

COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 01-Jul-2021
Data Lock Date: 30-Jun-2021 18:30:05

All UK spontaneous reports received between 9/12/20 and 30/06/21 for mRNA Pfizer/BioNTech vaccine analysis print.

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

Case Series Drug Analysis Print

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

Report Run Date: 01-Jul-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 30-Jun-2021 18:30:05
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	4	0
<i>Anaemias NEC</i>		
Anaemia	60	0
Anaemia macrocytic	1	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	2	0
Microcytic anaemia	1	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	5	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	8	1
<i>Anaemias haemolytic mechanical factor</i>		
Microangiopathic haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	25	0
Spontaneous haematoma	1	0
<i>Coagulation factor deficiencies</i>		
Acquired haemophilia	2	0
<i>Coagulopathies</i>		
Abnormal clotting factor	3	0
Antiphospholipid syndrome	4	0
Coagulopathy	7	1
Disseminated intravascular coagulation	1	0
Hypercoagulation	3	0
Thrombotic microangiopathy	2	0
<i>Eosinophilic disorders</i>		
Eosinophilia	11	0
<i>Haematological disorders</i>		
Blood disorder	2	0
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	5	0
<i>Leukopenias NEC</i>		
Leukopenia	3	0
Lymphopenia	3	0
<i>Lymphatic system disorders NEC</i>		
Abdominal lymphadenopathy	2	0
Hilar lymphadenopathy	1	0
Lymph node pain	934	0
Lymphadenitis	96	0
Lymphadenopathy	6310	0
Lymphatic disorder	1	0
Necrotic lymphadenopathy	2	0

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Pseudolymphoma	6	0
Retroperitoneal lymphadenopathy	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplasia pure red cell	2	0
Myelosuppression	1	0
Pancytopenia	5	0
<i>Neutropenias</i>		
Autoimmune neutropenia	2	0
Neutropenia	31	0
<i>Platelet disorders NEC</i>		
Platelet anisocytosis	1	0
<i>Purpuras (excl thrombocytopenic)</i>		
Purpura non-thrombocytopenic	1	0
<i>Red blood cell abnormal findings NEC</i>		
Polychromasia	2	0
Red blood cell abnormality	3	0
<i>Spleen disorders</i>		
Spleen atrophy	1	0
Splenic infarction	1	0
Splenic vein thrombosis	1	0
Splenomegaly	9	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	63	0
Thrombocytopenia	144	1
Thrombocytopenic purpura	4	0
Thrombotic thrombocytopenic purpura	5	0
<i>Thrombocytoses</i>		
Thrombocytosis	4	0
Blood disorders SOC TOTAL	7809	3

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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 first degree	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	25	0
Cardiac dysfunction	1	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	3	0
Intracardiac thrombus	2	0
<i>Cardiac hypertensive complications</i>		
Hypertensive heart disease	1	0
<i>Cardiac infections and inflammations NEC</i>		
Carditis	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	5	0
Palpitations	1493	0
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	1	0
Heart valve incompetence	1	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	2	0
Congestive cardiomyopathy	3	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	38	6
Cardiac failure acute	2	0
Cardiac failure chronic	1	0
Cardiac failure congestive	3	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	74	0
Angina unstable	1	0
Arteriospasm coronary	1	0
Microvascular coronary artery disease	2	0
Myocardial infarction	124	25
Myocardial ischaemia	6	2
<i>Left ventricular failures</i>		
Acute left ventricular failure	1	1
Left ventricular failure	4	2
<i>Mitral valvular disorders</i>		
Mitral valve incompetence	3	0

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Cardiac disorders Cardiac disorders cont'd		
Mitral valve prolapse	1	0
Myocardial disorders NEC		
Cardiac amyloidosis	1	0
Cardiomegaly	8	1
Left atrial dilatation	1	0
Left ventricular dysfunction	4	0
Left ventricular enlargement	1	0
Myocardial fibrosis	1	0
Myocardial haemorrhage	1	0
Myocardial oedema	3	0
Myocardial rupture	1	0
Right ventricular enlargement	1	0
Ventricular hypertrophy	2	0
Noninfectious myocarditis		
Myocarditis	74	0
Noninfectious pericarditis		
Pericarditis	50	1
Pericardial disorders NEC		
Pericardial effusion	10	0
Pericardial haemorrhage	3	3
Rate and rhythm disorders NEC		
Arrhythmia	59	0
Bradycardia	42	0
Cardiac flutter	116	0
Extrasystoles	71	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	7	0
Tachyarrhythmia	1	0
Tachycardia	530	0
Right ventricular failures		
Cor pulmonale	1	0
Supraventricular arrhythmias		
Arrhythmia supraventricular	8	0
Atrial fibrillation	123	0
Atrial flutter	10	0
Atrial tachycardia	4	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	1	0
Sinus bradycardia	5	0
Sinus tachycardia	35	0
Supraventricular tachycardia	24	0
Tricuspid valvular disorders		
Tricuspid valve incompetence	1	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	77	29
Cardio-respiratory arrest	1	1
Pulseless electrical activity	3	0
Ventricular arrhythmia	4	0
Ventricular extrasystoles	11	0
Ventricular fibrillation	6	1
Ventricular tachycardia	9	0
Cardiac disorders SOC TOTAL	3158	77

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	7	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>		
Arnold-Chiari malformation	1	0
Hereditary ataxia	1	0
<i>Cerebral disorders congenital</i>		
Cerebral palsy	2	0
<i>Chemically-induced congenital syndromes</i>		
Foetal warfarin syndrome	1	0
<i>Coagulation disorders congenital</i>		
Haemophilia	1	0
<i>Congenital disorders NEC</i>		
Foetal malformation	1	0
Young's syndrome	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
Neonatal alloimmune thrombocytopenia	1	0
<i>Haemoglobinopathies congenital</i>		
Congenital methaemoglobinaemia	1	0
<i>Lymphatic system disorders congenital</i>		
Cystic lymphangioma	2	0
<i>Male reproductive tract disorders congenital</i>		
Cryptorchism	1	0
Micropenis	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Developmental hip dysplasia	1	0
<i>Musculoskeletal and connective tissue disorders of skull congenital</i>		
Craniosynostosis	2	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital multiplex arthrogyposis	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	2	0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
<i>Palate disorders congenital</i>		
Cleft lip and palate	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>		

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
Ankyloglossia congenital	1	0
Congenital disorders SOC TOTAL	40	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	13	0
Ear discomfort	55	0
Ear disorder	12	0
Ear haemorrhage	7	0
Ear pain	579	0
Ear pruritus	6	0
Ear swelling	20	0
Otorrhoea	3	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	1	0
Eustachian tube dysfunction	6	0
Eustachian tube obstruction	2	0
<i>External ear disorders NEC</i>		
Auricular swelling	1	0
Excessive cerumen production	2	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	5	0
Diplacusis	1	0
<i>Hearing losses</i>		
Conductive deafness	1	0
Deafness	140	0
Deafness bilateral	6	0
Deafness neurosensory	12	0
Deafness transitory	3	0
Deafness unilateral	23	0
Hypoacusis	111	0
Sudden hearing loss	27	0
<i>Hyperacusia</i>		
Hyperacusis	30	0
Misophonia	3	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	1	0
Inner ear disorder	8	0
Meniere's disease	8	0
Vestibular disorder	7	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	4	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	34	0
Tinnitus	1149	0
Vertigo	835	0
Vertigo labyrinthine	9	0
Vertigo positional	57	0
<i>Mastoid disorders</i>		
Mastoid effusion	1	0
<i>Middle ear disorders NEC</i>		
Middle ear disorder	3	0

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Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
Ear disorders SOC TOTAL	3193	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
Thyroiditis	9	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>Anterior pituitary hyperfunction</i>		
Pituitary-dependent Cushing's syndrome	1	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	2	0
Premature menarche	13	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	18	0
Ovulation delayed	9	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0
Goitre	8	0
Thyroid disorder	4	0
Thyroid mass	1	0
Thyroid pain	3	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	2	0
Hyperthyroidism	16	0
Thyrotoxic crisis	2	0
<i>Thyroid hypofunction disorders</i>		
Autoimmune hypothyroidism	1	0
Hypothyroidism	18	0
Endocrine disorders SOC TOTAL	122	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	5	0
<i>Cataract conditions</i>		
Cataract	8	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	44	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	3	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	26	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	3	0
<i>Corneal infections, oedemas and inflammations</i>		
Keratitis	4	0
Ulcerative keratitis	4	0
<i>Eyelid movement disorders</i>		
Blepharospasm	79	0
Excessive eye blinking	2	0
Eyelid function disorder	3	0
Eyelid myokymia	2	0
Eyelid ptosis	30	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	2	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	1	0
Iridocyclitis	8	0
Iritis	4	0
Uveitis	24	0
<i>Lacrimation disorders</i>		
Dry eye	91	0
Lacrimation increased	90	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	3	0
Erythema of eyelid	4	0
Eyelid cyst	4	0
Eyelid irritation	2	0
Eyelid margin crusting	3	0
Eyelid oedema	3	0

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Eye disorders Eye disorders cont'd		
Eyelid rash	12	0
Swelling of eyelid	84	0
<i>Lid, lash and lacrimal structural disorders</i>		
Dermatochalasis	1	0
Eyelash changes	1	0
Eyelid exfoliation	2	0
Eyelid skin dryness	2	0
Growth of eyelashes	2	0
Lagophthalmos	2	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	4	0
Eye haemorrhage	17	0
Ocular vascular disorder	1	0
Ophthalmic vein thrombosis	1	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	6	0
Eye disorder	17	0
Eye oedema	9	0
Eye pain	651	0
Eye swelling	316	0
Eye symptom	7	0
Eye ulcer	2	0
Eyelid disorder	9	0
Eyelid pain	9	0
Eyelids pruritus	4	0
Ocular discomfort	19	0
Periorbital oedema	15	0
Periorbital pain	1	0
Periorbital swelling	80	0
Retinal disorder	1	0
Vitreous disorder	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	7	0
Eye discharge	15	0
Eye inflammation	16	0
Eye irritation	66	0
Eye pruritus	164	0
Limbal swelling	2	0
Ocular hyperaemia	144	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	20	0
Ocular myasthenia	1	0
Ophthalmoplegia	2	0
Strabismus	3	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	9	0
Asthenopia	99	0
Eye paraesthesia	1	0
Foreign body sensation in eyes	15	0
Hypoaesthesia eye	11	0

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Eye disorders Eye disorders cont'd		
Photophobia	255	0
Optic disc abnormalities NEC		
Papilloedema	4	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	15	0
Pupil fixed	2	0
Pupils unequal	6	0
Refractive and accommodative disorders		
Altered visual depth perception	1	0
Astigmatism	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal artery occlusion	5	0
Retinal artery thrombosis	1	0
Retinal haemorrhage	3	0
Retinal vein occlusion	20	0
Retinal vein thrombosis	2	0
Retinal structural change, deposit and degeneration		
Macular degeneration	2	0
Macular hole	2	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	1	0
Retinal detachment	3	0
Retinal tear	2	0
Retinal toxicity	3	0
Retinal, choroid and vitreous infections and inflammations		
Cystoid macular oedema	1	0
Macular oedema	2	0
Retinal vasculitis	2	0
Retinopathies NEC		
Retinal exudates	2	0
Retinopathy	1	0
Scleral infections, irritations and inflammations		
Episcleritis	7	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	107	0
Glare	1	0

