

## Case Series Drug Analysis Print

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

Report Run Date: 14-Jun-2021  
Data Lock Date: 09-Jun-2021 19:00:03

All UK spontaneous reports received up to and including 09/06/2021 for COVID-19 vaccine mRNA Pfizer BioNTech.

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

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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	44	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	19	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	5	0
Disseminated intravascular coagulation	1	0
Hypercoagulation	3	0
Thrombotic microangiopathy	2	0
<i><b>Eosinophilic disorders</b></i>		
Eosinophilia	10	0
<i><b>Haematological disorders</b></i>		
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	2	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	820	0
Lymphadenitis	96	0
Lymphadenopathy	5611	0
Lymphatic disorder	1	0
Necrotic lymphadenopathy	1	0
Pseudolymphoma	5	0
Retroperitoneal lymphadenopathy	1	0
<i><b>Marrow depression and hypoplastic anaemias</b></i>		

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<b>Blood disorders</b> Blood disorders cont'd		
Aplasia pure red cell	2	0
Myelosuppression	1	0
Pancytopenia	3	0
<b>Neutropenias</b>		
Autoimmune neutropenia	2	0
Neutropenia	29	0
<b>Platelet disorders NEC</b>		
Platelet anisocytosis	1	0
<b>Purpuras (excl thrombocytopenic)</b>		
Purpura non-thrombocytopenic	1	0
<b>Red blood cell abnormal findings NEC</b>		
Polychromasia	1	0
Red blood cell abnormality	2	0
<b>Spleen disorders</b>		
Spleen atrophy	1	0
Splenic infarction	1	0
Splenic vein thrombosis	1	0
Splenomegaly	7	0
<b>Thrombocytopenias</b>		
Immune thrombocytopenia	55	0
Thrombocytopenia	124	1
Thrombocytopenic purpura	2	0
Thrombotic thrombocytopenic purpura	6	0
<b>Thrombocytoses</b>		
Thrombocytosis	4	0
<b>Blood disorders SOC TOTAL</b>	<b>6923</b>	<b>2</b>

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<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	21	0
Cardiac dysfunction	1	0
Cardiovascular disorder	1	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	3	0
Palpitations	1228	0
<i><b>Cardiac valve disorders NEC</b></i>		
Cardiac valve disease	1	0
<i><b>Cardiomyopathies</b></i>		
Cardiomyopathy	2	0
Congestive cardiomyopathy	2	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	28	4
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	52	0
Angina unstable	1	0
Arteriospasm coronary	1	0
Microvascular coronary artery disease	2	0
Myocardial infarction	119	24
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	1	0
Mitral valve prolapse	1	0
<i><b>Myocardial disorders NEC</b></i>		
Cardiac amyloidosis	1	0
Cardiomegaly	3	0
Left ventricular dysfunction	3	0

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<b>Cardiac disorders</b> Cardiac disorders cont'd		
Myocardial fibrosis	1	0
Myocardial haemorrhage	1	0
Myocardial oedema	2	0
Myocardial rupture	1	0
Right ventricular enlargement	1	0
Ventricular hypertrophy	2	0
<b>Noninfectious myocarditis</b>		
Myocarditis	39	0
<b>Noninfectious pericarditis</b>		
Pericarditis	27	1
<b>Pericardial disorders NEC</b>		
Pericardial effusion	7	0
Pericardial haemorrhage	2	2
<b>Rate and rhythm disorders NEC</b>		
Arrhythmia	43	0
Bradycardia	36	0
Cardiac flutter	76	0
Extrasystoles	48	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	7	0
Tachyarrhythmia	1	0
Tachycardia	493	0
<b>Right ventricular failures</b>		
Cor pulmonale	1	0
<b>Supraventricular arrhythmias</b>		
Arrhythmia supraventricular	8	0
Atrial fibrillation	113	0
Atrial flutter	9	0
Atrial tachycardia	3	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus bradycardia	3	0
Sinus tachycardia	33	0
Supraventricular tachycardia	21	0
<b>Tricuspid valvular disorders</b>		
Tricuspid valve incompetence	1	0
<b>Ventricular arrhythmias and cardiac arrest</b>		
Cardiac arrest	68	26
Cardio-respiratory arrest	1	1
Pulseless electrical activity	3	0
Ventricular arrhythmia	4	0
Ventricular extrasystoles	11	0
Ventricular fibrillation	5	1
Ventricular tachycardia	6	0
<b>Cardiac disorders SOC TOTAL</b>	<b>2615</b>	<b>69</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	5	0
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	1	0
<i>Central nervous system disorders congenital NEC</i>		
Spina bifida	1	0
<i>Cerebellar disorders congenital</i>		
Hereditary ataxia	1	0
<i>Cerebral disorders congenital</i>		
Cerebral palsy	1	0
<i>Coagulation disorders congenital</i>		
Haemophilia	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	1	0
<i>Gastrointestinal tract disorders congenital NEC</i>		
Gastroschisis	1	0
<i>Great vessel disorders congenital</i>		
Transposition of the great vessels	1	0
<i>Haematological disorders congenital NEC</i>		
Amegakaryocytic thrombocytopenia	1	0
<i>Haemoglobinopathies congenital</i>		
Congenital methaemoglobinaemia	1	0
Thalassaemia minor	1	0
<i>Lymphatic system disorders congenital</i>		
Cystic lymphangioma	1	0
<i>Musculoskeletal and connective tissue disorders of skull congenital</i>		
Craniosynostosis	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital multiplex 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>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>27</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	45	0
Ear disorder	11	0
Ear haemorrhage	6	0
Ear pain	510	0
Ear pruritus	6	0
Ear swelling	18	0
Otorrhoea	2	0
<i><b>Eustachian tube disorders</b></i>		
Eustachian tube disorder	1	0
Eustachian tube dysfunction	6	0
Eustachian tube obstruction	1	0
<i><b>External ear disorders NEC</b></i>		
Excessive cerumen production	1	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
<i><b>Hearing losses</b></i>		
Conductive deafness	1	0
Deafness	115	0
Deafness bilateral	5	0
Deafness neurosensory	11	0
Deafness transitory	3	0
Deafness unilateral	22	0
Hypoacusis	88	0
Sudden hearing loss	21	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	23	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	7	0
Vestibular disorder	3	0
<i><b>Inner ear infections and inflammations</b></i>		
Inner ear inflammation	3	0
<i><b>Inner ear signs and symptoms</b></i>		
Motion sickness	30	0
Tinnitus	981	0
Vertigo	728	0
Vertigo labyrinthine	8	0
Vertigo positional	49	0
<i><b>Mastoid disorders</b></i>		
Mastoid effusion	1	0
<i><b>Middle ear disorders NEC</b></i>		
Middle ear disorder	3	0
<i><b>Middle ear infections and inflammations</b></i>		
Middle ear inflammation	1	0

