

## COVID-19 mRNA Pfizer- BioNTech Vaccine Analysis Print

Report Run Date: 26-Jun-2021  
Data Lock Date: 23-Jun-2021 18:30:09

All UK spontaneous reports received between 09/12/20 and 23/06/21 for mRNA Pfizer/BioNTech vaccine.

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

## Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<i><b>Anaemia deficiencies</b></i>		
Anaemia vitamin B12 deficiency	2	0
Deficiency anaemia	1	0
Iron deficiency anaemia	3	0
<i><b>Anaemias NEC</b></i>		
Anaemia	53	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	2	0
<i><b>Anaemias haemolytic NEC</b></i>		
Haemolytic anaemia	5	0
<i><b>Anaemias haemolytic immune</b></i>		
Autoimmune haemolytic anaemia	8	1
<i><b>Anaemias haemolytic mechanical factor</b></i>		
Microangiopathic haemolytic anaemia	1	0
<i><b>Bleeding tendencies</b></i>		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	23	0
Spontaneous haematoma	1	0
<i><b>Coagulation factor deficiencies</b></i>		
Acquired haemophilia	2	0
<i><b>Coagulopathies</b></i>		
Abnormal clotting factor	3	0
Antiphospholipid syndrome	4	0
Coagulopathy	6	0
Disseminated intravascular coagulation	1	0
Hypercoagulation	3	0
Thrombotic microangiopathy	2	0
<i><b>Eosinophilic disorders</b></i>		
Eosinophilia	11	0
<i><b>Haematological disorders</b></i>		
Blood disorder	1	0
Mast cell activation syndrome	3	0
Methaemoglobinaemia	1	0
<i><b>Haemolyses NEC</b></i>		
Haemolysis	7	0
Intravascular haemolysis	1	0
<i><b>Leukocytoses NEC</b></i>		
Leukocytosis	1	0
Lymphocytosis	4	0
Neutrophilia	3	0
<i><b>Leukopenias NEC</b></i>		
Leukopenia	3	0
Lymphopenia	2	0
<i><b>Lymphatic system disorders NEC</b></i>		
Abdominal lymphadenopathy	2	0
Hilar lymphadenopathy	1	0
Lymph node pain	892	0
Lymphadenitis	96	0
Lymphadenopathy	6057	0
Lymphatic disorder	1	0
Necrotic lymphadenopathy	1	0
Pseudolymphoma	5	0
Retroperitoneal lymphadenopathy	1	0

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<b>Blood disorders</b> Blood disorders cont'd		
<b><i>Marrow depression and hypoplastic anaemias</i></b>		
Aplasia pure red cell	2	0
Myelosuppression	1	0
Pancytopenia	4	1
<b><i>Neutropenias</i></b>		
Autoimmune neutropenia	2	0
Neutropenia	30	0
<b><i>Platelet disorders NEC</i></b>		
Platelet anisocytosis	1	0
<b><i>Purpuras (excl thrombocytopenic)</i></b>		
Purpura non-thrombocytopenic	1	0
<b><i>Red blood cell abnormal findings NEC</i></b>		
Polychromasia	2	0
Red blood cell abnormality	2	0
<b><i>Spleen disorders</i></b>		
Spleen atrophy	1	0
Splenic infarction	1	0
Splenic vein thrombosis	1	0
Splenomegaly	9	0
<b><i>Thrombocytopenias</i></b>		
Immune thrombocytopenia	54	0
Thrombocytopenia	136	1
Thrombocytopenic purpura	3	0
Thrombotic thrombocytopenic purpura	5	0
<b><i>Thrombocytoses</i></b>		
Thrombocytosis	4	0
<b>Blood disorders SOC TOTAL</b>	<b>7474</b>	<b>3</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac conduction disorders</b></i>		
Atrioventricular block	4	0
Atrioventricular block complete	1	0
Atrioventricular block second degree	1	0
Bundle branch block	2	0
Bundle branch block right	1	0
<i><b>Cardiac disorders NEC</b></i>		
Acute cardiac event	3	0
Cardiac disorder	24	0
Cardiac dysfunction	1	0
Cardiovascular disorder	2	0
Intracardiac thrombus	2	0
<i><b>Cardiac hypertensive complications</b></i>		
Hypertensive heart disease	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Cardiac discomfort	4	0
Palpitations	1377	0
<i><b>Cardiac valve disorders NEC</b></i>		
Cardiac valve disease	1	0
Heart valve incompetence	1	0
<i><b>Cardiomyopathies</b></i>		
Cardiomyopathy	2	0
Congestive cardiomyopathy	3	0
Stress cardiomyopathy	2	0
<i><b>Coronary artery disorders NEC</b></i>		
Coronary artery disease	4	2
Coronary artery occlusion	1	0
Coronary artery thrombosis	1	0
<i><b>Heart failures NEC</b></i>		
Cardiac failure	35	5
Cardiac failure acute	2	0
Cardiac failure chronic	1	0
Cardiac failure congestive	3	1
Cardiogenic shock	4	0
Cardiopulmonary failure	1	1
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute coronary syndrome	3	0
Acute myocardial infarction	16	1
Angina pectoris	66	0
Angina unstable	1	0
Arteriospasm coronary	1	0
Microvascular coronary artery disease	2	0
Myocardial infarction	124	26
Myocardial ischaemia	6	2
<i><b>Left ventricular failures</b></i>		
Acute left ventricular failure	1	1
Left ventricular failure	4	2
<i><b>Mitral valvular disorders</b></i>		
Mitral valve incompetence	3	0
Mitral valve prolapse	1	0
<i><b>Myocardial disorders NEC</b></i>		
Cardiac amyloidosis	1	0
Cardiomegaly	7	0

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<b>Cardiac disorders</b> Cardiac disorders cont'd		
Left atrial dilatation	1	0
Left ventricular dysfunction	4	0
Left ventricular enlargement	1	0
Myocardial fibrosis	1	0
Myocardial haemorrhage	1	0
Myocardial oedema	3	0
Myocardial rupture	1	0
Right ventricular enlargement	1	0
Ventricular hypertrophy	2	0
<b>Noninfectious myocarditis</b>		
Myocarditis	60	0
<b>Noninfectious pericarditis</b>		
Pericarditis	42	1
<b>Pericardial disorders NEC</b>		
Pericardial effusion	9	0
Pericardial haemorrhage	2	2
<b>Rate and rhythm disorders NEC</b>		
Arrhythmia	50	0
Bradycardia	42	0
Cardiac flutter	92	0
Extrasystoles	60	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	7	0
Tachyarrhythmia	1	0
Tachycardia	518	0
<b>Right ventricular failures</b>		
Cor pulmonale	1	0
<b>Supraventricular arrhythmias</b>		
Arrhythmia supraventricular	8	0
Atrial fibrillation	119	0
Atrial flutter	10	0
Atrial tachycardia	4	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus bradycardia	5	0
Sinus tachycardia	33	0
Supraventricular tachycardia	23	0
<b>Tricuspid valvular disorders</b>		
Tricuspid valve incompetence	1	0
<b>Ventricular arrhythmias and cardiac arrest</b>		
Cardiac arrest	76	27
Cardio-respiratory arrest	1	1
Pulseless electrical activity	3	0
Ventricular arrhythmia	4	0
Ventricular extrasystoles	11	0
Ventricular fibrillation	5	1
Ventricular tachycardia	7	0
<b>Cardiac disorders SOC TOTAL</b>	<b>2932</b>	<b>73</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	6	0
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	1	0
<i>Central nervous system disorders congenital NEC</i>		
Encephalocele	1	0
Spina bifida	1	0
<i>Cerebellar disorders congenital</i>		
Hereditary ataxia	1	0
<i>Cerebral disorders congenital</i>		
Cerebral palsy	2	0
<i>Coagulation disorders congenital</i>		
Haemophilia	1	0
<i>Congenital disorders NEC</i>		
Foetal malformation	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	1	0
<i>Gastrointestinal tract disorders congenital NEC</i>		
Gastroschisis	1	0
<i>Great vessel disorders congenital</i>		
Transposition of the great vessels	1	0
<i>Haematological disorders congenital NEC</i>		
Amegakaryocytic thrombocytopenia	1	0
Neonatal alloimmune thrombocytopenia	1	0
<i>Haemoglobinopathies congenital</i>		
Congenital methaemoglobinaemia	1	0
<i>Lymphatic system disorders congenital</i>		
Cystic lymphangioma	2	0
<i>Male reproductive tract disorders congenital</i>		
Cryptorchism	1	0
Micropenis	1	0
<i>Musculoskeletal and connective tissue disorders of skull congenital</i>		
Craniosynostosis	2	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital multiplex arthrogryposis	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	2	0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
<i>Palate disorders congenital</i>		
Cleft lip and palate	1	0
<i>Peripheral nervous system disorders congenital NEC</i>		
Hereditary neuropathy with liability to pressure palsies	1	0
<i>Pulmonary and bronchial disorders congenital</i>		
Congenital cystic lung	1	0
<i>Retinal disorders congenital</i>		
Retinitis pigmentosa	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
<b>Congenital disorders SOC TOTAL</b>	<b>36</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear canal erythema	1	0
Ear congestion	13	0
Ear discomfort	52	0
Ear disorder	11	0
Ear haemorrhage	6	0
Ear pain	553	0
Ear pruritus	6	0
Ear swelling	20	0
Otorrhoea	3	0
<i><b>Eustachian tube disorders</b></i>		
Eustachian tube disorder	1	0
Eustachian tube dysfunction	6	0
Eustachian tube obstruction	2	0
<i><b>External ear disorders NEC</b></i>		
Auricular swelling	1	0
Excessive cerumen production	2	0
External ear pain	2	0
Red ear syndrome	2	0
<i><b>External ear infections and inflammations</b></i>		
External ear inflammation	2	0
<i><b>Hearing disorders NEC</b></i>		
Auditory disorder	4	0
Diplacusis	1	0
<i><b>Hearing losses</b></i>		
Conductive deafness	1	0
Deafness	132	0
Deafness bilateral	6	0
Deafness neurosensory	11	0
Deafness transitory	3	0
Deafness unilateral	24	0
Hypoacusis	99	0
Sudden hearing loss	25	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	26	0
Misophonia	3	0
<i><b>Inner ear disorders NEC</b></i>		
Acute vestibular syndrome	1	0
Inner ear disorder	7	0
Meniere's disease	8	0
Vestibular disorder	6	0
<i><b>Inner ear infections and inflammations</b></i>		
Inner ear inflammation	4	0
<i><b>Inner ear signs and symptoms</b></i>		
Motion sickness	32	0
Tinnitus	1086	0
Vertigo	800	0
Vertigo labyrinthine	9	0
Vertigo positional	55	0
<i><b>Mastoid disorders</b></i>		
Mastoid effusion	1	0
<i><b>Middle ear disorders NEC</b></i>		
Middle ear disorder	3	0

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<b>Ear disorders</b>	Ear disorders cont'd		
<i>Middle ear infections and inflammations</i>			
Middle ear inflammation		1	0
<b>Ear disorders SOC TOTAL</b>		<b>3031</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	8	0
Thyroiditis subacute	2	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	1	0
Adrenocortical insufficiency acute	8	0
<i>Adrenal gland disorders NEC</i>		
Adrenal haemorrhage	1	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	1	0
Premature menarche	12	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	11	0
Ovulation delayed	5	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0
Goitre	8	0
Thyroid disorder	3	0
Thyroid mass	1	0
Thyroid pain	3	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	2	0
Hyperthyroidism	16	0
Thyrotoxic crisis	1	0
<i>Thyroid hypofunction disorders</i>		
Autoimmune hypothyroidism	1	0
Hypothyroidism	16	0
<b>Endocrine disorders SOC TOTAL</b>	<b>102</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Eye disorders</b>		
<i><b>Amblyopic vision impairment</b></i>		
Amblyopia	5	0
<i><b>Cataract conditions</b></i>		
Cataract	7	0
<i><b>Choroid and vitreous haemorrhages and vascular disorders</b></i>		
Choroidal haemorrhage	1	0
Choroidal neovascularisation	1	0
Vitreous haemorrhage	3	0
<i><b>Choroid and vitreous structural change, deposit and degeneration</b></i>		
Chorioretinopathy	2	0
Vitreous detachment	15	0
Vitreous floaters	44	0
<i><b>Colour blindness (incl acquired)</b></i>		
Dyschromatopsia	3	0
<i><b>Conjunctival and corneal bleeding and vascular disorders</b></i>		
Conjunctival haemorrhage	26	0
<i><b>Conjunctival infections, irritations and inflammations</b></i>		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	3	0
<i><b>Corneal infections, oedemas and inflammations</b></i>		
Keratitis	4	0
Ulcerative keratitis	4	0
<i><b>Eyelid movement disorders</b></i>		
Blepharospasm	69	0
Excessive eye blinking	1	0
Eyelid function disorder	3	0
Eyelid myokymia	2	0
Eyelid ptosis	28	0
<i><b>Glaucomas (excl congenital)</b></i>		
Angle closure glaucoma	2	0
Glaucoma	5	0
<i><b>Iris and ciliary body structural change, deposit and degeneration</b></i>		
Eye colour change	1	0
<i><b>Iris and uveal tract infections, irritations and inflammations</b></i>		
Autoimmune uveitis	1	0
Iridocyclitis	7	0
Iritis	3	0
Uveitis	22	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	89	0
Lacrimation increased	86	0
<i><b>Lid bleeding and vascular disorders</b></i>		
Eyelid bleeding	1	0
<i><b>Lid, lash and lacrimal infections, irritations and inflammations</b></i>		
Blepharitis	7	0
Chalazion	3	0
Eczema eyelids	2	0
Erythema of eyelid	4	0
Eyelid cyst	3	0
Eyelid irritation	2	0
Eyelid margin crusting	3	0
Eyelid oedema	3	0

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Eyelid rash	10	0
Swelling of eyelid	82	0
<b>Lid, lash and lacrimal structural disorders</b>		
Dermatochalasis	1	0
Eyelash changes	1	0
Eyelid exfoliation	2	0
Eyelid skin dryness	1	0
Growth of eyelashes	2	0
Lagophthalmos	2	0
<b>Ocular bleeding and vascular disorders NEC</b>		
Eye haematoma	3	0
Eye haemorrhage	14	0
Ocular vascular disorder	1	0
Ophthalmic vein thrombosis	1	0
<b>Ocular disorders NEC</b>		
Dark circles under eyes	6	0
Eye disorder	15	0
Eye oedema	9	0
Eye pain	615	0
Eye swelling	305	0
Eye symptom	7	0
Eye ulcer	2	0
Eyelid disorder	9	0
Eyelid pain	9	0
Eyelids pruritus	4	0
Ocular discomfort	19	0
Periorbital oedema	15	0
Periorbital pain	1	0
Periorbital swelling	79	0
Retinal disorder	1	0
Vitreous disorder	1	0
<b>Ocular infections, inflammations and associated manifestations</b>		
Eye allergy	7	0
Eye discharge	15	0
Eye inflammation	16	0
Eye irritation	65	0
Eye pruritus	160	0
Limbal swelling	2	0
Ocular hyperaemia	138	0
<b>Ocular nerve and muscle disorders</b>		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Extraocular muscle paresis	1	0
Eye movement disorder	19	0
Ocular myasthenia	1	0
Ophthalmoplegia	2	0
Strabismus	3	0
<b>Ocular sensation disorders</b>		
Abnormal sensation in eye	9	0
Asthenopia	91	0
Eye paraesthesia	1	0
Foreign body sensation in eyes	14	0
Hypoaesthesia eye	10	0