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Eye disorders Eye disorders cont'd		
Halo vision	6	0
Metamorphopsia	13	0
Oscillopsia	2	0
Photopsia	76	0
Scintillating scotoma	3	0
Vision blurred	714	0
Visual brightness	3	0
Visual snow syndrome	2	0
Visual field disorders		
Visual field defect	11	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	2	0
Blindness	66	0
Blindness transient	7	0
Blindness unilateral	9	0
Central vision loss	2	0
Sudden visual loss	3	0
Visual acuity reduced	12	0
Visual impairment	196	0
Visual pathway disorders		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	3948	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
Gastrointestinal sounds abnormal	13	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	1	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	0
Pancreatitis	8	0
Pancreatitis acute	7	0
Pancreatitis necrotising	1	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	1	0
Anal sphincter atony	1	0
<i>Anal and rectal pains</i>		
Proctalgia	8	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
Rectal tenesmus	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	3	0
Tongue cyst	4	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	1	0
Colitis	29	1
Colitis ischaemic	1	0
Colitis microscopic	1	0
Colitis ulcerative	45	0
Crohn's disease	26	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	1	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Teething	4	0
Tooth disorder	2	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	5	0
Dental paraesthesia	10	0
Hyperaesthesia teeth	25	0
Toothache	87	0
<i>Dental surface disorders</i>		
Tooth discolouration	3	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	3	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	3393	2
Diarrhoea haemorrhagic	15	0
<i>Diverticula</i>		
Diverticulum	3	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Diverticulum intestinal	1	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	1	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	3	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	232	0
Epigastric discomfort	10	0
Eructation	30	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	10	0
Faecaloma	2	0
Faeces discoloured	32	0
Faeces hard	1	0
Faeces pale	3	0
Faeces soft	10	0
Mucous stools	4	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	247	0
Aerophagia	3	0
Flatulence	115	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	5	1
Mallory-Weiss syndrome	1	0
Oesophageal varices haemorrhage	1	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	6	0
<i>Gastritis (excl infective)</i>		
Chronic gastritis	2	0
Gastritis	27	0
Reflux gastritis	4	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	2	0
Abdominal pain	837	0
Abdominal pain lower	66	0
Abdominal pain upper	1360	0
Abdominal rigidity	10	0
Abdominal tenderness	7	0
Gastrointestinal pain	86	0
Oesophageal pain	3	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	158	0
Duodenogastric reflux	2	0
Gastric dilatation	5	0
Gastrooesophageal reflux disease	73	0
Impaired gastric emptying	6	0
Infrequent bowel movements	2	0
Intestinal pseudo-obstruction	2	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	2	0
Functional gastrointestinal disorder	6	0
Gastric disorder	5	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Jul-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 30-Jun-2021 18:30:05
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Gastrointestinal disorder	8	0
Stomach mass	3	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Change of bowel habit	3	0
Dyschezia	1	0
Gastrointestinal motility disorder	1	0
Oesophageal achalasia	1	0
<i>Gastrointestinal fistulae</i>		
Diverticular fistula	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Duodenitis	1	0
Enteritis	4	0
Epiploic appendagitis	2	0
Gastrointestinal inflammation	2	0
Intestinal angioedema	2	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	4	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	397	0
Abdominal symptom	1	0
Acute abdomen	4	0
Anal incontinence	13	0
Breath odour	13	0
Dysphagia	125	1
Odynophagia	17	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Cardiospasm	1	0
Defaecation urgency	7	0
Frequent bowel movements	16	0
Irritable bowel syndrome	48	0
Oesophageal spasm	3	0
Pylorospasm	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	2	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	5	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	4	2
Mesenteric vein thrombosis	4	0
Omental infarction	1	0
Visceral venous thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	11	0
Gingival discomfort	2	0
Gingival disorder	3	0
Gingival erythema	1	0
Gingival oedema	1	0
Gingival pain	72	0
Gingival pruritus	1	0
Gingival swelling	23	0
Gingival ulceration	1	0
Gingivitis ulcerative	1	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 30-Jun-2021 18:30:05
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Noninfective gingivitis	4	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	40	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Gastric varices	1	0
Haemorrhoids	19	0
Haemorrhoids thrombosed	1	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	11	0
Rectal haemorrhage	42	0
Small intestinal haemorrhage	5	0
<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	8	0
Steatorrhoea	4	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	9	0
Infantile vomiting	2	0
Nausea	9093	1
Regurgitation	1	0
Retching	62	0
Vomiting	2639	1
Vomiting projectile	38	0
<i>Non-mechanical ileus</i>		
Ileus paralytic	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	10	0
Haematemesis	23	2
Haematochezia	31	0
Melaena	8	0
Upper gastrointestinal haemorrhage	2	0
<i>Oesophageal stenosis and obstruction</i>		
Oesophageal stenosis	2	0
<i>Oesophagitis (excl infective)</i>		
Eosinophilic oesophagitis	1	0
Oesophagitis	2	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	2	0
Dry mouth	355	0
Lip dry	30	0
Saliva altered	4	0
Salivary hypersecretion	34	0
<i>Oral soft tissue disorders NEC</i>		
Angina bullosa haemorrhagica	1	0
Chapped lips	15	0
Cheilitis	19	0
Enlarged uvula	10	0
Lip blister	18	0
Lip disorder	4	0
Oral disorder	6	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Oral lichen planus	5	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	2	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	8	0
Oral blood blister	9	0
Oral purpura	1	0
Oral soft tissue infections		
Angular cheilitis	1	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	1	0
Burning mouth syndrome	4	0
Coating in mouth	1	0
Hypoaesthesia oral	328	0
Lip discolouration	4	0
Lip erythema	2	0
Lip exfoliation	5	0
Lip pain	39	0
Lip pruritus	8	0
Lip scab	1	0
Oral discomfort	55	0
Oral dysaesthesia	1	0
Oral mucosal blistering	12	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	11	0
Oral mucosal erythema	3	0
Oral mucosal exfoliation	7	0
Oral mucosal roughening	3	0
Oral pain	117	0
Oral pruritus	18	0
Paraesthesia oral	692	0
Pigmentation lip	1	0
Oral soft tissue swelling and oedema		
Lip oedema	3	0
Lip swelling	481	0
Mouth swelling	62	0
Oedema mouth	4	0
Palatal oedema	2	0
Palatal swelling	1	0
Peptic ulcers and perforation		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	8	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

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Salivary gland disorders NEC</i>		
Salivary gland pain	10	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	7	0
Salivary gland enlargement	3	0
Submaxillary gland enlargement	6	0
<i>Salivary gland infections and inflammations</i>		
Noninfective sialoadenitis	1	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	31	0
Lip ulceration	12	0
Mouth ulceration	283	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	43	0
<i>Tongue disorders</i>		
Glossitis	12	0
Plicated tongue	2	0
Tongue disorder	27	0
Tongue haemorrhage	2	0
Tongue ulceration	22	0
Trichoglossia	3	0
<i>Tongue signs and symptoms</i>		
Glossodynia	145	0
Scalloped tongue	5	0
Stiff tongue	3	0
Swollen tongue	350	0
Tongue blistering	12	0
Tongue coated	14	0
Tongue discolouration	20	0
Tongue discomfort	32	0
Tongue dry	12	0
Tongue eruption	8	0
Tongue erythema	6	0
Tongue exfoliation	1	0
Tongue movement disturbance	3	0
Tongue oedema	19	0
Tongue pruritus	1	0
Tongue rough	2	0
Tongue spasm	8	0
<i>Tooth missing</i>		
Tooth loss	2	0
Gastrointestinal disorders SOC TOTAL	23491	14

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Earliest Reaction Date: 13-Apr-1968

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	5	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	12	0
Administration site rash	2	0
Administration site swelling	2	0
Administration site urticaria	1	0
Administration site warmth	2	0
Puncture site bruise	22	0
Puncture site pain	5	0
Puncture site reaction	1	0
Puncture site swelling	2	0
Vessel puncture site bruise	2	0
Vessel puncture site erythema	1	0
Vessel puncture site pain	1	0
<i>Adverse effect absent</i>		
No adverse event	12	0
<i>Application and instillation site reactions</i>		
Application site acne	2	0
Application site bruise	5	0
Application site burn	1	0
Application site erythema	8	0
Application site haemorrhage	1	0
Application site hypoaesthesia	1	0
Application site irritation	1	0
Application site joint erythema	1	0
Application site joint pain	1	0
Application site mass	1	0
Application site odour	1	0
Application site pain	9	0
Application site pruritus	4	0
Application site rash	2	0
Application site reaction	1	0
Application site swelling	2	0
Application site vesicles	4	0
Instillation site warmth	4	0
<i>Asthenic conditions</i>		
Asthenia	1040	1
Chronic fatigue syndrome	43	0
Decreased activity	4	0
Fatigue	14217	0
Malaise	3181	0
Sluggishness	8	0
<i>Body temperature altered</i>		
Hyperthermia	5	0
Hypothermia	18	0
Temperature regulation disorder	6	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Breast complications associated with device</i>		
Capsular contracture associated with breast implant	1	0
<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>		
Brain death	1	1
Clinical death	1	1
Death	130	130
Sudden death	23	23
<i>Febrile disorders</i>		
Hyperpyrexia	6	0
Pyrexia	9401	0
<i>Feelings and sensations NEC</i>		
Chills	6235	0
Feeling abnormal	868	0
Feeling cold	764	0
Feeling drunk	53	0
Feeling hot	722	0
Feeling jittery	13	0
Feeling of body temperature change	209	0
Hangover	42	0
Hunger	20	0
Sensation of foreign body	36	0
Temperature intolerance	21	0
Thirst	220	0
<i>Fibrosis NEC</i>		
Fibrosis	1	0
<i>Gait disturbances</i>		
Gait disturbance	101	0
Gait inability	42	0
Loss of control of legs	10	0
<i>General signs and symptoms NEC</i>		
Adhesion	1	0
Chronic disease	1	0
Condition aggravated	97	0
Crepitations	1	0
Crying	78	0
Deformity	2	0
Developmental delay	1	0
Discharge	5	0
Disease progression	2	0
Disease recurrence	21	0
Effusion	2	0
Energy increased	11	0
Exercise tolerance decreased	9	0
Foaming at mouth	1	0
General physical health deterioration	13	1
General symptom	2	0
Glassy eyes	3	0
High-pitched crying	2	0

Case Series Drug Analysis Print

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 Earliest Reaction Date: 13-Apr-1968

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Illness	1062	0
Induration	7	0
Influenza like illness	1525	0
Irritability postvaccinal	2	0
Local reaction	66	0
Moaning	2	0
Multiple organ dysfunction syndrome	4	2
Nonspecific reaction	1	0
Organ failure	1	1
Peripheral swelling	2121	0
Pre-existing condition improved	8	0
Prolapse	1	0
Screaming	12	0
Secretion discharge	8	0
Swelling	1573	0
Swelling face	535	0
Symptom recurrence	1	0
Implant and catheter site reactions		
Implant site discolouration	2	0
Implant site pain	1	0
Implant site rash	1	0
Implant site swelling	1	0
Implant site urticaria	1	0
Implant site warmth	1	0
Inflamations		
Granuloma	1	0
Inflammation	214	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	21	0
Injection site bruising	46	0
Injection site coldness	1	0
Injection site cyst	2	0
Injection site discolouration	5	0
Injection site discomfort	9	0
Injection site erythema	249	0
Injection site haemorrhage	5	0
Injection site hypoaesthesia	8	0
Injection site indentation	2	0
Injection site induration	3	0
Injection site inflammation	26	0
Injection site joint discomfort	1	0
Injection site joint movement impairment	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site joint pain	12	0
Injection site lymphadenopathy	1	0
Injection site macule	1	0
Injection site mass	314	0
Injection site movement impairment	1	0
Injection site necrosis	3	0
Injection site oedema	11	0
Injection site pain	2067	0
Injection site paraesthesia	10	0
Injection site pruritus	120	0
Injection site rash	100	0
Injection site reaction	20	0
Injection site scab	2	0
Injection site scar	3	0
Injection site swelling	214	0
Injection site urticaria	17	0
Injection site vesicles	6	0
Injection site warmth	117	0
Interactions		
Alcohol interaction	2	0
Drug interaction	16	0
Inhibitory drug interaction	2	0
Mass conditions NEC		
Cyst	19	0
Mass	31	0
Nodule	26	0
Mucosal findings abnormal		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	6	0
Mucosal inflammation	1	0
Oedema mucosal	1	0
Polyp	1	0
Necrosis NEC		
Fat necrosis	2	0
Necrosis	2	0
Oedema NEC		
Face oedema	24	0
Generalised oedema	1	0
Localised oedema	15	0
Oedema	40	0
Oedema peripheral	56	0
Pain and discomfort NEC		
Axillary pain	1478	0
Chest discomfort	857	0
Chest pain	1661	0
Discomfort	202	0
Facial discomfort	12	0
Facial pain	132	0
Inflammatory pain	5	0
Non-cardiac chest pain	17	0
Pain	4870	0
Suprapubic pain	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Tenderness	429	0
Visceral pain	1	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	33	1
Adverse event	3	0
Adverse food reaction	1	0
Adverse reaction	9	0
Drug ineffective	155	1
Drug intolerance	2	0
Immediate post-injection reaction	2	0
Inadequate analgesia	4	0
No reaction on previous exposure to drug	37	0
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	44	0
Treatment failure	6	0
Vaccination failure	9	0
Trophic disorders		
Calcinosis	1	0
Ulcers NEC		
Ulcer	14	0
Ulcer haemorrhage	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	9	0
Shoulder injury related to vaccine administration	14	0
Vaccination site bruising	77	0
Vaccination site coldness	1	0
Vaccination site cyst	3	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	10	0
Vaccination site discomfort	35	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	417	0
Vaccination site granuloma	1	0
Vaccination site haematoma	1	0
Vaccination site haemorrhage	11	0
Vaccination site hypersensitivity	2	0
Vaccination site hypoaesthesia	10	0
Vaccination site induration	61	0
Vaccination site inflammation	44	0
Vaccination site irritation	8	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	6	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	14	0
Vaccination site joint pain	24	0
Vaccination site joint swelling	2	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	3	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site macule	1	0
Vaccination site mass	165	0
Vaccination site movement impairment	54	0
Vaccination site nerve damage	1	0
Vaccination site nodule	2	0
Vaccination site oedema	3	0
Vaccination site pain	1498	0
Vaccination site paraesthesia	4	0
Vaccination site pruritus	108	0
Vaccination site rash	85	0
Vaccination site reaction	25	0
Vaccination site scab	1	0
Vaccination site scar	1	0
Vaccination site swelling	401	0
Vaccination site ulcer	1	0
Vaccination site urticaria	8	0
Vaccination site vesicles	3	0
Vaccination site warmth	201	0
<i>Vascular complications associated with device</i>		
Vascular stent thrombosis	1	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	4	0
Withdrawal syndrome	17	0
General disorders SOC TOTAL	61974	162

