	0
Rectal injury	1	0
Splenic rupture	3	0
Tongue injury	1	0
Tooth fracture	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	13	0
<i>Anaesthetic and allied procedural complications</i>		
Delayed recovery from anaesthesia	3	0
Sedation complication	1	0
<i>Atmospheric pressure injuries</i>		
Barotitis media	1	0
Hypobarism	1	0
<i>Bone and joint injuries NEC</i>		
Joint injury	3	0
<i>Cardiovascular injuries</i>		
Heart injury	2	0
Vascular injury	3	0
<i>Cerebral injuries NEC</i>		
Concussion	1	0
Subdural haematoma	4	0
Subdural haemorrhage	3	0
Traumatic intracranial haemorrhage	1	1
<i>Chemical injuries</i>		
Chemical cystitis	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	7	0
<i>Conditions caused by cold</i>		
Chillblains	35	0
<i>Cranial nerve injuries</i>		
Vth nerve injury	1	0
<i>Ear injuries NEC</i>		
Ear injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	8	0
Exposure via breast milk	18	0
Foetal exposure during pregnancy	9	0
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	392	0
Maternal exposure during pregnancy	201	0
Maternal exposure timing unspecified	1	0
Paternal exposure before pregnancy	1	0
Paternal exposure during pregnancy	4	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	1	0
<i>Eye and ear procedural complications</i>		
Toxic anterior segment syndrome	1	0
<i>Eye injuries NEC</i>		
Eye contusion	11	0
Eye injury	8	0

Case Series Drug Analysis Print

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

Report Run Date: 03-Jun-2021
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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Foreign body in eye	1	0
Injury corneal	1	0
Periorbital haematoma	1	0
Retinal injury	2	0
Fractures and dislocations NEC		
Bone fragmentation	1	0
Fracture	1	0
Joint dislocation	1	0
Gastrointestinal and hepatobiliary procedural complications		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	5	0
Procedural vomiting	1	0
Heat injuries (excl thermal burns)		
Heat exhaustion	1	0
Heat illness	1	0
Heat oedema	7	0
Heat stroke	3	0
Intentional product use issues		
Intentional product use issue	1	0
Limb fractures and dislocations		
Atypical femur fracture	1	0
Clavicle fracture	16	0
Wrist fracture	1	0
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	1	0
Dose calculation error	1	0
Medication error	11	0
Prescription drug used without a prescription	2	0
Product use complaint	1	0
Product use issue	9	0
Vaccination error	4	0
Wrong dose	2	0
Wrong drug	8	0
Wrong technique in product usage process	3	0
Muscle, tendon and ligament injuries		
Epicondylitis	7	0
Ligament sprain	4	0
Mallet finger	1	0
Muscle injury	5	0
Muscle rupture	2	0
Muscle strain	16	0
Tendon injury	5	0
Tendon rupture	2	0
Musculoskeletal procedural complications		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
Nerve injuries NEC		
Nerve injury	22	0
Neurological and psychiatric procedural complications		
Post procedural stroke	1	0
Procedural dizziness	9	0
Non-occupational environmental exposures		

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Exposure to extreme temperature	1	0
Non-site specific injuries NEC		
Arthropod sting	1	0
Bite	1	0
Electric shock	8	0
Fall	83	1
Foreign body	2	0
Injury	5	0
Traumatic haematoma	1	0
Wound	4	0
Wound complication	6	0
Wound haematoma	1	0
Wound haemorrhage	1	0
Wound secretion	2	0
Non-site specific procedural complications		
Incision site pain	2	0
Infusion related reaction	6	0
Injection related reaction	33	0
Post procedural complication	3	0
Procedural pain	1	0
Occupational exposures		
Occupational exposure to SARS-CoV-2	1	0
Occupational exposure to product	1	0
Off label uses		
Off label use	40	0
Overdoses NEC		
Overdose	14	0
Pathways and sources of exposure		
Exposure via unknown route	1	0
Peripheral nerve injuries		
Brachial plexus injury	1	0
Ulnar nerve injury	4	0
Poisoning and toxicity		
Alcohol poisoning	1	0
Poisoning	6	0
Toxicity to various agents	2	0
Product administration errors and issues		
Accidental overdose	3	0
Contraindicated product administered	1	0
Expired product administered	7	0
Inappropriate schedule of product administration	49	0
Incomplete course of vaccination	1	0
Incorrect dose administered	48	0
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	2	0
Poor quality product administered	2	0
Product administered at inappropriate site	7	0
Product administered to patient of inappropriate age	1	0
Product administration error	4	0
Product dose omission issue	3	0
Wrong product administered	12	0
Product confusion errors and issues		

Case Series Drug Analysis Print

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

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Product label confusion	1	0
Product dispensing errors and issues		
Product dispensing error	3	0
Product monitoring errors and issues		
Drug monitoring procedure incorrectly performed	1	0
Product preparation errors and issues		
Product preparation error	1	0
Product preparation issue	4	0
Product prescribing errors and issues		
Contraindicated product prescribed	2	0
Product selection errors and issues		
Product selection error	2	0
Radiation injuries		
Sunburn	9	0
Renal and urinary tract injuries NEC		
Foreign body in urogenital tract	1	0
Site specific injuries NEC		
Face crushing	1	0
Head injury	19	0
Limb crushing injury	2	0
Limb injury	35	0
Nasal injury	1	0
Skin injuries NEC		
Contusion	501	0
Nail avulsion	1	0
Scar	4	0
Scratch	2	0
Skin abrasion	4	0
Skin injury	1	0
Skin wound	1	0
Subcutaneous haematoma	1	0
Skull fractures, facial bone fractures and dislocations		
Fractured skull depressed	1	0
Spinal fractures and dislocations		
Spinal fracture	3	0
Stoma complications		
Gastrointestinal stoma complication	1	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
Thermal burns		
Airway burns	1	0
Burn oesophageal	1	0
Burn of internal organs	1	0
Burn oral cavity	1	0
Burns second degree	4	0
Thermal burn	12	0
Thermal burns of eye	8	0
Underdoses NEC		
Underdose	5	0
Vaccination related complications		
Adverse event following immunisation	1	0
Vaccination complication	37	0

