

COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

All UK spontaneous reports received between 9/12/20 and 21/07/21 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: 22-Jul-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 21-Jul-2021 18:30:10
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia folate deficiency	1	0
Anaemia vitamin B12 deficiency	2	0
Deficiency anaemia	1	0
Iron deficiency anaemia	6	0
<i>Anaemias NEC</i>		
Anaemia	73	0
Anaemia macrocytic	1	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	2	0
Microcytic anaemia	1	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	4	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	26	0
Spontaneous haematoma	2	0
<i>Coagulation factor deficiencies</i>		
Acquired haemophilia	2	0
<i>Coagulopathies</i>		
Abnormal clotting factor	3	0
Antiphospholipid syndrome	5	0
Coagulopathy	12	1
Disseminated intravascular coagulation	2	0
Hypercoagulation	3	0
Thrombotic microangiopathy	2	0
<i>Eosinophilic disorders</i>		
Eosinophilia	12	0
<i>Haematological disorders</i>		
Blood disorder	2	0
Mast cell activation syndrome	4	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	6	0
Intravascular haemolysis	1	0
<i>Leukocytoses NEC</i>		
Leukocytosis	1	0
Lymphocytosis	5	0
Neutrophilia	6	0
<i>Leukopenias NEC</i>		
Leukopenia	3	0
Lymphopenia	3	0
<i>Lymphatic system disorders NEC</i>		
Abdominal lymphadenopathy	1	0
Hilar lymphadenopathy	2	0
Lymph node pain	1046	0
Lymphadenitis	102	0
Lymphadenopathy	7046	0
Lymphatic disorder	1	0

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Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Necrotic lymphadenopathy	3	0
Pseudolymphoma	7	0
Retroperitoneal lymphadenopathy	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplasia pure red cell	2	0
Hypoplastic anaemia	1	0
Myelosuppression	1	0
Pancytopenia	6	0
<i>Neutropenias</i>		
Autoimmune neutropenia	2	0
Neutropenia	33	0
<i>Platelet disorders NEC</i>		
Platelet anisocytosis	1	0
Platelet disorder	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	8	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	63	0
Thrombocytopenia	155	1
Thrombocytopenic purpura	4	0
Thrombotic thrombocytopenic purpura	5	0
<i>Thrombocytoses</i>		
Thrombocytosis	4	0
Blood disorders SOC TOTAL	8707	3

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	7	1
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	34	0
Cardiac dysfunction	1	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	4	0
Intracardiac thrombus	3	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	7	0
Cardiovascular symptom	1	0
Palpitations	1917	0
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	1	0
Heart valve incompetence	1	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	4	0
Congestive cardiomyopathy	4	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>Endocarditis NEC</i>		
Endocarditis noninfective	1	1
<i>Heart failures NEC</i>		
Cardiac failure	47	6
Cardiac failure acute	2	0
Cardiac failure chronic	1	0
Cardiac failure congestive	3	1
Cardiogenic shock	4	1
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	3	0
Acute myocardial infarction	17	1
Angina pectoris	102	0
Angina unstable	2	0
Arteriospasm coronary	1	0
Microvascular coronary artery disease	2	0
Myocardial infarction	150	26
Myocardial ischaemia	6	2
<i>Left ventricular failures</i>		
Acute left ventricular failure	1	1

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Cardiac disorders Cardiac disorders cont'd		
Left ventricular failure	5	2
Mitral valvular disorders		
Mitral valve incompetence	3	0
Mitral valve prolapse	1	0
Myocardial disorders NEC		
Cardiac amyloidosis	1	0
Cardiomegaly	10	1
Left atrial dilatation	1	0
Left ventricular dysfunction	4	0
Left ventricular enlargement	1	0
Left ventricular hypertrophy	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	134	1
Noninfectious pericarditis		
Pericarditis	117	1
Pericardial disorders NEC		
Pericardial effusion	16	0
Pericardial haemorrhage	3	3
Pericardial rub	1	0
Rate and rhythm disorders NEC		
Arrhythmia	81	0
Bradycardia	45	0
Bradycardia foetal	1	1
Cardiac flutter	215	0
Extrasystoles	89	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	11	0
Tachyarrhythmia	1	0
Tachycardia	569	0
Right ventricular failures		
Cor pulmonale	1	0
Supraventricular arrhythmias		
Arrhythmia supraventricular	8	0
Atrial fibrillation	140	0
Atrial flutter	11	0
Atrial tachycardia	4	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	1	0
Sinus bradycardia	5	0
Sinus tachycardia	37	0
Supraventricular extrasystoles	1	0
Supraventricular tachycardia	27	0
Tricuspid valvular disorders		
Tricuspid valve incompetence	1	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	79	32

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Cardiac disorders Cardiac disorders cont'd		
Cardio-respiratory arrest	1	1
Pulseless electrical activity	3	0
Ventricular arrhythmia	4	0
Ventricular extrasystoles	12	0
Ventricular fibrillation	6	1
Ventricular tachycardia	10	0
Cardiac disorders SOC TOTAL	4020	86

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	10	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	2	0
<i>External ear disorders congenital</i>		
Anotia	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	3	0
<i>Male reproductive tract disorders congenital</i>		
Cryptorchism	1	0
Micropenis	2	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Developmental hip dysplasia	1	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
Tourette's disorder	2	0
<i>Ocular disorders congenital NEC</i>		
Colour blindness	2	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

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Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
<i>Retinal disorders congenital</i>		
Retinitis pigmentosa	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
Congenital disorders SOC TOTAL	49	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	19	0
Ear discomfort	68	0
Ear disorder	13	0
Ear haemorrhage	8	0
Ear pain	663	0
Ear pruritus	6	0
Ear swelling	23	0
Otorrhoea	3	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	2	0
Eustachian tube dysfunction	7	0
Eustachian tube obstruction	2	0
<i>External ear disorders NEC</i>		
Auricular swelling	1	0
Excessive cerumen production	4	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	6	0
Diplacusis	1	0
<i>Hearing losses</i>		
Conductive deafness	1	0
Deafness	167	0
Deafness bilateral	6	0
Deafness neurosensory	12	0
Deafness transitory	4	0
Deafness unilateral	25	0
Hypoacusis	123	0
Sudden hearing loss	28	0
<i>Hyperacusia</i>		
Hyperacusis	35	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	8	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	5	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	36	0
Tinnitus	1328	0
Vertigo	934	0
Vertigo labyrinthine	9	0
Vertigo positional	60	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		
Middle ear effusion	1	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
Ear disorders SOC TOTAL	3640	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 acute	1	0
Thyroiditis subacute	2	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	1	0
Adrenocortical insufficiency acute	9	0
<i>Adrenal gland disorders NEC</i>		
Adrenal haemorrhage	2	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	3	0
Premature menarche	13	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	23	0
Ovulation delayed	18	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0
Goitre	10	0
Thyroid disorder	6	0
Thyroid mass	1	0
Thyroid pain	3	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	3	0
Hyperthyroidism	18	0
Thyrotoxic crisis	3	0
<i>Thyroid hypofunction disorders</i>		
Autoimmune hypothyroidism	1	0
Hypothyroidism	20	0
Myxoedema	1	0
Endocrine disorders SOC TOTAL	151	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	5	0
<i>Cataract conditions</i>		
Cataract	10	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	16	0
Vitreous floaters	52	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	4	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	30	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	5	0
Ulcerative keratitis	4	0
<i>Eyelid movement disorders</i>		
Blepharospasm	95	0
Excessive eye blinking	3	0
Eyelid function disorder	3	0
Eyelid myokymia	3	0
Eyelid ptosis	37	0
Paralytic lagophthalmos	2	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	9	0
Iritis	4	0
Uveitis	26	0
<i>Lacrimation disorders</i>		
Dry eye	98	0
Lacrimation increased	95	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	6	0
Eczema eyelids	4	0
Erythema of eyelid	5	0
Eyelid cyst	4	0
Eyelid irritation	2	0
Eyelid margin crusting	3	0

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Eye disorders Eye disorders cont'd		
Eyelid oedema	3	0
Eyelid rash	12	0
Swelling of eyelid	93	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
Floppy eyelid syndrome	1	0
Growth of eyelashes	2	0
Lagophthalmos	2	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	4	0
Eye haemorrhage	20	0
Ocular vascular disorder	1	0
Ophthalmic vein thrombosis	1	0
<i>Ocular disorders NEC</i>		
Dark circles under eyes	6	0
Eye disorder	22	0
Eye oedema	9	0
Eye pain	715	0
Eye swelling	345	0
Eye symptom	8	0
Eye ulcer	2	0
Eyelid disorder	10	0
Eyelid pain	9	0
Eyelids pruritus	5	0
Ocular discomfort	20	0
Periorbital oedema	16	0
Periorbital pain	1	0
Periorbital swelling	93	0
Retinal disorder	1	0
Vitreous disorder	1	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	7	0
Eye discharge	16	0
Eye inflammation	19	0
Eye irritation	75	0
Eye pruritus	180	0
Limbal swelling	2	0
Ocular hyperaemia	154	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	23	0
Ocular myasthenia	1	0
Ophthalmoplegia	3	0
Strabismus	5	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	10	0
Asthenopia	111	0
Eye paraesthesia	1	0

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Eye disorders Eye disorders cont'd		
Foreign body sensation in eyes	16	0
Hypoaesthesia eye	12	0
Photophobia	286	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	17	0
Pupil fixed	2	0
Pupils unequal	7	0
Refractive and accommodative disorders		
Altered visual depth perception	1	0
Astigmatism	1	0
Myopia	1	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal artery occlusion	6	0
Retinal artery thrombosis	1	0
Retinal haemorrhage	5	0
Retinal vein occlusion	24	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	2	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	3	0
Retinopathies NEC		
Acute macular outer retinopathy	1	0
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	3	0
Cyanopsia	1	0
Erythroptia	2	0

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Eye disorders Eye disorders cont'd		
Xanthopsia	1	0
Visual disorders NEC		
Charles Bonnet syndrome	1	0
Diplopia	118	0
Glare	1	0
Halo vision	6	0
Metamorphopsia	15	0
Oscillopsia	2	0
Photopsia	87	0
Scintillating scotoma	3	0
Vision blurred	795	0
Visual brightness	3	0
Visual snow syndrome	3	0
Visual field disorders		
Visual field defect	13	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	2	0
Blindness	81	0
Blindness transient	9	0
Blindness unilateral	10	0
Central vision loss	2	0
Sudden visual loss	3	0
Visual acuity reduced	15	0
Visual acuity reduced transiently	1	0
Visual impairment	225	0
Visual pathway disorders		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	4407	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
Gastrointestinal sounds abnormal	14	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	1	0
<i>Abdominal wall conditions NEC</i>		
Abdominal wall haematoma	1	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	0
Pancreatitis	9	0
Pancreatitis acute	9	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	4	0
Tongue cyst	4	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	1	0
Colitis	30	1
Colitis ischaemic	1	0
Colitis microscopic	1	0
Colitis ulcerative	51	0
Crohn's disease	27	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	2	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Teeth brittle	1	0
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	106	0
<i>Dental surface disorders</i>		
Tooth discolouration	4	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	4	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	3704	2

Case Series Drug Analysis Print

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

Report Run Date: 22-Jul-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 21-Jul-2021 18:30:10
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Diarrhoea haemorrhagic	18	0
<i>Diverticula</i>		
Diverticulum	4	0
Diverticulum intestinal	1	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	1	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	3	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	268	0
Epigastric discomfort	12	0
Eructation	33	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	12	0
Faecaloma	2	0
Faeces discoloured	37	0
Faeces hard	1	0
Faeces pale	3	0
Faeces soft	10	0
Mucous stools	6	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	311	0
Aerophagia	3	0
Flatulence	127	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	32	0
Reflux gastritis	4	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	2	0
Abdominal pain	932	0
Abdominal pain lower	80	0
Abdominal pain upper	1541	0
Abdominal rigidity	14	0
Abdominal tenderness	9	0
Gastrointestinal pain	89	0
Oesophageal pain	4	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	170	0
Duodenogastric reflux	3	0
Gastric dilatation	6	0
Gastrooesophageal reflux disease	82	0
Impaired gastric emptying	5	0
Infrequent bowel movements	2	0
Intestinal pseudo-obstruction	2	0
<i>Gastrointestinal disorders NEC</i>		