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	5	0
Cholangitis	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholelithiasis	6	0
<i>Cholestasis and jaundice</i>		
Cholestasis	2	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	7	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	2	1
<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	2	0
Hepatic vein thrombosis	4	0
Portal vein thrombosis	3	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	16	0
Hepatomegaly	1	0
Liver tenderness	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	3	0
Drug-induced liver injury	2	0
Hepatitis	8	0
Immune-mediated hepatic disorder	1	0
Liver injury	8	0
Hepatic disorders SOC TOTAL	95	1

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	10	0
<i>Allergic conditions NEC</i>		
Allergic oedema	11	0
Allergy to animal	1	0
Allergy to arthropod bite	2	0
Allergy to arthropod sting	1	0
Allergy to metals	1	0
Allergy to sting	1	0
Hypersensitivity	609	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	6	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 reaction	1	0
Drug hypersensitivity	18	0
Food allergy	14	0
Oral allergy syndrome	2	0
Reaction to colouring	1	0
Reaction to excipient	7	0
Reaction to preservatives	3	0
Rubber sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	357	2
Anaphylactic shock	33	0
Anaphylactoid reaction	19	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	1	0
Seasonal allergy	55	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	22	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	28	0
Graft versus host disease	1	0
Immune system disorder	16	0
Immune-mediated adverse reaction	5	0
Immunisation reaction	1	0
Sensitisation	3	0
Systemic immune activation	2	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
Immunosuppression	1	0
<i>Transplant rejections</i>		
Corneal graft rejection	4	0

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Reaction Name	Total	Fatal
Immune system disorders		
Immune system disorders cont'd		
Kidney transplant rejection	1	0
Solid organ transplant rejection	1	0
Immune system disorders SOC TOTAL	1291	2

Case Series Drug Analysis Print

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

Report Run Date: 01-Jul-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 30-Jun-2021 18:30:05
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Abdominal abscess	1	0
Abdominal infection	1	0
Anal abscess	2	0
Appendicitis	20	0
Appendicitis perforated	1	0
Diverticulitis	4	0
Dysentery	1	0
Gastric infection	2	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	3	0
Bacterial diarrhoea	1	0
Bacterial infection	8	0
Cellulitis	123	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
Folliculitis	10	0
Injection site cellulitis	2	0
Meningitis bacterial	3	0
Paronychia	2	0
Perichondritis	1	0
Periorbital cellulitis	1	0
Sinusitis bacterial	1	0
Skin bacterial infection	1	0
Tonsillitis bacterial	2	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	14	0
<i>Bartonella infections</i>		
Cat scratch disease	1	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	37	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	25	0
Oral candidiasis	33	0
Systemic candida	1	0

Case Series Drug Analysis Print

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Report Run Date: 01-Jul-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 30-Jun-2021 18:30:05
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Vulvovaginal candidiasis	23	0
Cardiac infections		
Pericarditis infective	1	0
Central nervous system and spinal infections		
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	14	0
Meningitis	4	0
Meningitis aseptic	1	0
Myelitis	4	0
Clostridia infections		
Clostridium difficile infection	2	0
Coronavirus infections		
Asymptomatic COVID-19	11	0
COVID-19	733	33
COVID-19 pneumonia	34	13
Coronavirus infection	6	0
Severe acute respiratory syndrome	1	0
Suspected COVID-19	41	1
Coxiella infections		
Q fever	9	0
Cytomegaloviral infections		
Cytomegalovirus syndrome	1	0
Dental and oral soft tissue infections		
Abscess oral	4	0
Gingivitis	7	0
Parotitis	8	0
Pulpitis dental	1	0
Sialoadenitis	3	0
Tooth abscess	7	0
Tooth infection	7	0
Ear infections		
Ear infection	52	0
Labyrinthitis	66	0
Mastoiditis	1	0
Otitis media	3	0
Otitis media acute	1	0
Ectoparasitic infestations		
Acarodermatitis	4	0
Bed bug infestation	1	0
Epstein-Barr viral infections		
Epstein-Barr virus infection	1	0
Infectious mononucleosis	19	0
Eye and eyelid infections		
Conjunctivitis	44	0
Eye abscess	1	0
Eye infection	15	0
Eyelid infection	2	0
Hordeolum	17	0
Periorbital infection	2	0
Female reproductive tract infections		
Bartholinitis	1	0
Endometritis	2	0

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
Infections Infections cont'd		
Funisitis	1	0
Pelvic inflammatory disease	1	0
Vaginal infection	1	0
Vulval abscess	1	0
<i>Fungal infections NEC</i>		
Fungal infection	7	0
Fungal skin infection	2	0
Onychomycosis	1	0
Oral fungal infection	1	0
Pneumonia fungal	2	0
Vulvovaginal mycotic infection	4	0
<i>Hepatitis virus infections</i>		
Hepatitis A	1	0
Hepatitis E	1	0
<i>Hepatobiliary and spleen infections</i>		
Biliary sepsis	1	0
Cholecystitis infective	1	0
<i>Herpes viral infections</i>		
Disseminated varicella zoster virus infection	1	0
Eczema herpeticum	2	0
Genital herpes	56	0
Genital herpes simplex	5	0
Herpes ophthalmic	3	0
Herpes simplex	19	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	2	0
Herpes virus infection	6	0
Herpes zoster	1015	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	9	0
Herpes zoster reactivation	1	0
Nasal herpes	3	0
Ophthalmic herpes zoster	3	0
Oral herpes	213	0
Varicella	18	0
Varicella zoster virus infection	1	0
<i>Infections NEC</i>		
Abscess	26	0
Abscess limb	4	0
Abscess soft tissue	1	0
Genital abscess	1	0
Infected bite	1	0
Infected cyst	2	0
Infection	146	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	18	0
Lymph gland infection	5	0
Lymph node abscess	2	0
Opportunistic infection	1	0
Respiratory tract infection	4	0
Vaccination site abscess	3	0
Vaccination site infection	11	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Vaccine breakthrough infection	23	0
Vestibulitis	2	0
Wound infection	1	0
<i>Infectious transmissions</i>		
Secondary transmission	7	0
Vaccine bacteria shedding	1	0
<i>Influenza viral infections</i>		
Influenza	980	0
<i>Klebsiella infections</i>		
Klebsiella infection	1	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	10	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	124	7
Pneumonia	75	10
Sputum purulent	1	0
<i>Male reproductive tract infections</i>		
Epididymitis	2	0
Orchitis	3	0
Prostate infection	1	0
<i>Mumps viral infections</i>		
Mumps	5	0
<i>Muscle and soft tissue infections</i>		
Abscess neck	1	0
Infective tenosynovitis	1	0
Necrotising fasciitis	1	0
Soft tissue infection	1	0
<i>Neisseria infections</i>		
Gonorrhoea	1	0
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	1	0
<i>Retroviral infections</i>		
HIV infection	1	0
<i>Rotaviral infections</i>		
Gastroenteritis rotavirus	1	0
<i>Rubeola viral infections</i>		
Measles	3	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Bacteraemia	1	0
Neutropenic sepsis	3	1
Sepsis	29	5
Sepsis syndrome	1	0
Septic rash	1	0
Septic shock	4	1
Urosepsis	4	0
<i>Skin structures and soft tissue infections</i>		
Abscess sweat gland	1	0
Acne pustular	1	0
Blister infected	1	0
Dermatitis infected	1	0
Impetigo	4	0
Infected skin ulcer	1	0
Injection site pustule	1	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Nail infection	1	0
Pustule	9	0
Rash pustular	9	0
Skin infection	24	0
Subcutaneous abscess	6	0
Vaccination site pustule	3	0
Staphylococcal infections		
Furuncle	28	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 infection	1	0
Streptococcal sepsis	1	0
Tinea infections		
Body tinea	1	0
Tinea infection	1	0
Tinea versicolour	1	0
Treponema infections		
Syphilis	1	0
Trypanosomal infections		
African trypanosomiasis	1	0
Tuberculous infections		
Lymph node tuberculosis	1	0
Pulmonary tuberculosis	1	0
Upper respiratory tract infections		
Acute sinusitis	2	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	16	0
Nasopharyngitis	551	0
Peritonsillar abscess	2	0
Pharyngitis	17	0
Rhinitis	33	0
Sinusitis	84	0
Tonsillitis	67	0
Tracheitis	4	0
Upper respiratory tract infection	5	0
Urinary tract infections		
Cystitis	51	0
Kidney infection	21	0
Pyelonephritis	1	0
Urinary tract infection	106	0
Vascular infections		
Haematoma infection	1	0
Infusion site infection	1	0
Lymphangitis	7	0
Viral infections NEC		

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Encephalitis viral	3	0
Eye infection viral	2	0
Gastroenteritis viral	13	0
Hepatitis viral	2	0
Meningitis viral	7	0
Oral viral infection	1	0
Pleurisy viral	1	0
Pneumonia viral	2	1
Post viral fatigue syndrome	27	0
Sweating fever	64	0
Vestibular neuronitis	18	0
Viral diarrhoea	2	0
Viral infection	32	0
Viral labyrinthitis	3	0
Viral pericarditis	1	0
Viral pharyngitis	12	0
Viral rash	33	0
Viral sinusitis	1	0
Viral tonsillitis	1	0
Infections SOC TOTAL	5712	74

Case Series Drug Analysis Print

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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	4	0
Tongue injury	1	0
Tooth fracture	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	14	0
<i>Anaesthetic and allied procedural complications</i>		
Delayed recovery from anaesthesia	2	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	4	0
<i>Cardiovascular injuries</i>		
Heart injury	3	0
Vascular injury	4	0
<i>Cerebral injuries NEC</i>		
Brain herniation	1	0
Concussion	1	0
Cranio-cerebral injury	1	0
Subdural haematoma	4	0
Subdural haemorrhage	4	0
Traumatic intracranial haemorrhage	1	1
<i>Chemical injuries</i>		
Chemical cystitis	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	8	0
Foreign body in throat	1	0
<i>Conditions caused by cold</i>		
Chillblains	45	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	28	0
Foetal exposure during pregnancy	15	0
Maternal exposure before pregnancy	2	0
Maternal exposure during breast feeding	740	0
Maternal exposure during pregnancy	354	0
Maternal exposure timing unspecified	1	0
Paternal exposure before pregnancy	1	0
Paternal exposure during pregnancy	3	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	1	0
Exposure to vaccinated person	1	0
<i>Eye and ear procedural complications</i>		