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<b>Eye disorders</b> Eye disorders cont'd		
Photophobia	244	0
<b>Optic disc abnormalities NEC</b>		
Papilloedema	3	0
<b>Optic nerve bleeding and vascular disorders</b>		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	2	0
<b>Orbital infections, inflammations and irritations</b>		
Parophthalmia	1	0
<b>Orbital structural change, deposit and degeneration</b>		
Orbital oedema	2	0
<b>Pupil disorders</b>		
Miosis	2	0
Mydriasis	12	0
Pupil fixed	2	0
Pupils unequal	6	0
<b>Refractive and accommodative disorders</b>		
Astigmatism	1	0
<b>Retinal bleeding and vascular disorders (excl retinopathy)</b>		
Retinal artery occlusion	5	0
Retinal artery thrombosis	1	0
Retinal haemorrhage	3	0
Retinal vein occlusion	19	0
Retinal vein thrombosis	2	0
<b>Retinal structural change, deposit and degeneration</b>		
Macular degeneration	2	0
Macular hole	1	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	1	0
Retinal detachment	3	0
Retinal tear	1	0
Retinal toxicity	2	0
<b>Retinal, choroid and vitreous infections and inflammations</b>		
Cystoid macular oedema	1	0
Macular oedema	2	0
Retinal vasculitis	2	0
<b>Retinopathies NEC</b>		
Retinal exudates	2	0
Retinopathy	1	0
<b>Scleral infections, irritations and inflammations</b>		
Episcleritis	7	0
Scleritis	2	0
<b>Scleral structural change, deposit and degeneration</b>		
Scleral discolouration	2	0
<b>Visual colour distortions</b>		
Chloropsia	2	0
Cyanopsia	1	0
Erythropsia	2	0
Xanthopsia	1	0
<b>Visual disorders NEC</b>		
Diplopia	102	0
Glare	1	0
Halo vision	6	0

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<b>Eye disorders</b> Eye disorders cont'd		
Metamorphopsia	11	0
Oscillopsia	2	0
Photopsia	74	0
Scintillating scotoma	3	0
Vision blurred	668	0
Visual brightness	3	0
Visual snow syndrome	2	0
<b>Visual field disorders</b>		
Visual field defect	11	0
<b>Visual impairment and blindness (excl colour blindness)</b>		
Amaurosis fugax	1	0
Blindness	58	0
Blindness transient	6	0
Blindness unilateral	8	0
Central vision loss	2	0
Sudden visual loss	2	0
Visual acuity reduced	12	0
Visual impairment	184	0
<b>Visual pathway disorders</b>		
Optic nerve disorder	1	0
<b>Eye disorders SOC TOTAL</b>	<b>3741</b>	<b>0</b>

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<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
Gastrointestinal sounds abnormal	11	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	1	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	0
Pancreatitis	6	0
Pancreatitis acute	6	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	7	0
<i>Anal and rectal signs and symptoms</i>		
Anal hypoaesthesia	1	0
Anal spasm	1	0
Anorectal discomfort	3	0
Anorectal swelling	1	0
Rectal discharge	1	0
Rectal tenesmus	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	3	0
Tongue cyst	3	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	1	0
Colitis	28	1
Colitis ischaemic	1	0
Colitis microscopic	1	0
Colitis ulcerative	42	0
Crohn's disease	25	0
Eosinophilic colitis	1	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Teething	4	0
Tooth disorder	2	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	5	0
Dental paraesthesia	9	0
Hyperaesthesia teeth	22	0
Toothache	81	0
<i>Dental surface disorders</i>		
Tooth discolouration	3	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	3	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	3231	2
Diarrhoea haemorrhagic	15	0
<i>Diverticula</i>		
Diverticulum	3	0
Diverticulum intestinal	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i><b>Small intestinal disorders cont'd</b></i>		
<i><b>Duodenal and small intestinal stenosis and obstruction</b></i>		
Small intestinal obstruction	1	0
<i><b>Duodenal ulcers and perforation</b></i>		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	3	0
<i><b>Dyspeptic signs and symptoms</b></i>		
Dyspepsia	214	0
Epigastric discomfort	10	0
Eructation	29	0
<i><b>Faecal abnormalities NEC</b></i>		
Abnormal faeces	10	0
Faecaloma	2	0
Faeces discoloured	29	0
Faeces hard	1	0
Faeces pale	3	0
Faeces soft	10	0
Mucous stools	3	0
<i><b>Flatulence, bloating and distension</b></i>		
Abdominal distension	217	0
Aerophagia	3	0
Flatulence	109	0
<i><b>Gastric and oesophageal haemorrhages</b></i>		
Gastric haemorrhage	5	1
Mallory-Weiss syndrome	1	0
Oesophageal varices haemorrhage	1	0
<i><b>Gastric ulcers and perforation</b></i>		
Gastric ulcer	6	0
<i><b>Gastritis (excl infective)</b></i>		
Chronic gastritis	2	0
Gastritis	25	0
Reflux gastritis	4	0
<i><b>Gastrointestinal and abdominal pains (excl oral and throat)</b></i>		
Abdominal migraine	2	0
Abdominal pain	774	0
Abdominal pain lower	59	0
Abdominal pain upper	1265	0
Abdominal rigidity	9	0
Abdominal tenderness	5	0
Gastrointestinal pain	83	0
Oesophageal pain	3	0
<i><b>Gastrointestinal atonic and hypomotility disorders NEC</b></i>		
Constipation	149	0
Duodenogastric reflux	2	0
Gastric dilatation	4	0
Gastrooesophageal reflux disease	67	0
Impaired gastric emptying	6	0
Infrequent bowel movements	2	0
Intestinal pseudo-obstruction	2	0
<i><b>Gastrointestinal disorders NEC</b></i>		
Food poisoning	2	0
Functional gastrointestinal disorder	6	0
Gastric disorder	5	0
Gastrointestinal disorder	8	0

## Case Series Drug Analysis Print

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

Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Stomach mass	3	0
<b>Gastrointestinal dyskinetic disorders</b>		
Bowel movement irregularity	1	0
Change of bowel habit	3	0
Dyschezia	1	0
Gastrointestinal motility disorder	1	0
Oesophageal achalasia	1	0
<b>Gastrointestinal fistulae</b>		
Diverticular fistula	1	0
<b>Gastrointestinal inflammatory disorders NEC</b>		
Duodenitis	1	0
Enteritis	3	0
Epiploic appendagitis	1	0
Gastrointestinal inflammation	2	0
Intestinal angioedema	2	0
<b>Gastrointestinal mucosal dystrophies and secretion disorders</b>		
Hyperchlorhydria	4	0
<b>Gastrointestinal signs and symptoms NEC</b>		
Abdominal discomfort	374	0
Abdominal symptom	1	0
Acute abdomen	3	0
Anal incontinence	13	0
Breath odour	11	0
Dysphagia	120	1
Odynophagia	14	0
<b>Gastrointestinal spastic and hypermotility disorders</b>		
Defaecation urgency	7	0
Frequent bowel movements	16	0
Irritable bowel syndrome	46	0
Oesophageal spasm	3	0
Pylorospasm	1	0
<b>Gastrointestinal stenosis and obstruction NEC</b>		
Intestinal obstruction	2	0
<b>Gastrointestinal vascular malformations</b>		
Gastric antral vascular ectasia	5	0
<b>Gastrointestinal vascular occlusion and infarction</b>		
Intestinal ischaemia	4	2
Mesenteric vein thrombosis	4	0
Omental infarction	1	0
Visceral venous thrombosis	1	0
<b>Gingival disorders, signs and symptoms NEC</b>		
Gingival blister	10	0
Gingival discomfort	2	0
Gingival disorder	3	0
Gingival erythema	1	0
Gingival pain	67	0
Gingival pruritus	1	0
Gingival swelling	21	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	4	0
<b>Gingival haemorrhages</b>		
Gingival bleeding	34	0
<b>Haemorrhoids and gastrointestinal varices (excl oesophageal)</b>		



## Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Gastric varices	1	0
Haemorrhoids	18	0
Haemorrhoids thrombosed	1	0
<b>Intestinal haemorrhages</b>		
Anal haemorrhage	11	0
Rectal haemorrhage	40	0
Small intestinal haemorrhage	5	0
<b>Intestinal ulcers and perforation NEC</b>		
Intestinal perforation	4	2
Large intestine perforation	1	0
<b>Malabsorption syndromes</b>		
Bile acid malabsorption	1	0
Coeliac disease	8	0
Steatorrhoea	4	0
<b>Nausea and vomiting symptoms</b>		
Discoloured vomit	9	0
Infantile vomiting	1	0
Nausea	8734	1
Regurgitation	1	0
Retching	59	0
Vomiting	2526	1
Vomiting projectile	38	0
<b>Non-mechanical ileus</b>		
Ileus paralytic	1	0
<b>Non-site specific gastrointestinal haemorrhages</b>		
Gastrointestinal haemorrhage	10	0
Haematemesis	22	2
Haematochezia	28	0
Melaena	8	0
Upper gastrointestinal haemorrhage	2	0
<b>Oesophageal stenosis and obstruction</b>		
Oesophageal stenosis	2	0
<b>Oesophagitis (excl infective)</b>		
Eosinophilic oesophagitis	1	0
Oesophagitis	2	0
<b>Oral dryness and saliva altered</b>		
Aptyalism	2	0
Dry mouth	347	0
Lip dry	28	0
Saliva altered	3	0
Salivary hypersecretion	29	0
<b>Oral soft tissue disorders NEC</b>		
Angina bullosa haemorrhagica	1	0
Chapped lips	13	0
Cheilitis	19	0
Enlarged uvula	10	0
Lip blister	17	0
Lip disorder	4	0
Oral disorder	6	0
Oral lichen planus	4	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	2	0

## Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Oral soft tissue haemorrhages</i></b>		
Mouth haemorrhage	7	0
Oral blood blister	9	0
Oral purpura	1	0
<b><i>Oral soft tissue infections</i></b>		
Angular cheilitis	1	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Anaesthesia oral	1	0
Burning mouth syndrome	4	0
Coating in mouth	1	0
Hypoaesthesia oral	313	0
Lip discolouration	3	0
Lip erythema	2	0
Lip exfoliation	5	0
Lip pain	39	0
Lip pruritus	8	0
Lip scab	1	0
Oral discomfort	51	0
Oral dysaesthesia	1	0
Oral mucosal blistering	12	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	11	0
Oral mucosal erythema	3	0
Oral mucosal exfoliation	7	0
Oral mucosal roughening	3	0
Oral pain	113	0
Oral pruritus	17	0
Paraesthesia oral	686	0
Pigmentation lip	1	0
<b><i>Oral soft tissue swelling and oedema</i></b>		
Lip oedema	3	0
Lip swelling	463	0
Mouth swelling	59	0
Oedema mouth	4	0
Palatal oedema	2	0
Palatal swelling	1	0
<b><i>Peptic ulcers and perforation</i></b>		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	7	0
<b><i>Peritoneal and retroperitoneal disorders</i></b>		
Ascites	1	0
<b><i>Peritoneal and retroperitoneal fibrosis and adhesions</i></b>		
Abdominal adhesions	1	0
<b><i>Peritoneal and retroperitoneal haemorrhages</i></b>		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	1
<b><i>Rectal inflammations NEC</i></b>		
Proctitis	1	0
Proctitis ulcerative	1	0
<b><i>Salivary gland disorders NEC</i></b>		
Salivary gland pain	10	0
<b><i>Salivary gland enlargements</i></b>		
Parotid gland enlargement	7	0

## Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Salivary gland enlargement	3	0
Submaxillary gland enlargement	6	0
<b>Salivary gland infections and inflammations</b>		
Noninfective sialoadenitis	1	0
<b>Stomatitis and ulceration</b>		
Aphthous ulcer	28	0
Lip ulceration	11	0
Mouth ulceration	271	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	42	0
<b>Tongue disorders</b>		
Glossitis	11	0
Plicated tongue	2	0
Tongue disorder	27	0
Tongue haemorrhage	2	0
Tongue ulceration	20	0
Trichoglossia	2	0
<b>Tongue signs and symptoms</b>		
Glossodynia	140	0
Scalloped tongue	4	0
Stiff tongue	3	0
Swollen tongue	337	0
Tongue blistering	12	0
Tongue coated	13	0
Tongue discolouration	20	0
Tongue discomfort	30	0
Tongue dry	11	0
Tongue eruption	8	0
Tongue erythema	5	0
Tongue exfoliation	1	0
Tongue movement disturbance	3	0
Tongue oedema	18	0
Tongue pruritus	1	0
Tongue rough	2	0
Tongue spasm	7	0
<b>Tooth missing</b>		
Tooth loss	1	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>22398</b>	<b>14</b>

## Case Series Drug Analysis Print

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Report Run Date: 26-Jun-2021

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Administration site reactions NEC</b></i>		
Administration site bruise	5	0
Administration site erythema	2	0
Administration site extravasation	2	0
Administration site haematoma	3	0
Administration site inflammation	1	0
Administration site irritation	1	0
Administration site joint discomfort	1	0
Administration site joint movement impairment	1	0
Administration site pain	12	0
Administration site rash	2	0
Administration site swelling	2	0
Administration site warmth	2	0
Puncture site bruise	21	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><b>Adverse effect absent</b></i>		
No adverse event	12	0
<i><b>Application and instillation site reactions</b></i>		
Application site acne	2	0
Application site bruise	5	0
Application site burn	1	0
Application site erythema	8	0
Application site haemorrhage	1	0
Application site hypoaesthesia	1	0
Application site irritation	1	0
Application site joint erythema	1	0
Application site joint pain	1	0
Application site mass	1	0
Application site odour	1	0
Application site pain	7	0
Application site pruritus	4	0
Application site rash	2	0
Application site reaction	1	0
Application site swelling	2	0
Application site vesicles	3	0
Instillation site warmth	3	0
<i><b>Asthenic conditions</b></i>		
Asthenia	982	1
Chronic fatigue syndrome	39	0
Decreased activity	4	0
Fatigue	13655	0
Malaise	3085	0
Sluggishness	7	0
<i><b>Body temperature altered</b></i>		
Hyperthermia	5	0
Hypothermia	18	0
Temperature regulation disorder	6	0
<i><b>Breast complications associated with device</b></i>		