Case Series Drug Analysis Print

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

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Injuries SOC TOTAL	1964	2

Case Series Drug Analysis Print

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

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Cortisol decreased	2	0
<i>Adrenal medulla tests</i>		
Epinephrine increased	1	0
<i>Auditory and vestibular diagnostic procedures</i>		
Acoustic stimulation tests	5	0
<i>Autoimmunity analyses</i>		
Antinuclear antibody	1	0
Antinuclear antibody increased	1	0
Rheumatoid factor	2	0
Rheumatoid factor increased	1	0
<i>Blood counts NEC</i>		
Blood count	3	0
Blood count abnormal	2	0
<i>Blood gas and acid base analyses</i>		
Blood lactic acid	3	0
Blood lactic acid decreased	1	0
Blood lactic acid increased	2	0
Blood pH	4	0
Blood pH increased	5	0
Oxygen consumption decreased	1	0
Oxygen saturation	5	0
Oxygen saturation decreased	42	0
<i>Bone marrow and immune tissue histopathology procedures</i>		
Biopsy lymph gland	1	0
<i>Bone marrow and immune tissue imaging procedures</i>		
Lymph nodes scan abnormal	1	0
Scan lymph nodes	1	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	6	0
Blood glucose abnormal	8	0
Blood glucose decreased	20	0
Blood glucose fluctuation	13	0
Blood glucose increased	72	0
Glycosylated haemoglobin increased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	9	0
Heart sounds	1	0
Heart sounds abnormal	2	0
<i>Cardiac function diagnostic procedures</i>		
Cardiac output	1	0
Central venous pressure	1	0
Stroke volume decreased	1	0
<i>Cell marker analyses</i>		
Prostatic specific antigen increased	1	0
<i>Central nervous system imaging procedures</i>		
Computerised tomogram head	2	0
Magnetic resonance imaging head	10	0
Magnetic resonance imaging head abnormal	1	0
<i>Chemistry analyses NEC</i>		
Inflammatory marker increased	3	0
<i>Cholesterol analyses</i>		
Blood cholesterol increased	2	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Remnant-like lipoprotein particles	1	0
Coagulation and bleeding analyses		
Activated partial thromboplastin time prolonged	14	0
Bleeding time	1	0
Bleeding time abnormal	1	0
Bleeding time prolonged	1	0
Blood thromboplastin	1	0
Clot retraction	1	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	3	0
Coagulation time shortened	1	0
Fibrin D dimer increased	4	0
International normalised ratio abnormal	4	0
International normalised ratio decreased	18	0
International normalised ratio fluctuation	1	0
International normalised ratio increased	41	0
ECG investigations		
Electrocardiogram	1	0
Electrocardiogram ST segment elevation	3	0
Electrocardiogram T wave inversion	2	0
Electrocardiogram abnormal	4	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	6	0
Faecal analyses NEC		
Faecal calprotectin	2	0
Faecal calprotectin increased	3	0
Fertility analyses		
Semen volume decreased	1	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate abnormal	1	1
Foetal non-stress test	1	0
Gastrointestinal and abdominal imaging procedures		
Computerised tomogram abdomen	1	0
Sigmoidoscopy abnormal	1	0
Gastrointestinal, pancreatic and APUD hormone analyses		
Blood insulin	1	0
Blood insulin decreased	1	0
Haematological analyses NEC		
Plasma viscosity	1	0
Red blood cell sedimentation rate increased	5	0
Heart rate and pulse investigations		
Heart rate	160	0
Heart rate abnormal	15	0
Heart rate decreased	22	0
Heart rate increased	357	0
Heart rate irregular	53	0
Pulse abnormal	9	0
Pulse pressure increased	1	0
Radial pulse abnormal	1	0
Sinus rhythm	1	0
Imaging procedures NEC		
Computerised tomogram	1	0
Magnetic resonance imaging	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Magnetic resonance imaging abnormal	1	0
Immunoglobulin analyses		
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	1	0
Immunology analyses NEC		
Antibody test	1	0
Immunology test	7	0
Immunology skin tests NEC		
Skin test positive	1	0
Investigations NEC		
Blood test	8	0
Blood test abnormal	13	0
False positive investigation result	1	0
Laboratory test	1	0
Polymerase chain reaction positive	33	0
Systemic lupus erythematosus disease activity index increased	1	0
Liver function analyses		
Alanine aminotransferase increased	11	0
Aspartate aminotransferase increased	1	0
Blood bilirubin increased	1	0
Gamma-glutamyltransferase increased	3	0
Hepatic enzyme increased	4	0
Liver function test	1	0
Liver function test abnormal	15	0
Liver function test increased	10	0
Transaminases increased	2	0
Metabolism tests NEC		
Blood ketone body	3	0
Blood ketone body increased	1	0
Blood uric acid increased	1	0
Ubiquinone	1	0
Microbiology and serology tests NEC		
Culture negative	1	0
Mineral and electrolyte analyses		
Blood copper increased	1	0
Blood iron	1	0
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	4	0
Blood potassium increased	1	0
Blood sodium decreased	5	0
Serum ferritin decreased	1	0
Serum ferritin increased	1	0
Musculoskeletal and soft tissue imaging procedures		
Skull X-ray	4	0
Musculoskeletal and soft tissue tests NEC		
Swollen joint count increased	1	0
Mycobacteria identification and serology		
Tuberculin test positive	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	2	0

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Lumbar puncture	1	0
Temperature perception test increased	1	0
Ophthalmic function diagnostic procedures		
Corneal reflex decreased	1	0
Intraocular pressure increased	5	0
Physical examination procedures and organ system status		
Body temperature	160	0
Body temperature abnormal	25	0
Body temperature decreased	25	0
Body temperature fluctuation	18	0
Body temperature increased	259	0
Body temperature normal	1	0
Breath sounds abnormal	1	0
General physical condition abnormal	1	0
Grip strength	2	0
Grip strength decreased	9	0
Head lag	1	0
Lymph node palpable	22	0
Ophthalmological examination	1	0
Orthopaedic examination abnormal	1	0
Palpatory finding abnormal	1	0
Product residue present	2	0
Psoriasis area severity index decreased	1	0
Respiratory rate	3	0
Respiratory rate decreased	4	0
Respiratory rate increased	24	0
Skin temperature	24	0
Temperature difference of extremities	6	0
Weight	1	0
Weight decreased	33	0
Weight increased	6	0
Pituitary analyses anterior		
Blood growth hormone	2	0
Blood prolactin increased	1	0
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	2	0
Platelet analyses		
Mean platelet volume decreased	1	0
Platelet count decreased	40	0
Platelet count increased	1	0
Protein analyses NEC		
C-reactive protein increased	10	0
Red blood cell analyses		
Haematocrit	1	0
Haemoglobin decreased	8	0
Renal function analyses		
Glomerular filtration rate decreased	1	0
Reproductive hormone analyses		
False negative pregnancy test	1	0
Pregnancy test	2	0
Pregnancy test false positive	1	0
Pregnancy test positive	1	0
Reproductive organ and breast histopathology procedures		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Smear cervix	1	0
Reproductive organ and breast imaging procedures		
Hysteroscopy	1	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume increased	2	0
Maximal voluntary ventilation	1	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	4	0
Pulmonary function test	2	0
Vital capacity	1	0
Respiratory tract and thoracic histopathology procedures		
Sputum abnormal	3	0
Respiratory tract and thoracic imaging procedures		
Chest X-ray	10	0
Chest X-ray normal	1	0
Computerised tomogram thorax	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	3	0
Troponin	1	0
Troponin increased	4	0
Therapeutic drug monitoring analyses		
Analgesic drug level	2	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 free increased	2	0
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	3	0
Tissue enzyme analyses NEC		
Blood alkaline phosphatase increased	2	0
Toxicology laboratory analyses		
Opiates	1	0
Urinalysis NEC		
Blood urine	7	0
Blood urine present	20	0
Cells in urine	1	0
Glucose urine present	1	0
Urine analysis abnormal	4	0
pH urine	5	0
pH urine increased	1	0
Urinary tract function analyses NEC		
Urine output	6	0
Urine output decreased	5	0
Urine output increased	4	0
Urinary tract imaging procedures		
Cystoscopy	2	0
Vascular imaging procedures NEC		
Venogram	1	0
Vascular tests NEC (incl blood pressure)		

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood pressure abnormal	4	0
Blood pressure decreased	35	0
Blood pressure diastolic	1	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	2	0
Blood pressure increased	135	0
Blood pressure measurement	23	0
Blood pressure systolic	1	0
Blood pressure systolic decreased	2	0
Blood pressure systolic increased	1	0
<i>Virus identification and serology</i>		
Coronavirus test	7	0
Coronavirus test positive	3	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	5	0
SARS-CoV-2 antibody test negative	10	0
SARS-CoV-2 antibody test positive	2	0
SARS-CoV-2 test	21	0
SARS-CoV-2 test false negative	1	0
SARS-CoV-2 test false positive	1	0
SARS-CoV-2 test negative	4	0
SARS-CoV-2 test positive	78	0
Viral test	4	0
<i>Vitamin analyses</i>		
Blood folate decreased	3	0
Vitamin B12 decreased	1	0
Vitamin D	2	0
Vitamin D decreased	1	0
<i>Water and electrolyte analyses NEC</i>		
Volume blood	1	0
<i>White blood cell analyses</i>		
Lymphocyte count	1	0
Lymphocyte count decreased	1	0
Neutrophil count	1	0
Neutrophil count decreased	2	0
White blood cell count	1	0
White blood cell count decreased	6	0
White blood cell count increased	3	0
Investigations SOC TOTAL	2327	2

Case Series Drug Analysis Print

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

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	7	0
Decreased appetite	677	0
Eating disorder symptom	1	0
Food craving	7	0
Food refusal	6	0
Hyperphagia	2	0
Hypophagia	9	0
Increased appetite	9	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	3	0
Tetany	2	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	26	0
Diabetes mellitus inadequate control	6	1
Increased insulin requirement	1	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	1	0
Type 1 diabetes mellitus	11	0
Type 2 diabetes mellitus	1	0
<i>Diabetic complications NEC</i>		
Diabetic complication	2	0
Diabetic ketoacidosis	8	0
Diabetic ketosis	1	0
<i>Disorders of purine metabolism</i>		
Gout	50	0
<i>Electrolyte imbalance NEC</i>		
Fluid imbalance	1	0
<i>Fluid intake increased</i>		
Polydipsia	4	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	2	0
Dairy intolerance	1	0
Food intolerance	4	0
Gluten sensitivity	2	0
Histamine intolerance	3	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	6	0
Abnormal weight gain	6	0
Cachexia	1	0
Feeding disorder	31	0
Food aversion	6	0
Neonatal insufficient breast milk syndrome	1	0
Overweight	1	0
Poor feeding infant	4	0
Weight loss poor	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	57	0
Insulin resistance	4	0
<i>Hypoglycaemic conditions NEC</i>		
Glycopenia	1	0
Hypoglycaemia	62	0