Case Series Drug Analysis Print

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

Report Run Date: 01-Jul-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 30-Jun-2021 18:30:05
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Toxic anterior segment syndrome	1	0
Eye injuries NEC		
Eye contusion	13	0
Eye injury	9	0
Foreign body in eye	1	0
Injury corneal	1	0
Periorbital haematoma	1	0
Retinal injury	2	0
Superficial injury of eye	1	0
Foetal and neonatal conditions associated with product exposure		
Intoxication by breast feeding	1	0
Fractures and dislocations NEC		
Bone fragmentation	1	0
Fracture	1	0
Joint dislocation	2	0
Gastrointestinal and hepatobiliary procedural complications		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	6	0
Procedural vomiting	1	0
Heat injuries (excl thermal burns)		
Heat cramps	1	0
Heat exhaustion	1	0
Heat illness	1	0
Heat oedema	7	0
Heat stroke	3	0
Limb fractures and dislocations		
Atypical femur fracture	1	0
Clavicle fracture	20	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
Inadequate aseptic technique in use of product	1	0
Medication error	15	0
Prescription drug used without a prescription	2	0
Product use complaint	1	0
Product use issue	12	0
Vaccination error	6	0
Wrong dose	3	0
Wrong drug	11	0
Wrong technique in product usage process	3	0
Muscle, tendon and ligament injuries		
Epicondylitis	11	0
Ligament sprain	6	0
Mallet finger	1	0
Muscle injury	11	0
Muscle rupture	2	0
Muscle strain	19	0
Tendon injury	5	0
Tendon rupture	2	0
Musculoskeletal procedural complications		
Periprosthetic osteolysis	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Post laminectomy syndrome	1	0
Nerve injuries NEC		
Nerve injury	33	0
Neurological and psychiatric procedural complications		
Post procedural stroke	1	0
Procedural dizziness	10	0
Non-occupational environmental exposures		
Exposure to extreme temperature	1	0
Non-site specific injuries NEC		
Arthropod sting	3	0
Bite	1	0
Electric shock	9	0
Fall	94	1
Foreign body	2	0
Injury	5	0
Nervous system injury	1	0
Traumatic haematoma	1	0
Wound	4	0
Wound complication	7	0
Wound haematoma	1	0
Wound haemorrhage	2	0
Wound secretion	3	0
Non-site specific procedural complications		
Incision site pain	2	0
Infusion related reaction	6	0
Injection related reaction	36	0
Post procedural complication	3	0
Procedural pain	1	0
Seroma	1	0
Occupational exposures		
Occupational exposure to SARS-CoV-2	1	0
Occupational exposure to product	1	0
Off label uses		
Off label use	40	0
Overdoses NEC		
Overdose	20	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	8	0
Toxicity to various agents	2	0
Product administration errors and issues		
Accidental overdose	3	0
Contraindicated product administered	1	0
Expired product administered	9	0
Inappropriate schedule of product administration	108	0
Incomplete course of vaccination	1	0
Incorrect dose administered	51	0
Incorrect drug administration rate	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Incorrect product formulation administered	2	0
Incorrect route of product administration	3	0
Poor quality product administered	2	0
Product administered at inappropriate site	9	0
Product administered to patient of inappropriate age	1	0
Product administration error	4	0
Product dose omission issue	3	0
Wrong product administered	14	0
Product confusion errors and issues		
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	5	0
Product prescribing errors and issues		
Contraindicated product prescribed	2	0
Product selection errors and issues		
Product selection error	2	0
Radiation injuries		
Sunburn	15	0
Renal and urinary tract injuries NEC		
Foreign body in urogenital tract	1	0
Site specific injuries NEC		
Face crushing	1	0
Head injury	24	0
Limb crushing injury	2	0
Limb injury	51	0
Nasal injury	1	0
Neck injury	1	0
Skin injuries NEC		
Contusion	660	0
Nail avulsion	1	0
Scar	7	0
Scratch	4	0
Skin abrasion	5	0
Skin injury	1	0
Skin wound	2	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

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Burn of internal organs	2	0
Burn oral cavity	1	0
Burns second degree	4	0
Thermal burn	12	0
Thermal burns of eye	8	0
<i>Underdoses NEC</i>		
Underdose	6	0
<i>Vaccination related complications</i>		
Adverse event following immunisation	1	0
Vaccination complication	40	0
Injuries SOC TOTAL	2852	2

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Cortisol decreased	3	0
<i>Adrenal medulla tests</i>		
Epinephrine increased	1	0
<i>Auditory and vestibular diagnostic procedures</i>		
Acoustic stimulation tests	5	0
Audiogram abnormal	1	0
<i>Autoimmunity analyses</i>		
Antinuclear antibody	1	0
Antinuclear antibody increased	1	0
Rheumatoid factor	3	0
<i>Blood counts NEC</i>		
Blood count	4	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	6	0
Blood pH increased	6	0
Oxygen consumption decreased	1	0
Oxygen saturation	5	0
Oxygen saturation decreased	45	0
<i>Bone marrow and immune tissue histopathology procedures</i>		
Aspiration bone marrow	1	0
Biopsy lymph gland	1	0
<i>Bone marrow and immune tissue imaging procedures</i>		
Lymph nodes scan abnormal	1	0
Scan lymph nodes	3	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	6	0
Blood glucose abnormal	9	0
Blood glucose decreased	24	0
Blood glucose fluctuation	14	0
Blood glucose increased	80	0
Glycosylated haemoglobin increased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	10	0
Heart sounds	2	0
Heart sounds abnormal	3	0
<i>Cardiac function diagnostic procedures</i>		
Cardiac monitoring	1	0
Cardiac output	1	0
Central venous pressure	1	0
Stroke volume decreased	1	0
<i>Cardiac imaging procedures</i>		
Scan myocardial perfusion abnormal	1	0
<i>Cell marker analyses</i>		
Prostatic specific antigen increased	2	0
<i>Central nervous system imaging procedures</i>		
Computerised tomogram head	4	0
Magnetic resonance imaging head	10	0
Magnetic resonance imaging head abnormal	1	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Cerebrospinal fluid tests (excl microbiology)</i>		
CSF pressure	1	0
<i>Chemistry analyses NEC</i>		
Inflammatory marker increased	3	0
<i>Cholesterol analyses</i>		
Blood cholesterol increased	3	0
Remnant-like lipoprotein particles	3	0
<i>Coagulation and bleeding analyses</i>		
Activated partial thromboplastin time prolonged	15	0
Activated partial thromboplastin time shortened	1	0
Bleeding time	1	0
Bleeding time abnormal	1	0
Bleeding time prolonged	2	0
Blood thromboplastin	1	0
Clot retraction	1	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	5	0
Coagulation time shortened	1	0
Fibrin D dimer increased	6	0
International normalised ratio abnormal	5	0
International normalised ratio decreased	18	0
International normalised ratio fluctuation	1	0
International normalised ratio increased	46	0
<i>ECG investigations</i>		
Electrocardiogram	2	0
Electrocardiogram QT prolonged	1	0
Electrocardiogram ST segment elevation	3	0
Electrocardiogram T wave inversion	3	0
Electrocardiogram abnormal	10	0
Electrocardiogram normal	1	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	19	0
<i>Faecal analyses NEC</i>		
Faecal calprotectin	2	0
Faecal calprotectin increased	4	0
<i>Fertility analyses</i>		
Infertility tests	1	0
Semen analysis abnormal	1	0
<i>Foetal and neonatal diagnostic procedures</i>		
Foetal heart rate abnormal	1	1
Foetal heart rate increased	1	0
Foetal non-stress test	1	0
<i>Gastrointestinal and abdominal imaging procedures</i>		
Computerised tomogram abdomen	1	0
Sigmoidoscopy abnormal	1	0
<i>Gastrointestinal, pancreatic and APUD hormone analyses</i>		
Blood insulin	1	0
Blood insulin decreased	1	0
<i>Haematological analyses NEC</i>		
Plasma viscosity	1	0
Red blood cell sedimentation rate increased	5	0
<i>Heart rate and pulse investigations</i>		
Carotid pulse	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Heart rate	212	0
Heart rate abnormal	28	0
Heart rate decreased	30	0
Heart rate increased	454	0
Heart rate irregular	79	0
Pulse abnormal	11	0
Pulse pressure increased	1	0
Radial pulse abnormal	1	0
Sinus rhythm	2	0
Imaging procedures NEC		
Computerised tomogram	1	0
Magnetic resonance imaging	1	0
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	4	0
Immunology test	7	0
Immunology skin tests NEC		
Skin test positive	1	0
Investigations NEC		
Blood test	8	0
Blood test abnormal	19	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	14	0
Aspartate aminotransferase increased	1	0
Blood bilirubin increased	2	0
Gamma-glutamyltransferase increased	4	0
Hepatic enzyme increased	4	0
Liver function test	1	0
Liver function test abnormal	18	0
Liver function test increased	11	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
Brain natriuretic peptide 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 iron decreased	2	0
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Jul-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 30-Jun-2021 18:30:05
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood phosphorus increased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	4	0
Blood potassium increased	2	0
Blood sodium decreased	8	0
Serum ferritin	1	0
Serum ferritin decreased	2	0
Serum ferritin increased	1	0
<i>Musculoskeletal and soft tissue imaging procedures</i>		
Skull X-ray	6	0
<i>Musculoskeletal and soft tissue tests NEC</i>		
Swollen joint count increased	1	0
<i>Mycobacteria identification and serology</i>		
Tuberculin test positive	1	0
<i>Neurologic diagnostic procedures</i>		
Coma scale abnormal	3	0
Hoover's sign of leg paresis	1	0
Lumbar puncture	3	0
Temperature perception test increased	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Corneal reflex decreased	1	0
Intraocular pressure increased	7	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	177	0
Body temperature abnormal	27	0
Body temperature decreased	29	0
Body temperature fluctuation	21	0
Body temperature increased	283	0
Body temperature normal	1	0
Breath sounds abnormal	1	0
General physical condition abnormal	1	0
Grip strength	2	0
Grip strength decreased	11	0
Head lag	3	0
Lymph node palpable	28	0
Menstruation normal	1	0
Muscle strength abnormal	1	0
Ophthalmological examination	2	0
Palpatory finding abnormal	1	0
Product residue present	2	0
Psoriasis area severity index decreased	1	0
Respiratory rate	7	0
Respiratory rate decreased	9	0
Respiratory rate increased	25	0
Skin temperature	26	0
Temperature difference of extremities	6	0
Weight	1	0
Weight decreased	48	0
Weight increased	8	0
<i>Pituitary analyses anterior</i>		
Blood corticotrophin	1	0
Blood growth hormone	2	0
Blood prolactin	1	0

Case Series Drug Analysis Print

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Data Lock Date: 30-Jun-2021 18:30:05
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
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	1	0
Platelet count decreased	47	0
Platelet count increased	1	0
Protein analyses NEC		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	12	0
Red blood cell analyses		
Haematocrit	1	0
Haemoglobin decreased	10	0
Red blood cell count decreased	1	0
Renal function analyses		
Blood creatinine increased	1	0
Glomerular filtration rate decreased	2	0
Reproductive hormone analyses		
False negative pregnancy test	5	0
Female sex hormone level	1	0
Pregnancy test	11	0
Pregnancy test positive	1	0
Reproductive organ and breast histopathology procedures		
Smear cervix	1	0
Reproductive organ and breast imaging procedures		
Hysteroscopy	2	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	18	0
Chest X-ray normal	1	0
Chest scan	1	0
Computerised tomogram thorax	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	4	0
Troponin	1	0
Troponin increased	6	0
Therapeutic drug monitoring analyses		
Analgesic drug level	4	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		

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	3	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		
Drug screen positive	2	0
Opiates	1	0
Urinalysis NEC		
Blood urine	10	0
Blood urine present	29	0
Cells in urine	1	0
Glucose urine present	1	0
Urine analysis abnormal	4	0
pH urine	5	0
pH urine increased	2	0
Urinary tract function analyses NEC		
Urine output	10	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)		
Blood pressure abnormal	5	0
Blood pressure decreased	45	0
Blood pressure diastolic	1	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	2	0
Blood pressure increased	149	0
Blood pressure measurement	27	0
Blood pressure normal	1	0
Blood pressure systolic	1	0
Blood pressure systolic decreased	3	0
Blood pressure systolic increased	1	0
Virus identification and serology		
Coronavirus test	10	0
Coronavirus test positive	3	0
Cytomegalovirus test	1	0
HIV test	1	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	9	0
SARS-CoV-2 antibody test negative	12	0
SARS-CoV-2 antibody test positive	2	0
SARS-CoV-2 test	22	0
SARS-CoV-2 test false negative	1	0
SARS-CoV-2 test false positive	2	0
SARS-CoV-2 test negative	7	0
SARS-CoV-2 test positive	85	0
Viral test	4	0

Case Series Drug Analysis Print

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 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Vitamin analyses</i>		
Blood folate decreased	3	0
Vitamin B12	1	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	3	0
White blood cell count	1	0
White blood cell count decreased	9	0
White blood cell count increased	5	0
Investigations SOC TOTAL	2860	2