Case Series Drug Analysis Print

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Report Run Date: 22-Jul-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 21-Jul-2021 18:30:10
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Food poisoning	2	0
Functional gastrointestinal disorder	6	0
Gastric disorder	6	0
Gastrointestinal disorder	11	0
Stomach mass	3	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	1	0
Change of bowel habit	3	0
Dyschezia	2	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	424	0
Abdominal symptom	1	0
Acute abdomen	4	0
Anal incontinence	16	0
Breath odour	15	0
Dysphagia	146	1
Odynophagia	24	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Cardiospasm	1	0
Defaecation urgency	7	0
Frequent bowel movements	20	0
Irritable bowel syndrome	54	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	5	2
Mesenteric vein thrombosis	4	0
Omental infarction	1	0
Thrombosis mesenteric vessel	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	2	0
Gingival oedema	1	0
Gingival pain	78	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Gingival pruritus	1	0
Gingival swelling	23	0
Gingival ulceration	1	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	5	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	44	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Gastric varices	1	0
Haemorrhoids	23	0
Haemorrhoids thrombosed	1	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	12	0
Intestinal haemorrhage	1	0
Rectal haemorrhage	47	0
Small intestinal haemorrhage	6	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	10	0
Infantile vomiting	4	0
Nausea	9847	1
Regurgitation	1	0
Retching	73	0
Vomiting	2864	1
Vomiting projectile	39	0
<i>Non-mechanical ileus</i>		
Ileus paralytic	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	12	0
Haematemesis	25	2
Haematochezia	37	0
Melaena	8	0
Upper gastrointestinal haemorrhage	3	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	376	0
Lip dry	30	0
Saliva altered	4	0
Salivary hypersecretion	36	0
<i>Oral soft tissue disorders NEC</i>		
Angina bullosa haemorrhagica	1	0
Chapped lips	15	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Cheilitis	19	0
Enlarged uvula	11	0
Leukoplakia oral	1	0
Lip blister	18	0
Lip disorder	4	0
Oral disorder	7	0
Oral lichen planus	8	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	2	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	10	0
Oral blood blister	10	0
Oral purpura	2	0
Oral soft tissue infections		
Angular cheilitis	1	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	1	0
Burning mouth syndrome	5	0
Coating in mouth	1	0
Hypoaesthesia oral	364	0
Lip discolouration	6	0
Lip erythema	2	0
Lip exfoliation	5	0
Lip pain	40	0
Lip pruritus	10	0
Lip scab	1	0
Oral discomfort	61	0
Oral dysaesthesia	1	0
Oral mucosal blistering	12	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	11	0
Oral mucosal erythema	5	0
Oral mucosal exfoliation	7	0
Oral mucosal roughening	3	0
Oral pain	129	0
Oral pruritus	18	0
Paraesthesia oral	730	0
Pigmentation lip	1	0
Oral soft tissue swelling and oedema		
Lip oedema	3	0
Lip swelling	525	0
Mouth swelling	65	0
Oedema mouth	4	0
Palatal oedema	2	0
Palatal swelling	1	0
Peptic ulcers and perforation		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	9	0
Peritoneal and retroperitoneal disorders		
Ascites	1	0
Peritoneal and retroperitoneal fibrosis and adhesions		
Abdominal adhesions	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Peritoneal and retroperitoneal haemorrhages</i>		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	1
<i>Rectal inflammations NEC</i>		
Proctitis	1	0
Proctitis ulcerative	1	0
<i>Salivary gland disorders NEC</i>		
Salivary gland disorder	1	0
Salivary gland pain	11	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	8	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	32	0
Lip ulceration	12	0
Mouth ulceration	316	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	46	0
<i>Tongue disorders</i>		
Glossitis	14	0
Plicated tongue	3	0
Tongue disorder	29	0
Tongue haemorrhage	2	0
Tongue ulceration	26	0
Trichoglossia	4	0
<i>Tongue signs and symptoms</i>		
Glossodynia	159	0
Scalloped tongue	5	0
Stiff tongue	3	0
Swollen tongue	372	0
Tongue blistering	15	0
Tongue coated	14	0
Tongue discolouration	26	0
Tongue discomfort	32	0
Tongue dry	12	0
Tongue eruption	9	0
Tongue erythema	6	0
Tongue exfoliation	1	0
Tongue movement disturbance	5	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	25681	14

Case Series Drug Analysis Print

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Report Run Date: 22-Jul-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 21-Jul-2021 18:30:10
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	5	0
Administration site erythema	3	0
Administration site extravasation	3	0
Administration site haematoma	3	0
Administration site inflammation	1	0
Administration site irritation	1	0
Administration site joint discomfort	1	0
Administration site joint movement impairment	1	0
Administration site nerve damage	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	23	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	9	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	11	0
Application site pruritus	4	0
Application site rash	2	0
Application site reaction	1	0
Application site swelling	2	0
Application site vesicles	5	0
Instillation site warmth	4	0
<i>Asthenic conditions</i>		
Asthenia	1181	1
Chronic fatigue syndrome	56	0
Decreased activity	5	0
Fatigue	15526	0
Malaise	3455	0
Sluggishness	11	0
<i>Body temperature altered</i>		
Hyperthermia	5	0
Hypothermia	19	0

Case Series Drug Analysis Print

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 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Temperature regulation disorder	7	0
Breast complications associated with device		
Capsular contracture associated with breast implant	1	0
Cardiac complications associated with device		
Prosthetic cardiac valve thrombosis	1	0
Complications associated with device NEC		
Capsular contracture associated with implant	1	0
Injury associated with device	2	0
Medical device pain	1	0
Medical device site swelling	1	0
Phantom shocks	1	0
Death and sudden death		
Brain death	1	1
Clinical death	1	1
Death	128	128
Sudden death	25	25
Febrile disorders		
Hyperpyrexia	7	0
Pyrexia	10103	0
Feelings and sensations NEC		
Chills	6580	0
Feeling abnormal	994	0
Feeling cold	802	0
Feeling drunk	60	0
Feeling hot	780	0
Feeling jittery	16	0
Feeling of body temperature change	220	0
Hangover	51	0
Hunger	26	0
Sensation of blood flow	1	0
Sensation of foreign body	37	0
Temperature intolerance	25	0
Thirst	236	0
Fibrosis NEC		
Fibrosis	1	0
Gait disturbances		
Gait disturbance	120	0
Gait inability	47	0
Loss of control of legs	11	0
General signs and symptoms NEC		
Adhesion	1	0
Chronic disease	1	0
Condition aggravated	122	0
Crepitations	1	0
Crying	90	0
Deformity	2	0
Discharge	6	0
Disease progression	2	0
Disease recurrence	22	0
Effusion	2	0
Energy increased	13	0
Exercise tolerance decreased	10	0
Foaming at mouth	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
General physical health deterioration	13	1
General symptom	2	0
Glassy eyes	3	0
High-pitched crying	2	0
Illness	1190	0
Induration	10	0
Influenza like illness	1609	0
Irritability postvaccinal	2	0
Local reaction	67	0
Moaning	2	0
Multiple organ dysfunction syndrome	4	2
Nonspecific reaction	1	0
Organ failure	1	1
Perforation	2	0
Peripheral swelling	2333	0
Pre-existing condition improved	8	0
Prolapse	1	0
Screaming	14	0
Secretion discharge	10	0
Swelling	1793	0
Swelling face	578	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	258	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	23	0
Injection site bruising	49	0
Injection site coldness	1	0
Injection site cyst	2	0
Injection site discolouration	5	0
Injection site discomfort	9	0
Injection site erythema	267	0
Injection site haemorrhage	6	0
Injection site hypersensitivity	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site hypoaesthesia	8	0
Injection site indentation	5	0
Injection site induration	3	0
Injection site inflammation	27	0
Injection site joint discomfort	1	0
Injection site joint movement impairment	1	0
Injection site joint pain	12	0
Injection site lymphadenopathy	1	0
Injection site macule	1	0
Injection site mass	348	0
Injection site movement impairment	1	0
Injection site necrosis	3	0
Injection site oedema	11	0
Injection site pain	2180	0
Injection site paraesthesia	11	0
Injection site pruritus	128	0
Injection site rash	107	0
Injection site reaction	21	0
Injection site scab	2	0
Injection site scar	4	0
Injection site swelling	220	0
Injection site urticaria	19	0
Injection site vesicles	8	0
Injection site warmth	132	0
Interactions		
Alcohol interaction	2	0
Drug interaction	17	0
Inhibitory drug interaction	3	0
Mass conditions NEC		
Cyst	25	0
Mass	44	0
Nodule	27	0
Mucosal findings abnormal		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	9	0
Mucosal inflammation	2	0
Oedema mucosal	1	0
Polyp	2	0
Necrosis NEC		
Fat necrosis	2	0
Necrosis	3	0
Oedema NEC		
Face oedema	25	0
Generalised oedema	2	0
Localised oedema	15	0
Oedema	44	0
Oedema peripheral	61	0
Pain and discomfort NEC		
Axillary pain	1713	0
Chest discomfort	1014	0
Chest pain	2160	1
Discomfort	259	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Facial discomfort	14	0
Facial pain	152	0
Inflammatory pain	6	0
Non-cardiac chest pain	19	0
Pain	5576	0
Suprapubic pain	1	0
Tenderness	463	0
Visceral pain	1	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	25	0
Adverse event	4	0
Adverse food reaction	1	0
Adverse reaction	2	0
Drug ineffective	173	1
Drug intolerance	2	0
Immediate post-injection reaction	2	0
Inadequate analgesia	5	0
No reaction on previous exposure to drug	35	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	53	0
Treatment failure	6	0
Vaccination failure	8	0
Trophic disorders		
Atrophy	1	0
Calcinosis	1	0
Ulcers NEC		
Ulcer	18	0
Ulcer haemorrhage	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	9	0
Shoulder injury related to vaccine administration	17	0
Vaccination site bruising	87	0
Vaccination site coldness	1	0
Vaccination site cyst	4	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	11	0
Vaccination site discomfort	37	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	451	0
Vaccination site granuloma	1	0
Vaccination site haematoma	1	0
Vaccination site haemorrhage	14	0
Vaccination site hypersensitivity	2	0
Vaccination site hypoaesthesia	13	0
Vaccination site induration	64	0
Vaccination site inflammation	46	0
Vaccination site irritation	10	0
Vaccination site joint discomfort	2	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site joint erythema	7	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	16	0
Vaccination site joint pain	26	0
Vaccination site joint swelling	3	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	3	0
Vaccination site macule	1	0
Vaccination site mass	182	0
Vaccination site movement impairment	59	0
Vaccination site nerve damage	1	0
Vaccination site nodule	2	0
Vaccination site oedema	3	0
Vaccination site pain	1613	0
Vaccination site paraesthesia	4	0
Vaccination site phlebitis	1	0
Vaccination site pruritus	117	0
Vaccination site rash	97	0
Vaccination site reaction	27	0
Vaccination site scab	2	0
Vaccination site scar	1	0
Vaccination site swelling	428	0
Vaccination site ulcer	1	0
Vaccination site urticaria	9	0
Vaccination site vesicles	4	0
Vaccination site warmth	214	0
<i>Vascular complications associated with device</i>		
Vascular stent thrombosis	1	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	5	0
Withdrawal syndrome	23	0
General disorders SOC TOTAL	68130	162