Case Series Drug Analysis Print

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Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Postprandial hypoglycaemia	1	0
Iron deficiencies		
Iron deficiency	2	0
Lipid metabolism and deposit disorders NEC		
Body fat disorder	1	0
Metabolic acidoses (excl diabetic acidoses)		
Ketoacidosis	4	0
Metabolic acidosis	2	0
Mixed acid-base disorders		
Acidosis	3	0
Potassium imbalance		
Hyperkalaemia	2	0
Hypokalaemia	2	0
Hypokalaemic syndrome	1	0
Sodium imbalance		
Hyponatraemia	6	0
Hyponatraemic syndrome	2	0
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	1	0
Total fluid volume decreased		
Dehydration	92	0
Total fluid volume increased		
Fluid retention	24	0
Hypervolaemia	1	0
Vitamin deficiencies NEC		
Hypovitaminosis	2	0
Metabolic disorders SOC TOTAL	1177	1

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	138	0
Arthropathy	16	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	1	0
Polyarthritis	10	0
Sacroiliitis	3	0
Seronegative arthritis	1	0
<i>Bone disorders NEC</i>		
Jaw disorder	3	0
Medial tibial stress syndrome	3	0
Osteitis	2	0
Osteonecrosis of jaw	2	0
Spinal disorder	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	207	0
Bone swelling	4	0
Coccydynia	1	0
Pain in jaw	176	0
Pubic pain	1	0
Spinal pain	30	0
<i>Bursal disorders</i>		
Bursitis	32	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	27	0
Osteochondritis	1	0
Polychondritis	2	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	1	0
Polymyalgia rheumatica	29	0
Sjogren's syndrome	4	0
<i>Crystal arthropathic disorders</i>		
Crystal arthropathy	1	0
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		
Bone deformity	1	0
Foot deformity	1	0
Hand deformity	2	0
Knee deformity	1	0
Limb deformity	1	0
Musculoskeletal deformity	1	0
<i>Joint related disorders NEC</i>		
Chondromalacia	1	0
Joint destruction	1	0
Joint laxity	2	0
Joint lock	11	0
Patellofemoral pain syndrome	1	0
Periarthritis	66	0
Rotator cuff syndrome	6	0
Temporomandibular joint syndrome	3	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
<i>Joint related signs and symptoms</i>		
Arthralgia	5100	0
Jaw clicking	4	0
Joint effusion	12	0
Joint noise	15	0
Joint range of motion decreased	8	0
Joint stiffness	118	0
Joint swelling	245	0
Joint vibration	1	0
Joint warmth	9	0
Loose body in joint	1	0
<i>Ligament disorders</i>		
Symphysiolysis	1	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	13	0
<i>Metabolic bone disorders</i>		
Osteopenia	1	0
Osteoporosis	1	0
<i>Muscle infections and inflammations</i>		
Antisynthetase syndrome	1	0
Myositis	13	0
Polymyositis	3	0
<i>Muscle pains</i>		
Fibromyalgia	52	0
Myalgia	6530	0
Myalgia intercostal	1	0
Myofascial pain syndrome	6	0
<i>Muscle related signs and symptoms NEC</i>		
Haematoma muscle	1	0
Muscle atrophy	8	0
Muscle discomfort	2	0
Muscle disorder	3	0
Muscle fatigue	200	0
Muscle mass	2	0
Muscle spasms	488	0
Muscle swelling	13	0
Muscle tightness	39	0
Muscle twitching	163	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	7	0
Nuchal rigidity	8	0
Torticollis	3	0
Trismus	15	0
<i>Muscle weakness conditions</i>		
Muscular weakness	448	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Back disorder	1	0
Limb mass	8	0
Mandibular mass	2	0
Mastication disorder	1	0
Mobility decreased	41	0
Musculoskeletal disorder	7	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Musculoskeletal stiffness	661	0
Posture abnormal	1	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Dactylitis	1	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	5	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1151	0
Flank pain	22	0
Limb discomfort	774	0
Musculoskeletal chest pain	89	0
Musculoskeletal discomfort	48	0
Musculoskeletal pain	30	0
Neck pain	982	0
Pain in extremity	6468	0
Rheumatic disorder	4	0
<i>Myopathies</i>		
Myopathy	4	0
Rhabdomyolysis	4	0
<i>Osteoarthropathies</i>		
Nodal osteoarthritis	1	0
Osteoarthritis	25	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	10	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	69	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	142	0
Fluctuance	1	0
Groin pain	58	0
Neck mass	14	0
Purple glove syndrome	1	0
Soft tissue swelling	3	0
<i>Spine and neck deformities</i>		
Kyphosis	1	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	6	0
Arthritis reactive	21	0
Spondylitis	1	0
<i>Synovial disorders</i>		
Synovial cyst	11	0
Synovitis	4	0
<i>Tendon disorders</i>		
Enthesopathy	1	0
Tendon pain	8	0
Tendonitis	15	0
Tenosynovitis	2	0
Tenosynovitis stenosaurs	1	0
Trigger finger	11	0

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
<i>Trunk deformities</i>		
Drooping shoulder syndrome	1	0
Muscle & tissue disorders SOC TOTAL	25054	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Neoplasms		
<i>B-cell lymphomas NEC</i>		
Follicular lymphoma	3	0
<i>Bone neoplasms unspecified malignancy</i>		
Bone neoplasm	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	22	0
Breast cancer stage I	1	0
Breast cancer stage III	1	0
Invasive ductal breast carcinoma	1	0
Triple negative breast cancer	2	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	1	0
Colorectal cancer	1	0
Rectal cancer	1	0
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Thyroid neoplasm	1	0
<i>Follicular lymphomas</i>		
Primary gastrointestinal follicular lymphoma	1	0
<i>Gastric neoplasms malignant</i>		
Gastric cancer	1	1
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	2	0
<i>Hodgkin's disease NEC</i>		
Hodgkin's disease	1	0
<i>Islet cell neoplasms and APUDoma NEC</i>		
Pancreatic neuroendocrine tumour	1	0
<i>Leukaemias acute NEC</i>		
Acute leukaemia	1	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	2	0
<i>Lip and oral cavity neoplasms malignant</i>		
Lip and/or oral cavity cancer recurrent	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	12	1
<i>Metastases to specified sites</i>		
Metastases to liver	1	0
Metastases to lymph nodes	5	0
<i>Metastases to unknown and unspecified sites</i>		
Metastasis	1	0
<i>Myeloproliferative disorders (excl leukaemias)</i>		
Essential thrombocythaemia	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Neoplasm malignant	2	0
Second primary malignancy	1	0
Squamous cell carcinoma	3	0
<i>Neoplasms unspecified malignancy and site unspecified NEC</i>		
Neoplasm	1	0
Neoplasm recurrence	1	0
<i>Nervous system neoplasms benign NEC</i>		
Cranial nerve neoplasm benign	1	0
<i>Nervous system neoplasms unspecified malignancy NEC</i>		
Brain neoplasm	1	0
<i>Neuromas</i>		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Acoustic neuroma	1	0
Non-Hodgkin's lymphomas NEC		
Non-Hodgkin's lymphoma	1	0
Oesophageal neoplasms malignant		
Oesophageal cancer metastatic	1	0
Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified		
Tonsil cancer	2	0
Pancreatic neoplasms malignant (excl islet cell and carcinoid)		
Pancreatic carcinoma	4	0
Plasma cell myelomas		
POEMS syndrome	1	0
Plasma cell myeloma	1	0
Plasma cell neoplasms NEC		
TEMPI syndrome	1	0
Prostatic neoplasms malignant		
Prostate cancer	2	0
Renal neoplasms malignant		
Renal cancer	2	0
Respiratory tract and pleural neoplasms malignant cell type unspecified NEC		
Lung neoplasm malignant	4	0
Skin melanomas (excl ocular)		
Malignant melanoma	1	0
Skin neoplasms benign		
Acrochordon	2	0
Anogenital warts	2	0
Haemangioma of skin	1	0
Melanocytic naevus	4	0
Skin papilloma	4	0
Skin neoplasms malignant and unspecified (excl melanoma)		
Basal cell carcinoma	2	0
Neoplasm skin	1	0
Squamous cell carcinoma of skin	1	0
Soft tissue neoplasms benign NEC		
Lipoma	1	0
Lymphangioma	1	0
Soft tissue sarcomas histology unspecified		
Sarcoma	1	0
Thyroid neoplasms malignant		
Papillary thyroid cancer	2	0
Thyroid cancer	1	0
Uterine neoplasms benign		
Uterine leiomyoma	5	0
Neoplasms SOC TOTAL	124	2