## Case Series Drug Analysis Print

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Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Capsular contracture associated with breast implant	1	0
<b>Complications associated with device NEC</b>		
Capsular contracture associated with implant	1	0
Injury associated with device	2	0
Medical device pain	1	0
Medical device site swelling	1	0
<b>Death and sudden death</b>		
Clinical death	1	1
Death	131	131
Sudden death	23	23
<b>Febrile disorders</b>		
Hyperpyrexia	6	0
Pyrexia	9110	0
<b>Feelings and sensations NEC</b>		
Chills	6078	0
Feeling abnormal	816	0
Feeling cold	742	0
Feeling drunk	52	0
Feeling hot	694	0
Feeling jittery	12	0
Feeling of body temperature change	202	0
Hangover	40	0
Hunger	17	0
Sensation of foreign body	34	0
Temperature intolerance	21	0
Thirst	208	0
<b>Gait disturbances</b>		
Gait disturbance	93	0
Gait inability	38	0
Loss of control of legs	10	0
<b>General signs and symptoms NEC</b>		
Adhesion	1	0
Condition aggravated	92	0
Crepitations	1	0
Crying	72	0
Deformity	2	0
Developmental delay	1	0
Discharge	4	0
Disease progression	2	0
Disease recurrence	18	0
Effusion	2	0
Energy increased	10	0
Exercise tolerance decreased	6	0
Foaming at mouth	1	0
General physical health deterioration	13	1
General symptom	2	0
Glassy eyes	3	0
High-pitched crying	2	0
Illness	1010	0
Induration	6	0
Influenza like illness	1487	0
Irritability postvaccinal	2	0
Local reaction	65	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Moaning	1	0
Multiple organ dysfunction syndrome	4	2
Nonspecific reaction	1	0
Organ failure	1	1
Peripheral swelling	2026	0
Pre-existing condition improved	8	0
Prolapse	1	0
Screaming	12	0
Secretion discharge	7	0
Swelling	1519	0
Swelling face	519	0
Symptom recurrence	1	0
<b>Implant and catheter site reactions</b>		
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
<b>Inflammations</b>		
Granuloma	1	0
Inflammation	198	0
Papillitis	1	0
Serositis	1	0
Systemic inflammatory response syndrome	1	0
<b>Infusion site reactions</b>		
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
<b>Injection site reactions</b>		
Injected limb mobility decreased	21	0
Injection site bruising	43	0
Injection site coldness	1	0
Injection site cyst	2	0
Injection site discolouration	5	0
Injection site discomfort	9	0
Injection site erythema	240	0
Injection site haemorrhage	5	0
Injection site hypoaesthesia	8	0
Injection site indentation	2	0
Injection site induration	3	0
Injection site inflammation	25	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	300	0
Injection site necrosis	3	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Injection site oedema	11	0
Injection site pain	2005	0
Injection site paraesthesia	10	0
Injection site pruritus	115	0
Injection site rash	96	0
Injection site reaction	20	0
Injection site scab	2	0
Injection site scar	3	0
Injection site swelling	207	0
Injection site urticaria	16	0
Injection site vesicles	6	0
Injection site warmth	108	0
<b>Interactions</b>		
Alcohol interaction	2	0
Drug interaction	16	0
Inhibitory drug interaction	2	0
<b>Mass conditions NEC</b>		
Cyst	17	0
Mass	29	0
Nodule	21	0
<b>Mucosal findings abnormal</b>		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	5	0
Mucosal inflammation	1	0
Oedema mucosal	1	0
Polyp	1	0
<b>Necrosis NEC</b>		
Fat necrosis	1	0
Necrosis	2	0
<b>Oedema NEC</b>		
Face oedema	23	0
Generalised oedema	1	0
Localised oedema	15	0
Oedema	37	0
Oedema peripheral	52	0
<b>Pain and discomfort NEC</b>		
Axillary pain	1411	0
Chest discomfort	805	0
Chest pain	1482	0
Discomfort	186	0
Facial discomfort	12	0
Facial pain	127	0
Inflammatory pain	4	0
Non-cardiac chest pain	16	0
Pain	4593	0
Suprapubic pain	1	0
Tenderness	418	0
Visceral pain	1	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	25	0
Adverse event	4	0
Adverse food reaction	1	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Adverse reaction	9	0
Drug ineffective	148	1
Drug intolerance	2	0
Immediate post-injection reaction	2	0
Inadequate analgesia	4	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	43	0
Treatment failure	6	0
Vaccination failure	7	0
<b>Trophic disorders</b>		
Calcinosis	1	0
<b>Ulcers NEC</b>		
Ulcer	13	0
Ulcer haemorrhage	1	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	9	0
Shoulder injury related to vaccine administration	14	0
Vaccination site bruising	76	0
Vaccination site coldness	1	0
Vaccination site cyst	3	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	9	0
Vaccination site discomfort	36	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	402	0
Vaccination site granuloma	1	0
Vaccination site haematoma	1	0
Vaccination site haemorrhage	11	0
Vaccination site hypersensitivity	2	0
Vaccination site hypoaesthesia	10	0
Vaccination site induration	60	0
Vaccination site inflammation	43	0
Vaccination site irritation	8	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	6	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	14	0
Vaccination site joint pain	24	0
Vaccination site joint swelling	2	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	3	0
Vaccination site macule	1	0
Vaccination site mass	155	0
Vaccination site movement impairment	52	0
Vaccination site nerve damage	1	0
Vaccination site nodule	2	0
Vaccination site oedema	3	0



## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Vaccination site pain	1457	0
Vaccination site paraesthesia	4	0
Vaccination site pruritus	100	0
Vaccination site rash	77	0
Vaccination site reaction	24	0
Vaccination site scab	1	0
Vaccination site scar	1	0
Vaccination site swelling	391	0
Vaccination site ulcer	1	0
Vaccination site urticaria	8	0
Vaccination site vesicles	3	0
Vaccination site warmth	197	0
<b>Vascular complications associated with device</b>		
Vascular stent thrombosis	1	0
<b>Withdrawal and rebound effects</b>		
Drug withdrawal syndrome	4	0
Withdrawal syndrome	15	0
<b>General disorders SOC TOTAL</b>	<b>59493</b>	<b>161</b>

## Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i><b>Bile duct infections and inflammations</b></i>		
Biliary colic	4	0
Cholangitis	1	0
<i><b>Cholecystitis and cholelithiasis</b></i>		
Cholelithiasis	6	0
<i><b>Cholestasis and jaundice</b></i>		
Cholestasis	2	0
Cholestasis of pregnancy	1	0
Jaundice	13	0
Jaundice cholestatic	2	0
<i><b>Gallbladder disorders NEC</b></i>		
Gallbladder disorder	1	0
<i><b>Hepatic and hepatobiliary disorders NEC</b></i>		
Liver disorder	6	0
<i><b>Hepatic enzymes and function abnormalities</b></i>		
Hepatic function abnormal	1	0
<i><b>Hepatic failure and associated disorders</b></i>		
Acute hepatic failure	1	0
Hepatic failure	2	1
<i><b>Hepatic fibrosis and cirrhosis</b></i>		
Hepatic cirrhosis	1	0
<i><b>Hepatic vascular disorders</b></i>		
Congestive hepatopathy	1	0
Hepatic artery embolism	1	0
Hepatic haemorrhage	1	0
Hepatic vein thrombosis	4	0
Portal vein thrombosis	2	0
<i><b>Hepatobiliary signs and symptoms</b></i>		
Hepatic pain	14	0
Hepatomegaly	1	0
Liver tenderness	3	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Autoimmune hepatitis	4	0
Drug-induced liver injury	2	0
Hepatitis	7	0
Immune-mediated hepatic disorder	1	0
Immune-mediated hepatitis	1	0
Liver injury	8	0
<b>Hepatic disorders SOC TOTAL</b>	<b>91</b>	<b>1</b>

## Case Series Drug Analysis Print

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Report Run Date: 26-Jun-2021

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	10	0
<i>Allergic conditions NEC</i>		
Allergic oedema	11	0
Allergy to animal	1	0
Allergy to arthropod bite	2	0
Allergy to arthropod sting	1	0
Allergy to metals	1	0
Hypersensitivity	587	0
Mite allergy	1	0
Multiple allergies	5	0
Serum sickness	2	0
Serum sickness-like reaction	3	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	1	0
Type IV hypersensitivity reaction	6	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	4	0
Allergy to chemicals	2	0
Allergy to vaccine	27	0
Contrast media reaction	1	0
Drug hypersensitivity	18	0
Food allergy	13	0
Oral allergy syndrome	2	0
Reaction to colouring	1	0
Reaction to excipient	7	0
Reaction to preservatives	3	0
Rubber sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	359	2
Anaphylactic shock	32	0
Anaphylactoid reaction	18	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	1	0
Seasonal allergy	43	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	21	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	27	0
Graft versus host disease	1	0
Immune system disorder	15	0
Immune-mediated adverse reaction	4	0
Immunisation reaction	1	0
Sensitisation	3	0
Systemic immune activation	2	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
Immunosuppression	1	0
<i>Transplant rejections</i>		
Corneal graft rejection	4	0
Kidney transplant rejection	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Immune system disorders		
Immune system disorders cont'd		
Solid organ transplant rejection	1	0
Immune system disorders SOC TOTAL	1251	2

## Case Series Drug Analysis Print

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

Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Infections</b>		
<i><b>Abdominal and gastrointestinal infections</b></i>		
Abdominal abscess	1	0
Abdominal infection	1	0
Anal abscess	2	0
Appendicitis	19	0
Appendicitis perforated	1	0
Diverticulitis	4	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	21	0
Mesenteric abscess	1	0
Peritonitis	1	1
Rectal abscess	1	0
<i><b>Aspergillus infections</b></i>		
Bronchopulmonary aspergillosis	1	0
<i><b>Bacterial infections NEC</b></i>		
Arthritis bacterial	2	0
Bacterial diarrhoea	1	0
Bacterial infection	6	0
Cellulitis	122	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
Folliculitis	8	0
Injection site cellulitis	2	0
Meningitis bacterial	3	0
Paronychia	1	0
Perichondritis	1	0
Periorbital cellulitis	1	0
Skin bacterial infection	1	0
Tonsillitis bacterial	2	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	14	0
<i><b>Bartonella infections</b></i>		
Cat scratch disease	1	0
<i><b>Bone and joint infections</b></i>		
Abscess jaw	1	0
Osteomyelitis	1	0
<i><b>Borrelial infections</b></i>		
Lyme disease	1	0
Relapsing fever	1	0
<i><b>Breast infections</b></i>		
Breast abscess	2	0
Mastitis	36	0
<i><b>Caliciviral infections</b></i>		
Gastroenteritis norovirus	1	0
<i><b>Campylobacter infections</b></i>		
Campylobacter gastroenteritis	1	0
<i><b>Candida infections</b></i>		
Anal candidiasis	2	0
Candida infection	22	0
Oral candidiasis	30	0
Systemic candida	1	0
Vulvovaginal candidiasis	20	0

## Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Infections</b>		
<i>Infections cont'd</i>		
<b><i>Central nervous system and spinal infections</i></b>		
Cavernous sinus thrombosis	1	0
Encephalitis	13	0
Meningitis	4	0
Meningitis aseptic	1	0
Myelitis	4	0
<b><i>Clostridia infections</i></b>		
Clostridium difficile infection	2	0
<b><i>Coronavirus infections</i></b>		
Asymptomatic COVID-19	10	0
COVID-19	708	32
COVID-19 pneumonia	33	13
Coronavirus infection	6	0
Severe acute respiratory syndrome	1	0
Suspected COVID-19	41	1
<b><i>Coxiella infections</i></b>		
Q fever	9	0
<b><i>Cytomegaloviral infections</i></b>		
Cytomegalovirus syndrome	1	0
<b><i>Dental and oral soft tissue infections</i></b>		
Abscess oral	4	0
Gingivitis	7	0
Parotitis	8	0
Pulpitis dental	1	0
Sialoadenitis	3	0
Tooth abscess	7	0
Tooth infection	5	0
<b><i>Ear infections</i></b>		
Ear infection	50	0
Labyrinthitis	61	0
Mastoiditis	1	0
Otitis media	2	0
Otitis media acute	1	0
<b><i>Ectoparasitic infestations</i></b>		
Acarodermatitis	4	0
Bed bug infestation	1	0
<b><i>Epstein-Barr viral infections</i></b>		
Epstein-Barr virus infection	1	0
Infectious mononucleosis	17	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	43	0
Eye abscess	1	0
Eye infection	15	0
Eyelid infection	2	0
Hordeolum	17	0
Periorbital infection	2	0
<b><i>Female reproductive tract infections</i></b>		
Bartholinitis	1	0
Endometritis	1	0
Pelvic inflammatory disease	1	0
Vulval abscess	1	0
<b><i>Fungal infections NEC</i></b>		
Fungal infection	7	0

## Case Series Drug Analysis Print

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

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Fungal skin infection	2	0
Onychomycosis	1	0
Pneumonia fungal	2	0
Vulvovaginal mycotic infection	3	0
<b>Hepatitis virus infections</b>		
Hepatitis A	1	0
Hepatitis E	1	0
<b>Hepatobiliary and spleen infections</b>		
Biliary sepsis	1	0
<b>Herpes viral infections</b>		
Disseminated varicella zoster virus infection	1	0
Eczema herpeticum	2	0
Genital herpes	51	0
Genital herpes simplex	4	0
Herpes ophthalmic	3	0
Herpes simplex	17	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	2	0
Herpes virus infection	6	0
Herpes zoster	983	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	9	0
Herpes zoster reactivation	1	0
Nasal herpes	3	0
Ophthalmic herpes zoster	2	0
Oral herpes	206	0
Varicella	18	0
Varicella zoster virus infection	1	0
<b>Infections NEC</b>		
Abscess	25	0
Abscess limb	4	0
Abscess soft tissue	1	0
Genital abscess	1	0
Infected bite	1	0
Infected cyst	2	0
Infection	138	0
Injection site abscess	1	0
Injection site infection	4	0
Localised infection	18	0
Lymph gland infection	5	0
Lymph node abscess	2	0
Opportunistic infection	1	0
Respiratory tract infection	4	0
Vaccination site abscess	3	0
Vaccination site infection	11	0
Vaccine breakthrough infection	23	0
Vestibulitis	2	0
Wound infection	1	0
<b>Infectious transmissions</b>		
Secondary transmission	7	0
Vaccine bacteria shedding	1	0
<b>Influenza viral infections</b>		
Influenza	942	0

## Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
<b><i>Klebsiella infections</i></b>		
Klebsiella infection	1	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Bronchitis	9	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	119	7
Pneumonia	72	9
Sputum purulent	1	0
<b><i>Male reproductive tract infections</i></b>		
Epididymitis	2	0
Orchitis	3	0
Prostate infection	1	0
<b><i>Mumps viral infections</i></b>		
Mumps	5	0
<b><i>Muscle and soft tissue infections</i></b>		
Abscess neck	1	0
Infective tenosynovitis	1	0
Necrotising fasciitis	1	0
Soft tissue infection	1	0
<b><i>Neisseria infections</i></b>		
Gonorrhoea	1	0
<b><i>Pneumocystis infections</i></b>		
Pneumocystis jirovecii pneumonia	1	0
<b><i>Retroviral infections</i></b>		
HIV infection	1	0
<b><i>Rotaviral infections</i></b>		
Gastroenteritis rotavirus	1	0
<b><i>Rubeola viral infections</i></b>		
Measles	2	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Bacteraemia	1	0
Neutropenic sepsis	2	0
Sepsis	29	4
Sepsis syndrome	1	0
Septic rash	1	0
Septic shock	4	1
Urosepsis	4	0
<b><i>Skin structures and soft tissue infections</i></b>		
Abscess sweat gland	1	0
Acne pustular	1	0
Dermatitis infected	1	0
Impetigo	4	0
Infected skin ulcer	1	0
Injection site pustule	1	0
Nail infection	1	0
Pustule	9	0
Rash pustular	9	0
Skin infection	24	0
Subcutaneous abscess	6	0
Vaccination site pustule	3	0
<b><i>Staphylococcal infections</i></b>		
Furuncle	27	0
Pneumonia staphylococcal	1	0



## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Staphylococcal abscess	1	0
Staphylococcal infection	2	0
Staphylococcal sepsis	1	0
<b>Streptococcal infections</b>		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	5	0
Streptococcal abscess	1	0
Streptococcal endocarditis	1	0
Streptococcal sepsis	1	0
<b>Tinea infections</b>		
Body tinea	1	0
Tinea infection	1	0
Tinea versicolour	1	0
<b>Treponema infections</b>		
Syphilis	1	0
<b>Trypanosomal infections</b>		
African trypanosomiasis	1	0
<b>Tuberculous infections</b>		
Lymph node tuberculosis	1	0
Pulmonary tuberculosis	1	0
<b>Upper respiratory tract infections</b>		
Acute sinusitis	2	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	16	0
Nasopharyngitis	524	0
Peritonsillar abscess	2	0
Pharyngitis	14	0
Rhinitis	33	0
Sinusitis	81	0
Tonsillitis	61	0
Tracheitis	4	0
Upper respiratory tract infection	3	0
<b>Urinary tract infections</b>		
Cystitis	47	0
Kidney infection	20	0
Pyelonephritis	1	0
Urinary tract infection	96	0
<b>Vascular infections</b>		
Haematoma infection	1	0
Infusion site infection	1	0
Lymphangitis	6	0
<b>Viral infections NEC</b>		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Encephalitis viral	3	0
Eye infection viral	2	0
Gastroenteritis viral	12	0
Hepatitis viral	2	0
Meningitis viral	7	0
Oral viral infection	1	0
Pneumonia viral	1	1
Post viral fatigue syndrome	25	0

## Case Series Drug Analysis Print

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Report Run Date: 26-Jun-2021

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name		Total	Fatal
<b>Infections</b>	Infections cont'd		
Sweating fever		61	0
Vestibular neuronitis		16	0
Viral diarrhoea		1	0
Viral infection		30	0
Viral labyrinthitis		3	0
Viral pericarditis		1	0
Viral pharyngitis		12	0
Viral rash		33	0
Viral sinusitis		1	0
Viral tonsillitis		1	0
<b>Infections SOC TOTAL</b>		<b>5464</b>	<b>70</b>

## Case Series Drug Analysis Print

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Report Run Date: 26-Jun-2021