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Reaction Name		Total	Fatal
Ear disorders	Ear disorders cont'd		
Ear disorders SOC TOTAL		2745	0



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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i><b>Acute and chronic thyroiditis</b></i>		
Thyroiditis	6	0
Thyroiditis subacute	2	0
<i><b>Adrenal cortical hypofunctions</b></i>		
Addison's disease	1	0
Adrenocortical insufficiency acute	8	0
<i><b>Adrenal gland disorders NEC</b></i>		
Adrenal haemorrhage	1	0
<i><b>Endocrine abnormalities of puberty</b></i>		
Delayed menarche	1	0
Premature menarche	8	0
<i><b>Female gonadal function disorders</b></i>		
Anovulatory cycle	7	0
Ovulation delayed	3	0
<i><b>Thyroid disorders NEC</b></i>		
Autoimmune thyroid disorder	1	0
Goitre	7	0
Thyroid disorder	2	0
Thyroid pain	2	0
<i><b>Thyroid hyperfunction disorders</b></i>		
Basedow's disease	1	0
Hyperthyroidism	15	0
<i><b>Thyroid hypofunction disorders</b></i>		
Autoimmune hypothyroidism	1	0
Hypothyroidism	14	0
<b>Endocrine disorders SOC TOTAL</b>	<b>80</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	5	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	42	0
<i><b>Colour blindness (incl acquired)</b></i>		
Dyschromatopsia	1	0
<i><b>Conjunctival and corneal bleeding and vascular disorders</b></i>		
Conjunctival haemorrhage	25	0
<i><b>Conjunctival infections, irritations and inflammations</b></i>		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	2	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	62	0
Excessive eye blinking	1	0
Eyelid function disorder	2	0
Eyelid myokymia	2	0
Eyelid ptosis	26	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	19	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	84	0
Lacrimation increased	81	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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<b>Eye disorders</b> Eye disorders cont'd		
Eyelid rash	10	0
Swelling of eyelid	70	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	13	0
Ocular vascular disorder	1	0
Ophthalmic vein thrombosis	1	0
<b>Ocular disorders NEC</b>		
Dark circles under eyes	4	0
Eye disorder	15	0
Eye oedema	8	0
Eye pain	567	0
Eye swelling	280	0
Eye symptom	5	0
Eye ulcer	2	0
Eyelid disorder	5	0
Eyelid pain	8	0
Eyelids pruritus	3	0
Ocular discomfort	18	0
Periorbital oedema	14	0
Periorbital pain	1	0
Periorbital swelling	71	0
Retinal disorder	1	0
Vitreous disorder	1	0
<b>Ocular infections, inflammations and associated manifestations</b>		
Eye allergy	4	0
Eye discharge	14	0
Eye inflammation	15	0
Eye irritation	60	0
Eye pruritus	147	0
Limbal swelling	2	0
Ocular hyperaemia	128	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	16	0
Ocular myasthenia	1	0
Ophthalmoplegia	2	0
Strabismus	2	0
<b>Ocular sensation disorders</b>		
Abnormal sensation in eye	9	0
Asthenopia	87	0
Eye paraesthesia	1	0
Foreign body sensation in eyes	14	0
Hypoaesthesia eye	8	0

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<b>Eye disorders</b> Eye disorders cont'd		
Photophobia	215	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	11	0
Pupil fixed	1	0
Pupils unequal	5	0
<b>Retinal bleeding and vascular disorders (excl retinopathy)</b>		
Retinal artery occlusion	4	0
Retinal artery thrombosis	1	0
Retinal haemorrhage	2	0
Retinal vein occlusion	16	0
Retinal vein thrombosis	2	0
<b>Retinal structural change, deposit and degeneration</b>		
Macular degeneration	1	0
Macular hole	1	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	1	0
Retinal detachment	3	0
Retinal tear	1	0
Retinal toxicity	2	0
<b>Retinal, choroid and vitreous infections and inflammations</b>		
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	6	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	90	0
Glare	1	0
Halo vision	6	0
Metamorphopsia	9	0
Oscillopsia	2	0
Photopsia	70	0

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<b>Eye disorders</b> Eye disorders cont'd		
Scintillating scotoma	3	0
Vision blurred	593	0
Visual brightness	2	0
Visual snow syndrome	2	0
<b>Visual field disorders</b>		
Visual field defect	10	0
<b>Visual impairment and blindness (excl colour blindness)</b>		
Amaurosis fugax	1	0
Blindness	46	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	170	0
<b>Visual pathway disorders</b>		
Optic nerve disorder	1	0
<b>Eye disorders SOC TOTAL</b>	<b>3398</b>	<b>0</b>