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	11	0
Decreased appetite	774	0
Diet refusal	1	0
Eating disorder symptom	1	0
Food craving	8	0
Food refusal	6	0
Hyperphagia	3	0
Hypophagia	11	0
Increased appetite	15	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	3	0
Tetany	2	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	32	0
Diabetes mellitus inadequate control	9	1
Increased insulin requirement	1	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	2	0
Type 1 diabetes mellitus	11	0
Type 2 diabetes mellitus	2	0
<i>Diabetic complications NEC</i>		
Diabetic complication	2	0
Diabetic ketoacidosis	11	0
Diabetic ketosis	1	0
<i>Disorders of purine metabolism</i>		
Gout	63	0
<i>Electrolyte imbalance NEC</i>		
Fluid imbalance	1	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	1	0
<i>Fluid intake increased</i>		
Polydipsia	5	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	2	0
Dairy intolerance	1	0
Food intolerance	5	0
Gluten sensitivity	4	0
Histamine intolerance	3	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	7	0
Abnormal weight gain	7	0
Cachexia	1	0
Feeding disorder	38	0
Food aversion	7	0
Neonatal insufficient breast milk syndrome	2	0
Overweight	1	0
Poor feeding infant	6	0
Weight loss poor	2	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	58	0
Insulin resistance	4	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
<i>Hypoglycaemic conditions NEC</i>		
Glycopenia	1	0
Hypoglycaemia	65	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	1	0
<i>Iron deficiencies</i>		
Iron deficiency	8	0
<i>Iron excess</i>		
Haemochromatosis	1	0
Iron overload	1	0
<i>Lipid metabolism and deposit disorders NEC</i>		
Body fat disorder	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Ketoacidosis	4	0
Metabolic acidosis	2	0
<i>Mixed acid-base disorders</i>		
Acidosis	3	0
<i>Potassium imbalance</i>		
Hyperkalaemia	2	0
Hypokalaemia	3	0
Hypokalaemic syndrome	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	6	0
Hyponatraemic syndrome	3	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	1	0
<i>Total fluid volume decreased</i>		
Dehydration	113	0
<i>Total fluid volume increased</i>		
Fluid retention	32	0
Hypervolaemia	1	0
<i>Vitamin deficiencies NEC</i>		
Hypovitaminosis	3	0
<i>Water soluble vitamin deficiencies</i>		
Folate deficiency	2	0
Vitamin B12 deficiency	1	0
Metabolic disorders SOC TOTAL	1383	1

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	161	0
Arthropathy	19	0
Autoimmune arthritis	3	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	1	0
Polyarthritis	13	0
Rheumatic fever	1	0
Sacroiliitis	3	0
Seronegative arthritis	2	0
<i>Bone disorders NEC</i>		
Jaw disorder	3	0
Medial tibial stress syndrome	3	0
Osteitis	3	0
Osteonecrosis of jaw	2	0
Spinal disorder	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	237	0
Bone swelling	4	0
Coccydynia	2	0
Metatarsalgia	1	0
Pain in jaw	220	0
Pubic pain	2	0
Spinal pain	36	0
<i>Bursal disorders</i>		
Bursitis	40	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	32	0
Osteochondritis	1	0
Polychondritis	2	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	1	0
Polymyalgia rheumatica	36	0
Reynold's syndrome	1	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
Finger deformity	1	0
Foot deformity	1	0
Hand deformity	2	0
Knee deformity	1	0
Limb deformity	4	0
Musculoskeletal deformity	1	0
<i>Intervertebral disc disorders NEC</i>		
Intervertebral disc protrusion	1	0
<i>Joint related disorders NEC</i>		
Chondromalacia	1	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Joint deposit	1	0
Joint destruction	1	0
Joint laxity	3	0
Joint lock	15	0
Patellofemoral pain syndrome	1	0
Periarthritis	84	0
Rotator cuff syndrome	8	0
Temporomandibular joint syndrome	6	0
Joint related signs and symptoms		
Arthralgia	5731	0
Jaw clicking	4	0
Joint effusion	12	0
Joint noise	18	0
Joint range of motion decreased	9	0
Joint stiffness	143	0
Joint swelling	292	0
Joint vibration	1	0
Joint warmth	11	0
Loose body in joint	1	0
Ligament disorders		
Symphysiolysis	1	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	14	0
Metabolic bone disorders		
Osteopenia	1	0
Osteoporosis	1	0
Muscle infections and inflammations		
Antisynthetase syndrome	2	0
Myositis	16	0
Polymyositis	3	0
Muscle pains		
Fibromyalgia	63	0
Myalgia	7304	0
Myalgia intercostal	1	0
Myofascial pain syndrome	6	0
Muscle related signs and symptoms NEC		
Haematoma muscle	1	0
Muscle atrophy	11	0
Muscle discomfort	2	0
Muscle disorder	3	0
Muscle fatigue	230	0
Muscle haemorrhage	1	0
Muscle mass	3	0
Muscle spasms	876	0
Muscle swelling	14	0
Muscle tightness	47	0
Muscle twitching	221	0
Muscle tone abnormalities		
Muscle rigidity	10	0
Nuchal rigidity	10	0
Torticollis	3	0
Trismus	21	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
<i>Muscle weakness conditions</i>		
Muscular weakness	531	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Back disorder	1	0
Growth disorder	1	0
Limb mass	9	0
Mandibular mass	2	0
Mastication disorder	3	0
Mobility decreased	48	0
Musculoskeletal disorder	8	0
Musculoskeletal stiffness	786	0
Posture abnormal	1	0
Weight bearing difficulty	1	0
<i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i>		
Head deformity	1	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Dactylitis	2	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	5	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	1399	0
Flank pain	27	0
Limb discomfort	947	0
Musculoskeletal chest pain	113	0
Musculoskeletal discomfort	59	0
Musculoskeletal pain	33	0
Neck pain	1143	0
Pain in extremity	7925	0
Rheumatic disorder	8	0
<i>Myopathies</i>		
Myopathy	4	0
Rhabdomyolysis	6	0
<i>Osteoarthropathies</i>		
Nodal osteoarthritis	1	0
Osteoarthritis	26	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	11	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	78	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	155	0
Fluctuance	1	0
Groin pain	70	0
Neck mass	17	0
Purple glove syndrome	1	0
Soft tissue disorder	2	0
Soft tissue swelling	3	0
<i>Spine and neck deformities</i>		
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Scoliosis	1	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	6	0
Arthritis reactive	23	0
Spondylitis	1	0
<i>Synovial disorders</i>		
Synovial cyst	13	0
Synovitis	4	0
<i>Tendon disorders</i>		
Enthesopathy	1	0
Tendon disorder	1	0
Tendon pain	12	0
Tendonitis	18	0
Tenosynovitis	2	0
Tenosynovitis stenosaurs	1	0
Trigger finger	14	0
<i>Trunk deformities</i>		
Drooping shoulder syndrome	1	0
Muscle & tissue disorders SOC TOTAL	29595	0

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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 benign</i>		
Benign breast neoplasm	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	28	0
Breast cancer female	1	0
Breast cancer male	1	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>Cardiovascular neoplasms benign</i>		
Pericardial lipoma	1	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>Endometrial neoplasms malignant</i>		
Endometrial cancer	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	2	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	15	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>Myelodysplastic syndromes</i>		
Myelodysplastic syndrome	1	0
<i>Myeloproliferative disorders (excl leukaemias)</i>		
Essential thrombocythaemia	1	0
<i>Neoplasms benign site unspecified NEC</i>		
Adenoma benign	1	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Neoplasms malignant site unspecified NEC</i>		
Neoplasm malignant	3	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>		
Acoustic neuroma	1	0
<i>Non-Hodgkin's lymphomas NEC</i>		
Non-Hodgkin's lymphoma	1	0
<i>Oesophageal neoplasms malignant</i>		
Oesophageal cancer metastatic	4	0
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	2	0
<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>		
Pancreatic carcinoma	4	0
<i>Plasma cell myelomas</i>		
POEMS syndrome	1	0
Plasma cell myeloma	1	0
<i>Plasma cell neoplasms NEC</i>		
TEMPI syndrome	1	0
<i>Prostatic neoplasms malignant</i>		
Prostate cancer	4	0
<i>Renal neoplasms malignant</i>		
Renal cancer	2	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Bronchial carcinoma	1	0
Lung neoplasm malignant	5	0
<i>Skin melanomas (excl ocular)</i>		
Malignant melanoma	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	2	0
Anogenital warts	3	0
Haemangioma of skin	3	0
Melanocytic naevus	4	0
Skin papilloma	6	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	2	0
Bowen's disease	1	0
Neoplasm skin	1	0
Squamous cell carcinoma of skin	2	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	3	0
Lymphangioma	1	0
<i>Soft tissue sarcomas histology unspecified</i>		
Sarcoma	1	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Thyroid neoplasms malignant</i>		
Papillary thyroid cancer	2	0
Thyroid cancer	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	5	0
Neoplasms SOC TOTAL	158	2