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Abdominal and gastrointestinal injuries NEC</i></b>		
Mouth injury	3	0
Oral contusion	1	0
Palate injury	1	0
Rectal injury	1	0
Splenic rupture	4	0
Tongue injury	1	0
Tooth fracture	1	0
<b><i>Accidental exposures to product</i></b>		
Accidental exposure to product	14	0
<b><i>Anaesthetic and allied procedural complications</i></b>		
Delayed recovery from anaesthesia	2	0
Sedation complication	1	0
<b><i>Atmospheric pressure injuries</i></b>		
Barotitis media	1	0
Hypobarism	1	0
<b><i>Bone and joint injuries NEC</i></b>		
Joint injury	3	0
<b><i>Cardiovascular injuries</i></b>		
Heart injury	2	0
Vascular injury	4	0
<b><i>Cerebral injuries NEC</i></b>		
Brain herniation	1	0
Concussion	1	0
Craniocerebral injury	1	0
Subdural haematoma	4	0
Subdural haemorrhage	4	0
Traumatic intracranial haemorrhage	1	1
<b><i>Chemical injuries</i></b>		
Chemical cystitis	1	0
<b><i>Chest and respiratory tract injuries NEC</i></b>		
Chest crushing	8	0
Foreign body in throat	1	0
<b><i>Conditions caused by cold</i></b>		
Chillblains	44	0
<b><i>Cranial nerve injuries</i></b>		
Vth nerve injury	1	0
<b><i>Ear injuries NEC</i></b>		
Ear injury	1	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure during pregnancy	8	0
Exposure via breast milk	23	0
Foetal exposure during pregnancy	14	0
Maternal exposure before pregnancy	2	0
Maternal exposure during breast feeding	640	0
Maternal exposure during pregnancy	311	0
Maternal exposure timing unspecified	1	0
Paternal exposure before pregnancy	1	0
Paternal exposure during pregnancy	2	0
<b><i>Exposures to agents or circumstances NEC</i></b>		
Exposure to SARS-CoV-2	1	0
Exposure to vaccinated person	1	0
<b><i>Eye and ear procedural complications</i></b>		

## Case Series Drug Analysis Print

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

Report Run Date: 26-Jun-2021

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Toxic anterior segment syndrome	1	0
<b>Eye injuries NEC</b>		
Eye contusion	13	0
Eye injury	8	0
Foreign body in eye	1	0
Injury corneal	1	0
Periorbital haematoma	1	0
Retinal injury	2	0
Superficial injury of eye	1	0
<b>Fractures and dislocations NEC</b>		
Bone fragmentation	1	0
Fracture	1	0
Joint dislocation	2	0
<b>Gastrointestinal and hepatobiliary procedural complications</b>		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	6	0
Procedural vomiting	1	0
<b>Heat injuries (excl thermal burns)</b>		
Heat cramps	1	0
Heat exhaustion	1	0
Heat illness	1	0
Heat oedema	7	0
Heat stroke	3	0
<b>Limb fractures and dislocations</b>		
Atypical femur fracture	1	0
Clavicle fracture	20	0
Wrist fracture	1	0
<b>Medication errors, product use errors and issues NEC</b>		
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	14	0
Prescription drug used without a prescription	2	0
Product use complaint	1	0
Product use issue	10	0
Vaccination error	6	0
Wrong dose	2	0
Wrong drug	10	0
Wrong technique in product usage process	3	0
<b>Muscle, tendon and ligament injuries</b>		
Epicondylitis	9	0
Ligament sprain	5	0
Mallet finger	1	0
Muscle injury	11	0
Muscle rupture	2	0
Muscle strain	19	0
Tendon injury	5	0
Tendon rupture	2	0
<b>Musculoskeletal procedural complications</b>		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
<b>Nerve injuries NEC</b>		

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Nerve injury	29	0
<b>Neurological and psychiatric procedural complications</b>		
Post procedural stroke	1	0
Procedural dizziness	10	0
<b>Non-occupational environmental exposures</b>		
Exposure to extreme temperature	1	0
<b>Non-site specific injuries NEC</b>		
Arthropod sting	2	0
Bite	1	0
Electric shock	9	0
Fall	91	1
Foreign body	2	0
Injury	5	0
Traumatic haematoma	1	0
Wound	4	0
Wound complication	7	0
Wound haematoma	1	0
Wound haemorrhage	1	0
Wound secretion	2	0
<b>Non-site specific procedural complications</b>		
Incision site pain	2	0
Infusion related reaction	6	0
Injection related reaction	34	0
Post procedural complication	3	0
Procedural pain	1	0
Seroma	1	0
<b>Occupational exposures</b>		
Occupational exposure to SARS-CoV-2	1	0
Occupational exposure to product	1	0
<b>Off label uses</b>		
Off label use	38	0
<b>Overdoses NEC</b>		
Overdose	19	0
<b>Pathways and sources of exposure</b>		
Exposure via unknown route	1	0
<b>Peripheral nerve injuries</b>		
Brachial plexus injury	1	0
Ulnar nerve injury	4	0
<b>Poisoning and toxicity</b>		
Alcohol poisoning	1	0
Poisoning	8	0
Toxicity to various agents	2	0
<b>Product administration errors and issues</b>		
Accidental overdose	3	0
Contraindicated product administered	2	0
Expired product administered	9	0
Inappropriate schedule of product administration	90	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

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Product administered at inappropriate site	8	0
Product administered to patient of inappropriate age	1	0
Product administration error	4	0
Product dose omission issue	3	0
Wrong product administered	13	0
<b>Product confusion errors and issues</b>		
Product label confusion	1	0
<b>Product dispensing errors and issues</b>		
Product dispensing error	3	0
<b>Product monitoring errors and issues</b>		
Drug monitoring procedure incorrectly performed	1	0
<b>Product preparation errors and issues</b>		
Product preparation error	1	0
Product preparation issue	5	0
<b>Product prescribing errors and issues</b>		
Contraindicated product prescribed	2	0
<b>Product selection errors and issues</b>		
Product selection error	2	0
<b>Radiation injuries</b>		
Sunburn	14	0
<b>Renal and urinary tract injuries NEC</b>		
Foreign body in urogenital tract	1	0
<b>Site specific injuries NEC</b>		
Face crushing	1	0
Head injury	22	0
Limb crushing injury	2	0
Limb injury	48	0
Nasal injury	1	0
Neck injury	1	0
<b>Skin injuries NEC</b>		
Contusion	614	0
Nail avulsion	1	0
Scar	6	0
Scratch	4	0
Skin abrasion	5	0
Skin injury	1	0
Skin wound	2	0
Subcutaneous haematoma	1	0
<b>Skull fractures, facial bone fractures and dislocations</b>		
Fractured skull depressed	1	0
<b>Spinal fractures and dislocations</b>		
Spinal fracture	3	0
<b>Stoma complications</b>		
Gastrointestinal stoma complication	1	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
<b>Thermal burns</b>		
Airway burns	1	0
Burn oesophageal	1	0
Burn of internal organs	1	0
Burn oral cavity	1	0
Burns second degree	4	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Thermal burn	12	0
Thermal burns of eye	8	0
<b>Underdoses NEC</b>		
Underdose	6	0
<b>Vaccination related complications</b>		
Adverse event following immunisation	1	0
Vaccination complication	40	0
<b>Injuries SOC TOTAL</b>	<b>2600</b>	<b>2</b>

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Investigations</b>		
<i><b>Adrenal cortex tests</b></i>		
Cortisol decreased	2	0
<i><b>Adrenal medulla tests</b></i>		
Epinephrine increased	1	0
<i><b>Auditory and vestibular diagnostic procedures</b></i>		
Acoustic stimulation tests	5	0
Audiogram abnormal	1	0
<i><b>Autoimmunity analyses</b></i>		
Antinuclear antibody	1	0
Antinuclear antibody increased	1	0
Rheumatoid factor	3	0
<i><b>Blood counts NEC</b></i>		
Blood count	4	0
Blood count abnormal	2	0
<i><b>Blood gas and acid base analyses</b></i>		
Blood lactic acid	3	0
Blood lactic acid decreased	1	0
Blood lactic acid increased	2	0
Blood pH	6	0
Blood pH increased	6	0
Oxygen consumption decreased	1	0
Oxygen saturation	5	0
Oxygen saturation decreased	43	0
<i><b>Bone marrow and immune tissue histopathology procedures</b></i>		
Aspiration bone marrow	1	0
Biopsy lymph gland	1	0
<i><b>Bone marrow and immune tissue imaging procedures</b></i>		
Lymph nodes scan abnormal	1	0
Scan lymph nodes	1	0
<i><b>Carbohydrate tolerance analyses (incl diabetes)</b></i>		
Blood glucose	6	0
Blood glucose abnormal	9	0
Blood glucose decreased	22	0
Blood glucose fluctuation	13	0
Blood glucose increased	77	0
Glycosylated haemoglobin increased	1	0
<i><b>Cardiac auscultatory investigations</b></i>		
Cardiac murmur	10	0
Heart sounds	2	0
Heart sounds abnormal	2	0
<i><b>Cardiac function diagnostic procedures</b></i>		
Cardiac output	1	0
Central venous pressure	1	0
Stroke volume decreased	1	0
<i><b>Cell marker analyses</b></i>		
Prostatic specific antigen increased	2	0
<i><b>Central nervous system imaging procedures</b></i>		
Computerised tomogram head	3	0
Magnetic resonance imaging head	10	0
Magnetic resonance imaging head abnormal	1	0
<i><b>Cerebrospinal fluid tests (excl microbiology)</b></i>		
CSF pressure	1	0
<i><b>Chemistry analyses NEC</b></i>		



## Case Series Drug Analysis Print

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

Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Inflammatory marker increased	3	0
<b><i>Cholesterol analyses</i></b>		
Blood cholesterol increased	3	0
Remnant-like lipoprotein particles	3	0
<b><i>Coagulation and bleeding analyses</i></b>		
Activated partial thromboplastin time prolonged	14	0
Activated partial thromboplastin time shortened	1	0
Bleeding time	1	0
Bleeding time abnormal	1	0
Bleeding time prolonged	2	0
Blood thromboplastin	1	0
Clot retraction	1	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	5	0
Coagulation time shortened	1	0
Fibrin D dimer increased	5	0
International normalised ratio abnormal	4	0
International normalised ratio decreased	18	0
International normalised ratio fluctuation	1	0
International normalised ratio increased	43	0
<b><i>ECG investigations</i></b>		
Electrocardiogram	2	0
Electrocardiogram ST segment elevation	3	0
Electrocardiogram T wave inversion	3	0
Electrocardiogram abnormal	9	0
<b><i>Endocrine analyses and imaging NEC</i></b>		
Hormone level abnormal	12	0
<b><i>Faecal analyses NEC</i></b>		
Faecal calprotectin	2	0
Faecal calprotectin increased	4	0
<b><i>Fertility analyses</i></b>		
Infertility tests	1	0
<b><i>Foetal and neonatal diagnostic procedures</i></b>		
Foetal heart rate abnormal	1	1
Foetal non-stress test	1	0
<b><i>Gastrointestinal and abdominal imaging procedures</i></b>		
Computerised tomogram abdomen	1	0
Sigmoidoscopy abnormal	1	0
<b><i>Gastrointestinal, pancreatic and APUD hormone analyses</i></b>		
Blood insulin	1	0
Blood insulin decreased	1	0
<b><i>Haematological analyses NEC</i></b>		
Plasma viscosity	1	0
Red blood cell sedimentation rate increased	5	0
<b><i>Heart rate and pulse investigations</i></b>		
Carotid pulse	1	0
Heart rate	201	0
Heart rate abnormal	26	0
Heart rate decreased	28	0
Heart rate increased	427	0
Heart rate irregular	77	0
Pulse abnormal	11	0
Pulse pressure increased	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Radial pulse abnormal	1	0
Sinus rhythm	2	0
<b>Imaging procedures NEC</b>		
Computerised tomogram	1	0
Magnetic resonance imaging	1	0
Magnetic resonance imaging abnormal	1	0
<b>Immunoglobulin analyses</b>		
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	1	0
<b>Immunology analyses NEC</b>		
Antibody test	3	0
Immunology test	6	0
<b>Immunology skin tests NEC</b>		
Skin test positive	1	0
<b>Investigations NEC</b>		
Blood test	8	0
Blood test abnormal	17	0
False positive investigation result	1	0
Laboratory test	1	0
Polymerase chain reaction positive	33	0
Systemic lupus erythematosus disease activity index increased	1	0
<b>Liver function analyses</b>		
Alanine aminotransferase increased	11	0
Aspartate aminotransferase increased	1	0
Blood bilirubin increased	2	0
Gamma-glutamyltransferase increased	3	0
Hepatic enzyme increased	4	0
Liver function test	1	0
Liver function test abnormal	18	0
Liver function test increased	11	0
Transaminases increased	2	0
<b>Metabolism tests NEC</b>		
Blood ketone body	3	0
Blood ketone body increased	1	0
Blood uric acid increased	1	0
Brain natriuretic peptide increased	1	0
Ubiquinone	1	0
<b>Microbiology and serology tests NEC</b>		
Culture negative	1	0
<b>Mineral and electrolyte analyses</b>		
Blood copper increased	1	0
Blood iron	1	0
Blood iron decreased	2	0
Blood magnesium decreased	1	0
Blood phosphorus	1	0
Blood phosphorus decreased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	4	0
Blood potassium increased	1	0
Blood sodium decreased	7	0
Serum ferritin decreased	1	0
Serum ferritin increased	1	0

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Report Run Date: 26-Jun-2021

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
<b><i>Musculoskeletal and soft tissue imaging procedures</i></b>		
Skull X-ray	5	0
<b><i>Musculoskeletal and soft tissue tests NEC</i></b>		
Swollen joint count increased	1	0
<b><i>Mycobacteria identification and serology</i></b>		
Tuberculin test positive	1	0
<b><i>Neurologic diagnostic procedures</i></b>		
Coma scale abnormal	3	0
Hoover's sign of leg paresis	1	0
Lumbar puncture	1	0
Temperature perception test abnormal	1	0
Temperature perception test increased	1	0
<b><i>Ophthalmic function diagnostic procedures</i></b>		
Corneal reflex decreased	1	0
Intraocular pressure increased	6	0
<b><i>Physical examination procedures and organ system status</i></b>		
Body temperature	173	0
Body temperature abnormal	25	0
Body temperature decreased	28	0
Body temperature fluctuation	19	0
Body temperature increased	275	0
Body temperature normal	1	0
Breath sounds abnormal	1	0
General physical condition abnormal	1	0
Grip strength	2	0
Grip strength decreased	11	0
Head lag	3	0
Lymph node palpable	27	0
Menstruation normal	1	0
Muscle strength abnormal	1	0
Ophthalmological examination	2	0
Palpatory finding abnormal	1	0
Product residue present	2	0
Psoriasis area severity index decreased	1	0
Respiratory rate	6	0
Respiratory rate decreased	8	0
Respiratory rate increased	25	0
Skin temperature	25	0
Temperature difference of extremities	6	0
Weight	1	0
Weight decreased	45	0
Weight increased	7	0
<b><i>Pituitary analyses anterior</i></b>		
Blood growth hormone	2	0
Blood prolactin increased	1	0
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	2	0
<b><i>Platelet analyses</i></b>		
Mean platelet volume decreased	1	0
Platelet count	1	0
Platelet count decreased	47	0
Platelet count increased	1	0
<b><i>Protein analyses NEC</i></b>		

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Investigations</b>		
Investigations cont'd		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	11	0
<b>Red blood cell analyses</b>		
Haematocrit	1	0
Haemoglobin decreased	10	0
Red blood cell count decreased	1	0
<b>Renal function analyses</b>		
Blood creatinine increased	1	0
Glomerular filtration rate decreased	2	0
<b>Reproductive hormone analyses</b>		
False negative pregnancy test	5	0
Pregnancy test	8	0
Pregnancy test positive	1	0
<b>Reproductive organ and breast histopathology procedures</b>		
Smear cervix	1	0
<b>Reproductive organ and breast imaging procedures</b>		
Hysteroscopy	1	0
<b>Respiratory and pulmonary function diagnostic procedures</b>		
Forced expiratory volume increased	2	0
Maximal voluntary ventilation	1	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	4	0
Pulmonary function test	2	0
Vital capacity	1	0
<b>Respiratory tract and thoracic histopathology procedures</b>		
Sputum abnormal	3	0
<b>Respiratory tract and thoracic imaging procedures</b>		
Chest X-ray	17	0
Chest X-ray normal	1	0
Chest scan	1	0
Computerised tomogram thorax	1	0
<b>Skeletal and cardiac muscle analyses</b>		
Blood creatine phosphokinase increased	4	0
Troponin	1	0
Troponin increased	4	0
<b>Therapeutic drug monitoring analyses</b>		
Analgesic drug level	3	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
<b>Thyroid analyses</b>		
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
<b>Tissue enzyme analyses NEC</b>		
Blood alkaline phosphatase increased	2	0
<b>Toxicology laboratory analyses</b>		
Drug screen positive	2	0
Opiates	1	0