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	6	0
Cholangitis	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	1	0
Cholecystitis acute	1	0
Cholelithiasis	6	0
<i>Cholestasis and jaundice</i>		
Cholestasis	2	0
Jaundice	14	0
Jaundice cholestatic	6	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	8	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	2	0
Hepatic artery embolism	1	0
Hepatic haemorrhage	2	0
Hepatic vein thrombosis	5	0
Portal vein thrombosis	3	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	18	0
Hepatomegaly	1	0
Liver tenderness	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	4	0
Drug-induced liver injury	2	0
Hepatitis	9	0
Immune-mediated hepatic disorder	1	0
Liver injury	8	0
Hepatic disorders SOC TOTAL	110	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	5	0
Allergy to arthropod sting	1	0
Allergy to metals	1	0
Allergy to sting	1	0
Hypersensitivity	666	0
Infusion related hypersensitivity reaction	1	0
Mite allergy	1	0
Multiple allergies	6	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	29	0
Contrast media reaction	1	0
Drug hypersensitivity	19	0
Food allergy	15	0
Oral allergy syndrome	2	0
Reaction to colouring	1	0
Reaction to excipient	8	0
Reaction to preservatives	4	0
Rubber sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	379	2
Anaphylactic shock	35	0
Anaphylactoid reaction	19	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	1	0
Seasonal allergy	70	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	26	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	30	0
Graft versus host disease	1	0
Immune system disorder	16	0
Immune-mediated adverse reaction	5	0
Immunisation reaction	1	0
Sensitisation	4	0
Systemic immune activation	2	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
Immunosuppression	1	0
<i>Transplant rejections</i>		

Case Series Drug Analysis Print

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

Report Run Date: 22-Jul-2021

Data Lock Date: 21-Jul-2021 18:30:10

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Immune system disorders		
Immune system disorders cont'd		
Corneal graft rejection	5	0
Kidney transplant rejection	1	0
Solid organ transplant rejection	1	0
Immune system disorders SOC TOTAL	1406	2

Case Series Drug Analysis Print

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

Report Run Date: 22-Jul-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 21-Jul-2021 18:30:10
 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	3	0
Appendicitis	22	0
Appendicitis perforated	2	0
Diverticulitis	6	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	21	0
Mesenteric abscess	1	0
Peritonitis	1	1
Rectal abscess	1	0
<i>Adenoviral infections</i>		
Adenoviral conjunctivitis	1	0
<i>Aspergillus infections</i>		
Bronchopulmonary aspergillosis	1	0
<i>Bacterial infections NEC</i>		
Abscess bacterial	1	0
Arthritis bacterial	3	0
Bacterial colitis	1	0
Bacterial diarrhoea	1	0
Bacterial infection	9	0
Cellulitis	130	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
Folliculitis	11	0
Gangrene	1	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	2	0
Tonsillitis bacterial	3	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	15	0
Zoonotic bacterial infection	1	1
<i>Bartonella infections</i>		
Cat scratch disease	1	0
<i>Bone and joint infections</i>		
Abscess jaw	1	0
Arthritis infective	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	42	0
<i>Caliciviral infections</i>		
Gastroenteritis norovirus	1	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 21-Jul-2021 18:30:10
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Campylobacter infections</i>		
Campylobacter gastroenteritis	1	0
Campylobacter infection	1	0
<i>Candida infections</i>		
Anal candidiasis	2	0
Candida infection	38	0
Oral candidiasis	33	0
Systemic candida	1	0
Vulvovaginal candidiasis	33	0
<i>Cardiac infections</i>		
Pericarditis infective	1	0
<i>Central nervous system and spinal infections</i>		
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	14	0
Meningitis	4	0
Meningitis aseptic	1	0
Myelitis	4	0
<i>Clostridia infections</i>		
Clostridium difficile infection	2	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	11	0
COVID-19	809	34
COVID-19 pneumonia	34	13
Coronavirus infection	6	0
Post-acute COVID-19 syndrome	1	0
Severe acute respiratory syndrome	1	0
Suspected COVID-19	44	1
<i>Coxiella infections</i>		
Q fever	9	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	2	0
Cytomegalovirus syndrome	1	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	4	0
Gingivitis	7	0
Parotitis	9	0
Pulpitis dental	1	0
Sialoadenitis	3	0
Tooth abscess	8	0
Tooth infection	7	0
<i>Ear infections</i>		
Ear infection	55	0
Labyrinthitis	69	0
Mastoiditis	1	0
Otitis media	3	0
Otitis media acute	1	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	4	0
Bed bug infestation	1	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	3	0
Infectious mononucleosis	21	0

Case Series Drug Analysis Print

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 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 21-Jul-2021 18:30:10
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Eye and eyelid infections</i>		
Conjunctivitis	52	0
Eye abscess	1	0
Eye infection	15	0
Eyelid infection	2	0
Hordeolum	18	0
Periorbital infection	2	0
<i>Female reproductive tract infections</i>		
Bartholinitis	1	0
Endometritis	3	0
Funisitis	1	0
Pelvic inflammatory disease	1	0
Vaginal infection	1	0
Vulval abscess	1	0
Vulvitis	1	0
<i>Fungal infections NEC</i>		
Fungal infection	8	0
Fungal skin infection	2	0
Onychomycosis	1	0
Oral fungal infection	1	0
Pneumonia fungal	2	0
Vulvovaginal mycotic infection	6	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	64	0
Genital herpes simplex	5	0
Herpes ophthalmic	3	0
Herpes simplex	22	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	2	0
Herpes virus infection	9	0
Herpes zoster	1099	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	10	0
Herpes zoster reactivation	1	0
Nasal herpes	3	0
Ophthalmic herpes zoster	3	0
Oral herpes	232	0
Varicella	20	0
Varicella zoster virus infection	1	0
<i>Infections NEC</i>		
Abscess	28	0
Abscess limb	5	0
Abscess soft tissue	1	0
Genital abscess	1	0
Infected bite	1	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		
Infected cyst	2	0
Infection	164	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	19	0
Lymph gland infection	6	0
Lymph node abscess	4	0
Opportunistic infection	1	0
Respiratory tract infection	6	0
Vaccination site abscess	6	0
Vaccination site infection	13	0
Vaccine breakthrough infection	23	0
Vestibulitis	2	0
Wound infection	1	0
<i>Infectious transmissions</i>		
Secondary transmission	8	0
<i>Influenza viral infections</i>		
Influenza	1064	0
<i>Klebsiella infections</i>		
Klebsiella infection	1	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	16	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	146	7
Pneumonia	83	9
Sputum purulent	1	0
<i>Male reproductive tract infections</i>		
Epididymitis	3	0
Orchitis	3	0
Prostate infection	1	0
<i>Mumps viral infections</i>		
Mumps	7	0
<i>Muscle and soft tissue infections</i>		
Abscess neck	1	0
Infective tenosynovitis	1	0
Necrotising fasciitis	2	0
Soft tissue infection	1	0
<i>Neisseria infections</i>		
Gonorrhoea	1	0
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	1	0
<i>Prion-associated disorders</i>		
Creutzfeldt-Jakob disease	1	0
<i>Retroviral infections</i>		
HIV infection	1	0
<i>Rotaviral infections</i>		
Gastroenteritis rotavirus	1	0
<i>Rubeola viral infections</i>		
Measles	4	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Bacteraemia	1	0
Neutropenic sepsis	3	1
Sepsis	35	5

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Sepsis syndrome	1	0
Septic rash	1	0
Septic shock	4	1
Urosepsis	5	0
<i>Skin structures and soft tissue infections</i>		
Abscess sweat gland	1	0
Acne pustular	1	0
Blister infected	1	0
Dermatitis infected	2	0
Impetigo	5	0
Infected skin ulcer	1	0
Injection site pustule	1	0
Nail infection	1	0
Pustule	9	0
Rash pustular	9	0
Skin infection	26	0
Subcutaneous abscess	6	0
Vaccination site pustule	4	0
<i>Staphylococcal infections</i>		
Furuncle	30	0
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	3	0
Staphylococcal sepsis	1	0
<i>Streptococcal infections</i>		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	5	0
Streptococcal abscess	1	0
Streptococcal endocarditis	1	0
Streptococcal infection	1	0
Streptococcal sepsis	1	0
<i>Tinea infections</i>		
Body tinea	1	0
Tinea infection	1	0
Tinea pedis	1	0
Tinea versicolour	1	0
<i>Treponema infections</i>		
Syphilis	1	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	1	0
<i>Tuberculous infections</i>		
Lymph node tuberculosis	1	0
Pulmonary tuberculosis	1	0
Tuberculosis	1	0
<i>Upper respiratory tract infections</i>		
Acute sinusitis	3	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	20	0
Nasopharyngitis	632	0
Peritonsillar abscess	2	0
Pharyngitis	21	0
Rhinitis	34	0

Case Series Drug Analysis Print

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 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Sinusitis	105	0
Tonsillitis	71	0
Tracheitis	4	0
Tracheostomy infection	1	0
Upper respiratory tract infection	6	0
Urinary tract infections		
Cystitis	56	0
Kidney infection	28	0
Pyelonephritis	1	0
Urinary tract infection	121	0
Vascular infections		
Haematoma infection	1	0
Infected lymphocele	1	0
Infusion site infection	1	0
Lymphangitis	7	0
Viral infections NEC		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Encephalitis viral	3	0
Eye infection viral	2	0
Gastroenteritis viral	19	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	34	0
Sweating fever	68	0
Vestibular neuronitis	19	0
Viral diarrhoea	2	0
Viral infection	36	0
Viral labyrinthitis	3	0
Viral pericarditis	2	0
Viral pharyngitis	13	0
Viral rash	36	0
Viral sinusitis	1	0
Viral tonsillitis	1	0
Infections SOC TOTAL	6341	75

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	3	0
Palate injury	1	0
Rectal injury	1	0
Splenic rupture	5	0
Tongue injury	1	0
Tooth fracture	1	0
Tooth injury	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	15	0
<i>Anaesthetic and allied procedural complications</i>		
Airway complication of anaesthesia	1	0
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	6	0
<i>Cardiovascular injuries</i>		
Heart injury	4	0
Vascular injury	4	0
<i>Cerebral injuries NEC</i>		
Brain contusion	1	0
Brain herniation	1	0
Concussion	2	0
Cranio-cerebral injury	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	5	0
Subdural haemorrhage	5	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	49	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	7	0
Exposure via breast milk	30	0
Foetal exposure during pregnancy	19	0
Maternal exposure before pregnancy	2	0
Maternal exposure during breast feeding	936	0
Maternal exposure during pregnancy	442	0
Maternal exposure timing unspecified	1	0
Paternal exposure before pregnancy	2	0
<i>Exposures to agents or circumstances NEC</i>		

Case Series Drug Analysis Print

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

Report Run Date: 22-Jul-2021
Earliest Reaction Date: 13-Apr-1968

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Exposure to SARS-CoV-2	1	0
Exposure to vaccinated person	3	0
Eye and ear procedural complications		
Toxic anterior segment syndrome	1	0
Eye injuries NEC		
Eye contusion	13	0
Eye injury	13	0
Foreign body in eye	2	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
Multiple fractures	1	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	2	0
Heat exhaustion	2	0
Heat illness	1	0
Heat oedema	7	0
Heat stroke	3	0
Intentional product use issues		
Intentional product use issue	1	0
Limb fractures and dislocations		
Atypical femur fracture	1	0
Clavicle fracture	20	0
Femoral neck fracture	1	0
Hip fracture	1	0
Upper limb fracture	1	0
Wrist fracture	1	0
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	1	0
Dose calculation error	1	0
Inadequate aseptic technique in use of product	1	0
Medication error	17	0
Prescription drug used without a prescription	2	0
Product use complaint	1	0
Product use issue	13	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	12	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Ligament sprain	6	0
Mallet finger	1	0
Muscle injury	12	0
Muscle rupture	4	0
Muscle strain	21	0
Post-traumatic neck syndrome	1	0
Tendon injury	5	0
Tendon rupture	6	0
Musculoskeletal procedural complications		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
Nerve injuries NEC		
Nerve injury	45	0
Neurological and psychiatric procedural complications		
Post procedural stroke	1	0
Procedural dizziness	11	0
Non-occupational environmental exposures		
Exposure to extreme temperature	1	0
Non-site specific injuries NEC		
Arthropod bite	2	0
Arthropod sting	3	0
Bite	1	0
Electric shock	10	0
Fall	107	1
Foreign body	2	0
Injury	5	0
Nervous system injury	1	0
Post concussion syndrome	1	0
Traumatic haematoma	1	0
Wound	5	0
Wound complication	8	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	37	0
Post procedural complication	3	0
Procedural pain	2	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	44	0
Overdoses NEC		
Overdose	26	0
Pathways and sources of exposure		
Exposure via unknown route	1	0
Pelvic fractures and dislocations		
Pelvic fracture	1	0
Peripheral nerve injuries		