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<b>Gastrointestinal disorders</b>		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
Gastrointestinal sounds abnormal	10	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	1	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	0
Pancreatitis	4	0
Pancreatitis acute	6	0
Pancreatitis necrotising	1	0
<i>Anal and rectal disorders NEC</i>		
Anal 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
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	3	0
Tongue cyst	2	0
<i>Colitis (excl infective)</i>		
Colitis	23	1
Colitis ischaemic	1	0
Colitis microscopic	1	0
Colitis ulcerative	40	0
Crohn's disease	21	0
Eosinophilic colitis	1	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Teething	3	0
Tooth disorder	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	3	0
Dental paraesthesia	7	0
Hyperaesthesia teeth	20	0
Toothache	74	0
<i>Dental surface disorders</i>		
Tooth discolouration	1	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	3	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	2933	2
Diarrhoea haemorrhagic	14	0
<i>Diverticula</i>		
Diverticulum	2	0
Diverticulum intestinal	1	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	1	0

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Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Duodenal ulcers and perforation</i></b>		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	2	0
<b><i>Dyspeptic signs and symptoms</i></b>		
Dyspepsia	188	0
Epigastric discomfort	10	0
Eructation	29	0
<b><i>Faecal abnormalities NEC</i></b>		
Abnormal faeces	9	0
Faecaloma	1	0
Faeces discoloured	25	0
Faeces hard	1	0
Faeces pale	3	0
Faeces soft	9	0
Mucous stools	3	0
<b><i>Flatulence, bloating and distension</i></b>		
Abdominal distension	163	0
Aerophagia	3	0
Flatulence	96	0
<b><i>Gastric and oesophageal haemorrhages</i></b>		
Gastric haemorrhage	4	1
Mallory-Weiss syndrome	1	0
Oesophageal varices haemorrhage	1	0
<b><i>Gastric ulcers and perforation</i></b>		
Gastric ulcer	3	0
<b><i>Gastritis (excl infective)</i></b>		
Chronic gastritis	2	0
Gastritis	26	0
Reflux gastritis	4	0
<b><i>Gastrointestinal and abdominal pains (excl oral and throat)</i></b>		
Abdominal migraine	2	0
Abdominal pain	671	0
Abdominal pain lower	45	0
Abdominal pain upper	1109	0
Abdominal rigidity	7	0
Abdominal tenderness	5	0
Gastrointestinal pain	72	0
Oesophageal pain	2	0
<b><i>Gastrointestinal atonic and hypomotility disorders NEC</i></b>		
Constipation	128	0
Duodenogastric reflux	2	0
Gastric dilatation	3	0
Gastrooesophageal reflux disease	61	0
Impaired gastric emptying	5	0
Infrequent bowel movements	2	0
Intestinal pseudo-obstruction	2	0
<b><i>Gastrointestinal disorders NEC</i></b>		
Food poisoning	1	0
Functional gastrointestinal disorder	5	0
Gastric disorder	4	0
Gastrointestinal disorder	8	0
Stomach mass	1	0
<b><i>Gastrointestinal dyskinetic disorders</i></b>		