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
<b>Urinalysis NEC</b>		
Blood urine	9	0
Blood urine present	28	0
Cells in urine	1	0
Glucose urine present	1	0
Urine analysis abnormal	4	0
pH urine	5	0
pH urine increased	1	0
<b>Urinary tract function analyses NEC</b>		
Urine output	10	0
Urine output decreased	5	0
Urine output increased	4	0
<b>Urinary tract imaging procedures</b>		
Cystoscopy	2	0
<b>Vascular imaging procedures NEC</b>		
Venogram	1	0
<b>Vascular tests NEC (incl blood pressure)</b>		
Blood pressure abnormal	4	0
Blood pressure decreased	40	0
Blood pressure diastolic	1	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	2	0
Blood pressure increased	146	0
Blood pressure measurement	26	0
Blood pressure normal	1	0
Blood pressure systolic	1	0
Blood pressure systolic decreased	3	0
Blood pressure systolic increased	1	0
<b>Virus identification and serology</b>		
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	5	0
SARS-CoV-2 antibody test negative	11	0
SARS-CoV-2 antibody test positive	2	0
SARS-CoV-2 test	21	0
SARS-CoV-2 test false negative	1	0
SARS-CoV-2 test false positive	2	0
SARS-CoV-2 test negative	4	0
SARS-CoV-2 test positive	81	0
Viral test	4	0
<b>Vitamin analyses</b>		
Blood folate decreased	3	0
Vitamin B12	1	0
Vitamin B12 decreased	1	0
Vitamin D	2	0
Vitamin D decreased	1	0
<b>Water and electrolyte analyses NEC</b>		
Volume blood	1	0
<b>White blood cell analyses</b>		
Lymphocyte count	1	0
Lymphocyte count decreased	1	0

## Case Series Drug Analysis Print

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Report Run Date: 26-Jun-2021

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name		Total	Fatal
<b>Investigations</b>	Investigations cont'd		
Neutrophil count		1	0
Neutrophil count decreased		3	0
White blood cell count		1	0
White blood cell count decreased		9	0
White blood cell count increased		3	0
<b>Investigations SOC TOTAL</b>		<b>2702</b>	<b>2</b>

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	11	0
Decreased appetite	742	0
Diet refusal	1	0
Eating disorder symptom	1	0
Food craving	8	0
Food refusal	6	0
Hyperphagia	3	0
Hypophagia	11	0
Increased appetite	14	0
Salt craving	2	0
<i><b>Calcium metabolism disorders</b></i>		
Hypocalcaemia	3	0
Tetany	2	0
<i><b>Diabetes mellitus (incl subtypes)</b></i>		
Diabetes mellitus	31	0
Diabetes mellitus inadequate control	7	1
Increased insulin requirement	1	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	1	0
Type 1 diabetes mellitus	11	0
Type 2 diabetes mellitus	2	0
<i><b>Diabetic complications NEC</b></i>		
Diabetic complication	2	0
Diabetic ketoacidosis	11	0
Diabetic ketosis	1	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	62	0
<i><b>Electrolyte imbalance NEC</b></i>		
Fluid imbalance	1	0
<i><b>Fat soluble vitamin deficiencies and disorders</b></i>		
Vitamin D deficiency	1	0
<i><b>Fluid intake increased</b></i>		
Polydipsia	5	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Alcohol intolerance	2	0
Dairy intolerance	1	0
Food intolerance	4	0
Gluten sensitivity	2	0
Histamine intolerance	3	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	6	0
Abnormal weight gain	7	0
Cachexia	1	0
Feeding disorder	38	0
Food aversion	6	0
Neonatal insufficient breast milk syndrome	2	0
Overweight	1	0
Poor feeding infant	6	0
Weight loss poor	1	0
<i><b>Hyperglycaemic conditions NEC</b></i>		
Hyperglycaemia	58	0
Insulin resistance	4	0

## Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Metabolic disorders</b> Metabolic disorders cont'd		
<b><i>Hypoglycaemic conditions NEC</i></b>		
Glycopenia	1	0
Hypoglycaemia	64	0
Postprandial hypoglycaemia	1	0
<b><i>Iron deficiencies</i></b>		
Iron deficiency	5	0
<b><i>Lipid metabolism and deposit disorders NEC</i></b>		
Body fat disorder	1	0
<b><i>Metabolic acidoses (excl diabetic acidoses)</i></b>		
Ketoacidosis	4	0
Metabolic acidosis	2	0
<b><i>Mixed acid-base disorders</i></b>		
Acidosis	3	0
<b><i>Potassium imbalance</i></b>		
Hyperkalaemia	2	0
Hypokalaemia	3	0
Hypokalaemic syndrome	1	0
<b><i>Sodium imbalance</i></b>		
Hyponatraemia	6	0
Hyponatraemic syndrome	2	0
<b><i>Sugar intolerance (excl glucose intolerance)</i></b>		
Lactose intolerance	1	0
<b><i>Total fluid volume decreased</i></b>		
Dehydration	106	0
<b><i>Total fluid volume increased</i></b>		
Fluid retention	31	0
Hypervolaemia	1	0
<b><i>Vitamin deficiencies NEC</i></b>		
Hypovitaminosis	3	0
<b><i>Water soluble vitamin deficiencies</i></b>		
Folate deficiency	1	0
Vitamin B12 deficiency	1	0
<b>Metabolic disorders SOC TOTAL</b>	<b>1322</b>	<b>1</b>



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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	156	0
Arthropathy	18	0
Autoimmune arthritis	3	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	1	0
Polyarthritis	13	0
Rheumatic fever	1	0
Sacroiliitis	3	0
Seronegative arthritis	1	0
<i><b>Bone disorders NEC</b></i>		
Jaw disorder	3	0
Medial tibial stress syndrome	3	0
Osteitis	2	0
Osteonecrosis of jaw	2	0
Spinal disorder	1	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	226	0
Bone swelling	4	0
Coccydynia	2	0
Pain in jaw	209	0
Pubic pain	2	0
Spinal pain	36	0
<i><b>Bursal disorders</b></i>		
Bursitis	37	0
<i><b>Cartilage disorders</b></i>		
Chondritis	1	0
Costochondritis	32	0
Osteochondritis	1	0
Polychondritis	2	0
<i><b>Connective tissue disorders NEC</b></i>		
Connective tissue disorder	1	0
Polymyalgia rheumatica	36	0
Reynold's syndrome	1	0
Sjogren's syndrome	4	0
<i><b>Crystal arthropathic disorders</b></i>		
Crystal arthropathy	1	0
<i><b>Epiphyseal disorders</b></i>		
Epiphyses premature fusion	1	0
<i><b>Extremity deformities</b></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><b>Intervertebral disc disorders NEC</b></i>		
Intervertebral disc protrusion	1	0
<i><b>Joint related disorders NEC</b></i>		
Chondromalacia	1	0
Joint deposit	1	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Joint destruction	1	0
Joint laxity	3	0
Joint lock	14	0
Patellofemoral pain syndrome	1	0
Periarthritis	76	0
Rotator cuff syndrome	6	0
Temporomandibular joint syndrome	5	0
<b>Joint related signs and symptoms</b>		
Arthralgia	5557	0
Jaw clicking	4	0
Joint effusion	12	0
Joint noise	18	0
Joint range of motion decreased	9	0
Joint stiffness	137	0
Joint swelling	282	0
Joint vibration	1	0
Joint warmth	10	0
Loose body in joint	1	0
<b>Ligament disorders</b>		
Symphysiolysis	1	0
<b>Lupus erythematosus (incl subtypes)</b>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	13	0
<b>Metabolic bone disorders</b>		
Osteopenia	1	0
Osteoporosis	1	0
<b>Muscle infections and inflammations</b>		
Antisynthetase syndrome	1	0
Myositis	16	0
Polymyositis	3	0
<b>Muscle pains</b>		
Fibromyalgia	61	0
Myalgia	7113	0
Myalgia intercostal	1	0
Myofascial pain syndrome	6	0
<b>Muscle related signs and symptoms NEC</b>		
Haematoma muscle	1	0
Muscle atrophy	9	0
Muscle discomfort	2	0
Muscle disorder	3	0
Muscle fatigue	221	0
Muscle haemorrhage	1	0
Muscle mass	2	0
Muscle spasms	730	0
Muscle swelling	14	0
Muscle tightness	43	0
Muscle twitching	201	0
<b>Muscle tone abnormalities</b>		
Muscle rigidity	9	0
Nuchal rigidity	9	0
Torticollis	3	0
Trismus	19	0
<b>Muscle weakness conditions</b>		

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Muscular weakness	503	0
<b>Musculoskeletal and connective tissue conditions NEC</b>		
Back disorder	1	0
Limb mass	8	0
Mandibular mass	2	0
Mastication disorder	3	0
Mobility decreased	45	0
Musculoskeletal disorder	8	0
Musculoskeletal stiffness	763	0
Posture abnormal	1	0
Weight bearing difficulty	1	0
<b>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</b>		
Head deformity	1	0
<b>Musculoskeletal and connective tissue infections and inflammations NEC</b>		
Dactylitis	1	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	5	0
<b>Musculoskeletal and connective tissue pain and discomfort</b>		
Back pain	1323	0
Flank pain	25	0
Limb discomfort	910	0
Musculoskeletal chest pain	107	0
Musculoskeletal discomfort	56	0
Musculoskeletal pain	33	0
Neck pain	1099	0
Pain in extremity	7546	0
Rheumatic disorder	7	0
<b>Myopathies</b>		
Myopathy	4	0
Rhabdomyolysis	6	0
<b>Osteoarthropathies</b>		
Nodal osteoarthritis	1	0
Osteoarthritis	26	0
<b>Psoriatic arthropathies</b>		
Psoriatic arthropathy	11	0
<b>Rheumatoid arthropathies</b>		
Rheumatoid arthritis	78	0
<b>Soft tissue disorders NEC</b>		
Axillary mass	149	0
Fluctuance	1	0
Groin pain	70	0
Neck mass	16	0
Purple glove syndrome	1	0
Soft tissue disorder	1	0
Soft tissue swelling	3	0
<b>Spine and neck deformities</b>		
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
<b>Spondyloarthropathies</b>		

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Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
Ankylosing spondylitis	6	0
Arthritis reactive	22	0
Spondylitis	1	0
<b>Synovial disorders</b>		
Synovial cyst	11	0
Synovitis	4	0
<b>Tendon disorders</b>		
Enthesopathy	1	0
Tendon disorder	1	0
Tendon pain	11	0
Tendonitis	18	0
Tenosynovitis	2	0
Tenosynovitis stenosaurs	1	0
Trigger finger	13	0
<b>Trunk deformities</b>		
Drooping shoulder syndrome	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>28359</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<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	26	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>Colorectal neoplasms malignant</i>		
Colon cancer	1	0
Colorectal cancer	1	0
Rectal cancer	1	0
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Thyroid neoplasm	1	0
<i>Endometrial neoplasms malignant</i>		
Endometrial cancer	1	0
<i>Follicular lymphomas</i>		
Primary gastrointestinal follicular lymphoma	1	0
<i>Gastric neoplasms malignant</i>		
Gastric cancer	1	1
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	2	0
<i>Hodgkin's disease NEC</i>		
Hodgkin's disease	2	0
<i>Islet cell neoplasms and APUDoma NEC</i>		
Pancreatic neuroendocrine tumour	1	0
<i>Leukaemias acute NEC</i>		
Acute leukaemia	1	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	2	0
<i>Lip and oral cavity neoplasms malignant</i>		
Lip and/or oral cavity cancer recurrent	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	15	1
<i>Metastases to specified sites</i>		
Metastases to liver	1	0
Metastases to lymph nodes	5	0
<i>Metastases to unknown and unspecified sites</i>		
Metastasis	1	0
<i>Myelodysplastic syndromes</i>		
Myelodysplastic syndrome	1	0
<i>Myeloproliferative disorders (excl leukaemias)</i>		
Essential thrombocythaemia	1	0
<i>Neoplasms benign site unspecified NEC</i>		
Adenoma benign	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Neoplasm malignant	2	0

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

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Reaction Name		Total	Fatal
<b>Neoplasms</b>	Neoplasms cont'd		
<i>Uterine neoplasms benign</i>			
Uterine leiomyoma		5	0
<b>Neoplasms SOC TOTAL</b>		<b>148</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Abnormal reflexes</b></i>		
Areflexia	4	0
Extensor plantar response	1	0
Hyperreflexia	2	0
Hyporeflexia	5	0
<i><b>Abnormal sleep-related events</b></i>		
Sleep paralysis	11	0
<i><b>Absence seizures</b></i>		
Petit mal epilepsy	17	0
<i><b>Acute polyneuropathies</b></i>		
Guillain-Barre syndrome	39	2
Subacute inflammatory demyelinating polyneuropathy	1	0
<i><b>Autonomic nervous system disorders</b></i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	5	0
Horner's syndrome	1	0
<i><b>Central nervous system aneurysms and dissections</b></i>		
Intracranial aneurysm	1	0
Vertebral artery dissection	1	0
<i><b>Central nervous system haemorrhages and cerebrovascular accidents</b></i>		
Brain stem infarction	1	1
Brain stem stroke	1	0
Carotid artery thrombosis	2	0
Cerebellar haemorrhage	1	0
Cerebellar infarction	2	0
Cerebellar ischaemia	1	0
Cerebellar stroke	3	0
Cerebral artery embolism	3	1
Cerebral artery occlusion	1	0
Cerebral artery thrombosis	3	0
Cerebral haemorrhage	30	6
Cerebral infarction	23	1
Cerebral thrombosis	7	1
Cerebrovascular accident	267	12
Embolitic stroke	6	0
Haemorrhage intracranial	8	2
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	8	3
Internal capsule infarction	1	0
Intracranial haematoma	1	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	31	1
Lacunar infarction	2	0
Lacunar stroke	2	0
Lateral medullary syndrome	1	0
Subarachnoid haemorrhage	10	3
Thalamic infarction	1	0
Thrombotic stroke	2	0
<i><b>Central nervous system inflammatory disorders NEC</b></i>		
Gliosis	1	0
<i><b>Central nervous system vascular disorders NEC</b></i>		
Brain hypoxia	1	1
Central nervous system vasculitis	1	0