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	4	0
Extensor plantar response	1	0
Hyperreflexia	1	0
Hyporeflexia	4	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	9	0
<i>Absence seizures</i>		
Petit mal epilepsy	15	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	38	2
Subacute inflammatory demyelinating polyneuropathy	1	0
<i>Autonomic nervous system disorders</i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	5	0
Horner's syndrome	1	0
<i>Central nervous system aneurysms and dissections</i>		
Intracranial aneurysm	1	0
Vertebral artery dissection	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	1
Brain stem stroke	1	0
Carotid artery thrombosis	2	0
Cerebellar haemorrhage	1	0
Cerebellar infarction	2	0
Cerebellar ischaemia	1	0
Cerebellar stroke	3	0
Cerebral artery embolism	3	1
Cerebral artery occlusion	1	0
Cerebral artery thrombosis	3	0
Cerebral haemorrhage	27	6
Cerebral infarction	22	1
Cerebral thrombosis	4	0
Cerebrovascular accident	236	12
Embolic stroke	4	0
Haemorrhage intracranial	5	0
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	8	3
Internal capsule infarction	1	0
Intracranial haematoma	1	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	29	1
Lacunar infarction	2	0
Lacunar stroke	2	0
Lateral medullary syndrome	1	0
Subarachnoid haemorrhage	7	2
Thalamic infarction	1	0
Thrombotic stroke	2	0
<i>Central nervous system inflammatory disorders NEC</i>		
Gliosis	1	0
<i>Central nervous system vascular disorders NEC</i>		
Central nervous system vasculitis	1	0
Cerebral small vessel ischaemic disease	1	0

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Cerebrovascular disorder	1	0
Reversible cerebral vasoconstriction syndrome	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	26	0
Cerebral venous thrombosis	4	0
Superior sagittal sinus thrombosis	3	0
Transverse sinus thrombosis	1	0
<i>Cervical spinal cord and nerve root disorders</i>		
Cervicobrachial syndrome	3	0
<i>Choreiform movements</i>		
Chorea	2	0
<i>Coma states</i>		
Coma	4	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	6	0
Balance disorder	190	0
Coordination abnormal	26	0
Dysdiadochokinesis	1	0
Dysstasia	25	0
Nystagmus	8	0
<i>Cortical dysfunction NEC</i>		
Aphasia	38	0
Apraxia	1	0
Neurologic neglect syndrome	1	0
Sensory processing disorder	1	0
Visuospatial deficit	1	0
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	2	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	8	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	3	0
Clinically isolated syndrome	1	0
Demyelination	7	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	8	0
Consciousness fluctuating	2	0
Depressed level of consciousness	23	1
Lethargy	1368	0
Loss of consciousness	240	0
Sedation	5	0
Somnolence	510	0
Stupor	3	0
Syncope	744	0
<i>Disturbances in sleep phase rhythm</i>		
Irregular sleep wake rhythm disorder	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	2	0
Bradykinesia	7	0

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Clumsiness	9	0
Dyskinesia	30	0
Extrapyramidal disorder	1	0
Fine motor skill dysfunction	7	0
Hyperkinesia	3	0
Hypokinesia	29	1
Motor dysfunction	2	0
Movement disorder	28	0
Psychomotor hyperactivity	13	0
Synkinesis	1	0
Tardive dyskinesia	2	0
Dystonias		
Dystonia	12	0
Writer's cramp	1	0
Encephalitis NEC		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	1	0
Encephalopathies NEC		
Encephalopathy	2	0
Posterior reversible encephalopathy syndrome	1	0
Eye movement disorders		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	4	0
IVth nerve paralysis	1	0
VIth nerve paralysis	5	0
Facial cranial nerve disorders		
Bell's palsy	264	0
Facial nerve disorder	3	0
Facial paralysis	194	0
Facial paresis	51	0
Facial spasm	23	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	19	0
Headaches NEC		
Cervicogenic headache	3	0
Cluster headache	122	0
Cold-stimulus headache	10	0
Drug withdrawal headache	2	0
Exertional headache	5	0
External compression headache	1	0
Headache	15317	0
Medication overuse headache	2	0
New daily persistent headache	4	0
Occipital neuralgia	6	0
Ophthalmoplegic migraine	1	0
Primary cough headache	3	0
Primary headache associated with sexual activity	1	0
Sinus headache	209	0
Tension headache	292	0
Thunderclap headache	3	0
Vascular headache	11	0
Hydrocephalic conditions		

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Hydrocephalus	1	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Increased intracranial pressure disorders		
Brain oedema	1	0
Idiopathic intracranial hypertension	2	0
Intracranial pressure increased	1	0
Intellectual disabilities		
Intellectual disability	1	0
Lumbar spinal cord and nerve root disorders		
Sciatica	36	0
Memory loss (excl dementia)		
Amnesia	72	0
Memory impairment	66	0
Transient global amnesia	6	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	42	0
Cognitive linguistic deficit	1	0
Disturbance in attention	154	0
Mental impairment	25	0
Migraine headaches		
Hemiplegic migraine	11	0
Migraine	1408	0
Migraine with aura	97	0
Migraine without aura	11	0
Ophthalmic migraine	4	0
Retinal migraine	19	0
Typical aura without headache	4	0
Vestibular migraine	10	0
Mixed cranial nerve disorders		
Bulbar palsy	1	0
Mononeuropathies		
Carpal tunnel syndrome	9	0
Cubital tunnel syndrome	1	0
Mononeuropathy	1	0
Nerve compression	9	0
Peripheral nerve lesion	1	0
Peroneal nerve palsy	6	0
Sciatic nerve neuropathy	2	0
Ulnar neuritis	1	0
Multiple sclerosis acute and progressive		
Band sensation	1	0
Multiple sclerosis	18	0
Multiple sclerosis relapse	16	0
Tumefactive multiple sclerosis	1	1
Muscle tone abnormal		
Hypotonia	8	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
Myelitis (incl infective)		
Myelitis transverse	17	0
Narcolepsy and hypersomnia		

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Cataplexy	1	0
Hypersomnia	50	0
Narcolepsy	3	0
<i>Nervous system disorders NEC</i>		
Central nervous system lesion	2	0
Nervous system disorder	6	0
<i>Neurologic visual problems NEC</i>		
Hemianopia	1	0
Hemianopia homonymous	1	0
Quadrantanopia	1	0
Tunnel vision	6	0
<i>Neurological signs and symptoms NEC</i>		
Clonus	1	0
Dizziness	5042	0
Dizziness exertional	27	0
Dizziness postural	445	0
Drooling	13	0
Fontanelle bulging	1	0
Head discomfort	152	0
Hyporesponsive to stimuli	2	0
Inability to crawl	2	0
Infant irritability	2	0
Myoclonus	10	0
Neurological symptom	25	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	8	0
Presyncope	279	0
Sensory overload	1	0
Slow response to stimuli	2	0
Tongue biting	2	0
Unresponsive to stimuli	26	1
<i>Neuromuscular disorders NEC</i>		
Muscle contractions involuntary	12	0
Muscle spasticity	8	0
Neuromuscular pain	2	0
<i>Neuromuscular junction dysfunction</i>		
Myasthenia gravis	6	0
Myasthenia gravis crisis	2	0
<i>Olfactory nerve disorders</i>		
Anosmia	118	0
Hyposmia	9	0
Parosmia	125	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	18	0
<i>Paraesthesias and dysaesthesias</i>		
Burning feet syndrome	3	0
Burning sensation	251	0
Dysaesthesia	5	0
Formication	26	0
Hand-arm vibration syndrome	2	0
Hemiparaesthesia	1	0
Hyperaesthesia	48	0
Hypoaesthesia	1324	0