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Brachial plexus injury	1	0
Ulnar nerve injury	4	0
Poisoning and toxicity		
Alcohol poisoning	1	0
Poisoning	9	0
Toxicity to various agents	2	0
Product administration errors and issues		
Accidental overdose	4	0
Contraindicated product administered	1	0
Expired product administered	10	0
Inappropriate schedule of product administration	231	0
Incomplete course of vaccination	1	0
Incorrect dose administered	51	0
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	3	0
Poor quality product administered	2	0
Product administered at inappropriate site	11	0
Product administered to patient of inappropriate age	1	0
Product administration error	5	0
Product dose omission issue	3	0
Wrong product administered	19	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 prescribing error	1	0
Product selection errors and issues		
Product selection error	2	0
Radiation injuries		
Sunburn	17	0
Renal and urinary tract injuries NEC		
Foreign body in urogenital tract	1	0
Site specific injuries NEC		
Face crushing	1	0
Head injury	30	0
Limb crushing injury	2	0
Limb injury	63	0
Nasal injury	2	0
Neck crushing	1	0
Neck injury	1	0
Skin injuries NEC		
Contusion	765	0
Nail avulsion	1	0
Scar	10	0
Scratch	7	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Skin abrasion	5	0
Skin injury	2	0
Skin laceration	2	0
Skin wound	2	0
Subcutaneous haematoma	2	0
<i>Skin procedural complications</i>		
Recall phenomenon	1	0
<i>Skull fractures, facial bone fractures and dislocations</i>		
Facial bones fracture	1	0
Fractured skull depressed	1	0
<i>Spinal fractures and dislocations</i>		
Spinal fracture	3	0
<i>Stoma complications</i>		
Gastrointestinal stoma complication	1	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
<i>Thermal burns</i>		
Airway burns	1	0
Burn oesophageal	2	0
Burn of internal organs	2	0
Burn oral cavity	2	0
Burns second degree	4	0
Thermal burn	16	0
Thermal burns of eye	9	0
<i>Underdoses NEC</i>		
Underdose	6	0
<i>Vaccination related complications</i>		
Adverse event following immunisation	1	0
Vaccination complication	41	0
Injuries SOC TOTAL	3512	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>		
Acid base balance abnormal	1	0
Blood lactic acid	2	0
Blood lactic acid decreased	1	0
Blood lactic acid increased	3	0
Blood pH	6	0
Blood pH increased	6	0
Oxygen consumption decreased	2	0
Oxygen saturation	6	0
Oxygen saturation decreased	49	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	4	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	6	0
Blood glucose abnormal	9	0
Blood glucose decreased	26	0
Blood glucose fluctuation	14	0
Blood glucose increased	83	0
Blood glucose normal	1	0
Glycosylated haemoglobin increased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	15	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
Echocardiogram	1	0
Stroke volume decreased	1	0
<i>Cardiac imaging procedures</i>		
Magnetic resonance imaging heart	1	0
Scan myocardial perfusion abnormal	1	0
<i>Cell marker analyses</i>		
Prostatic specific antigen increased	2	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Central nervous system imaging procedures		
Computerised tomogram head	4	0
Magnetic resonance imaging head	11	0
Magnetic resonance imaging head abnormal	1	0
Cerebrospinal fluid tests (excl microbiology)		
CSF pressure	1	0
Chemistry analyses NEC		
Inflammatory marker increased	3	0
Renin	1	0
Cholesterol analyses		
Blood cholesterol increased	5	0
Remnant-like lipoprotein particles	3	0
Coagulation and bleeding analyses		
Activated partial thromboplastin time prolonged	15	0
Activated partial thromboplastin time shortened	1	0
Bleeding time	1	0
Bleeding time abnormal	1	0
Bleeding time prolonged	3	0
Blood thromboplastin	1	0
Clot retraction	1	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	8	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	47	0
Digestive enzymes		
Amylase increased	1	0
ECG investigations		
Electrocardiogram	2	0
Electrocardiogram QRS complex prolonged	1	0
Electrocardiogram QT prolonged	2	0
Electrocardiogram ST segment elevation	3	0
Electrocardiogram ST-T segment abnormal	1	0
Electrocardiogram T wave inversion	3	0
Electrocardiogram abnormal	11	0
Electrocardiogram normal	2	0
QRS axis abnormal	1	0
Endocrine analyses and imaging NEC		
Hormone level abnormal	28	0
Faecal analyses NEC		
Faecal calprotectin	2	0
Faecal calprotectin increased	4	0
Fertility analyses		
Infertility tests	1	0
Semen analysis abnormal	1	0
Foetal and neonatal diagnostic procedures		
Foetal heart rate abnormal	2	2
Foetal heart rate increased	1	0
Foetal non-stress test	1	0
Gastrointestinal and abdominal imaging procedures		

Case Series Drug Analysis Print

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

Report Run Date: 22-Jul-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 21-Jul-2021 18:30:10
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Computerised tomogram abdomen	1	0
Sigmoidoscopy abnormal	1	0
<i>Gastrointestinal function diagnostic procedures</i>		
Gastric pH decreased	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
Heart rate	275	0
Heart rate abnormal	38	0
Heart rate decreased	44	0
Heart rate increased	542	0
Heart rate irregular	107	0
Maximum heart rate	1	0
Pulse abnormal	13	0
Pulse pressure increased	1	0
Radial pulse abnormal	1	0
Sinus rhythm	4	0
<i>Imaging procedures NEC</i>		
Computerised tomogram	3	0
Magnetic resonance imaging	1	0
Magnetic resonance imaging abnormal	1	0
Scan	1	0
<i>Immunoglobulin analyses</i>		
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	1	0
<i>Immunology analyses NEC</i>		
Antibody test	4	0
Immunology test	8	0
<i>Immunology skin tests NEC</i>		
Skin test positive	1	0
<i>Investigations NEC</i>		
Blood test	13	0
Blood test abnormal	25	0
False positive investigation result	1	0
Laboratory test	1	0
Polymerase chain reaction positive	33	0
Quality of life decreased	1	0
Systemic lupus erythematosus disease activity index increased	1	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	19	0
Aspartate aminotransferase	1	0
Aspartate aminotransferase increased	2	0
Blood bilirubin increased	3	0
Gamma-glutamyltransferase increased	4	0
Hepatic enzyme increased	4	0
Liver function test	1	0
Liver function test abnormal	20	0

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Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 21-Jul-2021 18:30:10
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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Liver function test increased	13	0
Transaminases increased	2	0
Metabolism tests NEC		
Blood ketone body	3	0
Blood ketone body increased	1	0
Blood uric acid increased	2	0
Brain natriuretic peptide increased	1	0
Ubiquinone	1	0
Urine ketone body present	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	3	0
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0
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	3	0
Serum ferritin increased	1	0
Musculoskeletal and soft tissue imaging procedures		
Skull X-ray	6	0
Musculoskeletal and soft tissue tests NEC		
Swollen joint count increased	1	0
Mycobacteria identification and serology		
Tuberculin test positive	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	3	0
Hoover's sign of leg paresis	1	0
Lumbar puncture	3	0
Temperature perception test increased	1	0
Ophthalmic function diagnostic procedures		
Corneal reflex decreased	1	0
Intraocular pressure increased	7	0
Intraocular pressure test	1	0
Physical examination procedures and organ system status		
Body temperature	189	0
Body temperature abnormal	31	0
Body temperature decreased	30	0
Body temperature fluctuation	24	0
Body temperature increased	304	0
Body temperature normal	1	0
Breath sounds abnormal	1	0
General physical condition abnormal	1	0
Grip strength	2	0
Grip strength decreased	14	0
Head lag	4	0
Lymph node palpable	30	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Menstruation normal	3	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	12	0
Respiratory rate increased	26	0
Skin temperature	27	0
Temperature difference of extremities	7	0
Weight	1	0
Weight decreased	59	0
Weight increased	17	0
<i>Pituitary analyses anterior</i>		
Blood corticotrophin	1	0
Blood follicle stimulating hormone	1	0
Blood growth hormone	3	0
Blood prolactin	2	0
Blood prolactin increased	1	0
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	3	0
<i>Platelet analyses</i>		
Mean platelet volume decreased	1	0
Mean platelet volume increased	1	0
Platelet count	1	0
Platelet count decreased	53	0
Platelet count increased	1	0
<i>Protein analyses NEC</i>		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	14	0
<i>Red blood cell analyses</i>		
Haematocrit	1	0
Haemoglobin decreased	10	0
<i>Renal function analyses</i>		
Blood creatinine increased	1	0
Glomerular filtration rate decreased	2	0
<i>Reproductive hormone analyses</i>		
Anti-Muellerian hormone level decreased	1	0
False negative pregnancy test	6	0
Female sex hormone level	2	0
Pregnancy test	15	0
Pregnancy test positive	1	0
<i>Reproductive organ and breast histopathology procedures</i>		
Smear cervix	1	0
<i>Reproductive organ and breast imaging procedures</i>		
Hysteroscopy	2	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Forced expiratory volume increased	2	0
Maximal voluntary ventilation	1	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	4	0

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Pulmonary function test	2	0
Total lung capacity decreased	1	0
Vital capacity	1	0
<i>Respiratory tract and thoracic histopathology procedures</i>		
Sputum abnormal	3	0
<i>Respiratory tract and thoracic imaging procedures</i>		
Chest X-ray	18	0
Chest X-ray normal	1	0
Chest scan	1	0
Computerised tomogram thorax	1	0
<i>Skeletal and cardiac muscle analyses</i>		
Blood creatine phosphokinase increased	4	0
Myocardial necrosis marker	1	0
Troponin increased	7	0
<i>Therapeutic drug monitoring analyses</i>		
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
<i>Thyroid analyses</i>		
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
<i>Tissue enzyme analyses NEC</i>		
Blood alkaline phosphatase increased	2	0
<i>Toxicology laboratory analyses</i>		
Blood caffeine decreased	1	0
Drug screen positive	2	0
Opiates	1	0
<i>Urinalysis NEC</i>		
Blood urine	10	0
Blood urine present	33	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
<i>Urinary tract function analyses NEC</i>		
Urine output	10	0
Urine output decreased	7	0
Urine output increased	5	0
<i>Urinary tract imaging procedures</i>		
Cystoscopy	2	0
<i>Vascular imaging procedures NEC</i>		
Venogram	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	6	0
Blood pressure decreased	48	0
Blood pressure diastolic	1	0
Blood pressure diastolic decreased	1	0

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Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood pressure diastolic increased	2	0
Blood pressure increased	167	0
Blood pressure measurement	29	0
Blood pressure normal	1	0
Blood pressure systolic	1	0
Blood pressure systolic decreased	3	0
Blood pressure systolic increased	1	0
<i>Virus identification and serology</i>		
Coronavirus test	10	0
Coronavirus test positive	3	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	23	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	89	0
Viral test	4	0
<i>Vitamin analyses</i>		
Blood folate decreased	3	0
Vitamin B12	1	0
Vitamin B12 abnormal	1	0
Vitamin B12 decreased	1	0
Vitamin D	2	0
Vitamin D decreased	2	0
<i>Water and electrolyte analyses NEC</i>		
Volume blood	1	0
<i>White blood cell analyses</i>		
Eosinophil count increased	1	0
Lymphocyte count	1	0
Lymphocyte count decreased	1	0
Neutrophil count	1	0
Neutrophil count decreased	4	0
White blood cell count	3	0
White blood cell count decreased	8	0
White blood cell count increased	6	0
Investigations SOC TOTAL	3287	3

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	11	0
Decreased appetite	839	0
Diet refusal	1	0
Eating disorder symptom	2	0
Food craving	8	0
Food refusal	6	0
Hyperphagia	6	0
Hypophagia	12	0
Increased appetite	20	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	3	0
Tetany	2	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	34	0
Diabetes mellitus inadequate control	10	1
Increased insulin requirement	1	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	2	0
Type 1 diabetes mellitus	14	0
Type 2 diabetes mellitus	3	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	72	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	8	0
Gluten sensitivity	5	0
Histamine intolerance	3	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	9	0
Abnormal weight gain	10	0
Cachexia	1	0
Feeding disorder	44	0
Food aversion	7	0
Malnutrition	1	0
Neonatal insufficient breast milk syndrome	4	0
Overweight	1	0
Poor feeding infant	8	0
Weight loss poor	2	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	58	0