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Cerebral small vessel ischaemic disease	1	0
Cerebrovascular disorder	1	0
Reversible cerebral vasoconstriction syndrome	1	0
<b>Cerebrovascular venous and sinus thrombosis</b>		
Cerebral venous sinus thrombosis	29	1
Cerebral venous thrombosis	4	0
Superior sagittal sinus thrombosis	3	0
Transverse sinus thrombosis	1	0
<b>Cervical spinal cord and nerve root disorders</b>		
Cervicobrachial syndrome	3	0
<b>Choreiform movements</b>		
Chorea	2	0
<b>Chronic polyneuropathies</b>		
Demyelinating polyneuropathy	1	0
<b>Coma states</b>		
Coma	7	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
<b>Coordination and balance disturbances</b>		
Ataxia	6	0
Balance disorder	219	0
Coordination abnormal	27	0
Dysdiadochokinesis	1	0
Dysstasia	31	0
Nystagmus	8	0
<b>Cortical dysfunction NEC</b>		
Aphasia	42	0
Apraxia	1	0
Neurologic neglect syndrome	1	0
Sensory processing disorder	1	0
Visuospatial deficit	1	0
<b>Cranial nerve disorders NEC</b>		
Cranial nerve disorder	2	0
<b>Dementia (excl Alzheimer's type)</b>		
Dementia	9	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
<b>Demyelinating disorders NEC</b>		
Acute disseminated encephalomyelitis	4	0
Clinically isolated syndrome	1	0
Demyelination	8	0
Neuromyelitis optica spectrum disorder	1	0
<b>Disturbances in consciousness NEC</b>		
Altered state of consciousness	9	0
Consciousness fluctuating	2	0
Depressed level of consciousness	28	1
Lethargy	1487	0
Loss of consciousness	304	0
Sedation	5	0
Somnolence	607	0
Stupor	3	0
Syncope	1019	0
<b>Disturbances in sleep phase rhythm</b>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Irregular sleep phase	1	0
Irregular sleep wake rhythm disorder	1	0
<b>Dyskinesias and movement disorders NEC</b>		
Akathisia	2	0
Bradykinesia	7	0
Clumsiness	10	0
Dyskinesia	38	0
Extrapyramidal disorder	1	0
Fine motor skill dysfunction	7	0
Hyperkinesia	3	0
Hypokinesia	31	1
Motor dysfunction	2	0
Movement disorder	31	0
Psychomotor hyperactivity	15	0
Synkinesis	1	0
Tardive dyskinesia	2	0
<b>Dystonias</b>		
Dystonia	13	0
Writer's cramp	1	0
<b>Encephalitis NEC</b>		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	1	0
<b>Encephalopathies NEC</b>		
Encephalopathy	3	0
Hashimoto's encephalopathy	1	0
Posterior reversible encephalopathy syndrome	1	0
<b>Eye movement disorders</b>		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	5	0
IVth nerve paralysis	1	0
VIth nerve paralysis	8	0
<b>Facial cranial nerve disorders</b>		
Bell's palsy	295	0
Facial nerve disorder	4	0
Facial paralysis	238	0
Facial paresis	64	0
Facial spasm	26	0
<b>Generalised tonic-clonic seizures</b>		
Generalised tonic-clonic seizure	23	0
<b>Headaches NEC</b>		
Cervicogenic headache	3	0
Cluster headache	130	0
Cold-stimulus headache	11	0
Drug withdrawal headache	2	0
Exertional headache	6	0
External compression headache	1	0
Headache	16824	0
Medication overuse headache	2	0
New daily persistent headache	4	0
Occipital neuralgia	6	0
Ophthalmoplegic migraine	1	0
Primary cough headache	3	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Primary headache associated with sexual activity	1	0
Sinus headache	229	0
Tension headache	333	0
Thunderclap headache	4	0
Vascular headache	11	0
<b>Hydrocephalic conditions</b>		
Hydrocephalus	1	0
<b>Hypoglossal nerve disorders</b>		
Tongue paralysis	1	0
<b>Increased intracranial pressure disorders</b>		
Brain oedema	2	0
Idiopathic intracranial hypertension	3	0
Intracranial pressure increased	1	0
<b>Intellectual disabilities</b>		
Intellectual disability	1	0
<b>Lumbar spinal cord and nerve root disorders</b>		
Sciatica	46	0
<b>Memory loss (excl dementia)</b>		
Amnesia	90	0
Memory impairment	77	0
Retrograde amnesia	1	0
Transient global amnesia	6	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	46	0
Cognitive linguistic deficit	1	0
Disturbance in attention	179	0
Mental impairment	29	0
<b>Migraine headaches</b>		
Hemiplegic migraine	14	0
Migraine	1634	0
Migraine with aura	115	0
Migraine without aura	12	0
Ophthalmic migraine	4	0
Retinal migraine	19	0
Typical aura without headache	5	0
Vestibular migraine	11	0
<b>Mixed cranial nerve disorders</b>		
Bulbar palsy	1	0
<b>Mononeuropathies</b>		
Carpal tunnel syndrome	13	0
Cubital tunnel syndrome	1	0
Meralgia paraesthetica	1	0
Mononeuropathy	1	0
Nerve compression	10	0
Peripheral nerve lesion	1	0
Peroneal nerve palsy	6	0
Sciatic nerve neuropathy	2	0
Ulnar neuritis	1	0
<b>Multiple sclerosis acute and progressive</b>		
Band sensation	1	0
Multiple sclerosis	21	0
Multiple sclerosis relapse	17	0
Tumefactive multiple sclerosis	1	1

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b><i>Muscle tone abnormal</i></b>		
Hypotonia	11	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
<b><i>Myelitis (incl infective)</i></b>		
Myelitis transverse	20	0
<b><i>Narcolepsy and hypersomnia</i></b>		
Cataplexy	1	0
Hypersomnia	55	0
Narcolepsy	3	0
<b><i>Nervous system disorders NEC</i></b>		
Central nervous system lesion	2	0
Nervous system disorder	6	0
<b><i>Neurologic visual problems NEC</i></b>		
Hemianopia	1	0
Hemianopia homonymous	1	0
Quadrantanopia	1	0
Tunnel vision	11	0
<b><i>Neurological signs and symptoms NEC</i></b>		
Clonus	2	0
Decerebrate posture	1	0
Dizziness	5842	0
Dizziness exertional	28	0
Dizziness postural	483	0
Drooling	14	0
Fontanelle bulging	1	0
Head discomfort	174	0
Hyporesponsive to stimuli	2	0
Inability to crawl	2	0
Infant irritability	2	0
Myoclonus	14	0
Neurological symptom	28	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	10	0
Presyncope	339	0
Sensory overload	2	0
Slow response to stimuli	2	0
Tongue biting	2	0
Unresponsive to stimuli	30	0
<b><i>Neuromuscular disorders NEC</i></b>		
Muscle contractions involuntary	12	0
Muscle spasticity	9	0
Neuromuscular pain	2	0
<b><i>Neuromuscular junction dysfunction</i></b>		
Myasthenia gravis	7	0
Myasthenia gravis crisis	2	0
<b><i>Olfactory nerve disorders</i></b>		
Anosmia	141	0
Hyposmia	10	0
Parosmia	147	0
<b><i>Optic nerve disorders NEC</i></b>		
Optic neuritis	19	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
<b><i>Paraesthesias and dysaesthesias</i></b>		
Burning feet syndrome	5	0
Burning sensation	292	0
Dysaesthesia	5	0
Formication	29	0
Hand-arm vibration syndrome	2	0
Hemiparaesthesia	2	0
Hyperaesthesia	56	0
Hypoaesthesia	1596	0
Paraesthesia	2252	0
Reversed hot-cold sensation	2	0
Synaesthesia	1	0
<b><i>Paralysis and paresis (excl cranial nerve)</i></b>		
Diplegia	6	1
Hemiparesis	29	0
Hemiplegia	23	0
Locked-in syndrome	1	0
Monoparesis	40	0
Monoplegia	35	0
Paralysis	72	0
Paraparesis	3	0
Paresis	4	0
<b><i>Parkinson's disease and parkinsonism</i></b>		
Freezing phenomenon	7	0
Parkinson's disease	3	0
Parkinsonian gait	1	0
Parkinsonism	4	0
Reduced facial expression	7	0
<b><i>Partial complex seizures</i></b>		
Dreamy state	6	0
Focal dyscognitive seizures	1	0
Temporal lobe epilepsy	1	0
<b><i>Peripheral neuropathies NEC</i></b>		
Neuralgic amyotrophy	1	0
Neuritis	5	0
Neuropathy peripheral	61	0
Peripheral sensory neuropathy	7	0
Thoracic outlet syndrome	1	0
<b><i>Seizures and seizure disorders NEC</i></b>		
Atonic seizures	4	0
Change in seizure presentation	1	0
Clonic convulsion	2	0
Epilepsy	115	0
Epileptic aura	2	0
Epileptic encephalopathy	1	0
Febrile convulsion	14	0
Partial seizures	13	0
Post stroke seizure	1	0
Psychogenic seizure	7	0
Seizure	327	0
Seizure anoxic	1	0
Seizure cluster	4	0
Seizure like phenomena	1	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Status epilepticus	42	0
Tonic clonic movements	2	0
Tonic convulsion	13	0
Tonic posturing	1	0
<b>Sensory abnormalities NEC</b>		
Ageusia	317	0
Allodynia	12	0
Aura	11	0
Complex regional pain syndrome	2	0
Dysgeusia	841	0
Electric shock sensation	19	0
Hypergeusia	1	0
Hypogeusia	1	0
Loss of proprioception	3	0
Neuralgia	303	0
Persistent genital arousal disorder	1	0
Phantom limb syndrome	3	0
Post herpetic neuralgia	13	0
Restless legs syndrome	63	0
Sensory disturbance	46	0
Sensory loss	40	0
Taste disorder	171	0
Visual perseveration	1	0
<b>Sleep disturbances NEC</b>		
Sleep deficit	2	0
Sudden onset of sleep	1	0
<b>Speech and language abnormalities</b>		
Dysarthria	102	0
Incoherent	6	0
Language disorder	1	0
Repetitive speech	1	0
Slow speech	8	0
Speech disorder	31	0
<b>Spinal cord and nerve root disorders NEC</b>		
Radiculitis brachial	7	0
Radiculopathy	4	0
<b>Structural brain disorders NEC</b>		
Brain injury	3	2
Hyperintensity in brain deep nuclei	1	0
<b>Transient cerebrovascular events</b>		
Transient ischaemic attack	101	1
<b>Tremor (excl congenital)</b>		
Action tremor	1	0
Essential tremor	3	0
Head titubation	5	0
Resting tremor	2	0
Tremor	967	0
<b>Trigeminal disorders</b>		
Facial neuralgia	13	0
Numb chin syndrome	1	0
Trigeminal nerve disorder	1	0
Trigeminal neuralgia	29	0
<b>Vertigos NEC</b>		

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Vertigo CNS origin	1	0
Nervous system disorders SOC TOTAL	40874	42

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Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions not specified as induced or spontaneous</i>		
Abortion missed	2	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	151	3
Abortion threatened	1	0
<i>Foetal complications NEC</i>		
Foetal hypokinesia	2	0
<i>Foetal growth complications</i>		
Foetal growth restriction	1	1
<i>Foetal position and presentation abnormalities</i>		
High foetal head	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	4	1
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	1	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	1	0
Premature labour	1	0
Premature rupture of membranes	1	0
<i>Maternal complications of labour NEC</i>		
Uterine hypertonus	2	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	2	0
Ectopic pregnancy	1	0
Morning sickness	13	0
Preterm premature rupture of membranes	2	0
<i>Newborn complications NEC</i>		
Neonatal disorder	1	0
<i>Normal newborn status</i>		
Normal newborn	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	18	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	4	0
<i>Stillbirth and foetal death</i>		
Foetal death	5	1
Stillbirth	4	1
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	2	0
Pregnancy on contraceptive	1	0
Pregnancy on oral contraceptive	1	0
Pregnancy with contraceptive device	1	0
Pregnancy with implant contraceptive	2	0
Unintended pregnancy	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>227</b>	<b>7</b>



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Reaction Name	Total	Fatal
<b><i>Device issues NEC</i></b>		
Device connection issue	1	0
Device issue	2	0
<b><i>Device malfunction events NEC</i></b>		
Device infusion issue	1	0
Device pacing issue	1	0
Device stimulation issue	1	0
Oversensing	13	0
Thrombosis in device	5	0
<b><i>Device physical property and chemical issues</i></b>		
Device defective	6	0
Device kink	1	0
Needle issue	2	0
<b><i>Product contamination and sterility issues</i></b>		
Product contamination	6	0
Product contamination physical	1	0
<b><i>Product physical issues</i></b>		
Liquid product physical issue	7	0
Product odour abnormal	1	0
Product physical issue	2	0
Product taste abnormal	6	0
<b><i>Product quality issues NEC</i></b>		
Product origin unknown	5	0
<b><i>Product supply and availability issues</i></b>		
Product availability issue	1	0
<b>null SOC TOTAL</b>	<b>62</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	9	0
Behaviour disorder	1	0
Breath holding	1	0
Staring	3	0
<b><i>Adjustment disorders</i></b>		
Adjustment disorder with depressed mood	2	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	5	0
Constricted affect	1	0
Flat affect	4	0
Inappropriate affect	10	0
<b><i>Amnesic symptoms</i></b>		
Paramnesia	3	0
<b><i>Anxiety symptoms</i></b>		
Agitation	52	0
Anxiety	384	0
Immunisation anxiety related reaction	1	0
Nervousness	110	0
Stress	30	0
Tension	20	0
<b><i>Attention deficit and disruptive behaviour disorders</i></b>		
Attention deficit hyperactivity disorder	3	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	7	0
Aversion	1	0
Indifference	5	0
Paranoia	14	0
Personality change	3	0
Social avoidant behaviour	5	0
Soliloquy	1	0
Suspiciousness	1	0
<b><i>Bipolar disorders</i></b>		
Bipolar I disorder	1	0
Bipolar disorder	4	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Daydreaming	4	0
Distractibility	1	0
Mental fatigue	131	0
<b><i>Communications disorders</i></b>		
Communication disorder	4	0
Mutism	2	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	540	0
Disorientation	168	0
<b><i>Decreased physical activity levels</i></b>		
Catatonia	1	0
<b><i>Deliria</i></b>		
Delirium	71	0
<b><i>Delusional symptoms</i></b>		
Delusion	6	0
<b><i>Depressive disorders</i></b>		
Agitated depression	2	0

## Case Series Drug Analysis Print

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

Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Depression	161	0
Depression suicidal	5	0
Major depression	3	0
Mixed anxiety and depressive disorder	1	0
<b>Dissociative states</b>		
Depersonalisation/derealisation disorder	5	0
Dissociation	19	0
Dissociative amnesia	2	0
Dissociative disorder	1	0
<b>Disturbances in initiating and maintaining sleep</b>		
Initial insomnia	12	0
Insomnia	705	0
Middle insomnia	17	0
Terminal insomnia	12	0
<b>Dyssomnias</b>		
Dyssomnia	1	0
Poor quality sleep	120	0
<b>Eating disorders NEC</b>		
Bulimia nervosa	1	0
Eating disorder	6	0
Selective eating disorder	1	0
<b>Emotional and mood disturbances NEC</b>		
Anger	14	0
Dysphoria	2	0
Emotional disorder	28	0
Emotional distress	19	0
Emotional poverty	1	0
Euphoric mood	27	0
Frustration tolerance decreased	1	0
Irritability	105	0
Mood altered	25	0
<b>Factitious disorders</b>		
Factitious disorder	2	0
<b>Fear symptoms and phobic disorders (incl social phobia)</b>		
Agoraphobia	1	0
Fear	9	0
Fear of falling	3	0
Fear of injection	2	0
Osmophobia	1	0
Phobia	1	0
Phonophobia	1	0
Social anxiety disorder	1	0
Social fear	1	0
<b>Fluctuating mood symptoms</b>		
Mood swings	46	0
<b>Hallucinations (excl sleep-related)</b>		
Hallucination	119	0
Hallucination, auditory	8	0
Hallucination, olfactory	6	0
Hallucination, tactile	1	0
Hallucination, visual	18	0
Hallucinations, mixed	1	0
<b>Increased physical activity levels</b>		

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Restlessness	86	0
<b>Infancy, childhood and adolescence psychiatric disorders NEC</b>		
Social (pragmatic) communication disorder	1	0
<b>Learning disorders</b>		
Learning disability	1	0
Learning disorder	1	0
<b>Mental disorders NEC</b>		
Mental disorder	8	0
Mental status changes	1	0
<b>Mental disorders due to a general medical condition NEC</b>		
Neuropsychiatric symptoms	1	0
<b>Mood alterations with depressive symptoms</b>		
Anhedonia	1	0
Decreased interest	7	0
Depressed mood	197	0
Feeling of despair	3	0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Sense of a foreshortened future	2	0
Tearfulness	24	0
<b>Mood alterations with manic symptoms</b>		
Hypomania	2	0
Mania	7	0
<b>Mood disorders NEC</b>		
Apathy	17	0
Boredom	1	0
Laziness	1	0
Listless	13	0
<b>Narcolepsy and associated conditions</b>		
Hypnagogic hallucination	3	0
Hypnopompic hallucination	2	0
Sleep attacks	3	0
<b>Obsessive-compulsive disorders and symptoms</b>		
Obsessive-compulsive symptom	1	0
<b>Orgasmic disorders and disturbances</b>		
Anorgasmia	2	0
Female orgasmic disorder	1	0
<b>Panic attacks and disorders</b>		
Panic attack	81	0
Panic disorder	3	0
Panic reaction	16	0
<b>Parasomnias</b>		
Abnormal dreams	115	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	1	0
Nightmare	128	0
Parasomnia	1	0
Sleep talking	2	0
Sleep terror	12	0
Somnambulism	2	0
<b>Perception disturbances NEC</b>		
Autoscopy	10	0