Case Series Drug Analysis Print

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

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Paraesthesia	1865	0
Reversed hot-cold sensation	2	0
Synaesthesia	1	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Diplegia	6	1
Hemiparesis	23	0
Hemiplegia	18	0
Locked-in syndrome	1	0
Monoparesis	34	0
Monoplegia	30	0
Paralysis	62	0
Paraparesis	2	0
Paresis	4	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	7	0
Parkinson's disease	3	0
Parkinsonian gait	1	0
Parkinsonism	4	0
Reduced facial expression	2	0
<i>Partial complex seizures</i>		
Dreamy state	5	0
Focal dyscognitive seizures	1	0
Temporal lobe epilepsy	1	0
<i>Peripheral neuropathies NEC</i>		
Neuralgic amyotrophy	1	0
Neuritis	5	0
Neuropathy peripheral	53	0
Peripheral sensory neuropathy	6	0
Thoracic outlet syndrome	1	0
<i>Seizures and seizure disorders NEC</i>		
Atonic seizures	4	0
Clonic convulsion	1	0
Epilepsy	105	0
Epileptic aura	2	0
Epileptic encephalopathy	1	0
Febrile convulsion	13	0
Partial seizures	10	0
Post stroke seizure	1	0
Psychogenic seizure	6	0
Seizure	271	0
Seizure anoxic	1	0
Seizure cluster	4	0
Seizure like phenomena	1	0
Status epilepticus	32	0
Tonic clonic movements	2	0
Tonic convulsion	12	0
<i>Sensory abnormalities NEC</i>		
Ageusia	269	0
Allodynia	11	0
Aura	10	0
Complex regional pain syndrome	1	0
Dysgeusia	750	0
Electric shock sensation	14	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Hypergeusia	1	0
Hypogeusia	1	0
Loss of proprioception	3	0
Neuralgia	261	0
Persistent genital arousal disorder	1	0
Phantom limb syndrome	3	0
Post herpetic neuralgia	12	0
Restless legs syndrome	53	0
Sensory disturbance	39	0
Sensory loss	38	0
Taste disorder	155	0
Visual perseveration	1	0
Sleep disturbances NEC		
Sleep deficit	2	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	90	0
Incoherent	5	0
Language disorder	1	0
Repetitive speech	1	0
Slow speech	6	0
Speech disorder	25	0
Spinal cord and nerve root disorders NEC		
Radiculitis brachial	7	0
Radiculopathy	3	0
Structural brain disorders NEC		
Brain injury	3	2
Hyperintensity in brain deep nuclei	1	0
Transient cerebrovascular events		
Transient ischaemic attack	89	1
Tremor (excl congenital)		
Action tremor	1	0
Essential tremor	2	0
Head titubation	4	0
Resting tremor	1	0
Tremor	862	0
Trigeminal disorders		
Facial neuralgia	12	0
Numb chin syndrome	1	0
Trigeminal nerve disorder	1	0
Trigeminal neuralgia	28	0
Vertigos NEC		
Vertigo CNS origin	1	0
Nervous system disorders SOC TOTAL	35953	37

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions not specified as induced or spontaneous</i>		
Abortion missed	2	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	92	1
<i>Foetal complications NEC</i>		
Foetal hypokinesia	2	0
Hydrops foetalis	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	1
<i>Labour onset and length abnormalities</i>		
Premature delivery	1	0
Premature labour	1	0
Premature rupture of membranes	1	0
<i>Maternal complications of pregnancy NEC</i>		
Morning sickness	9	0
Preterm premature rupture of membranes	2	0
<i>Normal newborn status</i>		
Normal newborn	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	15	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	5	0
<i>Stillbirth and foetal death</i>		
Foetal death	6	1
Stillbirth	2	0
<i>Umbilical cord complications</i>		
Umbilical cord abnormality	1	0
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	1	0
Pregnancy on contraceptive	1	0
Pregnancy on oral contraceptive	1	0
Pregnancy with contraceptive device	3	0
Pregnancy with implant contraceptive	1	0
Unintended pregnancy	1	0
Pregnancy conditions SOC TOTAL	150	3

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Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device connection issue	1	0
Device issue	2	0
<i>Device malfunction events NEC</i>		
Device infusion issue	1	0
Device pacing issue	1	0
Device stimulation issue	1	0
Oversensing	13	0
Thrombosis in device	3	0
<i>Device physical property and chemical issues</i>		
Device defective	6	0
Device kink	1	0
Needle issue	2	0
<i>Product contamination and sterility issues</i>		
Product contamination	3	0
Product contamination physical	1	0
<i>Product physical issues</i>		
Liquid product physical issue	7	0
Product odour abnormal	1	0
Product physical issue	2	0
Product taste abnormal	5	0
<i>Product quality issues NEC</i>		
Product origin unknown	4	0
null SOC TOTAL	54	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	8	0
Behaviour disorder	1	0
Staring	3	0
<i>Adjustment disorders</i>		
Adjustment disorder with depressed mood	1	0
<i>Affect alterations NEC</i>		
Affect lability	4	0
Constricted affect	1	0
Flat affect	4	0
Inappropriate affect	5	0
<i>Amnesic symptoms</i>		
Paramnesia	3	0
<i>Anxiety symptoms</i>		
Agitation	50	0
Anxiety	301	0
Immunisation anxiety related reaction	1	0
Nervousness	103	0
Stress	18	0
Tension	17	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	2	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	5	0
Aversion	1	0
Homicidal ideation	1	0
Indifference	5	0
Paranoia	12	0
Personality change	3	0
Social avoidant behaviour	4	0
Soliloquy	1	0
Suspiciousness	1	0
<i>Bipolar disorders</i>		
Bipolar I disorder	1	0
Bipolar disorder	4	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	3	0
Distractibility	1	0
Mental fatigue	112	0
<i>Communications disorders</i>		
Communication disorder	4	0
Mutism	2	0
<i>Confusion and disorientation</i>		
Confusional state	461	0
Disorientation	149	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	67	0
<i>Delusional symptoms</i>		
Delusion	6	0
<i>Depressive disorders</i>		
Agitated depression	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Depression	128	0
Depression suicidal	3	0
Major depression	3	0
Mixed anxiety and depressive disorder	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	4	0
Dissociation	14	0
Dissociative amnesia	1	0
Dissociative disorder	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	9	0
Insomnia	585	0
Middle insomnia	14	0
Terminal insomnia	9	0
<i>Dyssomnias</i>		
Dyssomnia	1	0
Poor quality sleep	101	0
<i>Eating disorders NEC</i>		
Bulimia nervosa	1	0
Eating disorder	6	0
Selective eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	10	0
Dysphoria	2	0
Emotional disorder	21	0
Emotional distress	13	0
Emotional poverty	1	0
Euphoric mood	25	0
Frustration tolerance decreased	1	0
Irritability	86	0
Mood altered	20	0
<i>Factitious disorders</i>		
Factitious disorder	2	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Agoraphobia	1	0
Fear	6	0
Fear of falling	3	0
Fear of injection	2	0
Osmophobia	1	0
Phobia	1	0
Phonophobia	1	0
Social fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	29	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	109	0
Hallucination, auditory	8	0
Hallucination, olfactory	4	0
Hallucination, tactile	1	0
Hallucination, visual	16	0
Hallucinations, mixed	1	0
<i>Increased physical activity levels</i>		
Restlessness	71	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Learning disorders</i>		
Learning disorder	1	0
<i>Mental disorders NEC</i>		
Mental disorder	7	0
<i>Mental disorders due to a general medical condition NEC</i>		
Neuropsychiatric symptoms	1	0
<i>Mood alterations with depressive symptoms</i>		
Decreased interest	7	0
Depressed mood	152	0
Feeling of despair	1	0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Sense of a foreshortened future	2	0
Tearfulness	22	0
<i>Mood alterations with manic symptoms</i>		
Hypomania	1	0
Mania	6	0
<i>Mood disorders NEC</i>		
Apathy	13	0
Laziness	1	0
Listless	13	0
<i>Narcolepsy and associated conditions</i>		
Hypnagogic hallucination	3	0
Hypnopompic hallucination	2	0
Sleep attacks	3	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive symptom	1	0
<i>Orgasmic disorders and disturbances</i>		
Anorgasmia	2	0
Female orgasmic disorder	1	0
<i>Panic attacks and disorders</i>		
Panic attack	60	0
Panic disorder	3	0
Panic reaction	11	0
<i>Parasomnias</i>		
Abnormal dreams	101	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Nightmare	109	0
Parasomnia	1	0
Sleep talking	2	0
Sleep terror	11	0
Somnambulism	2	0
<i>Perception disturbances NEC</i>		
Autoscopy	8	0
Deja vu	1	0
Derealisation	6	0
Flashback	2	0
Illusion	1	0
Near death experience	1	0
<i>Personality disorders NEC</i>		
Personality disorder	1	0
<i>Pervasive developmental disorders NEC</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Autism spectrum disorder	2	1
Psychiatric elimination disorders		
Enuresis	13	0
Psychiatric symptoms NEC		
Hypervigilance	3	0
Psychiatric symptom	2	0
Psychological trauma	1	0
Trance	1	0
Psychotic disorder NEC		
Psychotic behaviour	1	0
Psychotic disorder	11	0
Schizophrenia NEC		
Schizophrenia	1	0
Sexual desire disorders		
Libido decreased	4	0
Libido increased	2	0
Loss of libido	6	0
Sleep disorders NEC		
Sleep disorder	100	0
Sleep disorder due to general medical condition, insomnia type	1	0
Somatic symptom disorders		
Conversion disorder	3	0
Habit cough	11	0
Somatic symptom disorder	1	0
Vomiting psychogenic	1	0
Speech and language usage disturbances		
Disorganised speech	3	0
Logorrhoea	2	0
Speech articulation and rhythm disturbances		
Dysphemia	9	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
Stereotypies and automatisms		
Bruxism	7	0
Head banging	4	0
Stereotypy	1	0
Stress disorders		
Post-traumatic stress disorder	2	0
Substance related and addictive disorders		
Alcohol problem	1	0
Alcoholic hangover	1	0
Suicidal and self-injurious behaviour		
Intentional self-injury	4	0
Self-injurious ideation	2	0
Suicidal ideation	14	0
Suicide attempt	7	0
Thinking disturbances		
Bradyphrenia	23	0
Intrusive thoughts	3	0
Morbid thoughts	1	0
Tachyphrenia	2	0
Thinking abnormal	10	0
Tic disorders		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Tic	4	0
Psychiatric disorders SOC TOTAL	3514	1