## Case Series Drug Analysis Print

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

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

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>		
Change of bowel habit	3	0
Dyschezia	1	0
Gastrointestinal motility disorder	1	0
<b><i>Gastrointestinal fistulae</i></b>		
Diverticular fistula	1	0
<b><i>Gastrointestinal inflammatory disorders NEC</i></b>		
Duodenitis	1	0
Enteritis	3	0
Epiploic appendagitis	1	0
Gastrointestinal inflammation	1	0
Intestinal angioedema	1	0
<b><i>Gastrointestinal mucosal dystrophies and secretion disorders</i></b>		
Hyperchlorhydria	3	0
<b><i>Gastrointestinal signs and symptoms NEC</i></b>		
Abdominal discomfort	346	0
Abdominal symptom	1	0
Acute abdomen	3	0
Anal incontinence	10	0
Breath odour	9	0
Dysphagia	109	1
Odynophagia	11	0
<b><i>Gastrointestinal spastic and hypermotility disorders</i></b>		
Defaecation urgency	6	0
Frequent bowel movements	15	0
Irritable bowel syndrome	40	0
Oesophageal spasm	3	0
Pylorospasm	1	0
<b><i>Gastrointestinal stenosis and obstruction NEC</i></b>		
Intestinal obstruction	2	0
<b><i>Gastrointestinal vascular malformations</i></b>		
Gastric antral vascular ectasia	6	0
<b><i>Gastrointestinal vascular occlusion and infarction</i></b>		
Intestinal ischaemia	3	2
Mesenteric vein thrombosis	4	0
Visceral venous thrombosis	1	0
<b><i>Gingival disorders, signs and symptoms NEC</i></b>		
Gingival blister	8	0
Gingival discomfort	2	0
Gingival disorder	3	0
Gingival erythema	1	0
Gingival pain	57	0
Gingival pruritus	1	0
Gingival swelling	17	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	4	0
<b><i>Gingival haemorrhages</i></b>		
Gingival bleeding	28	0
<b><i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i></b>		
Gastric varices	1	0
Haemorrhoids	17	0
Haemorrhoids thrombosed	1	0
<b><i>Intestinal haemorrhages</i></b>		
Anal haemorrhage	10	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>		
Rectal haemorrhage	38	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
Celiac disease	7	0
Steatorrhoea	3	0
<b>Nausea and vomiting symptoms</b>		
Discoloured vomit	8	0
Nausea	8065	1
Regurgitation	1	0
Retching	51	0
Vomiting	2284	2
Vomiting projectile	36	0
<b>Non-mechanical ileus</b>		
Ileus paralytic	1	0
<b>Non-site specific gastrointestinal haemorrhages</b>		
Gastrointestinal haemorrhage	11	0
Haematemesis	22	2
Haematochezia	24	0
Melaena	7	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	1	0
<b>Oral dryness and saliva altered</b>		
Aptyalism	2	0
Dry mouth	326	0
Lip dry	27	0
Saliva altered	2	0
Salivary hypersecretion	26	0
<b>Oral soft tissue disorders NEC</b>		
Angina bullosa haemorrhagica	1	0
Chapped lips	13	0
Cheilitis	19	0
Enlarged uvula	9	0
Lip blister	15	0
Lip disorder	4	0
Oral disorder	7	0
Oral lichen planus	3	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	2	0
<b>Oral soft tissue haemorrhages</b>		
Mouth haemorrhage	6	0
Oral blood blister	8	0
Oral purpura	1	0
<b>Oral soft tissue infections</b>		
Angular cheilitis	1	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>Oral soft tissue signs and symptoms</i>		
Anaesthesia oral	1	0
Burning mouth syndrome	4	0
Coating in mouth	1	0
Hypoaesthesia oral	287	0
Lip discolouration	2	0
Lip erythema	1	0
Lip exfoliation	5	0
Lip pain	36	0
Lip pruritus	7	0
Lip scab	1	0
Oral discomfort	50	0
Oral dysaesthesia	1	0
Oral mucosal blistering	10	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	10	0
Oral mucosal erythema	3	0
Oral mucosal exfoliation	6	0
Oral mucosal roughening	3	0
Oral pain	109	0
Oral pruritus	15	0
Paraesthesia oral	658	0
Pigmentation lip	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip oedema	3	0
Lip swelling	429	0
Mouth swelling	55	0
Oedema mouth	4	0
Palatal oedema	2	0
Palatal swelling	1	0
<i>Peptic ulcers and perforation</i>		
Peptic ulcer haemorrhage	6	0
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	1	0
<i>Peritoneal and retroperitoneal fibrosis and adhesions</i>		
Abdominal adhesions	1	0
<i>Peritoneal and retroperitoneal haemorrhages</i>		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	1
<i>Rectal inflammations NEC</i>		
Proctitis	1	0
Proctitis ulcerative	1	0
<i>Salivary gland disorders NEC</i>		
Salivary gland pain	8	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	6	0
Salivary gland enlargement	3	0
Submaxillary gland enlargement	6	0
<i>Salivary gland infections and inflammations</i>		
Noninfective sialoadenitis	1	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	27	0
Lip ulceration	10	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>		
Mouth ulceration	249	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	39	0
<b><i>Tongue disorders</i></b>		
Glossitis	10	0
Plicated tongue	2	0
Tongue disorder	22	0
Tongue haemorrhage	1	0
Tongue ulceration	18	0
Trichoglossia	2	0
<b><i>Tongue signs and symptoms</i></b>		
Glossodynia	129	0
Scalloped tongue	4	0
Stiff tongue	2	0
Swollen tongue	314	0
Tongue blistering	10	0
Tongue coated	11	0
Tongue discolouration	18	0
Tongue discomfort	28	0
Tongue dry	11	0
Tongue eruption	8	0
Tongue erythema	4	0
Tongue exfoliation	1	0
Tongue movement disturbance	3	0
Tongue oedema	18	0
Tongue pruritus	1	0
Tongue rough	2	0
Tongue spasm	6	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>20395</b>	<b>15</b>