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Deja vu	2	0
Derealisation	7	0
Flashback	2	0
Illusion	1	0
Near death experience	1	0
<b>Personality disorders NEC</b>		
Personality disorder	1	0
<b>Pervasive developmental disorders NEC</b>		
Autism spectrum disorder	2	1
<b>Psychiatric elimination disorders</b>		
Enuresis	13	0
<b>Psychiatric symptoms NEC</b>		
Hypervigilance	5	0
Psychiatric symptom	3	0
Psychological trauma	1	0
Trance	1	0
<b>Psychotic disorder NEC</b>		
Psychotic behaviour	1	0
Psychotic disorder	12	0
<b>Schizophrenia NEC</b>		
Schizophrenia	1	0
<b>Sexual arousal disorders</b>		
Disturbance in sexual arousal	2	0
<b>Sexual desire disorders</b>		
Libido decreased	4	0
Libido increased	3	0
Loss of libido	9	0
<b>Sleep disorders NEC</b>		
Sleep disorder	114	0
Sleep disorder due to general medical condition, insomnia type	1	0
<b>Somatic symptom disorders</b>		
Conversion disorder	5	0
Habit cough	12	0
Somatic symptom disorder	1	0
Vomiting psychogenic	1	0
<b>Speech and language usage disturbances</b>		
Disorganised speech	4	0
Logorrhoea	2	0
<b>Speech articulation and rhythm disturbances</b>		
Dysphemia	11	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
<b>Stereotypies and automatisms</b>		
Bruxism	9	0
Head banging	4	0
Stereotypy	1	0
<b>Stress disorders</b>		
Burnout syndrome	1	0
Post-traumatic stress disorder	2	0
<b>Substance related and addictive disorders</b>		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	2	0

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
<i><b>Suicidal and self-injurious behaviour</b></i>		
Intentional self-injury	5	0
Self-injurious ideation	2	0
Suicidal ideation	15	0
Suicide attempt	11	0
<i><b>Thinking disturbances</b></i>		
Bradyphrenia	28	0
Intrusive thoughts	3	0
Morbid thoughts	1	0
Tachyphrenia	3	0
Thinking abnormal	11	0
<i><b>Tic disorders</b></i>		
Tic	5	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>4216</b>	<b>1</b>

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Bladder discomfort	2	0
Bladder irritation	1	0
Bladder pain	15	0
Dysuria	33	0
Incontinence	18	0
Lower urinary tract symptoms	2	0
Micturition disorder	1	0
Micturition urgency	20	0
Pollakiuria	69	0
Urethral pain	3	0
Urge incontinence	1	0
Urinary hesitation	1	0
Urinary incontinence	39	0
Urinary retention	30	0
Urine flow decreased	6	0
<i><b>Bladder disorders NEC</b></i>		
Bladder disorder	4	0
Bladder fibrosis	1	0
Urinary bladder haemorrhage	1	0
<i><b>Bladder infections and inflammations</b></i>		
Cystitis interstitial	2	0
<i><b>Genital and urinary tract disorders NEC</b></i>		
Genitourinary symptom	1	0
Urinary tract disorder	3	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Glomerulonephritis	1	0
Glomerulonephritis minimal lesion	4	0
Glomerulonephritis rapidly progressive	1	0
IgA nephropathy	1	0
Nephrotic syndrome	14	0
<i><b>Myoneurogenic bladder disorders</b></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><b>Nephritis NEC</b></i>		
Lupus nephritis	1	0
Nephritis	2	0
Tubulointerstitial nephritis	1	0
<i><b>Renal disorders NEC</b></i>		
Renal disorder	2	0
Renal haemorrhage	1	0
Renal mass	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	31	2
Anuria	3	0
Chronic kidney disease	1	0
Oliguria	1	0
Renal failure	12	1
Renal impairment	14	0
Renal injury	1	0

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i>Renal lithiasis</i>		
Nephrolithiasis	5	0
<i>Renal neoplasms</i>		
Renal cyst	1	0
<i>Renal structural abnormalities and trauma</i>		
Kidney small	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal infarct	1	0
Renal vasculitis	1	1
<i>Structural and obstructive urethral disorders (excl congenital)</i>		
Urethral stenosis	1	0
<i>Ureteric disorders NEC</i>		
Ureteric stenosis	1	0
<i>Urinary abnormalities</i>		
Albuminuria	1	0
Chromaturia	29	0
Haematuria	25	0
Proteinuria	5	0
Urine abnormality	8	0
Urine odour abnormal	4	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	10	0
Nocturia	2	0
Polyuria	3	0
Renal colic	1	0
Renal pain	158	0
Urinary tract pain	2	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>614</b>	<b>4</b>



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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Benign and malignant breast neoplasms</b></i>		
Breast cyst	7	0
<i><b>Breast disorders NEC</b></i>		
Breast enlargement	4	0
Breast mass	56	0
Gynaecomastia	2	0
<i><b>Breast signs and symptoms</b></i>		
Breast discharge	2	0
Breast discomfort	5	0
Breast engorgement	2	0
Breast haematoma	1	0
Breast oedema	4	0
Breast pain	270	0
Breast swelling	55	0
Breast tenderness	29	0
Nipple pain	15	0
Nipple swelling	3	0
<i><b>Cervix disorders NEC</b></i>		
Cervical dysplasia	2	0
Cervix disorder	1	0
Cervix haemorrhage uterine	1	0
Ectropion of cervix	2	0
<i><b>Cervix neoplasms</b></i>		
Cervical polyp	1	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Ejaculation disorder	1	0
Ejaculation failure	1	0
Erectile dysfunction	27	0
Erection increased	2	0
Organic erectile dysfunction	3	0
Painful ejaculation	1	0
<i><b>Lactation disorders</b></i>		
Breast milk discolouration	2	0
Galactorrhoea	4	0
Lactation puerperal increased	1	0
Suppressed lactation	10	0
<i><b>Menopausal effects NEC</b></i>		
Artificial menopause	1	0
Menopausal symptoms	7	0
Premature menopause	7	0
<i><b>Menopausal effects on the genitourinary tract</b></i>		
Atrophic vulvovaginitis	1	0
Postmenopausal haemorrhage	87	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Abnormal uterine bleeding	5	0
Dysmenorrhoea	623	0
Intermenstrual bleeding	296	0
Menstrual discomfort	5	0
Menstrual disorder	443	0
Menstruation irregular	760	0
Premenstrual dysphoric disorder	3	0
Premenstrual headache	2	0
Premenstrual pain	31	0

# Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
Premenstrual syndrome	22	0
Withdrawal bleed	4	0
<b>Menstruation with decreased bleeding</b>		
Amenorrhoea	163	0
Hypomenorrhoea	149	0
Menstruation delayed	1042	0
Oligomenorrhoea	37	0
<b>Menstruation with increased bleeding</b>		
Heavy menstrual bleeding	1451	0
Menometrorrhagia	10	0
Polymenorrhoea	188	0
<b>Ovarian and fallopian tube cysts and neoplasms</b>		
Ovarian cyst	5	0
Polycystic ovaries	15	0
<b>Ovarian and fallopian tube disorders NEC</b>		
Adnexal torsion	1	0
Ovarian haemorrhage	1	0
Ovulation pain	17	0
Premature ovulation	2	0
<b>Pelvis and broad ligament disorders NEC</b>		
Adnexa uteri pain	14	0
Pelvic haemorrhage	8	0
<b>Penile and scrotal infections and inflammations</b>		
Balanoposthitis	1	0
<b>Penile disorders NEC (excl erection and ejaculation)</b>		
Penile discomfort	1	0
Penile erythema	1	0
Penile swelling	4	0
Penis disorder	4	0
<b>Prostate and seminal vesicles infections and inflammations</b>		
Prostatitis	3	0
<b>Prostatic signs, symptoms and disorders NEC</b>		
Prostatic pain	1	0
Prostatomegaly	3	0
<b>Reproductive tract disorders NEC (excl neoplasms)</b>		
Genital haemorrhage	9	0
Genital lesion	1	0
Genital ulceration	4	0
<b>Reproductive tract infections and inflammations NEC</b>		
Genital tract inflammation	1	0
<b>Reproductive tract signs and symptoms NEC</b>		
Genital pain	2	0
Genital rash	1	0
Genital swelling	1	0
Pelvic discomfort	3	0
Pelvic pain	44	0
Perineal pain	1	0
Pruritus genital	2	0
<b>Scrotal disorders NEC</b>		
Scrotal discomfort	1	0
Scrotal erythema	1	0
Scrotal exfoliation	1	0
Scrotal pain	4	0

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
Reproductive & breast disorders cont'd		
Scrotal swelling	4	0
<b>Sexual function and fertility disorders NEC</b>		
Dyspareunia	2	0
Infertility	3	0
Sexual dysfunction	1	0
<b>Spermatogenesis and semen disorders</b>		
Aspermia	1	0
Haematospermia	6	0
Semen discolouration	1	0
<b>Testicular and epididymal disorders NEC</b>		
Testicular disorder	2	0
Testicular pain	20	0
Testicular swelling	5	0
Testis discomfort	1	0
<b>Uterine disorders NEC</b>		
Adenomyosis	1	0
Endometrial thickening	1	0
Endometriosis	25	0
Uterine haemorrhage	11	0
Uterine pain	5	0
<b>Uterine infections and inflammations (excl cervix)</b>		
Uterine inflammation	1	0
<b>Uterine neoplasms</b>		
Uterine polyp	1	0
<b>Uterine tone disorders</b>		
Uterine spasm	9	0
<b>Vulvovaginal cysts and neoplasms</b>		
Vaginal cyst	3	0
<b>Vulvovaginal disorders NEC</b>		
Vaginal haemorrhage	481	0
Vulval haemorrhage	9	0
Vulval ulceration	3	0
Vulvovaginal ulceration	3	0
<b>Vulvovaginal signs and symptoms</b>		
Clitoral engorgement	1	0
Coital bleeding	2	0
Vaginal discharge	14	0
Vaginal odour	1	0
Vulval oedema	1	0
Vulvovaginal burning sensation	2	0
Vulvovaginal dryness	2	0
Vulvovaginal pain	12	0
Vulvovaginal pruritus	3	0
Vulvovaginal swelling	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>6646</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	4	0
Apnoeic attack	1	0
Dyspnoea	2189	6
Dyspnoea at rest	7	0
Dyspnoea exertional	19	1
Hyperventilation	24	0
Hypopnoea	57	0
Irregular breathing	11	0
Mouth breathing	3	0
Nocturnal dyspnoea	1	0
Orthopnoea	3	0
Respiration abnormal	29	0
Respiratory arrest	8	0
Respiratory depression	1	0
Respiratory distress	11	0
Sleep apnoea syndrome	7	0
Tachypnoea	21	0
<i><b>Bronchial conditions NEC</b></i>		
Bronchial secretion retention	1	0
Bronchiectasis	11	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	185	0
Asthma late onset	2	0
Bronchospasm	12	0
Chronic obstructive pulmonary disease	14	1
Cough variant asthma	3	0
Obstructive airways disorder	6	0
Reversible airways obstruction	1	0
Wheezing	256	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Asphyxia	1	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	20	1
Respiratory acidosis	2	0
<i><b>Coughing and associated symptoms</b></i>		
Allergic cough	4	0
Cough	1421	2
Cough decreased	2	0
Haemoptysis	27	0
Productive cough	88	0
Sputum discoloured	4	0
Sputum increased	1	0
<i><b>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</b></i>		
Laryngeal disorder	1	0
Vocal cord disorder	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	1	0
Laryngospasm	1	0

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Stridor	18	0
<b>Lower respiratory tract inflammatory and immunologic conditions</b>		
Alveolitis	1	0
Hypersensitivity pneumonitis	1	0
Pneumonia aspiration	7	5
Pneumonitis	18	1
Pulmonary sarcoidosis	1	0
<b>Lower respiratory tract signs and symptoms</b>		
Hiccups	19	0
Increased bronchial secretion	1	0
Lung opacity	2	0
Pleuritic pain	10	0
Pulmonary pain	54	0
Rales	4	0
<b>Nasal congestion and inflammations</b>		
Nasal congestion	150	0
Nasal inflammation	1	0
Rhinitis allergic	10	0
<b>Nasal disorders NEC</b>		
Epistaxis	575	0
Intranasal hypoaesthesia	1	0
Intranasal paraesthesia	1	0
Nasal crusting	1	0
Nasal disorder	1	0
Nasal dryness	22	0
Nasal odour	6	0
Nasal oedema	4	0
Nasal pruritus	8	0
<b>Neonatal hypoxic conditions</b>		
Dry lung syndrome	1	0
Gasping syndrome	1	0
Infantile apnoea	1	0
<b>Paranasal sinus disorders (excl infections and neoplasms)</b>		
Allergic sinusitis	1	0
Paranasal sinus inflammation	1	0
Sinonasal obstruction	8	0
Sinus congestion	35	0
Sinus disorder	4	0
<b>Parenchymal lung disorders NEC</b>		
Atelectasis	1	0
Emphysema	2	0
Interstitial lung disease	6	0
Lung infiltration	1	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	3	0
<b>Pharyngeal disorders (excl infections and neoplasms)</b>		
Pharyngeal erythema	6	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	22	0
Pharyngeal inflammation	4	0
Pharyngeal oedema	9	0
Pharyngeal paraesthesia	42	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> Respiratory disorders cont'd		
Pharyngeal swelling	156	0
Pharyngeal ulceration	10	0
Tonsillar erythema	3	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	45	0
Tonsillar inflammation	3	0
Tonsillar ulcer	1	0
Tonsillolith	1	0
<b>Pleural infections and inflammations</b>		
Pleurisy	17	0
<b>Pneumothorax and pleural effusions NEC</b>		
Pleural effusion	12	0
Pneumothorax	5	0
Pneumothorax spontaneous	1	0
<b>Pulmonary hypertension</b>		
Pulmonary hypertension	2	0
<b>Pulmonary oedemas</b>		
Acute respiratory distress syndrome	1	0
Pulmonary congestion	6	0
Pulmonary oedema	14	1
<b>Pulmonary thrombotic and embolic conditions</b>		
Pulmonary embolism	262	19
Pulmonary infarction	3	0
Pulmonary thrombosis	2	0
<b>Respiratory failures (excl neonatal)</b>		
Acute respiratory failure	2	1
Respiratory failure	8	1
<b>Respiratory signs and symptoms NEC</b>		
Allergic respiratory symptom	5	0
Diaphragmalgia	4	0
Nasal flaring	1	0
Painful respiration	6	0
Respiratory symptom	8	0
Suffocation feeling	1	0
<b>Respiratory tract disorders NEC</b>		
Aspiration	3	2
Lung disorder	2	0
Pulmonary mass	2	0
Respiratory disorder	6	0
Respiratory tract congestion	2	0
Respiratory tract haemorrhage	1	0
Respiratory tract inflammation	1	0
Respiratory tract irritation	5	0
Respiratory tract oedema	2	0
<b>Thoracic musculoskeletal disorders</b>		
Respiratory muscle weakness	1	0
<b>Tracheal disorders (excl infections and neoplasms)</b>		
Tracheal pain	1	0
<b>Upper respiratory tract neoplasms</b>		
Tonsillar cyst	1	0
<b>Upper respiratory tract signs and symptoms</b>		
Aphonia	66	0
Catarrh	12	0

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> Respiratory disorders cont'd		
Choking	11	1
Choking sensation	3	0
Dry throat	116	0
Dysphonia	104	0
Increased upper airway secretion	4	0
Increased viscosity of upper respiratory secretion	19	0
Nasal discharge discolouration	2	0
Nasal discomfort	35	0
Nasal obstruction	2	0
Oropharyngeal blistering	9	0
Oropharyngeal discomfort	42	0
Oropharyngeal pain	1754	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	25	0
Rhinalgia	7	0
Rhinorrhoea	523	0
Sinus pain	127	0
Sneezing	220	0
Snoring	4	0
Throat clearing	6	0
Throat irritation	155	0
Throat tightness	170	0
Upper airway obstruction	2	0
Upper-airway cough syndrome	4	0
Yawning	12	0
<b>Vascular pulmonary disorders NEC</b>		
Acute chest syndrome	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>9577</b>	<b>42</b>