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	1	0
Bladder irritation	1	0
Bladder pain	14	0
Dysuria	29	0
Incontinence	17	0
Lower urinary tract symptoms	2	0
Micturition disorder	2	0
Micturition urgency	19	0
Pollakiuria	50	0
Urethral pain	1	0
Urge incontinence	1	0
Urinary hesitation	1	0
Urinary incontinence	36	0
Urinary retention	28	0
Urine flow decreased	5	0
<i>Bladder disorders NEC</i>		
Bladder disorder	3	0
Urinary bladder haemorrhage	1	0
<i>Bladder infections and inflammations</i>		
Cystitis interstitial	2	0
<i>Genital and urinary tract disorders NEC</i>		
Genitourinary symptom	1	0
Urinary tract disorder	3	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Glomerulonephritis	1	0
Glomerulonephritis minimal lesion	5	0
Glomerulonephritis rapidly progressive	1	0
IgA nephropathy	1	0
Nephrotic syndrome	13	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	3	0
Hypertonic bladder	1	0
Hypotonic urinary bladder	1	0
Loss of bladder sensation	1	0
Neurogenic bladder	1	0
<i>Nephritis NEC</i>		
Lupus nephritis	1	0
Nephritis	2	0
Tubulointerstitial nephritis	1	0
<i>Renal disorders NEC</i>		
Renal disorder	1	0
Renal haemorrhage	1	0
Renal mass	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	28	1
Anuria	3	0
Oliguria	1	0
Renal failure	11	1
Renal impairment	13	0
Renal injury	1	0
<i>Renal lithiasis</i>		
Nephrolithiasis	3	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Renal neoplasms</i>		
Renal cyst	1	0
<i>Renal structural abnormalities and trauma</i>		
Kidney small	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal infarct	1	0
Renal vasculitis	1	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	26	0
Haematuria	23	0
Proteinuria	4	0
Urine abnormality	8	0
Urine odour abnormal	4	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	8	0
Nocturia	1	0
Polyuria	3	0
Renal colic	1	0
Renal pain	141	0
Urinary tract pain	2	0
Renal & urinary disorders SOC TOTAL	542	3

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	5	0
<i>Breast disorders NEC</i>		
Breast mass	40	0
Gynaecomastia	2	0
<i>Breast signs and symptoms</i>		
Breast discharge	2	0
Breast discomfort	4	0
Breast engorgement	1	0
Breast haematoma	1	0
Breast oedema	4	0
Breast pain	227	0
Breast swelling	50	0
Breast tenderness	23	0
Nipple pain	12	0
Nipple swelling	3	0
<i>Cervix disorders NEC</i>		
Cervical dysplasia	2	0
Cervix disorder	1	0
<i>Cervix neoplasms</i>		
Cervical polyp	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation disorder	1	0
Erectile dysfunction	25	0
Erection increased	2	0
Organic erectile dysfunction	2	0
Painful ejaculation	1	0
<i>Lactation disorders</i>		
Galactorrhoea	2	0
Lactation puerperal increased	1	0
Suppressed lactation	6	0
<i>Menopausal effects NEC</i>		
Artificial menopause	1	0
Menopausal symptoms	7	0
Premature menopause	6	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	51	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	3	0
Dysmenorrhoea	192	0
Intermenstrual bleeding	115	0
Menstrual discomfort	1	0
Menstrual disorder	200	0
Menstruation irregular	273	0
Premenstrual dysphoric disorder	2	0
Premenstrual headache	1	0
Premenstrual pain	10	0
Premenstrual syndrome	5	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	75	0
Hypomenorrhoea	59	0
Menstruation delayed	286	0
Oligomenorrhoea	8	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	511	0
Menometrorrhagia	2	0
Polymenorrhoea	71	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	2	0
Polycystic ovaries	6	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Adnexal torsion	1	0
Ovarian haemorrhage	1	0
Ovulation pain	7	0
Premature ovulation	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	10	0
Pelvic haemorrhage	6	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile discomfort	1	0
Penile erythema	1	0
Penile swelling	4	0
Penis disorder	2	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	2	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatomegaly	3	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital haemorrhage	6	0
Genital lesion	1	0
Genital ulceration	3	0
<i>Reproductive tract infections and inflammations NEC</i>		
Genital tract inflammation	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital pain	2	0
Genital rash	1	1
Genital swelling	1	0
Pelvic discomfort	3	0
Pelvic pain	34	0
Perineal pain	1	0
Pruritus genital	1	0
<i>Scrotal disorders NEC</i>		
Scrotal discomfort	1	0
Scrotal erythema	1	0
Scrotal exfoliation	1	0
Scrotal pain	3	0
Scrotal swelling	4	0
<i>Sexual function and fertility disorders NEC</i>		
Dyspareunia	2	0
Infertility	1	0
<i>Spermatogenesis and semen disorders</i>		
Aspermia	2	0
Haematospermia	4	0
Semen discolouration	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Testicular pain	17	0
Testicular swelling	5	0
<i>Uterine disorders NEC</i>		
Adenomyosis	1	0
Endometriosis	18	0
Uterine haemorrhage	5	0
Uterine pain	5	0
<i>Uterine tone disorders</i>		
Uterine spasm	6	0
<i>Vulvovaginal cysts and neoplasms</i>		
Vaginal cyst	2	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	259	0
Vulval haemorrhage	8	0
Vulval ulceration	3	0
Vulvovaginal ulceration	3	0
<i>Vulvovaginal signs and symptoms</i>		
Coital bleeding	1	0
Vaginal discharge	8	0
Vaginal odour	1	0
Vulval oedema	1	0
Vulvovaginal burning sensation	2	0
Vulvovaginal dryness	2	0
Vulvovaginal pain	8	0
Vulvovaginal pruritus	2	0
Vulvovaginal swelling	1	0
Reproductive & breast disorders SOC TOTAL	2777	1

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	2	0
Apnoeic attack	1	0
Dyspnoea	1884	6
Dyspnoea at rest	5	0
Dyspnoea exertional	17	1
Hyperventilation	24	0
Hypopnoea	47	0
Irregular breathing	9	0
Mouth breathing	3	0
Nocturnal dyspnoea	1	0
Orthopnoea	3	0
Respiration abnormal	28	0
Respiratory arrest	8	0
Respiratory depression	1	0
Respiratory distress	11	0
Sleep apnoea syndrome	5	0
Tachypnoea	21	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	1	0
Bronchiectasis	10	0
<i>Bronchospasm and obstruction</i>		
Asthma	169	0
Asthma late onset	2	0
Bronchospasm	12	0
Chronic obstructive pulmonary disease	13	0
Cough variant asthma	3	0
Obstructive airways disorder	4	0
Reversible airways obstruction	1	0
Wheezing	240	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	1	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	20	1
Respiratory acidosis	2	0
<i>Coughing and associated symptoms</i>		
Allergic cough	4	0
Cough	1237	2
Cough decreased	2	0
Haemoptysis	22	0
Productive cough	76	0
Sputum discoloured	4	0
Sputum increased	1	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Laryngeal disorder	1	0
Vocal cord disorder	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	1	0
Laryngospasm	1	0