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>General disorders</b>		
<i><b>Administration site reactions NEC</b></i>		
Administration site bruise	4	0
Administration site erythema	2	0
Administration site extravasation	2	0
Administration site haematoma	3	0
Administration site inflammation	1	0
Administration site irritation	1	0
Administration site joint discomfort	1	0
Administration site joint movement impairment	1	0
Administration site pain	12	0
Administration site rash	1	0
Administration site swelling	2	0
Administration site warmth	2	0
Puncture site bruise	16	0
Puncture site pain	5	0
Puncture site reaction	1	0
Puncture site swelling	2	0
Vessel puncture site bruise	1	0
Vessel puncture site erythema	1	0
Vessel puncture site pain	1	0
<i><b>Adverse effect absent</b></i>		
No adverse event	16	0
<i><b>Application and instillation site reactions</b></i>		
Application site acne	2	0
Application site bruise	4	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	2	0
<i><b>Asthenic conditions</b></i>		
Asthenia	901	1
Chronic fatigue syndrome	36	0
Decreased activity	2	0
Fatigue	12612	0
Malaise	2915	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: 14-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> 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	126	126
Sudden death	23	23
<b>Febrile disorders</b>		
Hyperpyrexia	6	0
Pyrexia	8572	0
<b>Feelings and sensations NEC</b>		
Chills	5805	0
Feeling abnormal	722	0
Feeling cold	718	0
Feeling drunk	44	0
Feeling hot	653	0
Feeling jittery	12	0
Feeling of body temperature change	182	0
Hangover	37	0
Hunger	14	0
Sensation of foreign body	31	0
Temperature intolerance	19	0
Thirst	186	0
<b>Gait disturbances</b>		
Gait disturbance	87	0
Gait inability	36	0
Loss of control of legs	9	0
<b>General signs and symptoms NEC</b>		
Adhesion	1	0
Condition aggravated	85	0
Crepitations	1	0
Crying	57	0
Deformity	2	0
Developmental delay	1	0
Discharge	2	0
Disease progression	2	0
Disease recurrence	15	0
Effusion	2	0
Energy increased	9	0
Exercise tolerance decreased	4	0
Foaming at mouth	1	0
General physical health deterioration	11	1
General symptom	1	0
Glassy eyes	2	0
High-pitched crying	2	0
Illness	912	0
Induration	3	0
Influenza like illness	1429	0
Irritability postvaccinal	2	0
Local reaction	65	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>General disorders</b> General disorders cont'd		
Moaning	1	0
Multiple organ dysfunction syndrome	3	1
Nonspecific reaction	1	0
Peripheral swelling	1887	0
Pre-existing condition improved	8	0
Prolapse	1	0
Screaming	8	0
Secretion discharge	6	0
Swelling	1423	0
Swelling face	488	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 warmth	1	0
<b>Inflammations</b>		
Granuloma	1	0
Inflammation	174	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	20	0
Injection site bruising	37	0
Injection site coldness	1	0
Injection site cyst	2	0
Injection site discolouration	4	0
Injection site discomfort	9	0
Injection site erythema	225	0
Injection site haemorrhage	4	0
Injection site hypoaesthesia	8	0
Injection site indentation	2	0
Injection site induration	2	0
Injection site inflammation	23	0
Injection site joint discomfort	1	0
Injection site joint movement impairment	1	0
Injection site joint pain	11	0
Injection site lymphadenopathy	1	0
Injection site macule	1	0
Injection site mass	282	0
Injection site necrosis	3	0
Injection site oedema	11	0
Injection site pain	1864	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 paraesthesia	9	0
Injection site pruritus	107	0
Injection site rash	84	0
Injection site reaction	20	0
Injection site scab	2	0
Injection site scar	3	0
Injection site swelling	198	0
Injection site urticaria	16	0
Injection site vesicles	7	0
Injection site warmth	102	0
<b>Interactions</b>		
Alcohol interaction	2	0
Drug interaction	16	0
<b>Mass conditions NEC</b>		
Cyst	12	0
Mass	24	0
Nodule	17	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	1	0
<b>Oedema NEC</b>		
Face oedema	21	0
Generalised oedema	1	0
Localised oedema	14	0
Oedema	33	0
Oedema peripheral	49	0
<b>Pain and discomfort NEC</b>		
Axillary pain	1291	0
Chest discomfort	722	0
Chest pain	1255	0
Discomfort	163	0
Facial discomfort	11	0
Facial pain	118	0
Inflammatory pain	3	0
Non-cardiac chest pain	16	0
Pain	4184	0
Suprapubic pain	1	0
Tenderness	397	0
Visceral pain	1	0
<b>Therapeutic and nontherapeutic responses</b>		
Adverse drug reaction	15	0
Adverse event	3	0
Adverse reaction	8	0
Drug ineffective	139	1
Immediate post-injection reaction	2	0
Inadequate analgesia	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>General disorders</b> General disorders cont'd		
No reaction on previous exposure to drug	33	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	37	0
Treatment failure	5	0
Vaccination failure	6	0
<b>Trophic disorders</b>		
Calcinosis	1	0
<b>Ulcers NEC</b>		
Ulcer	10	0
<b>Vaccination site reactions</b>		
Extensive swelling of vaccinated limb	9	0
Shoulder injury related to vaccine administration	10	0
Vaccination site bruising	72	0
Vaccination site coldness	1	0
Vaccination site cyst	2	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	9	0
Vaccination site discomfort	35	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	385	0
Vaccination site granuloma	1	0
Vaccination site haematoma	1	0
Vaccination site haemorrhage	9	0
Vaccination site hypersensitivity	2	0
Vaccination site hypoaesthesia	10	0
Vaccination site induration	58	0
Vaccination site inflammation	40	0
Vaccination site irritation	7	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	6	0
Vaccination site joint movement impairment	12	0
Vaccination site joint pain	23	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	144	0
Vaccination site movement impairment	49	0
Vaccination site nerve damage	1	0
Vaccination site nodule	1	0
Vaccination site oedema	3	0
Vaccination site pain	1374	0
Vaccination site paraesthesia	4	0
Vaccination site pruritus	94	0
Vaccination site rash	70	0
Vaccination site reaction	22	0
Vaccination site scab	1	0
Vaccination site swelling	377	0



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Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Vaccination site ulcer	1	0
Vaccination site urticaria	8	0
Vaccination site vesicles	2	0
Vaccination site warmth	189	0
<b><i>Withdrawal and rebound effects</i></b>		
Drug withdrawal syndrome	4	0
Withdrawal syndrome	13	0
<b>General disorders SOC TOTAL</b>	<b>55292</b>	<b>154</b>

## Case Series Drug Analysis Print

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Report Run Date: 14-Jun-2021

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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	3	0
Cholangitis	1	0
<i><b>Cholecystitis and cholelithiasis</b></i>		
Cholelithiasis	5	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	5	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	1	0
<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	5	0
Portal vein thrombosis	2	0
<i><b>Hepatobiliary signs and symptoms</b></i>		
Hepatic pain	11	0
Liver tenderness	3	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Autoimmune hepatitis	3	0
Drug-induced liver injury	3	0
Hepatitis	7	0
Immune-mediated hepatic disorder	1	0
Liver injury	8	0
<b>Hepatic disorders SOC TOTAL</b>	<b>83</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 14-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	10	0
Allergy to arthropod bite	2	0
Allergy to arthropod sting	1	0
Allergy to metals	1	0
Hypersensitivity	536	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 allergy	1	0
Contrast media reaction	1	0
Drug hypersensitivity	16	0
Food allergy	11	0
Oral allergy syndrome	2	0
Reaction to colouring	1	0
Reaction to excipient	5	0
Reaction to preservatives	3	0
Rubber sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	328	2
Anaphylactic shock	26	0
Anaphylactoid reaction	18	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	1	0
Seasonal allergy	25	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	20	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	19	0
Graft versus host disease	1	0
Immune system disorder	13	0
Immune-mediated adverse reaction	4	0
Immunisation reaction	1	0
Sensitisation	2	0
Systemic immune activation	2	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
<i>Transplant rejections</i>		
Corneal graft rejection	4	0
Kidney transplant rejection	1	0
Solid organ transplant rejection	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Immune system disorders		
Immune system disorders cont'd		
Immune system disorders SOC TOTAL	1125	2