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	4	0
Extensor plantar response	1	0
Hyperreflexia	2	0
Hyporeflexia	5	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	14	0
<i>Absence seizures</i>		
Petit mal epilepsy	18	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	40	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	3	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	31	6
Cerebral infarction	23	1
Cerebral thrombosis	8	1
Cerebrovascular accident	274	12
Embolic stroke	6	0
Haemorrhage intracranial	9	2
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	31	1
Lacunar infarction	2	0
Lacunar stroke	2	0
Lateral medullary syndrome	1	0
Subarachnoid haemorrhage	12	4
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>		
Brain hypoxia	1	1
Central nervous system vasculitis	1	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Jul-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 30-Jun-2021 18:30:05
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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Cerebral congestion	1	0
Cerebral small vessel ischaemic disease	1	0
Cerebrovascular disorder	1	0
Reversible cerebral vasoconstriction syndrome	1	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	29	1
Cerebral venous thrombosis	4	0
Superior sagittal sinus thrombosis	3	0
Transverse sinus thrombosis	1	0
Cervical spinal cord and nerve root disorders		
Cervicobrachial syndrome	3	0
Choreiform movements		
Chorea	2	0
Chronic polyneuropathies		
Demyelinating polyneuropathy	1	0
Coma states		
Coma	6	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
Coordination and balance disturbances		
Ataxia	6	0
Balance disorder	231	0
Coordination abnormal	28	0
Dysdiadochokinesis	1	0
Dysstasia	31	0
Nystagmus	9	0
Cortical dysfunction NEC		
Aphasia	43	0
Apraxia	1	0
Neurologic neglect syndrome	1	0
Sensory processing disorder	1	0
Visuospatial deficit	1	0
Cranial nerve disorders NEC		
Cranial nerve disorder	2	0
Dementia (excl Alzheimer's type)		
Dementia	9	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	4	0
Clinically isolated syndrome	1	0
Demyelination	7	0
Neuromyelitis optica spectrum disorder	1	0
Disturbances in consciousness NEC		
Altered state of consciousness	9	0
Consciousness fluctuating	2	0
Depressed level of consciousness	28	1
Lethargy	1542	0
Loss of consciousness	323	0
Sedation	6	0
Somnolence	635	0
Stupor	3	0
Syncope	1152	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Disturbances in sleep phase rhythm</i>		
Irregular sleep phase	1	0
Irregular sleep wake rhythm disorder	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	3	0
Bradykinesia	7	0
Clumsiness	12	0
Dyskinesia	42	0
Extrapyramidal disorder	1	0
Fine motor skill dysfunction	7	0
Hyperkinesia	3	0
Hypokinesia	34	1
Motor dysfunction	2	0
Movement disorder	33	0
Psychomotor hyperactivity	15	0
Synkinesis	1	0
Tardive dyskinesia	2	0
<i>Dystonias</i>		
Dystonia	13	0
Writer's cramp	1	0
<i>Encephalitis NEC</i>		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	2	0
<i>Encephalopathies NEC</i>		
Encephalopathy	3	0
Hashimoto's encephalopathy	1	0
Posterior reversible encephalopathy syndrome	1	0
<i>Eye movement disorders</i>		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	5	0
IVth nerve paralysis	1	0
Microvascular cranial nerve palsy	1	0
VIth nerve paralysis	8	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	300	0
Facial nerve disorder	6	0
Facial paralysis	241	0
Facial paresis	65	0
Facial spasm	28	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	27	0
<i>Headaches NEC</i>		
Cervicogenic headache	3	0
Cluster headache	136	0
Cold-stimulus headache	11	0
Drug withdrawal headache	2	0
Exertional headache	7	0
External compression headache	1	0
Headache	17412	0
Medication overuse headache	2	0
New daily persistent headache	4	0
Occipital neuralgia	7	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Ophthalmoplegic migraine	1	0
Primary cough headache	4	0
Primary headache associated with sexual activity	1	0
Sinus headache	238	0
Tension headache	353	0
Thunderclap headache	4	0
Vascular headache	11	0
Hydrocephalic conditions		
Hydrocephalus	1	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Increased intracranial pressure disorders		
Brain compression	1	0
Brain oedema	4	0
Idiopathic intracranial hypertension	3	0
Intracranial pressure increased	1	0
Intellectual disabilities		
Intellectual disability	2	0
Lumbar spinal cord and nerve root disorders		
Sciatica	49	0
Memory loss (excl dementia)		
Amnesia	93	0
Memory impairment	89	0
Retrograde amnesia	1	0
Transient global amnesia	6	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	48	0
Cognitive linguistic deficit	1	0
Disturbance in attention	185	0
Mental impairment	30	0
Migraine headaches		
Hemiplegic migraine	15	0
Migraine	1736	0
Migraine with aura	121	0
Migraine without aura	12	0
Ophthalmic migraine	4	0
Retinal migraine	20	0
Typical aura without headache	5	0
Vestibular migraine	12	0
Mixed cranial nerve disorders		
Bulbar palsy	1	0
Mononeuropathies		
Carpal tunnel syndrome	14	0
Cubital tunnel syndrome	1	0
Meralgia paraesthetica	1	0
Mononeuropathy	1	0
Nerve compression	12	0
Peripheral nerve lesion	1	0
Peroneal nerve palsy	8	0
Sciatic nerve neuropathy	2	0
Ulnar neuritis	1	0
Multiple sclerosis acute and progressive		
Band sensation	1	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Multiple sclerosis	21	0
Multiple sclerosis relapse	18	0
Tumefactive multiple sclerosis	1	1
Muscle tone abnormal		
Hypotonia	12	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
Myelitis (incl infective)		
Myelitis transverse	21	0
Narcolepsy and hypersomnia		
Cataplexy	1	0
Hypersomnia	61	0
Narcolepsy	3	0
Nervous system disorders NEC		
Central nervous system lesion	2	0
Nervous system disorder	6	0
Neurologic visual problems NEC		
Hemianopia	1	0
Hemianopia homonymous	1	0
Quadrantanopia	1	0
Tunnel vision	11	0
Neurological signs and symptoms NEC		
Clonus	2	0
Decerebrate posture	1	0
Dizziness	6161	0
Dizziness exertional	31	0
Dizziness postural	504	0
Drooling	15	0
Fontanelle bulging	1	0
Head discomfort	179	0
Hyporesponsive to stimuli	2	0
Inability to crawl	2	0
Infant irritability	4	0
Myoclonus	14	0
Neurological symptom	30	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	10	0
Presyncope	361	0
Sensory overload	2	0
Slow response to stimuli	2	0
Tongue biting	3	0
Unresponsive to stimuli	32	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	12	0
Muscle spasticity	9	0
Neuromuscular pain	2	0
Neuromuscular junction dysfunction		
Myasthenia gravis	8	0
Myasthenia gravis crisis	2	0
Olfactory nerve disorders		
Anosmia	147	0
Hyposmia	10	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Parosmia	152	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	19	0
<i>Paraesthesias and dysaesthesias</i>		
Burning feet syndrome	5	0
Burning sensation	312	0
Burning sensation mucosal	1	0
Dysaesthesia	5	0
Formication	29	0
Hand-arm vibration syndrome	2	0
Hemianaesthesia	1	0
Hemiparaesthesia	2	0
Hyperaesthesia	57	0
Hypoaesthesia	1679	0
Paraesthesia	2378	0
Reversed hot-cold sensation	2	0
Synaesthesia	1	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Diplegia	7	1
Hemiparesis	31	0
Hemiplegia	24	0
Locked-in syndrome	1	0
Monoparesis	40	0
Monoplegia	40	0
Paralysis	74	0
Paraparesis	3	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	7	0
<i>Partial complex seizures</i>		
Dreamy state	6	0
Focal dyscognitive seizures	1	0
Temporal lobe epilepsy	1	0
<i>Partial simple seizures NEC</i>		
Autonomic seizure	1	0
<i>Peripheral neuropathies NEC</i>		
Neuralgic amyotrophy	1	0
Neuritis	5	0
Neuropathy peripheral	62	0
Peripheral sensory neuropathy	7	0
Thoracic outlet syndrome	1	0
<i>Seizures and seizure disorders NEC</i>		
Atonic seizures	4	0
Change in seizure presentation	1	0
Clonic convulsion	3	0
Epilepsy	113	0
Epileptic aura	2	0
Epileptic encephalopathy	1	0
Febrile convulsion	14	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Partial seizures	14	0
Post stroke seizure	1	0
Psychogenic seizure	7	0
Seizure	349	0
Seizure cluster	4	0
Seizure like phenomena	1	0
Status epilepticus	34	0
Tonic clonic movements	2	0
Tonic convulsion	15	0
Tonic posturing	1	0
Sensory abnormalities NEC		
Ageusia	327	0
Allodynia	12	0
Aura	11	0
Complex regional pain syndrome	2	0
Dysgeusia	865	0
Electric shock sensation	19	0
Hypergeusia	1	0
Hypogeusia	2	0
Loss of proprioception	3	0
Neuralgia	319	0
Persistent genital arousal disorder	1	0
Phantom limb syndrome	4	0
Post herpetic neuralgia	13	0
Restless legs syndrome	71	0
Sensory disturbance	49	0
Sensory loss	42	0
Taste disorder	178	0
Visual perseveration	1	0
Sleep disturbances NEC		
Sleep deficit	3	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	106	0
Incoherent	6	0
Language disorder	1	0
Repetitive speech	1	0
Slow speech	8	0
Speech disorder	36	0
Spinal cord and nerve root disorders NEC		
Radiculitis brachial	7	0
Radiculopathy	4	0
Structural brain disorders NEC		
Brain injury	3	2
Hyperintensity in brain deep nuclei	1	0
Transient cerebrovascular events		
Transient ischaemic attack	104	1
Tremor (excl congenital)		
Action tremor	1	0
Essential tremor	3	0
Head titubation	6	0
Resting tremor	2	0
Tremor	1012	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Trigeminal disorders</i>		
Facial neuralgia	13	0
Numb chin syndrome	1	0
Trigeminal nerve disorder	1	0
Trigeminal neuralgia	30	0
<i>Vagus nerve disorders</i>		
Vocal cord paralysis	1	0
<i>Vertigos NEC</i>		
Vertigo CNS origin	1	0
Nervous system disorders SOC TOTAL	42738	43

Case Series Drug Analysis Print

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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	169	4
Abortion threatened	1	0
<i>Foetal complications NEC</i>		
Foetal hypokinesia	3	0
<i>Foetal growth complications</i>		
Foetal growth restriction	1	1
<i>Foetal position and presentation abnormalities</i>		
High foetal head	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	5	1
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	1	0
Subchorionic haematoma	1	0
<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 labour NEC</i>		
Uterine hypertonus	4	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	2	0
Ectopic pregnancy	1	0
Morning sickness	14	0
Preterm premature rupture of membranes	2	0
Somatic symptom disorder of pregnancy	1	0
<i>Neonatal hepatobiliary disorders</i>		
Jaundice neonatal	1	0
<i>Newborn complications NEC</i>		
Neonatal disorder	1	0
<i>Normal newborn status</i>		
Normal newborn	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	23	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	1	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	4	0
<i>Stillbirth and foetal death</i>		
Foetal death	4	1
Stillbirth	4	1
<i>Umbilical cord complications</i>		
Umbilical cord abnormality	1	0
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	2	0
Pregnancy on contraceptive	2	0
Pregnancy on oral contraceptive	3	0
Pregnancy with contraceptive device	1	0
Pregnancy with implant contraceptive	2	0
Unintended pregnancy	1	0
Pregnancy conditions SOC TOTAL	262	8

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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	5	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	9	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	7	0
<i>Product quality issues NEC</i>		
Product origin unknown	5	0
<i>Product supply and availability issues</i>		
Product availability issue	1	0
null SOC TOTAL	66	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	12	0
Behaviour disorder	1	0
Breath holding	3	0
Staring	3	0
<i>Adjustment disorders</i>		
Adjustment disorder with depressed mood	2	0
<i>Affect alterations NEC</i>		
Affect lability	6	0
Constricted affect	1	0
Flat affect	4	0
Inappropriate affect	10	0
<i>Amnesic symptoms</i>		
Paramnesia	3	0
<i>Anxiety symptoms</i>		
Agitation	54	0
Anxiety	423	0
Immunisation anxiety related reaction	1	0
Nervousness	113	0
Stress	40	0
Tension	21	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	3	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	7	0
Aversion	1	0
Indifference	5	0
Paranoia	14	0
Personality change	3	0
Social avoidant behaviour	5	0
Soliloquy	1	0
Suspiciousness	1	0
<i>Bipolar disorders</i>		
Bipolar I disorder	2	0
Bipolar disorder	4	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	5	0
Distractibility	1	0
Mental fatigue	139	0
<i>Communications disorders</i>		
Communication disorder	4	0
Mutism	2	0
<i>Confusion and disorientation</i>		
Confusional state	563	0
Disorientation	173	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	75	0
<i>Delusional symptoms</i>		
Delusion	8	0
<i>Depressive disorders</i>		
Agitated depression	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Depression	178	0
Depression suicidal	5	0
Major depression	4	0
Mixed anxiety and depressive disorder	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	5	0
Dissociation	20	0
Dissociative amnesia	2	0
Dissociative disorder	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	12	0
Insomnia	759	0
Middle insomnia	20	0
Terminal insomnia	19	0
<i>Dyssomnias</i>		
Dyssomnia	1	0
Poor quality sleep	125	0
<i>Eating disorders NEC</i>		
Bulimia nervosa	1	0
Eating disorder	8	0
Selective eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	17	0
Dysphoria	2	0
Emotional disorder	30	0
Emotional distress	25	0
Emotional poverty	1	0
Euphoric mood	28	0
Frustration tolerance decreased	1	0
Irritability	116	0
Mood altered	29	0
<i>Factitious disorders</i>		
Factitious disorder	2	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Agoraphobia	1	0
Fear	9	0
Fear of falling	3	0
Fear of injection	2	0
Osmophobia	1	0
Phobia	1	0
Phonophobia	2	0
Social anxiety disorder	1	0
Social fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	58	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	123	0
Hallucination, auditory	8	0
Hallucination, olfactory	6	0
Hallucination, tactile	1	0
Hallucination, visual	19	0
Hallucinations, mixed	2	0
<i>Increased physical activity levels</i>		