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Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Insulin resistance	4	0
Hypoglycaemic conditions NEC		
Glycopenia	1	0
Hypoglycaemia	68	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	1	0
Iron deficiencies		
Iron deficiency	9	0
Iron excess		
Haemochromatosis	1	0
Iron overload	1	0
Lipid metabolism and deposit disorders NEC		
Body fat disorder	1	0
Metabolic acidoses (excl diabetic acidoses)		
Ketoacidosis	4	0
Lactic acidosis	1	0
Metabolic acidosis	2	0
Mixed acid-base disorders		
Acidosis	3	0
Potassium imbalance		
Hyperkalaemia	2	0
Hypokalaemia	3	0
Hypokalaemic syndrome	1	0
Sodium imbalance		
Hyponatraemia	6	0
Hyponatraemic syndrome	3	0
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	1	0
Total fluid volume decreased		
Dehydration	125	0
Total fluid volume increased		
Fluid retention	36	0
Hypervolaemia	1	0
Vitamin deficiencies NEC		
Hypovitaminosis	3	0
Water soluble vitamin deficiencies		
Folate deficiency	3	0
Vitamin B12 deficiency	3	0
Metabolic disorders SOC TOTAL	1518	1

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	175	0
Arthropathy	21	0
Autoimmune arthritis	4	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	4	0
Osteitis	3	0
Osteonecrosis of jaw	3	0
Spinal disorder	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	253	0
Bone swelling	5	0
Coccydynia	3	0
Metatarsalgia	1	0
Pain in jaw	245	0
Pubic pain	2	0
Spinal pain	42	0
<i>Bursal disorders</i>		
Bursitis	45	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	43	0
Osteochondritis	1	0
Polychondritis	2	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	1	0
Polymyalgia rheumatica	40	0
Reynold's syndrome	1	0
Sjogren's syndrome	4	0
<i>Crystal arthropathic disorders</i>		
Chondrocalcinosis pyrophosphate	2	0
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	2	0
<i>Joint related disorders NEC</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Chondromalacia	1	0
Joint deposit	1	0
Joint destruction	1	0
Joint laxity	3	0
Joint lock	17	0
Patellofemoral pain syndrome	1	0
Periarthritis	96	0
Rotator cuff syndrome	11	0
Temporomandibular joint syndrome	7	0
Joint related signs and symptoms		
Arthralgia	6177	0
Jaw clicking	4	0
Joint effusion	12	0
Joint noise	23	0
Joint range of motion decreased	13	0
Joint stiffness	160	0
Joint swelling	334	0
Joint vibration	2	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	15	0
Metabolic bone disorders		
Osteopenia	1	0
Osteoporosis	1	0
Muscle infections and inflammations		
Antisynthetase syndrome	2	0
Myositis	17	0
Polymyositis	4	0
Muscle pains		
Fibromyalgia	70	0
Myalgia	7822	0
Myalgia intercostal	1	0
Myofascial pain syndrome	6	0
Muscle related signs and symptoms NEC		
Haematoma muscle	1	0
Muscle atrophy	14	0
Muscle discomfort	2	0
Muscle disorder	3	0
Muscle fatigue	250	0
Muscle haemorrhage	1	0
Muscle mass	3	0
Muscle oedema	1	0
Muscle spasms	1187	0
Muscle swelling	18	0
Muscle tightness	59	0
Muscle twitching	278	0
Muscle tone abnormalities		
Muscle rigidity	12	0
Nuchal rigidity	10	0

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Torticollis	3	0
Trismus	25	0
Muscle weakness conditions		
Muscular weakness	593	0
Musculoskeletal and connective tissue conditions NEC		
Back disorder	1	0
Growth disorder	1	0
Limb mass	13	0
Mandibular mass	2	0
Mastication disorder	3	0
Mobility decreased	57	0
Musculoskeletal disorder	10	0
Musculoskeletal stiffness	847	0
Posture abnormal	1	0
Weight bearing difficulty	1	0
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		
Head deformity	2	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Dactylitis	2	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	6	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	1560	0
Flank pain	32	0
Limb discomfort	1049	0
Musculoskeletal chest pain	130	0
Musculoskeletal discomfort	69	0
Musculoskeletal pain	34	0
Neck pain	1246	0
Pain in extremity	8724	0
Rheumatic disorder	8	0
Myopathies		
Myopathy	4	0
Rhabdomyolysis	7	0
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	29	0
Spinal osteoarthritis	1	0
Psoriatic arthropathies		
Psoriatic arthropathy	13	0
Rheumatoid arthropathies		
Rheumatoid arthritis	82	0
Soft tissue disorders NEC		
Axillary mass	167	0
Fluctuance	1	0
Groin pain	80	0
Neck mass	19	0
Purple glove syndrome	1	0
Soft tissue disorder	2	0
Soft tissue swelling	3	0
Spine and neck deformities		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	6	0
Arthritis reactive	26	0
Spondylitis	1	0
<i>Synovial disorders</i>		
Synovial cyst	15	0
Synovitis	4	0
<i>Tendon disorders</i>		
Enthesopathy	1	0
Tendon disorder	2	0
Tendon pain	15	0
Tendonitis	24	0
Tenosynovitis	2	0
Tenosynovitis stenosaurs	2	0
Trigger finger	19	0
<i>Trunk deformities</i>		
Drooping shoulder syndrome	1	0
Muscle & tissue disorders SOC TOTAL	32555	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	27	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	2	0
<i>Follicular lymphomas</i>		
Primary gastrointestinal follicular lymphoma	1	0
<i>Gastric neoplasms malignant</i>		
Gastric cancer	1	1
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	3	0
<i>Hodgkin's disease NEC</i>		
Hodgkin's disease	3	0
<i>Islet cell neoplasms and APUDoma NEC</i>		
Pancreatic neuroendocrine tumour	1	0
<i>Leukaemias NEC</i>		
Leukaemia	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	18	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	2	0
<i>Myeloproliferative disorders (excl leukaemias)</i>		
Essential thrombocythaemia	1	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Neoplasms benign site unspecified NEC</i>		
Adenoma benign	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Adenocarcinoma metastatic	1	0
Neoplasm malignant	5	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
Neurilemmoma 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	2	0
<i>Oesophageal neoplasms malignant</i>		
Oesophageal cancer metastatic	4	0
<i>Oncologic complications and emergencies</i>		
Cancer pain	1	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	3	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	6	0
<i>Skin melanomas (excl ocular)</i>		
Malignant melanoma	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	2	0
Anogenital warts	4	0
Haemangioma of skin	3	0
Melanocytic naevus	4	0
Skin papilloma	8	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	2	0
Bowen's disease	1	0
Neoplasm skin	1	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Jul-2021

Data Lock Date: 21-Jul-2021 18:30:10

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Squamous cell carcinoma of skin	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	5	0
Lymphangioma	1	0
<i>Soft tissue sarcomas histology unspecified</i>		
Sarcoma	1	0
<i>Thyroid neoplasms malignant</i>		
Papillary thyroid cancer	2	0
Thyroid cancer	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	8	0
Neoplasms SOC TOTAL	178	2

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Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 21-Jul-2021 18:30:10
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	5	0
Extensor plantar response	1	0
Hyperreflexia	2	0
Hyporeflexia	7	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	16	0
<i>Absence seizures</i>		
Petit mal epilepsy	21	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	38	0
Subacute inflammatory demyelinating polyneuropathy	1	0
<i>Autonomic nervous system disorders</i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	6	0
Autonomic neuropathy	1	0
Horner's syndrome	1	0
<i>Central nervous system aneurysms and dissections</i>		
Intracranial aneurysm	2	1
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	2	0
Cerebellar infarction	2	0
Cerebellar ischaemia	1	0
Cerebellar stroke	4	0
Cerebral artery embolism	3	1
Cerebral artery occlusion	1	0
Cerebral artery thrombosis	3	0
Cerebral haemorrhage	35	7
Cerebral infarction	23	1
Cerebral thrombosis	8	0
Cerebrovascular accident	299	12
Embolic stroke	6	0
Haemorrhage intracranial	9	2
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	9	4
Internal capsule infarction	1	0
Intracranial haematoma	1	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	31	1
Lacunar infarction	2	0
Lacunar stroke	3	0
Lateral medullary syndrome	1	0
Pseudostroke	1	0
Subarachnoid haemorrhage	12	5
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>		

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Brain hypoxia	1	1
Central nervous system vasculitis	1	0
Cerebral amyloid angiopathy	1	0
Cerebral congestion	2	0
Cerebral small vessel ischaemic disease	1	0
Cerebrovascular disorder	1	0
Reversible cerebral vasoconstriction syndrome	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	32	2
Cerebral venous thrombosis	4	0
Superior sagittal sinus thrombosis	3	0
Transverse sinus thrombosis	1	0
<i>Cervical spinal cord and nerve root disorders</i>		
Cervicobrachial syndrome	3	0
<i>Choreiform movements</i>		
Chorea	2	0
<i>Chronic polyneuropathies</i>		
Demyelinating polyneuropathy	1	0
<i>Coma states</i>		
Coma	7	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	7	0
Balance disorder	265	0
Coordination abnormal	34	0
Dysdiadochokinesis	1	0
Dysstasia	35	0
Nystagmus	9	0
<i>Cortical dysfunction NEC</i>		
Alexia	1	0
Aphasia	50	0
Apraxia	1	0
Dyspraxia	1	0
Neurologic neglect syndrome	1	0
Sensory processing disorder	2	0
Visuospatial deficit	1	0
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	2	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	10	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	4	0
Clinically isolated syndrome	1	0
Demyelination	8	0
Neuromyelitis optica spectrum disorder	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	9	0
Consciousness fluctuating	2	0
Depressed level of consciousness	33	1
Infant sedation	1	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Lethargy	1634	0
Loss of consciousness	402	0
Postictal state	1	0
Sedation	6	0
Somnolence	710	0
Stupor	4	0
Syncope	1374	0
<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	11	0
Clumsiness	13	0
Dyskinesia	47	0
Extrapyramidal disorder	2	0
Fine motor skill dysfunction	7	0
Foetal movement disorder	1	0
Hyperkinesia	3	0
Hypokinesia	42	0
Motor dysfunction	2	0
Movement disorder	37	0
Psychomotor hyperactivity	17	0
Synkinesis	1	0
Tardive dyskinesia	2	0
<i>Dystonias</i>		
Dystonia	15	0
Writer's cramp	1	0
<i>Encephalitis NEC</i>		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	4	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	339	0
Facial nerve disorder	7	0
Facial paralysis	273	0
Facial paresis	71	0
Facial spasm	31	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	31	0
<i>Headaches NEC</i>		
Cervicogenic headache	3	0
Cluster headache	153	0