Case Series Drug Analysis Print

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

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Stridor	14	0
Lower respiratory tract inflammatory and immunologic conditions		
Alveolitis	1	0
Hypersensitivity pneumonitis	1	0
Pneumonia aspiration	7	5
Pneumonitis	17	1
Pulmonary sarcoidosis	1	0
Lower respiratory tract signs and symptoms		
Hiccups	11	0
Increased bronchial secretion	1	0
Lung opacity	1	0
Pleuritic pain	8	0
Pulmonary pain	49	0
Rales	3	0
Nasal congestion and inflammations		
Nasal congestion	128	0
Nasal inflammation	1	0
Rhinitis allergic	7	0
Nasal disorders NEC		
Epistaxis	492	0
Intranasal hyposaesthesia	1	0
Intranasal paraesthesia	1	0
Nasal crusting	1	0
Nasal disorder	1	0
Nasal dryness	17	0
Nasal odour	6	0
Nasal oedema	3	0
Nasal pruritus	8	0
Neonatal hypoxic conditions		
Dry lung syndrome	1	0
Infantile apnoea	1	0
Paranasal sinus disorders (excl infections and neoplasms)		
Allergic sinusitis	1	0
Paranasal sinus inflammation	1	0
Sinonasal obstruction	7	0
Sinus congestion	31	0
Sinus disorder	4	0
Parenchymal lung disorders NEC		
Atelectasis	1	0
Emphysema	2	0
Interstitial lung disease	4	0
Lung infiltration	1	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	3	0
Pharyngeal disorders (excl infections and neoplasms)		
Pharyngeal erythema	5	0
Pharyngeal haemorrhage	2	0
Pharyngeal hyposaesthesia	20	0
Pharyngeal inflammation	4	0
Pharyngeal oedema	6	0
Pharyngeal paraesthesia	39	0
Pharyngeal swelling	132	0

Case Series Drug Analysis Print

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

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Pharyngeal ulceration	10	0
Tonsillar erythema	3	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	39	0
Tonsillar inflammation	3	0
Tonsillar ulcer	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	16	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	11	0
Pneumothorax	3	0
Pneumothorax spontaneous	1	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	2	0
<i>Pulmonary oedemas</i>		
Acute respiratory distress syndrome	1	0
Pulmonary congestion	5	0
Pulmonary oedema	13	1
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	229	16
Pulmonary infarction	3	0
Pulmonary thrombosis	2	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	2	1
Respiratory failure	7	1
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	5	0
Diaphragmalgia	3	0
Nasal flaring	1	0
Painful respiration	5	0
Respiratory symptom	7	0
Suffocation feeling	1	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	3	2
Lung disorder	3	0
Pulmonary mass	2	0
Respiratory disorder	6	0
Respiratory tract congestion	2	0
Respiratory tract inflammation	1	0
Respiratory tract irritation	5	0
Respiratory tract oedema	2	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	1	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal pain	1	0
<i>Upper respiratory tract neoplasms</i>		
Tonsillar cyst	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	53	0
Catarrh	12	0
Choking	9	1
Choking sensation	1	0
Dry throat	102	0

Case Series Drug Analysis Print

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

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Dysphonia	87	0
Increased upper airway secretion	4	0
Increased viscosity of upper respiratory secretion	11	0
Nasal discharge discolouration	2	0
Nasal discomfort	30	0
Nasal obstruction	2	0
Oropharyngeal blistering	9	0
Oropharyngeal discomfort	36	0
Oropharyngeal pain	1513	0
Oropharyngeal plaque	1	0
Paranasal sinus discomfort	22	0
Rhinalgia	6	0
Rhinorrhoea	447	0
Sinus pain	109	0
Sneezing	189	0
Snoring	4	0
Throat clearing	4	0
Throat irritation	140	0
Throat tightness	154	0
Upper airway obstruction	2	0
Upper-airway cough syndrome	4	0
Yawning	11	0
Respiratory disorders SOC TOTAL	8314	38

Case Series Drug Analysis Print

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

Report Run Date: 03-Jun-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	39	0
Acne cystic	3	0
Dermatitis acneiform	3	0
<i>Alopecias</i>		
Alopecia	86	0
Alopecia areata	7	0
Alopecia totalis	1	0
Androgenetic alopecia	1	0
Madarosis	1	0
<i>Angioedemas</i>		
Angioedema	119	0
Circumoral swelling	1	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	1	0
Cold sweat	362	0
Hidradenitis	1	0
Hyperhidrosis	1043	0
Miliaria	48	0
Night sweats	346	0
<i>Bullous conditions</i>		
Blister	242	0
Blister rupture	1	0
Blood blister	19	0
Dermatitis bullous	9	0
Erythema multiforme	20	0
Fracture blisters	1	0
Pemphigoid	12	0
Pemphigus	5	0
Stevens-Johnson syndrome	4	0
Toxic epidermal necrolysis	2	1
<i>Connective tissue disorders</i>		
Dermatomyositis	4	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	127	0
Macule	2	0
Pain of skin	153	0
Papule	40	0
Pathergy reaction	1	0
Peau d'orange	2	0
Scab	11	0
Scar pain	10	0
Sensitive skin	87	0
Skin burning sensation	125	0
Skin degenerative disorder	1	0
Skin discolouration	62	0
Skin discomfort	2	0
Skin disorder	5	0
Skin fissures	3	0
Skin indentation	2	0
Skin induration	3	0

Case Series Drug Analysis Print

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

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin lesion	27	0
Skin lesion inflammation	1	0
Skin necrosis	1	0
Skin odour abnormal	10	0
Skin plaque	1	0
Skin reaction	77	0
Skin sensitisation	16	0
Skin swelling	46	0
Skin tightness	20	0
Skin warm	164	0
Skin weeping	5	0
Sticky skin	1	0
Transient acantholytic dermatosis	1	0
Yellow skin	8	0
<i>Dermatitis and eczema</i>		
Dermatitis	64	0
Dermatitis allergic	133	0
Dermatitis atopic	14	0
Dermatitis contact	5	0
Dermatitis diaper	1	0
Dyshidrotic eczema	10	0
Eczema	110	0
Eczema asteatotic	4	0
Eczema nummular	3	0
Eczema weeping	1	0
Perioral dermatitis	1	0
Seborrhoeic dermatitis	1	0
Skin irritation	57	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	21	0
Fixed eruption	1	0
Toxic skin eruption	1	0
<i>Erythemas</i>		
Erythema	1310	0
Palmar erythema	4	0
Red man syndrome	1	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	1	0
Dermatitis exfoliative generalised	2	0
Exfoliative rash	11	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	53	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Cutaneous sarcoidosis	1	0
Granuloma annulare	1	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	1	0
Keratosis pilaris	1	0
Lichenoid keratosis	2	0
<i>Hyperpigmentation disorders</i>		
Argyria	1	0
Chloasma	1	0
Ephelides	1	0

Case Series Drug Analysis Print

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Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin hyperpigmentation	2	0
Solar lentigo	2	0
Hypertrichoses		
Hirsutism	1	0
Hypopigmentation disorders		
Skin depigmentation	2	0
Skin hypopigmentation	1	0
Vitiligo	3	0
Lipodystrophies		
Lipoatrophy	2	0
Nail and nail bed conditions (excl infections and infestations)		
Nail discolouration	5	0
Nail disorder	2	0
Nail pigmentation	2	0
Onychalgia	6	0
Onychoclasia	3	0
Onychomadesis	2	0
Splinter haemorrhages	1	0
Panniculitides		
Erythema nodosum	14	0
Papulosquamous conditions		
Erythema annulare	2	0
Lichen planus	6	0
Lichen sclerosus	1	0
Parapsoriasis	2	0
Pityriasis rosea	52	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	26	0
Polymorphic light eruption	1	0
Pigmentation changes NEC		
Haemosiderin stain	1	0
Pigmentation disorder	4	0
Pilar disorders NEC		
Hair colour changes	6	0
Hair disorder	1	0
Hair growth abnormal	1	0
Hair texture abnormal	4	0
Piloerection	11	0
Pseudofolliculitis	1	0
Pruritus NEC		
Itching scar	5	0
Pruritus	2853	0
Psoriatic conditions		
Dermatitis psoriasiform	2	0
Guttate psoriasis	9	0
Palmoplantar pustulosis	1	0
Psoriasis	83	0
Pustular psoriasis	1	0
Purpura and related conditions		
Henoch-Schonlein purpura	2	0
Petechiae	70	0
Purpura	27	0
Pustular conditions		