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Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Restlessness	96	0
Infancy, childhood and adolescence psychiatric disorders NEC		
Social (pragmatic) communication disorder	1	0
Learning disorders		
Learning disability	1	0
Learning disorder	1	0
Mental disorders NEC		
Mental disorder	8	0
Mental status changes	1	0
Mental disorders due to a general medical condition NEC		
Neuropsychiatric symptoms	1	0
Mood alterations with depressive symptoms		
Anhedonia	2	0
Decreased interest	7	0
Depressed mood	213	0
Feeling of despair	3	0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Sense of a foreshortened future	2	0
Tearfulness	25	0
Mood alterations with manic symptoms		
Hypomania	2	0
Mania	8	0
Mood disorders NEC		
Apathy	19	0
Boredom	1	0
Laziness	1	0
Listless	13	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	3	0
Hypnopompic hallucination	2	0
Sleep attacks	3	0
Obsessive-compulsive disorders and symptoms		
Obsessive-compulsive symptom	1	0
Orgasmic disorders and disturbances		
Anorgasmia	2	0
Female orgasmic disorder	2	0
Panic attacks and disorders		
Panic attack	88	0
Panic disorder	3	0
Panic reaction	16	0
Parasomnias		
Abnormal dreams	119	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	1	0
Nightmare	132	0
Parasomnia	1	0
Sleep talking	3	0
Sleep terror	12	0
Somnambulism	2	0
Perception disturbances NEC		
Autoscopy	10	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Deja vu	2	0
Derealisation	7	0
Flashback	2	0
Illusion	1	0
Near death experience	1	0
Personality disorders NEC		
Personality disorder	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	1	0
Psychiatric elimination disorders		
Enuresis	15	0
Psychiatric symptoms NEC		
Hypervigilance	6	0
Psychiatric symptom	3	0
Psychological trauma	1	0
Trance	1	0
Psychotic disorder NEC		
Psychotic behaviour	1	0
Psychotic disorder	12	0
Schizophrenia NEC		
Schizophrenia	1	0
Sexual arousal disorders		
Disturbance in sexual arousal	2	0
Sexual desire disorders		
Libido decreased	5	0
Libido increased	3	0
Loss of libido	9	0
Sleep disorders NEC		
Sleep disorder	120	0
Sleep disorder due to general medical condition, insomnia type	1	0
Somatic symptom disorders		
Conversion disorder	6	0
Habit cough	13	0
Somatic symptom disorder	1	0
Vomiting psychogenic	1	0
Speech and language usage disturbances		
Disorganised speech	4	0
Logorrhoea	2	0
Speech articulation and rhythm disturbances		
Dysphemia	12	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
Stereotypies and automatisms		
Bruxism	9	0
Head banging	4	0
Stereotypy	1	0
Stress disorders		
Burnout syndrome	1	0
Post-traumatic stress disorder	2	0
Substance related and addictive disorders		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	2	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Nicotine dependence	1	0
<i>Suicidal and self-injurious behaviour</i>		
Intentional self-injury	5	0
Self-injurious ideation	2	0
Suicidal ideation	17	0
Suicide attempt	9	0
<i>Thinking disturbances</i>		
Bradyphrenia	29	0
Intrusive thoughts	3	0
Morbid thoughts	1	0
Tachyphrenia	4	0
Thinking abnormal	14	0
<i>Tic disorders</i>		
Tic	5	0
Psychiatric disorders SOC TOTAL	4524	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Jul-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 30-Jun-2021 18:30:05
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	2	0
Bladder irritation	2	0
Bladder pain	15	0
Dysuria	37	0
Incontinence	18	0
Lower urinary tract symptoms	2	0
Micturition disorder	1	0
Micturition urgency	21	0
Pollakiuria	72	0
Urethral pain	3	0
Urge incontinence	1	0
Urinary hesitation	1	0
Urinary incontinence	41	0
Urinary retention	30	0
Urine flow decreased	8	0
<i>Bladder disorders NEC</i>		
Bladder disorder	5	0
Bladder fibrosis	1	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	4	0
Glomerulonephritis rapidly progressive	1	0
IgA nephropathy	1	0
Nephrotic syndrome	14	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	4	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	3	1
Renal haemorrhage	1	0
Renal mass	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	31	2
Anuria	3	0
Chronic kidney disease	3	0
Oliguria	1	0
Renal failure	12	1
Renal impairment	14	0
Renal injury	1	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Renal lithiasis</i>		
Nephrolithiasis	5	0
<i>Renal neoplasms</i>		
Renal cyst	1	0
<i>Renal obstructive disorders</i>		
Hydronephrosis	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	33	0
Haematuria	25	0
Proteinuria	6	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	12	0
Nocturia	3	0
Polyuria	4	0
Renal colic	1	0
Renal pain	162	0
Urinary tract pain	2	0
Renal & urinary disorders SOC TOTAL	645	5

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	8	0
<i>Breast disorders NEC</i>		
Breast enlargement	4	0
Breast mass	58	0
Gynaecomastia	2	0
<i>Breast infections and inflammations</i>		
Breast inflammation	1	0
<i>Breast signs and symptoms</i>		
Breast discharge	2	0
Breast discomfort	5	0
Breast engorgement	3	0
Breast haematoma	1	0
Breast oedema	4	0
Breast pain	299	0
Breast swelling	57	0
Breast tenderness	30	0
Nipple pain	19	0
Nipple swelling	3	0
<i>Cervix disorders NEC</i>		
Cervical dysplasia	2	0
Cervix disorder	1	0
Cervix haemorrhage uterine	1	0
Ectropion of cervix	2	0
<i>Cervix neoplasms</i>		
Cervical polyp	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation disorder	1	0
Ejaculation failure	1	0
Erectile dysfunction	30	0
Erection increased	2	0
Organic erectile dysfunction	3	0
Painful ejaculation	1	0
<i>Lactation disorders</i>		
Breast milk discolouration	3	0
Breast milk odour abnormal	1	0
Galactorrhoea	4	0
Lactation disorder	2	0
Lactation puerperal increased	1	0
Suppressed lactation	9	0
<i>Menopausal effects NEC</i>		
Artificial menopause	1	0
Menopausal symptoms	9	0
Premature menopause	7	0
<i>Menopausal effects on the genitourinary tract</i>		
Atrophic vulvovaginitis	1	0
Postmenopausal haemorrhage	105	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	5	0
Dysmenorrhoea	935	0
Intermenstrual bleeding	415	0
Menstrual discomfort	7	0
Menstrual disorder	628	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Menstruation irregular	1057	0
Premenstrual dysphoric disorder	3	0
Premenstrual headache	2	0
Premenstrual pain	41	0
Premenstrual syndrome	38	0
Withdrawal bleed	8	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	217	0
Hypomenorrhoea	231	0
Menstruation delayed	1687	0
Oligomenorrhoea	56	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	2102	0
Menometrorrhagia	10	0
Polymenorrhoea	255	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	6	0
Polycystic ovaries	18	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Adnexal torsion	1	0
Hydrosalpinx	1	0
Ovarian haemorrhage	1	0
Ovulation pain	23	0
Premature ovulation	3	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	19	0
Pelvic haemorrhage	9	0
<i>Penile and scrotal infections and inflammations</i>		
Balanoposthitis	1	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile discomfort	1	0
Penile erythema	1	0
Penile haemorrhage	1	0
Penile swelling	4	0
Penis disorder	4	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	3	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatic pain	1	0
Prostatomegaly	3	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital haemorrhage	9	0
Genital lesion	1	0
Genital ulceration	5	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	2	0
Genital swelling	1	0
Pelvic discomfort	3	0
Pelvic pain	49	0
Perineal pain	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Pruritus genital	2	0
Scrotal disorders NEC		
Scrotal discomfort	1	0
Scrotal erythema	1	0
Scrotal exfoliation	1	0
Scrotal pain	4	0
Scrotal swelling	4	0
Sexual function and fertility disorders NEC		
Dyspareunia	2	0
Infertility	3	0
Sexual dysfunction	1	0
Spermatogenesis and semen disorders		
Aspermia	1	0
Haemospermia	6	0
Semen discolouration	1	0
Testicular and epididymal disorders NEC		
Testicular disorder	2	0
Testicular pain	22	0
Testicular swelling	5	0
Testis discomfort	1	0
Uterine disorders NEC		
Adenomyosis	1	0
Endometrial thickening	1	0
Endometriosis	37	0
Uterine haemorrhage	13	0
Uterine pain	7	0
Uterine infections and inflammations (excl cervix)		
Uterine inflammation	1	0
Uterine neoplasms		
Uterine polyp	1	0
Uterine tone disorders		
Uterine spasm	14	0
Vulvovaginal cysts and neoplasms		
Vaginal cyst	3	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	612	0
Vulval haemorrhage	13	0
Vulval ulceration	3	0
Vulvovaginal ulceration	3	0
Vulvovaginal signs and symptoms		
Clitoral engorgement	1	0
Coital bleeding	2	0
Vaginal discharge	25	0
Vaginal odour	1	0
Vulval oedema	1	0
Vulvovaginal burning sensation	3	0
Vulvovaginal dryness	2	0
Vulvovaginal pain	13	0
Vulvovaginal pruritus	3	0
Vulvovaginal swelling	1	0
Reproductive & breast disorders SOC TOTAL	9373	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	4	0
Apnoeic attack	1	0
Dyspnoea	2348	6
Dyspnoea at rest	7	0
Dyspnoea exertional	21	1
Hyperventilation	30	0
Hypopnoea	60	0
Irregular breathing	12	0
Mouth breathing	3	0
Nocturnal dyspnoea	1	0
Orthopnoea	3	0
Respiration abnormal	30	0
Respiratory arrest	8	0
Respiratory depression	1	0
Respiratory distress	13	0
Sleep apnoea syndrome	7	0
Tachypnoea	21	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	1	0
Bronchiectasis	11	0
<i>Bronchospasm and obstruction</i>		
Asthma	198	0
Asthma late onset	2	0
Bronchospasm	12	0
Chronic obstructive pulmonary disease	14	1
Cough variant asthma	3	0
Obstructive airways disorder	6	0
Reversible airways obstruction	1	0
Wheezing	274	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	1	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	21	1
Respiratory acidosis	2	0
<i>Coughing and associated symptoms</i>		
Allergic cough	4	0
Cough	1501	2
Cough decreased	2	0
Haemoptysis	29	0
Productive cough	97	0
Sputum discoloured	4	0
Sputum increased	1	0
<i>Diaphragmatic disorders</i>		
Diaphragm muscle weakness	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

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Laryngeal oedema	1	0
Laryngospasm	1	0
Stridor	18	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	1	0
Hypersensitivity pneumonitis	1	0
Pneumonia aspiration	7	5
Pneumonitis	19	1
Pulmonary sarcoidosis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	23	0
Increased bronchial secretion	1	0
Lung opacity	2	0
Pleuritic pain	11	0
Pulmonary pain	57	0
Rales	4	0
Respiratory fremitus	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	162	0
Nasal inflammation	1	0
Rhinitis allergic	10	0
<i>Nasal disorders NEC</i>		
Epistaxis	614	0
Intranasal hyposaesthesia	1	0
Intranasal paraesthesia	1	0
Nasal crusting	1	0
Nasal disorder	1	0
Nasal dryness	23	0
Nasal odour	6	0
Nasal oedema	4	0
Nasal pruritus	8	0
<i>Neonatal hypoxic conditions</i>		
Dry lung syndrome	1	0
Gasping syndrome	1	0
Infantile apnoea	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Allergic sinusitis	1	0
Paranasal sinus inflammation	1	0
Sinonasal obstruction	9	0
Sinus congestion	38	0
Sinus disorder	4	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	1	0
Combined pulmonary fibrosis and emphysema	1	0
Emphysema	2	0
Interstitial lung disease	7	0
Lung infiltration	1	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	3	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	6	0
Pharyngeal haemorrhage	2	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Pharyngeal hypoaesthesia	24	0
Pharyngeal inflammation	4	0
Pharyngeal oedema	9	0
Pharyngeal paraesthesia	43	0
Pharyngeal swelling	164	0
Pharyngeal ulceration	11	0
Tonsillar erythema	4	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	49	0
Tonsillar inflammation	3	0
Tonsillar ulcer	1	0
Tonsillolith	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	18	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	14	0
Pneumothorax	5	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	6	0
Pulmonary oedema	14	1
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	270	19
Pulmonary infarction	3	0
Pulmonary thrombosis	3	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	2	1
Respiratory failure	9	1
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	5	0
Diaphragmalgia	5	0
Nasal flaring	1	0
Painful respiration	6	0
Respiratory symptom	10	0
Suffocation feeling	1	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	3	2
Lung disorder	2	0
Pulmonary mass	4	0
Respiratory disorder	8	0
Respiratory tract congestion	2	0
Respiratory tract haemorrhage	1	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>		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Tonsillar cyst	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	68	0
Catarrh	12	0
Choking	11	1
Choking sensation	3	0
Dry throat	121	0
Dysphonia	108	0
Increased upper airway secretion	4	0
Increased viscosity of upper respiratory secretion	21	0
Nasal discharge discolouration	2	0
Nasal discomfort	36	0
Nasal obstruction	2	0
Oropharyngeal blistering	9	0
Oropharyngeal discomfort	43	0
Oropharyngeal pain	1842	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	29	0
Rhinalgia	10	0
Rhinorrhoea	565	0
Sinus pain	138	0
Sneezing	233	0
Snoring	5	0
Throat clearing	7	0
Throat irritation	163	0
Throat tightness	178	0
Upper airway obstruction	2	0
Upper-airway cough syndrome	4	0
Yawning	13	0
<i>Vascular pulmonary disorders NEC</i>		
Acute chest syndrome	1	0
Respiratory disorders SOC TOTAL	10175	42