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Cold-stimulus headache	12	0
Drug withdrawal headache	2	0
Exertional headache	7	0
External compression headache	1	0
Headache	18760	0
Medication overuse headache	2	0
New daily persistent headache	4	0
Occipital neuralgia	8	0
Ophthalmoplegic migraine	1	0
Primary cough headache	4	0
Primary headache associated with sexual activity	2	0
Sinus headache	260	0
Tension headache	392	0
Thunderclap headache	5	0
Vascular headache	13	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	6	0
Intracranial pressure increased	1	0
Intellectual disabilities		
Intellectual disability	2	0
Lumbar spinal cord and nerve root disorders		
Sciatica	58	0
Memory loss (excl dementia)		
Amnesia	105	0
Memory impairment	111	0
Transient global amnesia	7	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	58	0
Cognitive linguistic deficit	1	0
Disturbance in attention	214	0
Mental impairment	32	0
Migraine headaches		
Hemiplegic migraine	17	0
Migraine	1954	0
Migraine with aura	134	0
Migraine without aura	14	0
Ophthalmic migraine	4	0
Retinal migraine	21	0
Typical aura without headache	6	0
Vestibular migraine	14	0
Mixed cranial nerve disorders		
Bulbar palsy	2	0
Mononeuropathies		
Carpal tunnel syndrome	15	0
Cubital tunnel syndrome	1	0
Meralgia paraesthetica	1	0
Mononeuritis	2	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Mononeuropathy	1	0
Nerve compression	13	0
Peripheral nerve lesion	1	0
Peroneal nerve palsy	11	0
Sciatic nerve neuropathy	2	0
Ulnar neuritis	1	0
Multiple sclerosis acute and progressive		
Band sensation	1	0
Multiple sclerosis	23	0
Multiple sclerosis relapse	19	0
Tumefactive multiple sclerosis	1	1
Muscle tone abnormal		
Hypotonia	13	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
Myelitis (incl infective)		
Myelitis transverse	24	0
Narcolepsy and hypersomnia		
Cataplexy	1	0
Hypersomnia	72	0
Narcolepsy	4	0
Nervous system disorders NEC		
Central nervous system lesion	2	0
Cerebral disorder	1	0
Nervous system disorder	7	0
Neurologic visual problems NEC		
Hemianopia	1	0
Hemianopia homonymous	1	0
Quadrantanopia	1	0
Tunnel vision	12	0
Neurological signs and symptoms NEC		
Clonus	3	0
Decerebrate posture	1	0
Dizziness	6873	0
Dizziness exertional	33	0
Dizziness postural	537	0
Drooling	19	0
Fontanelle bulging	2	0
Head discomfort	209	0
Hyporesponsive to stimuli	2	0
Inability to crawl	2	0
Infant irritability	6	0
Myoclonus	17	0
Neurological symptom	33	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	12	0
Presyncope	429	0
Sensory overload	2	0
Slow response to stimuli	2	0
Tongue biting	3	0
Unresponsive to stimuli	34	0
Neuromuscular disorders NEC		

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Muscle contractions involuntary	16	0
Muscle spasticity	9	0
Neuromuscular pain	3	0
Neuromuscular junction dysfunction		
Myasthenia gravis	8	0
Myasthenia gravis crisis	2	0
Olfactory nerve disorders		
Anosmia	177	0
Hyposmia	12	0
Parosmia	171	0
Optic nerve disorders NEC		
Optic neuritis	19	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	5	0
Burning sensation	360	0
Burning sensation mucosal	2	0
Dysaesthesia	5	0
Formication	30	0
Hand-arm vibration syndrome	3	0
Hemianaesthesia	1	0
Hemiparaesthesia	2	0
Hyperaesthesia	61	0
Hypoaesthesia	1943	0
Paraesthesia	2723	0
Reversed hot-cold sensation	3	0
Synaesthesia	1	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	9	1
Hemiparesis	32	0
Hemiplegia	26	0
Locked-in syndrome	1	0
Monoparesis	43	0
Monoplegia	49	0
Paralysis	86	0
Paraparesis	3	0
Paresis	6	0
Quadriparesis	1	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	8	0
Parkinson's disease	3	0
Parkinsonian gait	1	0
Parkinsonism	4	0
Reduced facial expression	7	0
Partial complex seizures		
Dreamy state	6	0
Focal dyscognitive seizures	1	0
Temporal lobe epilepsy	1	0
Partial simple seizures NEC		
Autonomic seizure	1	0
Peripheral neuropathies NEC		
Neuralgic amyotrophy	1	0
Neuritis	5	0
Neuropathy peripheral	67	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Peripheral sensory neuropathy	7	0
Thoracic outlet syndrome	1	0
Seizures and seizure disorders NEC		
Atonic seizures	4	0
Change in seizure presentation	1	0
Clonic convulsion	3	0
Convulsions local	1	0
Epilepsy	123	0
Epileptic aura	2	0
Epileptic encephalopathy	1	0
Febrile convulsion	14	0
Partial seizures	15	0
Post stroke seizure	1	0
Psychogenic seizure	6	0
Seizure	398	0
Seizure anoxic	1	0
Seizure cluster	5	0
Seizure like phenomena	1	0
Status epilepticus	34	0
Tonic clonic movements	2	0
Tonic convulsion	16	0
Tonic posturing	1	0
Sensory abnormalities NEC		
Ageusia	365	0
Allodynia	13	0
Aura	12	0
Complex regional pain syndrome	3	0
Dysgeusia	922	0
Electric shock sensation	24	0
Hypergeusia	1	0
Hypogeusia	3	0
Intercostal neuralgia	1	0
Loss of proprioception	3	0
Neuralgia	345	0
Persistent genital arousal disorder	1	0
Phantom limb syndrome	4	0
Post herpetic neuralgia	13	0
Restless arm syndrome	1	0
Restless legs syndrome	83	0
Sensory disturbance	60	0
Sensory loss	54	0
Taste disorder	196	0
Visual perseveration	2	0
Sleep disturbances NEC		
Sleep deficit	3	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	126	0
Incoherent	8	0
Language disorder	1	0
Repetitive speech	2	0
Slow speech	10	0
Speech disorder	45	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculitis brachial	7	0
Radiculopathy	4	0
<i>Structural brain disorders NEC</i>		
Brain injury	4	2
Hyperintensity in brain deep nuclei	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	117	1
<i>Tremor (excl congenital)</i>		
Action tremor	1	0
Essential tremor	3	0
Head titubation	8	0
Resting tremor	2	0
Tremor	1119	0
<i>Trigeminal disorders</i>		
Facial neuralgia	14	0
Numb chin syndrome	2	0
Trigeminal nerve disorder	1	0
Trigeminal neuralgia	32	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	47255	44

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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	197	1
Abortion threatened	2	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Amniorrhoea	1	0
<i>Foetal complications NEC</i>		
Foetal hypokinesia	3	0
<i>Foetal growth complications</i>		
Foetal growth restriction	1	0
<i>Foetal position and presentation abnormalities</i>		
Oblique presentation	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	2	1
Term baby	1	0
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	1	0
Premature separation of placenta	1	0
Subchorionic haematoma	1	0
Subchorionic haemorrhage	1	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	1	0
Premature labour	2	0
Premature rupture of membranes	1	0
Threatened labour	1	0
<i>Maternal complications of labour NEC</i>		
Uterine contractions abnormal	1	0
Uterine hypertonus	5	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	4	0
Ectopic pregnancy	1	0
Morning sickness	8	0
Preterm premature rupture of membranes	2	0
Somatic symptom disorder of pregnancy	3	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>		
Labour pain	1	0
Live birth	1	0
Pregnancy	29	0
Uterine contractions during pregnancy	1	0
<i>Placental abnormalities (excl neoplasms)</i>		
Placental disorder	1	0
<i>Postpartum complications NEC</i>		
Postpartum haemorrhage	2	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	2	0
<i>Stillbirth and foetal death</i>		

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Reaction Name	Total	Fatal
Pregnancy conditions <small>Pregnancy conditions cont'd</small>		
Foetal death	4	2
Stillbirth	3	2
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	1	0
Pregnancy on contraceptive	2	0
Pregnancy on oral contraceptive	1	0
Pregnancy with contraceptive device	1	0
Unintended pregnancy	1	0
Pregnancy conditions SOC TOTAL	296	6

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device connection issue	1	0
Device failure	1	0
Device issue	2	0
<i>Device malfunction events NEC</i>		
Device infusion issue	1	0
Device pacing issue	1	0
Device stimulation issue	1	0
Oversensing	14	0
Thrombosis in device	7	0
<i>Device physical property and chemical issues</i>		
Device breakage	1	0
Device defective	7	0
Device kink	1	0
Needle issue	2	0
<i>Product contamination and sterility issues</i>		
Product contamination	9	0
Product contamination physical	2	0
<i>Product packaging issues</i>		
Product closure issue	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	8	0
<i>Product quality issues NEC</i>		
Product complaint	1	0
Product origin unknown	6	0
<i>Product supply and availability issues</i>		
Product availability issue	1	0
null SOC TOTAL	77	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	16	0
Behaviour disorder	1	0
Breath holding	6	0
Sexually inappropriate behaviour	1	0
Staring	5	0
<i>Adjustment disorders</i>		
Adjustment disorder with depressed mood	2	0
<i>Affect alterations NEC</i>		
Affect lability	8	0
Constricted affect	2	0
Flat affect	4	0
Inappropriate affect	13	0
<i>Amnesic symptoms</i>		
Paramnesia	4	0
<i>Anxiety disorders NEC</i>		
Generalised anxiety disorder	1	0
<i>Anxiety symptoms</i>		
Agitation	60	0
Anxiety	511	0
Immunisation anxiety related reaction	1	0
Nervousness	124	0
Stress	52	0
Tension	26	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	3	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	8	0
Aversion	1	0
Disinhibition	1	0
Indifference	6	0
Paranoia	15	0
Personality change	3	0
Social avoidant behaviour	5	0
Soliloquy	2	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	6	0
Distractibility	1	0
Mental fatigue	158	0
<i>Communications disorders</i>		
Communication disorder	5	0
Mutism	2	0
<i>Confusion and disorientation</i>		
Confusional state	615	0
Disorientation	190	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	80	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Delusional symptoms</i>		
Delusion	9	0
<i>Depressive disorders</i>		
Agitated depression	3	0
Depression	210	0
Depression suicidal	7	0
Major depression	5	0
Mixed anxiety and depressive disorder	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	6	0
Dissociation	21	0
Dissociative amnesia	2	0
Dissociative disorder	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	16	0
Insomnia	870	0
Middle insomnia	23	0
Terminal insomnia	25	0
<i>Dyssomnias</i>		
Dyssomnia	1	0
Poor quality sleep	140	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	24	0
Dysphoria	2	0
Emotional disorder	40	0
Emotional distress	31	0
Emotional poverty	1	0
Euphoric mood	31	0
Frustration tolerance decreased	3	0
Irritability	139	0
Mood altered	38	0
<i>Factitious disorders</i>		
Factitious disorder	2	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Agoraphobia	1	0
Fear	12	0
Fear of falling	3	0
Fear of injection	4	0
Osmophobia	1	0
Phobia	2	0
Phonophobia	2	0
Social anxiety disorder	1	0
Social fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	81	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	138	0
Hallucination, auditory	11	0
Hallucination, olfactory	9	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Jul-2021
 Earliest Reaction Date: 13-Apr-1968

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 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Psychiatric disorders ^{Psychiatric disorders cont'd}		
Hallucination, tactile	1	0
Hallucination, visual	21	0
Hallucinations, mixed	2	0
Increased physical activity levels		
Restlessness	105	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	13	0
Mental status changes	1	0
Mood alterations with depressive symptoms		
Anhedonia	2	0
Decreased interest	7	0
Depressed mood	242	0
Depressive symptom	1	0
Feeling of despair	3	0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Psychomotor retardation	1	0
Sense of a foreshortened future	2	0
Tearfulness	30	0
Mood alterations with manic symptoms		
Hypomania	2	0
Mania	8	0
Mood disorders NEC		
Affective disorder	1	0
Apathy	19	0
Boredom	1	0
Laziness	1	0
Listless	14	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	3	0
Female orgasmic disorder	2	0
Orgasm abnormal	3	0
Orgasmic sensation decreased	1	0
Premature ejaculation	1	0
Panic attacks and disorders		
Panic attack	112	0
Panic disorder	3	0
Panic reaction	18	0
Parasomnias		
Abnormal dreams	132	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Exploding head syndrome	1	0
Nightmare	140	0
Parasomnia	1	0
Sleep inertia	1	0
Sleep talking	3	0
Sleep terror	15	0
Somnambulism	2	0
Perception disturbances NEC		
Autoscopy	12	0
Deja vu	2	0
Derealisation	7	0
Flashback	2	0
Illusion	1	0
Near death experience	1	0
Time perception altered	1	0
Personality disorders NEC		
Personality disorder	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	2	0
Psychiatric elimination disorders		
Enuresis	16	0
Psychiatric symptoms NEC		
Hypervigilance	8	0
Psychiatric symptom	3	0
Psychological trauma	1	0
Trance	1	0
Psychotic disorder NEC		
Psychotic behaviour	1	0
Psychotic disorder	14	0
Schizophrenia NEC		
Schizophrenia	1	0
Sexual arousal disorders		
Disturbance in sexual arousal	2	0
Sexual desire disorders		
Libido decreased	6	0
Libido increased	4	0
Loss of libido	10	0
Sleep disorders NEC		
Sleep disorder	136	0
Sleep disorder due to general medical condition, insomnia type	2	0
Somatic symptom disorders		
Conversion disorder	11	0
Habit cough	13	0
Somatic symptom disorder	1	0
Vomiting psychogenic	1	0
Speech and language usage disturbances		
Disorganised speech	6	0
Logorrhoea	2	0
Speech articulation and rhythm disturbances		
Dysphemia	18	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
Stereotypies and automatisms		