Case Series Drug Analysis Print

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

Report Run Date: 03-Jun-2021
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Data Lock Date: 02-Jun-2021 18:30:03
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Acute generalised exanthematous pustulosis	1	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	3	0
Rash	2962	0
Rash erythematous	642	0
Rash macular	282	0
Rash maculo-papular	38	0
Rash morbilliform	24	0
Rash papular	188	0
Rash pruritic	649	0
Rash vesicular	35	0
Systemic lupus erythematosus rash	5	0
Rosaceas		
Rosacea	14	0
Scaly conditions		
Dandruff	1	0
Pityriasis	11	0
Sebaceous gland disorders		
Seborrhoea	2	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	2	0
Reactive perforating collagenosis	1	0
Skin mass	9	0
Skin and subcutaneous tissue ulcerations		
Mucocutaneous ulceration	1	0
Scleroderma associated digital ulcer	1	0
Skin erosion	17	0
Skin ulcer	7	0
Skin cysts and polyps		
Dermal cyst	4	0
Skin dystrophies		
Skin wrinkling	2	0
Skin haemorrhages		
Haemorrhage subcutaneous	4	0
Skin haemorrhage	6	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	1	0
Skin hypoplasias and atrophies		
Skin striae	4	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	2	0
Skin preneoplastic conditions NEC		
Actinic keratosis	1	0
Skin vasculitides		
Cutaneous vasculitis	7	0
Vasculitic rash	12	0
Skin vasomotor conditions		
Livedo reticularis	17	0
Urticarias		
Chronic spontaneous urticaria	3	0
Cold urticaria	2	0
Idiopathic urticaria	1	0
Mechanical urticaria	3	0

Case Series Drug Analysis Print

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

Report Run Date: 03-Jun-2021

Data Lock Date: 02-Jun-2021 18:30:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Solar urticaria	2	0
Urticaria	935	0
Urticaria chronic	5	0
Urticaria contact	1	0
Urticaria papular	2	0
Urticaria thermal	3	0
Urticarial vasculitis	2	0
Skin disorders SOC TOTAL	14351	1

Case Series Drug Analysis Print

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

Report Run Date: 03-Jun-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 02-Jun-2021 18:30:03
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Infant	1	0
Menopause	9	0
Postmenopause	2	0
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Dependents</i>		
Sick relative	1	0
<i>Disability issues</i>		
Bedridden	16	0
Breast prosthesis user	1	0
Hearing disability	1	0
Housebound	1	0
Immobile	8	0
Impaired driving ability	1	0
Impaired work ability	4	0
Loss of personal independence in daily activities	5	0
Physical disability	2	0
Sight disability	3	0
Sitting disability	1	0
Walking disability	1	0
<i>Economic circumstances</i>		
High income	1	0
Low income	1	0
<i>Employment issues</i>		
Retirement	2	0
<i>Non-occupational and unspecified environmental problems</i>		
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	5	0
<i>Social issues NEC</i>		
Hair dye user	2	0
<i>Tobacco use</i>		
Ex-tobacco user	1	0
Non-tobacco user	4	0
Social circumstances SOC TOTAL	76	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Nerve block	1	0
<i>Antiinfective therapies</i>		
COVID-19 treatment	2	0
<i>Arterial therapeutic procedures (excl aortic)</i>		
Splenic artery embolisation	1	0
<i>Blood and blood product treatment</i>		
Transfusion	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	1	0
<i>Bronchial and pulmonary therapeutic procedures</i>		
Airway secretion clearance therapy	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Cardiac operation	1	0
<i>Contraceptive methods female</i>		
Contraceptive implant	1	0
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	3	0
Nothing by mouth order	3	0
Wheat-free diet	1	0
<i>Fertility and fertilisation interventions female</i>		
Endometrial scratching	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Intestinal anastomosis	1	0
Prophylaxis of nausea and vomiting	11	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	1	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	60	1
Immunisation	16	0
<i>Joint therapeutic procedures</i>		
Joint surgery	1	0
Knee arthroplasty	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	7	0
Limb operation	4	0
<i>Lymphoid tissue therapeutic procedures</i>		
Lymphadenectomy	1	0
<i>Mastectomies</i>		
Breast conserving surgery	2	0
<i>Nail therapeutic procedures</i>		
Nail operation	1	0
<i>Nervous system therapeutic procedures NEC</i>		
Multiple sclerosis relapse prophylaxis	2	0
<i>Phototherapies</i>		
UV light therapy	1	0
<i>Prophylactic procedures NEC</i>		

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
Anaphylaxis prophylaxis	2	0
Immune tolerance induction	1	0
Reproductive system disorder prophylaxis	1	0
Psychiatric therapies		
Electroconvulsive therapy	1	0
Renal therapeutic procedures		
Dialysis	1	0
Respiratory tract therapeutic procedures NEC		
Asthma prophylaxis	2	0
Skin and subcutaneous tissue therapeutic procedures NEC		
Dermal filler injection	3	0
Therapeutic procedures NEC		
Abscess drainage	1	0
Anaphylaxis treatment	3	0
Bed rest	2	0
Fatigue management	1	0
Hospitalisation	4	0
Injection	11	0
Interchange of vaccine products	3	0
Mass excision	1	0
Medication dilution	1	0
Product used for unknown indication	2	0
Therapeutic procedure	1	0
Therapy change	1	0
Surgical & medical procedures SOC TOTAL	171	1

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	7	0
Hypertensive urgency	1	0
Malignant hypertension	3	0
<i>Aneurysms and dissections non-site specific</i>		
Artery dissection	1	0
<i>Aortic aneurysms and dissections</i>		
Acute aortic syndrome	1	0
Aortic aneurysm rupture	1	0
Aortic dissection	1	0
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	3	0
Aortic thrombosis	1	0
<i>Aortic necrosis and vascular insufficiency</i>		
Aortic stenosis	1	0
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	9	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	8	0
Labile blood pressure	2	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	2	0
<i>Circulatory collapse and shock</i>		
CT hypotension complex	2	0
Circulatory collapse	40	0
Hypoperfusion	1	0
Neurogenic shock	18	0
Peripheral circulatory failure	3	0
Shock	9	0
Shock symptom	1	0
<i>Haemorrhages NEC</i>		
Bloody discharge	3	0
Haematoma	21	0
Haemorrhage	189	2
Internal haemorrhage	5	0
Venous haemorrhage	1	0
<i>Lymphangiopathies</i>		
Lymphangiopathy	1	0
Lymphocele	3	0
<i>Lymphoedemas</i>		
Lymphoedema	129	0
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	2	0
Embolism	60	0
Embolism venous	2	0
Microembolism	1	0
Thrombosis	164	7
Venous thrombosis	4	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial occlusive disease	2	0
Haemorrhagic infarction	1	0
Infarction	2	0

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Ischaemia	3	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Superficial vein prominence	1	0
Vascular pain	10	0
Vasodilatation	15	0
Vein discolouration	4	0
Vein disorder	5	0
Vein rupture	3	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	15	0
Deep vein thrombosis	151	0
Femoral artery embolism	1	0
Jugular vein thrombosis	2	0
Pelvic venous thrombosis	3	0
Peripheral embolism	1	0
Subclavian vein thrombosis	1	0
Thrombophlebitis	13	0
Thrombophlebitis superficial	7	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	26	0
Erythromelalgia	1	0
Flushing	313	0
Hot flush	592	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Extremity necrosis	1	0
Intermittent claudication	1	0
Ischaemic limb pain	1	0
Peripheral arterial occlusive disease	1	0
Peripheral artery occlusion	1	0
Peripheral coldness	189	0
Peripheral ischaemia	9	0
Poor peripheral circulation	6	0
Raynaud's phenomenon	41	0
Vasoconstriction	2	0
<i>Phlebitis NEC</i>		
Phlebitis	17	0
Phlebitis superficial	3	0
<i>Site specific vascular disorders NEC</i>		
Pallor	143	0
<i>Varicose veins NEC</i>		
Spider vein	2	0
Varicophlebitis	1	0
Varicose vein	8	0
<i>Vascular hypertensive disorders NEC</i>		
Diastolic hypertension	1	0
Essential hypertension	2	0
Hypertension	319	1
Labile hypertension	1	0
Orthostatic hypertension	1	0
Secondary hypertension	1	0
Systolic hypertension	2	0
<i>Vascular hypotensive disorders</i>		

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Hypotension	220	0
Orthostatic hypotension	16	0
<i>Vasculitides NEC</i>		
Behcet's syndrome	4	0
Granulomatosis with polyangiitis	1	0
MAGIC syndrome	1	0
Vasculitis	30	0
<i>Vena caval embolism and thrombosis</i>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	2901	10
TOTAL REACTIONS FOR DRUG	193768	406
TOTAL REPORTS	67998	
TOTAL FATAL OUTCOME REPORTS		406