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	76	0
Acne cystic	7	0
Dermatitis acneiform	6	0
<i>Alopecias</i>		
Alopecia	112	0
Alopecia areata	11	0
Alopecia totalis	1	0
Androgenetic alopecia	1	0
Madarosis	1	0
<i>Angioedemas</i>		
Angioedema	136	0
Circumoral swelling	1	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	1	0
Cold sweat	444	0
Hidradenitis	1	0
Hyperhidrosis	1299	0
Miliaria	58	0
Night sweats	385	0
<i>Bullous conditions</i>		
Blister	300	0
Blister rupture	1	0
Blood blister	20	0
Dermatitis bullous	10	0
Erythema multiforme	22	0
Fracture blisters	1	0
Pemphigoid	13	0
Pemphigus	5	0
Stevens-Johnson syndrome	3	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	145	0
Macule	3	0
Neutrophilic dermatosis	1	0
Pain of skin	175	0
Papule	56	0
Pathergy reaction	1	0
Peau d'orange	2	0
Scab	12	0
Scar pain	11	0
Sensitive skin	97	0
Skin burning sensation	145	0
Skin degenerative disorder	1	0
Skin discolouration	74	0
Skin discomfort	3	0
Skin disorder	10	0
Skin fissures	3	0
Skin indentation	2	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin induration	3	0
Skin lesion	30	0
Skin lesion inflammation	1	0
Skin necrosis	1	0
Skin odour abnormal	12	0
Skin plaque	1	0
Skin reaction	92	0
Skin sensitisation	18	0
Skin swelling	54	0
Skin texture abnormal	1	0
Skin tightness	21	0
Skin warm	196	0
Skin weeping	6	0
Sticky skin	1	0
Target skin lesion	2	0
Transient acantholytic dermatosis	1	0
Yellow skin	12	0
<i>Dermatitis and eczema</i>		
Dermatitis	73	0
Dermatitis allergic	156	0
Dermatitis atopic	18	0
Dermatitis contact	9	0
Dermatitis diaper	2	0
Dyshidrotic eczema	13	0
Eczema	155	0
Eczema asteatotic	6	0
Eczema nummular	4	0
Eczema weeping	1	0
Perioral dermatitis	1	0
Seborrhoeic dermatitis	2	0
Skin irritation	68	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	25	0
Drug reaction with eosinophilia and systemic symptoms	1	0
Fixed eruption	1	0
Toxic skin eruption	1	0
<i>Erythemas</i>		
Erythema	1469	0
Palmar erythema	4	0
Red man syndrome	1	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	1	0
Dermatitis exfoliative generalised	3	0
Exfoliative rash	12	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	62	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	3	0
Lichenoid keratosis	2	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Hyperpigmentation disorders</i>		
Argyria	1	0
Chloasma	1	0
Ephelides	1	0
Skin hyperpigmentation	2	0
Solar lentigo	2	0
<i>Hypertrichoses</i>		
Hirsutism	1	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	3	0
Skin hypopigmentation	1	0
Vitiligo	6	0
<i>Lipodystrophies</i>		
Lipoatrophy	3	0
Lipodystrophy acquired	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	6	0
Nail disorder	2	0
Nail pigmentation	2	0
Nail ridging	1	0
Onychalgia	6	0
Onychoclasia	3	0
Onychomadesis	2	0
Splinter haemorrhages	2	0
<i>Panniculitides</i>		
Erythema nodosum	18	0
<i>Papulosquamous conditions</i>		
Erythema annulare	2	0
Lichen planus	8	0
Lichen sclerosus	4	0
Parapsoriasis	2	0
Pityriasis rosea	63	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	33	0
Polymorphic light eruption	1	0
Solar dermatitis	1	0
<i>Pigmentation changes NEC</i>		
Haemosiderin stain	1	0
Pigmentation disorder	7	0
<i>Pilar disorders NEC</i>		
Hair colour changes	7	0
Hair disorder	1	0
Hair growth abnormal	2	0
Hair texture abnormal	4	0
Piloerection	14	0
Pseudofolliculitis	1	0
<i>Pruritus NEC</i>		
Itching scar	5	0
Pruritus	3350	0
<i>Psoriatic conditions</i>		
Dermatitis psoriasiform	2	0
Guttate psoriasis	12	0
Nail psoriasis	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Palmoplantar pustulosis	2	0
Psoriasis	94	0
Pustular psoriasis	2	0
Purpura and related conditions		
Henoch-Schonlein purpura	4	0
Petechiae	91	0
Purpura	31	0
Pustular conditions		
Acute generalised exanthematous pustulosis	1	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	3	0
Rash	3581	0
Rash erythematous	772	0
Rash macular	327	0
Rash maculo-papular	43	0
Rash morbilliform	30	0
Rash papular	227	0
Rash pruritic	786	0
Rash vesicular	43	0
Systemic lupus erythematosus rash	5	0
Rosaceas		
Rosacea	18	0
Scaly conditions		
Dandruff	4	0
Pityriasis	13	0
Sebaceous gland disorders		
Seborrhoea	4	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	3	0
Reactive perforating collagenosis	1	0
Skin mass	11	0
Skin and subcutaneous tissue ulcerations		
Mucocutaneous ulceration	1	0
Scleroderma associated digital ulcer	1	0
Skin erosion	18	0
Skin ulcer	8	0
Skin cysts and polyps		
Dermal cyst	6	0
Skin dystrophies		
Keloid scar	2	0
Skin wrinkling	2	0
Skin haemorrhages		
Haemorrhage subcutaneous	5	0
Skin haemorrhage	7	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	2	0
Skin hypoplasias and atrophies		
Skin striae	4	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	2	0
Needle track marks	1	0
Skin preneoplastic conditions NEC		
Actinic keratosis	1	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Jul-2021

Data Lock Date: 30-Jun-2021 18:30:05

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
<i>Skin vasculitides</i>		
Cutaneous vasculitis	7	0
Vasculitic rash	13	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	17	0
<i>Telangiectasia and related conditions</i>		
Telangiectasia	1	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	3	0
Cold urticaria	2	0
Idiopathic urticaria	1	0
Mechanical urticaria	3	0
Solar urticaria	2	0
Urticaria	1124	0
Urticaria cholinergic	1	0
Urticaria chronic	7	0
Urticaria contact	1	0
Urticaria papular	2	0
Urticaria thermal	4	0
Urticarial vasculitis	2	0
Skin disorders SOC TOTAL	17145	1

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Infant	1	0
Menopause	11	0
Postmenopause	2	0
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Dependents</i>		
Sick relative	2	0
<i>Disability issues</i>		
Bedridden	17	0
Breast prosthesis user	3	0
Hearing disability	1	0
Housebound	1	0
Immobile	10	0
Impaired driving ability	2	0
Impaired work ability	6	0
Loss of personal independence in daily activities	12	0
Physical disability	2	0
Sight disability	7	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	3	0
<i>Non-occupational and unspecified environmental problems</i>		
Flooding	1	0
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	10	0
Multigravida	1	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	106	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Nerve block	1	0
<i>Antiinfective therapies</i>		
COVID-19 treatment	3	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
Mammoplasty	1	0
<i>Bronchial and pulmonary therapeutic procedures</i>		
Airway secretion clearance therapy	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Cardiac operation	1	0
<i>Contraceptive methods female</i>		
Contraceptive implant	1	0
Oral contraception	1	0
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	3	0
Nothing by mouth order	6	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	4	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	1	0
<i>Hernia repairs</i>		
Hernia repair	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
Hormone therapy	6	0
<i>Immunisations</i>		
COVID-19 immunisation	70	1
Immunisation	16	0
<i>Joint therapeutic procedures</i>		
Joint surgery	1	0
Knee arthroplasty	1	0
<i>Large intestine therapeutic procedures</i>		
Appendectomy	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	7	0
Limb operation	5	0
<i>Lymphoid tissue therapeutic procedures</i>		
Lymphadenectomy	1	0
<i>Mastectomies</i>		
Breast conserving surgery	3	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
<i>Nail therapeutic procedures</i>		
Nail operation	2	0
<i>Nervous system therapeutic procedures NEC</i>		
Multiple sclerosis relapse prophylaxis	2	0
<i>Orbit and globe therapeutic procedures</i>		
Strabismus correction	1	0
<i>Phototherapies</i>		
UV light therapy	1	0
<i>Prophylactic procedures NEC</i>		
Anaphylaxis prophylaxis	2	0
Immune tolerance induction	1	0
Reproductive system disorder prophylaxis	1	0
<i>Psychiatric therapies</i>		
Electroconvulsive therapy	1	0
<i>Renal therapeutic procedures</i>		
Dialysis	1	0
<i>Respiratory tract therapeutic procedures NEC</i>		
Asthma prophylaxis	2	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	4	0
<i>Small intestine therapeutic procedures</i>		
Ileostomy	1	0
<i>Therapeutic procedures NEC</i>		
Abscess drainage	1	0
Anaphylaxis treatment	3	0
Bed rest	2	0
Fatigue management	1	0
Hospitalisation	7	0
Injection	12	0
Interchange of vaccine products	2	0
Localised alternating hot and cold therapy	1	0
Magnetic therapy	1	0
Mass excision	2	0
Medication dilution	1	0
Physiotherapy	1	0
Product used for unknown indication	2	0
Therapeutic procedure	1	0
Therapy change	1	0
<i>Uterine therapeutic procedures</i>		
Endometrial ablation	1	0
Surgical & medical procedures SOC TOTAL	212	1

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	8	0
Hypertensive urgency	1	0
Malignant hypertension	3	0
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm	1	0
Artery dissection	1	0
<i>Aortic aneurysms and dissections</i>		
Acute aortic syndrome	1	0
Aortic aneurysm rupture	1	1
Aortic dissection	1	0
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	5	0
Aortic thrombosis	1	0
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	8	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	45	0
Hypoperfusion	1	0
Neurogenic shock	20	0
Peripheral circulatory failure	5	0
Shock	12	0
<i>Haemorrhages NEC</i>		
Bloody discharge	7	0
Haematoma	27	0
Haemorrhage	454	2
Internal haemorrhage	6	0
Venous haemorrhage	1	0
<i>Lymphangiopathies</i>		
Lymphangiopathy	1	0
Lymphocele	3	0
<i>Lymphoedemas</i>		
Lymphoedema	137	0
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	3	0
Embolism	63	0
Embolism venous	3	0
Microembolism	1	0
Thrombosis	222	6
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
Ischaemia	5	0
Vasospasm	1	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
<i>Non-site specific vascular disorders NEC</i>		
Capillary disorder	1	0
Superficial vein prominence	1	0
Vascular pain	10	0
Vasodilatation	19	0
Vein discolouration	4	0
Vein disorder	5	0
Vein rupture	3	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	18	0
Deep vein thrombosis	172	0
Femoral artery embolism	1	0
Jugular vein thrombosis	2	0
Pelvic venous thrombosis	4	0
Peripheral embolism	1	0
Subclavian artery embolism	1	0
Subclavian vein thrombosis	2	0
Thrombophlebitis	14	0
Thrombophlebitis superficial	10	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	28	0
Erythromelalgia	1	0
Flushing	329	0
Hot flush	704	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Extremity necrosis	2	0
Intermittent claudication	1	0
Ischaemic limb pain	1	0
Peripheral arterial occlusive disease	2	0
Peripheral artery occlusion	1	0
Peripheral coldness	214	0
Peripheral ischaemia	10	0
Poor peripheral circulation	7	0
Raynaud's phenomenon	45	0
Vasoconstriction	2	0
<i>Phlebitis NEC</i>		
Phlebitis	21	0
Phlebitis superficial	4	0
<i>Site specific vascular disorders NEC</i>		
Pallor	202	0
<i>Varicose veins NEC</i>		
Spider vein	2	0
Varicophlebitis	1	0
Varicose vein	10	0
<i>Vascular hypertensive disorders NEC</i>		
Diastolic hypertension	1	0
Essential hypertension	3	0
Hypertension	359	1
Labile hypertension	1	0
Orthostatic hypertension	1	0
Secondary hypertension	1	0
Systolic hypertension	2	0

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Reaction Name	Total	Fatal
Vascular disorders <i>Vascular disorders cont'd</i>		
<i>Vascular hypotensive disorders</i>		
Hypotension	266	0
Orthostatic hypotension	19	0
<i>Vasculitides NEC</i>		
Behcet's syndrome	4	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	1	0
MAGIC syndrome	1	0
Vasculitis	38	0
<i>Vena caval embolism and thrombosis</i>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	3628	10
TOTAL REACTIONS FOR DRUG	236555	450
TOTAL REPORTS	84421	
TOTAL FATAL OUTCOME REPORTS		450