## Case Series Drug Analysis Print

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

Report Run Date: 26-Jun-2021

Data Lock Date: 23-Jun-2021 18:30:09

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	57	0
Acne cystic	4	0
Dermatitis acneiform	3	0
<b><i>Alopecias</i></b>		
Alopecia	107	0
Alopecia areata	11	0
Alopecia totalis	1	0
Androgenetic alopecia	1	0
Madarosis	1	0
<b><i>Angioedemas</i></b>		
Angioedema	134	0
Circumoral swelling	1	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Anhidrosis	1	0
Cold sweat	416	0
Hidradenitis	1	0
Hyperhidrosis	1227	0
Miliaria	57	0
Night sweats	372	0
<b><i>Bullous conditions</i></b>		
Blister	278	0
Blister rupture	1	0
Blood blister	19	0
Dermatitis bullous	10	0
Erythema multiforme	21	0
Fracture blisters	1	0
Pemphigoid	13	0
Pemphigus	5	0
Stevens-Johnson syndrome	3	0
Toxic epidermal necrolysis	2	1
<b><i>Connective tissue disorders</i></b>		
Dermatomyositis	4	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	141	0
Macule	3	0
Pain of skin	166	0
Papule	49	0
Pathergy reaction	1	0
Peau d'orange	2	0
Scab	11	0
Scar pain	11	0
Sensitive skin	93	0
Skin burning sensation	138	0
Skin degenerative disorder	1	0
Skin discolouration	67	0
Skin discomfort	3	0
Skin disorder	7	0
Skin fissures	3	0
Skin indentation	2	0
Skin induration	3	0



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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Skin lesion	30	0
Skin lesion inflammation	1	0
Skin necrosis	1	0
Skin odour abnormal	11	0
Skin plaque	1	0
Skin reaction	88	0
Skin sensitisation	18	0
Skin swelling	50	0
Skin texture abnormal	1	0
Skin tightness	21	0
Skin warm	188	0
Skin weeping	5	0
Sticky skin	1	0
Target skin lesion	1	0
Transient acantholytic dermatosis	1	0
Yellow skin	11	0
<b>Dermatitis and eczema</b>		
Dermatitis	70	0
Dermatitis allergic	153	0
Dermatitis atopic	17	0
Dermatitis contact	8	0
Dermatitis diaper	2	0
Dyshidrotic eczema	12	0
Eczema	148	0
Eczema asteatotic	6	0
Eczema nummular	4	0
Eczema weeping	1	0
Perioral dermatitis	1	0
Seborrhoeic dermatitis	2	0
Skin irritation	64	0
<b>Dermatitis ascribed to specific agent</b>		
Drug eruption	24	0
Drug reaction with eosinophilia and systemic symptoms	1	0
Fixed eruption	1	0
Toxic skin eruption	1	0
<b>Erythemas</b>		
Erythema	1428	0
Palmar erythema	4	0
Red man syndrome	1	0
<b>Exfoliative conditions</b>		
Dermatitis exfoliative	1	0
Dermatitis exfoliative generalised	3	0
Exfoliative rash	12	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	59	0
<b>Granulomatous and deep cutaneous inflammatory conditions</b>		
Cutaneous sarcoidosis	1	0
Granuloma annulare	1	0
<b>Hyperkeratoses</b>		
Hyperkeratosis	1	0
Keratosis pilaris	3	0
Lichenoid keratosis	2	0
<b>Hyperpigmentation disorders</b>		

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Argyria	1	0
Chloasma	1	0
Ephelides	1	0
Skin hyperpigmentation	2	0
Solar lentigo	2	0
<b>Hypertrichoses</b>		
Hirsutism	1	0
<b>Hypopigmentation disorders</b>		
Skin depigmentation	3	0
Skin hypopigmentation	1	0
Vitiligo	4	0
<b>Lipodystrophies</b>		
Lipoatrophy	2	0
Lipodystrophy acquired	1	0
<b>Nail and nail bed conditions (excl infections and infestations)</b>		
Nail discolouration	6	0
Nail disorder	2	0
Nail pigmentation	2	0
Onychalgia	6	0
Onychoclasia	3	0
Onychomadesis	2	0
Splinter haemorrhages	2	0
<b>Panniculitides</b>		
Erythema nodosum	16	0
<b>Papulosquamous conditions</b>		
Erythema annulare	2	0
Lichen planus	8	0
Lichen sclerosus	3	0
Parapsoriasis	2	0
Pityriasis rosea	57	0
<b>Photosensitivity and photodermatosis conditions</b>		
Photosensitivity reaction	31	0
Polymorphic light eruption	1	0
Solar dermatitis	1	0
<b>Pigmentation changes NEC</b>		
Haemosiderin stain	1	0
Pigmentation disorder	6	0
<b>Pilar disorders NEC</b>		
Hair colour changes	7	0
Hair disorder	1	0
Hair growth abnormal	2	0
Hair texture abnormal	4	0
Piloerection	13	0
Pseudofolliculitis	1	0
<b>Pruritus NEC</b>		
Itching scar	5	0
Pruritus	3208	0
<b>Psoriatic conditions</b>		
Dermatitis psoriasiform	2	0
Guttate psoriasis	11	0
Nail psoriasis	1	0
Palmoplantar pustulosis	2	0
Psoriasis	93	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Pustular psoriasis	2	0
<b>Purpura and related conditions</b>		
Henoch-Schonlein purpura	4	0
Petechiae	87	0
Purpura	30	0
<b>Pustular conditions</b>		
Acute generalised exanthematous pustulosis	1	0
<b>Rashes, eruptions and exanthems NEC</b>		
Butterfly rash	3	0
Rash	3426	0
Rash erythematous	730	0
Rash macular	312	0
Rash maculo-papular	39	0
Rash morbilliform	27	0
Rash papular	213	0
Rash pruritic	750	0
Rash vesicular	39	0
Systemic lupus erythematosus rash	5	0
<b>Rosaceas</b>		
Rosacea	16	0
<b>Scaly conditions</b>		
Dandruff	4	0
Pityriasis	13	0
<b>Sebaceous gland disorders</b>		
Seborrhoea	3	0
<b>Skin and subcutaneous conditions NEC</b>		
Cutaneous symptom	3	0
Reactive perforating collagenosis	1	0
Skin mass	10	0
<b>Skin and subcutaneous tissue ulcerations</b>		
Mucocutaneous ulceration	1	0
Scleroderma associated digital ulcer	1	0
Skin erosion	18	0
Skin ulcer	8	0
<b>Skin cysts and polyps</b>		
Dermal cyst	6	0
<b>Skin dystrophies</b>		
Keloid scar	1	0
Skin wrinkling	2	0
<b>Skin haemorrhages</b>		
Haemorrhage subcutaneous	5	0
Skin haemorrhage	7	0
<b>Skin hyperplasias and hypertrophies</b>		
Skin hypertrophy	1	0
<b>Skin hypoplasias and atrophies</b>		
Skin striae	4	0
<b>Skin injuries and mechanical dermatoses</b>		
Decubitus ulcer	2	0
Needle track marks	1	0
<b>Skin preneoplastic conditions NEC</b>		
Actinic keratosis	1	0
<b>Skin vasculitides</b>		
Cutaneous vasculitis	7	0

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Vasculitic rash	13	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	17	0
<b>Telangiectasia and related conditions</b>		
Telangiectasia	1	0
<b>Urticarias</b>		
Chronic spontaneous urticaria	3	0
Cold urticaria	2	0
Idiopathic urticaria	1	0
Mechanical urticaria	3	0
Solar urticaria	2	0
Urticaria	1068	0
Urticaria chronic	6	0
Urticaria contact	1	0
Urticaria papular	2	0
Urticaria thermal	4	0
Urticarial vasculitis	2	0
<b>Skin disorders SOC TOTAL</b>	<b>16344</b>	<b>1</b>

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i><b>Age related issues</b></i>		
Infant	1	0
Menopause	9	0
Postmenopause	2	0
<i><b>Criminal activity</b></i>		
Verbal abuse	1	0
<i><b>Dependents</b></i>		
Sick relative	1	0
<i><b>Disability issues</b></i>		
Bedridden	17	0
Breast prosthesis user	3	0
Hearing disability	1	0
Housebound	1	0
Immobile	9	0
Impaired driving ability	1	0
Impaired work ability	5	0
Loss of personal independence in daily activities	9	0
Physical disability	2	0
Sight disability	6	0
Sitting disability	1	0
Walking disability	1	0
<i><b>Economic circumstances</b></i>		
High income	1	0
Low income	1	0
<i><b>Employment issues</b></i>		
Retirement	3	0
<i><b>Non-occupational and unspecified environmental problems</b></i>		
Water pollution	2	0
<i><b>Pregnancy related circumstances</b></i>		
Breast feeding	8	0
Multigravida	1	0
<i><b>Social issues NEC</b></i>		
Hair dye user	2	0
<i><b>Tobacco use</b></i>		
Ex-tobacco user	1	0
Non-tobacco user	4	0
<b>Social circumstances SOC TOTAL</b>	<b>93</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<i>Anaesthesia and allied procedures</i>		
Nerve block	1	0
<i>Antiinfective therapies</i>		
COVID-19 treatment	2	0
<i>Arterial therapeutic procedures (excl aortic)</i>		
Splenic artery embolisation	1	0
<i>Blood and blood product treatment</i>		
Transfusion	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	1	0
<i>Bronchial and pulmonary therapeutic procedures</i>		
Airway secretion clearance therapy	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Cardiac operation	1	0
<i>Contraceptive methods female</i>		
Contraceptive implant	1	0
Oral contraception	1	0
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	3	0
Nothing by mouth order	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	3	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	1	0
<i>Hernia repairs</i>		
Hernia repair	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
Hormone therapy	2	0
<i>Immunisations</i>		
COVID-19 immunisation	68	1
Immunisation	16	0
<i>Joint therapeutic procedures</i>		
Joint surgery	1	0
Knee arthroplasty	1	0
<i>Large intestine therapeutic procedures</i>		
Appendectomy	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	7	0
Limb operation	5	0
<i>Lymphoid tissue therapeutic procedures</i>		
Lymphadenectomy	1	0
<i>Mastectomies</i>		
Breast conserving surgery	3	0
<i>Nail therapeutic procedures</i>		

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
Surgical & medical procedures cont'd		
Nail operation	1	0
<b>Nervous system therapeutic procedures NEC</b>		
Multiple sclerosis relapse prophylaxis	2	0
<b>Orbit and globe therapeutic procedures</b>		
Strabismus correction	1	0
<b>Phototherapies</b>		
UV light therapy	1	0
<b>Prophylactic procedures NEC</b>		
Anaphylaxis prophylaxis	2	0
Immune tolerance induction	1	0
Reproductive system disorder prophylaxis	1	0
<b>Psychiatric therapies</b>		
Electroconvulsive therapy	1	0
<b>Renal therapeutic procedures</b>		
Dialysis	1	0
<b>Respiratory tract therapeutic procedures NEC</b>		
Asthma prophylaxis	2	0
<b>Skin and subcutaneous tissue therapeutic procedures NEC</b>		
Dermal filler injection	3	0
<b>Therapeutic procedures NEC</b>		
Abscess drainage	1	0
Anaphylaxis treatment	3	0
Bed rest	2	0
Fatigue management	1	0
Hospitalisation	7	0
Injection	12	0
Interchange of vaccine products	2	0
Localised alternating hot and cold therapy	1	0
Magnetic therapy	1	0
Mass excision	2	0
Medication dilution	1	0
Product used for unknown indication	2	0
Therapeutic procedure	1	0
Therapy change	1	0
<b>Uterine therapeutic procedures</b>		
Endometrial ablation	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>198</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<i><b>Accelerated and malignant hypertension</b></i>		
Hypertensive crisis	8	0
Hypertensive urgency	1	0
Malignant hypertension	3	0
<i><b>Aneurysms and dissections non-site specific</b></i>		
Artery dissection	1	0
<i><b>Aortic aneurysms and dissections</b></i>		
Acute aortic syndrome	1	0
Aortic aneurysm rupture	1	1
Aortic dissection	1	0
<i><b>Aortic embolism and thrombosis</b></i>		
Aortic embolus	4	0
Aortic thrombosis	1	0
<i><b>Arterial infections and inflammations</b></i>		
Arteritis	1	0
Giant cell arteritis	7	0
<i><b>Blood pressure disorders NEC</b></i>		
Blood pressure fluctuation	8	0
Labile blood pressure	2	0
<i><b>Bruising, ecchymosis and purpura</b></i>		
Achenbach syndrome	2	0
<i><b>Circulatory collapse and shock</b></i>		
CT hypotension complex	2	0
Circulatory collapse	44	0
Hypoperfusion	1	0
Neurogenic shock	20	0
Peripheral circulatory failure	4	0
Shock	12	0
<i><b>Haemorrhages NEC</b></i>		
Bloody discharge	5	0
Haematoma	25	0
Haemorrhage	360	2
Internal haemorrhage	6	0
Venous haemorrhage	1	0
<i><b>Lymphangiopathies</b></i>		
Lymphangiopathy	1	0
Lymphocele	3	0
<i><b>Lymphoedemas</b></i>		
Lymphoedema	134	0
<i><b>Non-site specific embolism and thrombosis</b></i>		
Arterial thrombosis	3	0
Embolism	62	0
Embolism venous	3	0
Microembolism	1	0
Thrombosis	200	6
Venous thrombosis	4	0
<i><b>Non-site specific necrosis and vascular insufficiency NEC</b></i>		
Arterial occlusive disease	2	0
Haemorrhagic infarction	1	0
Infarction	2	0
Ischaemia	5	0
Vasospasm	1	0
<i><b>Non-site specific vascular disorders NEC</b></i>		



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Reaction Name	Total	Fatal
<b>Vascular disorders</b> Vascular disorders cont'd		
Capillary disorder	1	0
Superficial vein prominence	1	0
Vascular pain	10	0
Vasodilatation	19	0
Vein discolouration	4	0
Vein disorder	5	0
Vein rupture	3	0
<b>Peripheral embolism and thrombosis</b>		
Axillary vein thrombosis	1	0
Blue toe syndrome	18	0
Deep vein thrombosis	170	0
Femoral artery embolism	1	0
Jugular vein thrombosis	2	0
Pelvic venous thrombosis	4	0
Peripheral embolism	1	0
Subclavian artery embolism	1	0
Subclavian vein thrombosis	2	0
Thrombophlebitis	14	0
Thrombophlebitis superficial	9	0
<b>Peripheral vascular disorders NEC</b>		
Cyanosis	29	0
Erythromelalgia	1	0
Flushing	323	0
Hot flush	677	0
<b>Peripheral vasoconstriction, necrosis and vascular insufficiency</b>		
Extremity necrosis	1	0
Intermittent claudication	1	0
Ischaemic limb pain	1	0
Peripheral arterial occlusive disease	1	0
Peripheral artery occlusion	1	0
Peripheral coldness	200	0
Peripheral ischaemia	10	0
Poor peripheral circulation	8	0
Raynaud's phenomenon	43	0
Vasoconstriction	2	0
<b>Phlebitis NEC</b>		
Phlebitis	21	0
Phlebitis superficial	4	0
<b>Site specific vascular disorders NEC</b>		
Pallor	185	0
<b>Varicose veins NEC</b>		
Spider vein	2	0
Varicophlebitis	1	0
Varicose vein	9	0
<b>Vascular hypertensive disorders NEC</b>		
Diastolic hypertension	1	0
Essential hypertension	3	0
Hypertension	350	1
Labile hypertension	1	0
Orthostatic hypertension	1	0
Secondary hypertension	1	0
Systolic hypertension	2	0
<b>Vascular hypotensive disorders</b>		

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Reaction Name	Total	Fatal
<b>Vascular disorders</b> Vascular disorders cont'd		
Capillary leak syndrome	1	0
Hypotension	256	0
Orthostatic hypotension	18	0
<b>Vasculitides NEC</b>		
Behcet's syndrome	4	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	1	0
MAGIC syndrome	1	0
Vasculitis	37	0
<b>Vena caval embolism and thrombosis</b>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>3409</b>	<b>10</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>223404</b>	<b>439</b>
<b>TOTAL REPORTS</b>	<b>79296</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>439</b>