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Bruxism	10	0
Head banging	5	0
Stereotypy	1	0
<i>Stress disorders</i>		
Burnout syndrome	1	0
Post-traumatic stress disorder	2	0
<i>Substance related and addictive disorders</i>		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	2	0
Nicotine dependence	1	0
<i>Suicidal and self-injurious behaviour</i>		
Intentional self-injury	6	0
Self-injurious ideation	2	0
Suicidal ideation	21	0
Suicide attempt	14	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	30	0
Intrusive thoughts	4	0
Morbid thoughts	1	0
Tachyphrenia	4	0
Thinking abnormal	14	0
Thought blocking	1	0
<i>Tic disorders</i>		
Tic	9	0
Psychiatric disorders SOC TOTAL	5224	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	2	0
Bladder irritation	3	0
Bladder pain	18	0
Dysuria	38	0
Incontinence	20	0
Lower urinary tract symptoms	2	0
Micturition disorder	1	0
Micturition urgency	25	0
Pollakiuria	82	0
Urethral pain	4	0
Urge incontinence	1	0
Urinary hesitation	1	0
Urinary incontinence	42	0
Urinary retention	31	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	4	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	15	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>Nephropathies and tubular disorders NEC</i>		
Nephropathy	1	0
<i>Renal disorders NEC</i>		
Renal disorder	4	1
Renal haemorrhage	1	0
Renal mass	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	34	2
Anuria	3	0
Chronic kidney disease	3	0
Oliguria	1	0
Renal failure	13	1

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Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Renal impairment	14	0
Renal injury	1	0
Renal lithiasis		
Nephrolithiasis	5	0
Renal neoplasms		
Renal cyst	1	0
Renal obstructive disorders		
Hydronephrosis	1	0
Renal structural abnormalities and trauma		
Kidney small	1	0
Renal vascular and ischaemic conditions		
Renal infarct	1	0
Renal vasculitis	1	1
Structural and obstructive urethral disorders (excl congenital)		
Urethral stenosis	1	0
Ureteric disorders NEC		
Ureteric stenosis	1	0
Urinary abnormalities		
Albuminuria	1	0
Chromaturia	36	0
Haematuria	26	0
Proteinuria	6	0
Urine abnormality	8	0
Urine odour abnormal	5	0
Urinary tract signs and symptoms NEC		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	16	0
Nocturia	3	0
Polyuria	5	0
Renal colic	3	0
Renal pain	184	0
Urinary tract pain	2	0
Renal & urinary disorders SOC TOTAL	712	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 disorder	1	0
Breast enlargement	13	0
Breast mass	73	0
Gynaecomastia	2	0
Mastoptosis	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	1	0
Nipple inflammation	1	0
<i>Breast signs and symptoms</i>		
Breast discharge	2	0
Breast discomfort	6	0
Breast engorgement	3	0
Breast haematoma	1	0
Breast oedema	4	0
Breast pain	366	0
Breast swelling	75	0
Breast tenderness	43	0
Nipple pain	24	0
Nipple swelling	3	0
<i>Cervix disorders NEC</i>		
Cervical dysplasia	2	0
Cervix disorder	1	0
Cervix haemorrhage uterine	2	0
Ectropion of cervix	2	0
<i>Cervix neoplasms</i>		
Cervical polyp	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation disorder	2	0
Ejaculation failure	1	0
Erectile dysfunction	31	0
Erection increased	2	0
Organic erectile dysfunction	5	0
Painful ejaculation	1	0
<i>Fallopian tube and ovary infections and inflammations</i>		
Noninfective oophoritis	1	0
<i>Lactation disorders</i>		
Breast milk discolouration	3	0
Breast milk odour abnormal	1	0
Galactorrhoea	5	0
Lactation disorder	3	0
Lactation puerperal increased	2	0
Suppressed lactation	13	0
<i>Menopausal effects NEC</i>		
Artificial menopause	1	0
Menopausal symptoms	11	0
Menopause delayed	1	0
Premature menopause	10	0
<i>Menopausal effects on the genitourinary tract</i>		
Atrophic vulvovaginitis	1	0
Postmenopausal haemorrhage	86	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	5	0
Dysmenorrhoea	1495	0
Intermenstrual bleeding	583	0
Menstrual discomfort	12	0
Menstrual disorder	917	0
Menstruation irregular	1574	0
Premenstrual dysphoric disorder	5	0
Premenstrual headache	4	0
Premenstrual pain	57	0
Premenstrual syndrome	69	0
Withdrawal bleed	10	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	318	0
Hypomenorrhoea	360	0
Menstruation delayed	2567	0
Oligomenorrhoea	77	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	3008	0
Menometrorrhagia	14	0
Polymenorrhoea	400	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	8	0
Polycystic ovaries	24	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Adnexal torsion	1	0
Hydrosalpinx	2	0
Ovarian haemorrhage	4	0
Ovulation disorder	1	0
Ovulation pain	31	0
Premature ovulation	4	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	26	0
Pelvic floor muscle weakness	1	0
Pelvic haemorrhage	10	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	2	0
Penile pain	1	0
Penile size reduced	1	0
Penile swelling	4	0
Penis disorder	5	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	13	0
Genital hypoaesthesia	1	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
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 burning sensation	2	0
Genital pain	3	0
Genital rash	2	0
Genital swelling	2	0
Pelvic discomfort	4	0
Pelvic pain	61	0
Perineal pain	2	0
Pruritus genital	2	0
<i>Scrotal disorders NEC</i>		
Scrotal discomfort	1	0
Scrotal erythema	1	0
Scrotal exfoliation	1	0
Scrotal pain	5	0
Scrotal swelling	4	0
<i>Sexual function and fertility disorders NEC</i>		
Dyspareunia	3	0
Infertility	2	0
Sexual dysfunction	1	0
<i>Spermatogenesis and semen disorders</i>		
Aspermia	1	0
Haemospermia	6	0
Semen discolouration	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	2	0
Testicular pain	28	0
Testicular swelling	5	0
Testis discomfort	1	0
<i>Uterine disorders NEC</i>		
Adenomyosis	4	0
Endometrial thickening	2	0
Endometriosis	50	0
Uterine haemorrhage	18	0
Uterine pain	9	0
<i>Uterine infections and inflammations (excl cervix)</i>		
Uterine inflammation	1	0
<i>Uterine neoplasms</i>		
Uterine polyp	4	0
<i>Uterine tone disorders</i>		
Uterine spasm	18	0
<i>Vulvovaginal cysts and neoplasms</i>		
Bartholin's cyst	1	0
Vaginal cyst	5	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	802	0
Vulval haemorrhage	15	0
Vulval ulceration	4	0
Vulvovaginal ulceration	3	0
<i>Vulvovaginal signs and symptoms</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Clitoral engorgement	1	0
Coital bleeding	2	0
Labia enlarged	1	0
Vaginal discharge	42	0
Vaginal odour	1	0
Vulval oedema	1	0
Vulvovaginal burning sensation	3	0
Vulvovaginal dryness	3	0
Vulvovaginal pain	15	0
Vulvovaginal pruritus	5	0
Vulvovaginal rash	1	0
Vulvovaginal swelling	2	0
Reproductive & breast disorders SOC TOTAL	13599	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	4	0
Apnoeic attack	1	0
Dyspnoea	2828	7
Dyspnoea at rest	9	0
Dyspnoea exertional	27	1
Hyperventilation	34	0
Hypopnoea	71	0
Hypoventilation	1	0
Irregular breathing	15	0
Mouth breathing	3	0
Nocturnal dyspnoea	1	0
Orthopnoea	3	0
Respiration abnormal	36	0
Respiratory arrest	11	0
Respiratory depression	1	0
Respiratory distress	14	0
Sleep apnoea syndrome	8	0
Tachypnoea	21	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	1	0
Bronchiectasis	11	0
<i>Bronchospasm and obstruction</i>		
Asthma	231	0
Asthma late onset	2	0
Bronchospasm	11	0
Chronic obstructive pulmonary disease	14	1
Cough variant asthma	4	0
Obstructive airways disorder	7	0
Reversible airways obstruction	1	0
Wheezing	295	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	1	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	22	1
Respiratory acidosis	2	0
<i>Coughing and associated symptoms</i>		
Allergic cough	5	0
Cough	1669	2
Cough decreased	2	0
Haemoptysis	34	0
Productive cough	115	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
Reflux laryngitis	1	0
Vocal cord disorder	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
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	8	5
Pneumonitis	22	1
Pulmonary sarcoidosis	2	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	25	0
Increased bronchial secretion	1	0
Lung opacity	2	0
Pleuritic pain	15	0
Pulmonary haemorrhage	1	0
Pulmonary pain	62	0
Rales	4	0
Respiratory fremitus	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	194	0
Nasal inflammation	2	0
Rhinitis allergic	12	0
<i>Nasal disorders NEC</i>		
Epistaxis	668	0
Intranasal hyposaesthesia	1	0
Intranasal paraesthesia	1	0
Nasal crusting	1	0
Nasal disorder	3	0
Nasal dryness	24	0
Nasal mucosal discolouration	1	0
Nasal odour	6	0
Nasal oedema	4	0
Nasal polyps	1	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	42	0
Sinus disorder	5	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 consolidation	1	0
Lung infiltration	1	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	4	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	6	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	28	0
Pharyngeal inflammation	4	0
Pharyngeal oedema	10	0
Pharyngeal paraesthesia	47	0
Pharyngeal swelling	179	0
Pharyngeal ulceration	14	0
Tonsillar erythema	4	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	52	0
Tonsillar inflammation	3	0
Tonsillar ulcer	1	0
Tonsillolith	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	22	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	16	0
Pneumothorax	6	0
Pneumothorax spontaneous	1	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	2	0
<i>Pulmonary oedemas</i>		
Acute respiratory distress syndrome	2	1
Pulmonary congestion	9	0
Pulmonary oedema	16	1
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	313	19
Pulmonary infarction	3	0
Pulmonary thrombosis	4	1
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	2	1
Respiratory failure	9	3
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	5	0
Diaphragmalgia	5	0
Nasal flaring	1	0
Painful respiration	6	0
Pleural rub	1	0
Respiratory symptom	11	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

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Respiratory tract irritation	5	0
Respiratory tract oedema	3	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	2	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal pain	1	0
<i>Upper respiratory tract neoplasms</i>		
Tonsillar cyst	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	79	0
Catarrh	15	0
Choking	11	1
Choking sensation	3	0
Dry throat	126	0
Dysphonia	117	0
Increased upper airway secretion	4	0
Increased viscosity of upper respiratory secretion	25	0
Nasal discharge discolouration	2	0
Nasal discomfort	39	0
Nasal obstruction	2	0
Oropharyngeal blistering	9	0
Oropharyngeal discomfort	45	0
Oropharyngeal pain	2029	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	32	0
Rhinalgia	10	0
Rhinorrhoea	627	0
Sinus pain	149	0
Sneezing	261	0
Snoring	7	0
Throat clearing	8	0
Throat irritation	176	0
Throat tightness	194	0
Upper airway obstruction	2	0
Upper-airway cough syndrome	6	0
Yawning	16	0
<i>Vascular pulmonary disorders NEC</i>		
Acute chest syndrome	1	0
Respiratory disorders SOC TOTAL	11516	47