## Case Series Drug Analysis Print

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

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Abdominal abscess	1	0
Abdominal infection	1	0
Anal abscess	1	0
Appendicitis	15	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
<b><i>Aspergillus infections</i></b>		
Bronchopulmonary aspergillosis	1	0
<b><i>Bacterial infections NEC</i></b>		
Arthritis bacterial	2	0
Bacterial diarrhoea	1	0
Bacterial infection	3	0
Cellulitis	117	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
Folliculitis	8	0
Injection site cellulitis	2	0
Meningitis bacterial	2	0
Paronychia	1	0
Perichondritis	1	0
Periorbital cellulitis	1	0
Tonsillitis bacterial	2	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	14	0
<b><i>Bartonella infections</i></b>		
Cat scratch disease	1	0
<b><i>Bone and joint infections</i></b>		
Abscess jaw	1	0
Osteomyelitis	1	0
<b><i>Borrelial infections</i></b>		
Lyme disease	1	0
Relapsing fever	1	0
<b><i>Breast infections</i></b>		
Breast abscess	2	0
Mastitis	28	0
<b><i>Caliciviral infections</i></b>		
Gastroenteritis norovirus	1	0
<b><i>Campylobacter infections</i></b>		
Campylobacter gastroenteritis	1	0
<b><i>Candida infections</i></b>		
Anal candidiasis	2	0
Candida infection	19	0
Oral candidiasis	28	0
Systemic candida	1	0
Vulvovaginal candidiasis	17	0
<b><i>Central nervous system and spinal infections</i></b>		

## Case Series Drug Analysis Print

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

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Cavernous sinus thrombosis	1	0
Encephalitis	12	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	670	32
COVID-19 pneumonia	26	12
Coronavirus infection	6	0
Severe acute respiratory syndrome	1	0
Suspected COVID-19	38	1
<b><i>Coxiella infections</i></b>		
Q fever	9	0
<b><i>Dental and oral soft tissue infections</i></b>		
Abscess oral	3	0
Gingivitis	7	0
Parotitis	7	0
Pulpitis dental	1	0
Sialoadenitis	3	0
Tooth abscess	6	0
Tooth infection	4	0
<b><i>Ear infections</i></b>		
Ear infection	46	0
Labyrinthitis	58	0
Mastoiditis	1	0
Otitis media	2	0
Otitis media acute	1	0
<b><i>Ectoparasitic infestations</i></b>		
Acarodermatitis	3	0
Bed bug infestation	1	0
<b><i>Epstein-Barr viral infections</i></b>		
Epstein-Barr virus infection	1	0
Infectious mononucleosis	15	0
<b><i>Eye and eyelid infections</i></b>		
Conjunctivitis	41	0
Eye abscess	1	0
Eye infection	12	0
Eyelid infection	2	0
Hordeolum	14	0
Periorbital infection	2	0
<b><i>Female reproductive tract infections</i></b>		
Bartholinitis	1	0
Endometritis	1	0
Vulval abscess	1	0
<b><i>Fungal infections NEC</i></b>		
Fungal infection	5	0
Fungal skin infection	1	0
Onychomycosis	1	0
Pneumonia fungal	1	0
Vulvovaginal mycotic infection	2	0

## Case Series Drug Analysis Print

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

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

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>Hepatitis virus infections</i></b>		
Hepatitis A	1	0
Hepatitis E	1	0
<b><i>Hepatobiliary and spleen infections</i></b>		
Biliary sepsis	1	0
<b><i>Herpes viral infections</i></b>		
Disseminated varicella zoster virus infection	1	0
Eczema herpeticum	2	0
Genital herpes	39	0
Genital herpes simplex	4	0
Herpes ophthalmic	3	0
Herpes simplex	14	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	2	0
Herpes virus infection	5	0
Herpes zoster	903	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	7	0
Herpes zoster reactivation	1	0
Nasal herpes	3	0
Ophthalmic herpes zoster	2	0
Oral herpes	193	0
Varicella	17	0
Varicella zoster virus infection	1	0
<b><i>Infections NEC</i></b>		
Abscess	24	0
Abscess limb	3	0
Abscess soft tissue	1	0
Genital abscess	1	0
Infected bite	1	0
Infected cyst	1	0
Infection	128	0
Injection site abscess	1	0
Injection site infection	4	0
Localised infection	17	0
Lymph gland infection	5	0
Lymph node abscess	2	0
Respiratory tract infection	4	0
Vaccination site abscess	3	0
Vaccination site infection	11	0
Vaccine breakthrough infection	23	0
Vestibulitis	2	0
<b><i>Infectious transmissions</i></b>		
Secondary transmission	2	0
<b><i>Influenza viral infections</i></b>		
Influenza	884	0
<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	111	7
Pneumonia	65	9