Case Series Drug Analysis Print

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

Report Run Date: 22-Jul-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 21-Jul-2021 18:30:10
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	104	0
Acne cystic	8	0
Dermatitis acneiform	8	0
<i>Alopecias</i>		
Alopecia	135	0
Alopecia areata	16	0
Alopecia totalis	1	0
Androgenetic alopecia	1	0
Madarosis	2	0
<i>Angioedemas</i>		
Angioedema	146	0
Circumoral swelling	1	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	1	0
Cold sweat	513	0
Hidradenitis	1	0
Hyperhidrosis	1470	0
Milia	1	0
Miliaria	64	0
Night sweats	413	0
<i>Bullous conditions</i>		
Blister	326	0
Blister rupture	1	0
Blood blister	21	0
Dermatitis bullous	10	0
Erythema multiforme	24	0
Fracture blisters	1	0
Pemphigoid	16	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	156	0
Macule	4	0
Neutrophilic dermatosis	1	0
Pain of skin	184	0
Papule	74	0
Pathergy reaction	1	0
Peau d'orange	2	0
Scab	17	0
Scar pain	11	0
Sensitive skin	112	0
Skin burning sensation	161	0
Skin degenerative disorder	1	0
Skin discolouration	82	0
Skin discomfort	3	0
Skin disorder	9	0
Skin fissures	3	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin indentation	2	0
Skin induration	3	0
Skin lesion	30	0
Skin lesion inflammation	1	0
Skin necrosis	1	0
Skin odour abnormal	14	0
Skin plaque	2	0
Skin reaction	99	0
Skin sensitisation	24	0
Skin swelling	57	0
Skin texture abnormal	1	0
Skin tightness	21	0
Skin warm	215	0
Skin weeping	7	0
Sticky skin	1	0
Target skin lesion	2	0
Transient acantholytic dermatosis	1	0
Yellow skin	15	0
<i>Dermatitis and eczema</i>		
Dermatitis	79	0
Dermatitis allergic	168	0
Dermatitis atopic	23	0
Dermatitis contact	11	0
Dermatitis diaper	3	0
Dyshidrotic eczema	15	0
Eczema	185	0
Eczema asteatotic	7	0
Eczema infantile	1	0
Eczema nummular	4	0
Eczema weeping	1	0
Perioral dermatitis	1	0
Seborrhoeic dermatitis	2	0
Skin irritation	75	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	26	0
Drug reaction with eosinophilia and systemic symptoms	1	0
Fixed eruption	1	0
Toxic skin eruption	1	0
<i>Erythemas</i>		
Erythema	1579	0
Palmar erythema	4	0
Red man syndrome	1	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	1	0
Dermatitis exfoliative generalised	4	0
Exfoliative rash	14	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	75	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Cutaneous sarcoidosis	1	0
Granuloma annulare	2	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Keratosis pilaris	3	0
Lichenoid keratosis	3	0
<i>Hyperpigmentation disorders</i>		
Argyria	1	0
Chloasma	1	0
Ephelides	1	0
Skin hyperpigmentation	3	0
Solar lentigo	2	0
<i>Hypertrichoses</i>		
Hirsutism	1	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	4	0
Skin hypopigmentation	1	0
Vitiligo	8	0
<i>Lipodystrophies</i>		
Lipoatrophy	4	0
Lipodystrophy acquired	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	7	0
Nail disorder	2	0
Nail pigmentation	2	0
Nail ridging	1	0
Onychalgia	6	0
Onychoclasia	4	0
Onychomadesis	2	0
Splinter haemorrhages	3	0
<i>Panniculitides</i>		
Erythema nodosum	21	0
<i>Papulosquamous conditions</i>		
Erythema annulare	2	0
Lichen planus	9	0
Lichen sclerosus	7	0
Parapsoriasis	2	0
Pityriasis rosea	74	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	42	0
Polymorphic light eruption	2	0
Solar dermatitis	1	0
<i>Pigmentation changes NEC</i>		
Haemosiderin stain	1	0
Pigmentation disorder	8	0
<i>Pilar disorders NEC</i>		
Hair colour changes	8	0
Hair disorder	1	0
Hair growth abnormal	3	0
Hair texture abnormal	4	0
Piloerection	19	0
Pseudofolliculitis	1	0
<i>Pruritus NEC</i>		
Itching scar	5	0
Pruritus	3704	0
<i>Psoriatic conditions</i>		
Dermatitis psoriasiform	2	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Guttate psoriasis	12	0
Nail psoriasis	1	0
Palmoplantar pustulosis	2	0
Psoriasis	113	0
Pustular psoriasis	2	0
<i>Purpura and related conditions</i>		
Henoch-Schonlein purpura	4	0
Petechiae	102	0
Purpura	32	0
<i>Pustular conditions</i>		
Acute generalised exanthematous pustulosis	1	0
<i>Rashes, eruptions and exanths NEC</i>		
Butterfly rash	3	0
Rash	3966	0
Rash erythematous	850	0
Rash macular	370	0
Rash maculo-papular	46	0
Rash morbilliform	33	0
Rash papular	249	0
Rash pruritic	862	0
Rash vesicular	48	0
Systemic lupus erythematosus rash	6	0
<i>Rosaceas</i>		
Rosacea	21	0
<i>Scaly conditions</i>		
Dandruff	4	0
Pityriasis	16	0
<i>Sebaceous gland disorders</i>		
Seborrhoea	5	0
<i>Skin and subcutaneous conditions NEC</i>		
Cutaneous symptom	4	0
Reactive perforating collagenosis	1	0
Skin mass	13	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Mucocutaneous ulceration	1	0
Scleroderma associated digital ulcer	1	0
Skin erosion	19	0
Skin ulcer	10	0
<i>Skin cysts and polyps</i>		
Dermal cyst	8	0
<i>Skin dystrophies</i>		
Keloid scar	2	0
Skin wrinkling	2	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	6	0
Skin haemorrhage	9	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	2	0
<i>Skin hypoplasias and atrophies</i>		
Skin atrophy	1	0
Skin striae	4	0
<i>Skin injuries and mechanical dermatoses</i>		
Decubitus ulcer	2	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Needle track marks	1	0
Skin preneoplastic conditions NEC		
Actinic keratosis	1	0
Skin vascular conditions NEC		
Skin oedema	3	0
Skin vasculitides		
Cutaneous vasculitis	9	0
Vasculitic rash	15	0
Skin vasomotor conditions		
Livedo reticularis	18	0
Telangiectasia and related conditions		
Telangiectasia	1	0
Urticarias		
Chronic spontaneous urticaria	3	0
Cold urticaria	2	0
Idiopathic urticaria	1	0
Mechanical urticaria	5	0
Solar urticaria	2	0
Urticaria	1249	0
Urticaria cholinergic	1	0
Urticaria chronic	8	0
Urticaria contact	1	0
Urticaria papular	3	0
Urticaria thermal	4	0
Urticularial vasculitis	3	0
Skin disorders SOC TOTAL	19044	1

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Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Infant	1	0
Menopause	19	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
Disability	1	0
Hearing disability	1	0
Housebound	1	0
Immobile	11	0
Impaired driving ability	2	0
Impaired work ability	7	0
Loss of personal independence in daily activities	24	0
Physical disability	3	0
Sight disability	8	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
Stress at work	1	0
<i>Family and partner issues</i>		
Bed sharing	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Flooding	1	0
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	13	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
Tobacco user	1	0
Social circumstances SOC TOTAL	137	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Local anaesthesia	1	0
Nerve block	3	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>		
Contraception	1	0
Contraceptive implant	1	0
Oral contraception	1	0
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	5	0
Nothing by mouth order	5	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	5	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	1	0
<i>Head, neck and oral cavity therapeutic procedures NEC</i>		
Neck lift	1	0
<i>Hernia repairs</i>		
Hernia repair	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
Hormone therapy	6	0
<i>Immunisations</i>		
COVID-19 immunisation	75	1
Immunisation	25	0
<i>Joint therapeutic procedures</i>		
Joint surgery	1	0
Knee arthroplasty	1	0
<i>Large intestine therapeutic procedures</i>		
Appendectomy	2	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	7	0
Limb operation	5	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
<i>Lymphoid tissue therapeutic procedures</i>		
Lymphadenectomy	1	0
Splenectomy	1	0
<i>Mastectomies</i>		
Breast conserving surgery	3	0
<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>Peripheral nerve therapeutic procedures</i>		
Peripheral nerve neurostimulation	1	0
<i>Phototherapies</i>		
UV light therapy	1	0
<i>Prophylactic procedures NEC</i>		
Anaphylaxis prophylaxis	2	0
Immune tolerance induction	1	0
Prophylaxis against transplant rejection	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>Retinal therapeutic procedures</i>		
Retinopexy	1	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	3	0
<i>Small intestine therapeutic procedures</i>		
Ileostomy	1	0
<i>Therapeutic bladder catheterisation</i>		
Bladder catheterisation	1	0
<i>Therapeutic procedures NEC</i>		
Abscess drainage	1	0
Anaphylaxis treatment	4	0
Bed rest	2	0
Fatigue management	1	0
Hospitalisation	9	0
Injection	22	0
Interchange of vaccine products	3	0
Localised alternating hot and cold therapy	1	0
Magnetic therapy	1	0
Mass excision	2	0
Medication dilution	1	0
Product used for unknown indication	2	0
Therapeutic procedure	1	0
Therapy change	1	0
<i>Tracheal therapeutic procedures</i>		
Tracheostomy	1	0
<i>Uterine therapeutic procedures</i>		
Endometrial ablation	1	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
Surgical & medical procedures SOC TOTAL	252	1

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Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	9	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	10	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	9	0
Labile blood pressure	3	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	3	0
<i>Circulatory collapse and shock</i>		
CT hypotension complex	2	0
Circulatory collapse	50	0
Hypoperfusion	1	0
Neurogenic shock	21	0
Peripheral circulatory failure	5	0
Shock	14	0
<i>Haemorrhages NEC</i>		
Bloody discharge	13	0
Haematoma	35	0
Haemorrhage	642	2
Internal haemorrhage	6	0
Venous haemorrhage	1	0
<i>Lymphangiopathies</i>		
Lymphangiopathy	1	0
Lymphocele	4	0
<i>Lymphoedemas</i>		
Lymphoedema	140	0
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	3	0
Embolism	62	0
Embolism venous	4	0
Microembolism	1	0
Thrombosis	294	6
Venous thrombosis	4	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial occlusive disease	2	0
Arteriosclerosis	1	0
Haemorrhagic infarction	1	0
Infarction	3	0
Ischaemia	6	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Capillary disorder	1	0
Superficial vein prominence	1	0
Vascular pain	14	0
Vasodilatation	24	0
Vein discolouration	5	0
Vein disorder	6	0
Vein rupture	4	0
<i>Peripheral embolism and thrombosis</i>		
Axillary vein thrombosis	1	0
Blue toe syndrome	21	0
Deep vein thrombosis	197	1
Femoral artery embolism	1	0
Jugular vein thrombosis	2	0
Pelvic venous thrombosis	4	0
Peripheral embolism	1	0
Subclavian vein thrombosis	3	0
Thrombophlebitis	16	0
Thrombophlebitis superficial	10	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	28	0
Erythromelalgia	1	0
Flushing	338	0
Hot flush	797	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	230	0
Peripheral ischaemia	11	0
Poor peripheral circulation	10	0
Raynaud's phenomenon	46	0
Vasoconstriction	2	0
<i>Phlebitis NEC</i>		
Phlebitis	23	0
Phlebitis superficial	5	0
<i>Site specific vascular disorders NEC</i>		
Inferior vena cava dilatation	1	0
Pallor	235	0
<i>Varicose veins NEC</i>		
Spider vein	3	0
Varicophlebitis	4	0
Varicose vein	15	0
<i>Vascular hypertensive disorders NEC</i>		
Diastolic hypertension	2	0
Essential hypertension	3	0
Hypertension	391	1
Labile hypertension	1	0
Orthostatic hypertension	1	0
Secondary hypertension	1	0

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Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Systolic hypertension	4	0
<i>Vascular hypotensive disorders</i>		
Hypotension	288	0
Orthostatic hypotension	23	0
<i>Vasculitides NEC</i>		
Behcet's syndrome	4	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	1	0
MAGIC syndrome	1	0
Vasculitis	39	0
<i>Vena caval embolism and thrombosis</i>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	4196	11
TOTAL REACTIONS FOR DRUG	266000	466
TOTAL REPORTS	95040	
TOTAL FATAL OUTCOME REPORTS		466