## Case Series Drug Analysis Print

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

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Sputum purulent	1	0
<b>Male reproductive tract infections</b>		
Epididymitis	2	0
Orchitis	3	0
Prostate infection	1	0
<b>Mumps viral infections</b>		
Mumps	5	0
<b>Muscle and soft tissue infections</b>		
Infective tenosynovitis	1	0
Necrotising fasciitis	1	0
Soft tissue infection	1	0
<b>Neisseria infections</b>		
Gonorrhoea	1	0
<b>Pneumocystis infections</b>		
Pneumocystis jirovecii pneumonia	1	0
<b>Polyomavirus infections</b>		
Progressive multifocal leukoencephalopathy	1	0
<b>Prion-associated disorders</b>		
Creutzfeldt-Jakob disease	1	0
<b>Retroviral infections</b>		
HIV infection	1	0
<b>Rotaviral infections</b>		
Gastroenteritis rotavirus	1	0
<b>Rubeola viral infections</b>		
Measles	2	0
<b>Sepsis, bacteraemia, viraemia and fungaemia NEC</b>		
Bacteraemia	1	0
Neutropenic sepsis	2	0
Sepsis	28	3
Sepsis syndrome	1	0
Septic shock	4	1
Urosepsis	3	0
<b>Skin structures and soft tissue infections</b>		
Abscess sweat gland	1	0
Acne pustular	1	0
Dermatitis infected	1	0
Impetigo	3	0
Infected skin ulcer	1	0
Injection site pustule	1	0
Pustule	8	0
Rash pustular	9	0
Skin infection	21	0
Subcutaneous abscess	6	0
Vaccination site pustule	2	0
<b>Staphylococcal infections</b>		
Furuncle	27	0
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	2	0
Staphylococcal sepsis	1	0
<b>Streptococcal infections</b>		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	5	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		
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	486	0
Pharyngitis	13	0
Rhinitis	32	0
Sinusitis	74	0
Tonsillitis	50	0
Tracheitis	4	0
Upper respiratory tract infection	3	0
<b>Urinary tract infections</b>		
Cystitis	38	0
Kidney infection	12	0
Pyelonephritis	1	0
Urinary tract infection	76	0
<b>Vascular infections</b>		
Haematoma infection	1	0
Infusion site infection	1	0
Lymphangitis	5	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
Sweating fever	59	0
Vestibular neuronitis	14	0
Viral diarrhoea	1	0
Viral infection	28	0
Viral labyrinthitis	3	0
Viral pericarditis	1	0
Viral pharyngitis	8	0

## Case Series Drug Analysis Print

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

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name		Total	Fatal
<b>Infections</b>	Infections cont'd		
Viral rash		32	0
Viral sinusitis		1	0
Viral tonsillitis		1	0
<b>Infections SOC TOTAL</b>		<b>5030</b>	<b>68</b>

## Case Series Drug Analysis Print

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

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

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	3	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	3	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	3	0
<b><i>Cerebral injuries NEC</i></b>		
Brain contusion	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	7	0
Foreign body in throat	1	0
<b><i>Conditions caused by cold</i></b>		
Chillblains	39	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	20	0
Foetal exposure during pregnancy	13	0
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	462	0
Maternal exposure during pregnancy	243	0
Paternal exposure before pregnancy	1	0
Paternal exposure during pregnancy	3	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>		
Toxic anterior segment syndrome	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
<b>Eye injuries NEC</b>		
Eye contusion	12	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	5	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>Intentional product use issues</b>		
Intentional product use issue	1	0
<b>Limb fractures and dislocations</b>		
Atypical femur fracture	1	0
Clavicle fracture	16	0
Wrist fracture	1	0
<b>Medication errors, product use errors and issues NEC</b>		
Circumstance or information capable of leading to medication error	2	0
Dose calculation error	1	0
Medication error	11	0
Prescription drug used without a prescription	2	0
Product use complaint	1	0
Product use issue	8	0
Vaccination error	5	0
Wrong dose	2	0
Wrong drug	9	0
Wrong technique in product usage process	3	0
<b>Muscle, tendon and ligament injuries</b>		
Epicondylitis	7	0
Ligament sprain	4	0
Mallet finger	1	0
Muscle injury	10	0
Muscle rupture	2	0
Muscle strain	17	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

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

Report Run Date: 14-Jun-2021

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Nerve injury	26	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	1	0
Bite	1	0
Electric shock	8	0
Fall	86	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	33	0
Post procedural complication	3	0
Procedural pain	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	42	0
<b>Overdoses NEC</b>		
Overdose	18	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	7	0
Toxicity to various agents	2	0
<b>Product administration errors and issues</b>		
Accidental overdose	3	0
Contraindicated product administered	1	0
Expired product administered	9	0
Inappropriate schedule of product administration	60	0
Incomplete course of vaccination	1	0
Incorrect dose administered	49	0
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	2	0
Poor quality product administered	2	0
Product administered at inappropriate site	8	0

## Case Series Drug Analysis Print

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Report Run Date: 14-Jun-2021

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Product administered to patient of inappropriate age	1	0
Product administration error	4	0
Product dose omission issue	3	0
Wrong product administered	12	0
<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	13	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	20	0
Limb crushing injury	2	0
Limb injury	40	0
Nasal injury	1	0
Neck injury	1	0
<b>Skin injuries NEC</b>		
Contusion	534	0
Nail avulsion	1	0
Scar	4	0
Scratch	3	0
Skin abrasion	5	0
Skin injury	1	0
Skin wound	1	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
Thermal burn	12	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Thermal burns of eye	8	0
<b>Underdoses NEC</b>		
Underdose	5	0
<b>Vaccination related complications</b>		
Adverse event following immunisation	1	0
Vaccination complication	39	0
<b>Injuries SOC TOTAL</b>	<b>2182</b>	<b>2</b>

## Case Series Drug Analysis Print

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

Report Run Date: 14-Jun-2021

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

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
<i><b>Autoimmunity analyses</b></i>		
Antinuclear antibody	1	0
Antinuclear antibody increased	1	0
Antiphospholipid antibodies	1	0
Rheumatoid factor	3	0
Rheumatoid factor increased	1	0
<i><b>Blood counts NEC</b></i>		
Blood count	3	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	4	0
Blood pH increased	5	0
Oxygen consumption decreased	1	0
Oxygen saturation	5	0
Oxygen saturation decreased	42	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	8	0
Blood glucose decreased	20	0
Blood glucose fluctuation	13	0
Blood glucose increased	73	0
Glycosylated haemoglobin increased	1	0
<i><b>Cardiac auscultatory investigations</b></i>		
Cardiac murmur	9	0
Heart sounds	1	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	1	0
<i><b>Central nervous system imaging procedures</b></i>		
Computerised tomogram head	2	0
Magnetic resonance imaging head	10	0
Magnetic resonance imaging head abnormal	1	0
<i><b>Chemistry analyses NEC</b></i>		
Inflammatory marker increased	3	0



## Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
<b><i>Cholesterol analyses</i></b>		
Blood cholesterol increased	2	0
Remnant-like lipoprotein particles	3	0
<b><i>Coagulation and bleeding analyses</i></b>		
Activated partial thromboplastin time prolonged	15	0
Bleeding time	1	0
Bleeding time abnormal	1	0
Bleeding time prolonged	1	0
Blood thromboplastin	1	0
Clot retraction	1	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	4	0
Coagulation time shortened	1	0
Fibrin D dimer increased	4	0
International normalised ratio abnormal	4	0
International normalised ratio decreased	18	0
International normalised ratio fluctuation	1	0
International normalised ratio increased	42	0
<b><i>ECG investigations</i></b>		
Electrocardiogram	1	0
Electrocardiogram ST segment elevation	3	0
Electrocardiogram T wave inversion	2	0
Electrocardiogram abnormal	7	0
<b><i>Endocrine analyses and imaging NEC</i></b>		
Hormone level abnormal	8	0
<b><i>Faecal analyses NEC</i></b>		
Faecal calprotectin	2	0
Faecal calprotectin increased	3	0
<b><i>Fertility analyses</i></b>		
Semen volume decreased	2	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	168	0
Heart rate abnormal	18	0
Heart rate decreased	24	0
Heart rate increased	381	0
Heart rate irregular	60	0
Pulse abnormal	9	0
Pulse pressure increased	1	0
Radial pulse abnormal	1	0
Sinus rhythm	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
<b><i>Imaging procedures NEC</i></b>		
Computerised tomogram	1	0
Magnetic resonance imaging	1	0
Magnetic resonance imaging abnormal	1	0
<b><i>Immunoglobulin analyses</i></b>		
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	1	0
<b><i>Immunology analyses NEC</i></b>		
Antibody test	1	0
Immunology test	6	0
<b><i>Immunology skin tests NEC</i></b>		
Skin test positive	1	0
<b><i>Investigations NEC</i></b>		
Blood test	8	0
Blood test abnormal	15	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><i>Liver function analyses</i></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	17	0
Liver function test increased	10	0
Transaminases increased	2	0
<b><i>Metabolism tests NEC</i></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><i>Microbiology and serology tests NEC</i></b>		
Culture negative	1	0
<b><i>Mineral and electrolyte analyses</i></b>		
Blood copper increased	1	0
Blood iron	1	0
Blood iron decreased	2	0
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	4	0
Blood potassium increased	1	0
Blood sodium decreased	5	0
Serum ferritin decreased	1	0
Serum ferritin increased	1	0
<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>		

## Case Series Drug Analysis Print

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

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
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	2	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	5	0
<b><i>Physical examination procedures and organ system status</i></b>		
Body temperature	165	0
Body temperature abnormal	25	0
Body temperature decreased	25	0
Body temperature fluctuation	18	0
Body temperature increased	261	0
Body temperature normal	1	0
Breath sounds abnormal	1	0
General physical condition abnormal	1	0
Grip strength	2	0
Grip strength decreased	10	0
Head lag	1	0
Lymph node palpable	24	0
Muscle strength abnormal	1	0
Ophthalmological examination	1	0
Orthopaedic examination abnormal	1	0
Palpatory finding abnormal	1	0
Product residue present	2	0
Psoriasis area severity index decreased	1	0
Respiratory rate	3	0
Respiratory rate decreased	4	0
Respiratory rate increased	25	0
Skin temperature	24	0
Temperature difference of extremities	6	0
Weight	1	0
Weight decreased	35	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 decreased	43	0
Platelet count increased	1	0
<b><i>Protein analyses NEC</i></b>		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	11	0
<b><i>Red blood cell analyses</i></b>		

## Case Series Drug Analysis Print

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

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Haematocrit	1	0
Haemoglobin decreased	8	0
Red blood cell count decreased	1	0
<b>Renal function analyses</b>		
Glomerular filtration rate decreased	1	0
<b>Reproductive hormone analyses</b>		
False negative pregnancy test	1	0
Pregnancy test	2	0
Pregnancy test false positive	1	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	11	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	3	0
Troponin	1	0
Troponin increased	4	0
<b>Therapeutic drug monitoring analyses</b>		
Analgesic drug level	2	0
Anticoagulation drug level above therapeutic	1	0
Anticoagulation drug level below therapeutic	5	0
Anticoagulation drug level increased	1	0
Drug level decreased	1	0
<b>Thyroid analyses</b>		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	2	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	1	0
Opiates	1	0
<b>Urinalysis NEC</b>		
Blood urine	7	0
Blood urine present	20	0
Cells in urine	1	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>Investigations</b>		
Investigations cont'd		
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	8	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	37	0
Blood pressure diastolic	1	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	2	0
Blood pressure increased	137	0
Blood pressure measurement	24	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	8	0
Coronavirus test positive	3	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	5	0
SARS-CoV-2 antibody test negative	10	0
SARS-CoV-2 antibody test positive	2	0
SARS-CoV-2 test	20	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	80	0
Viral test	4	0
<b>Vitamin analyses</b>		
Blood folate decreased	3	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
Neutrophil count	1	0
Neutrophil count decreased	2	0
White blood cell count	1	0
White blood cell count decreased	8	0
White blood cell count increased	3	0
<b>Investigations SOC TOTAL</b>	<b>2436</b>	<b>2</b>

## Case Series Drug Analysis Print

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

Report Run Date: 14-Jun-2021

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	7	0
Decreased appetite	697	0
Eating disorder symptom	1	0
Food craving	7	0
Food refusal	6	0
Hyperphagia	2	0
Hypophagia	10	0
Increased appetite	11	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	29	0
Diabetes mellitus inadequate control	6	1
Increased insulin requirement	1	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	1	0
Type 1 diabetes mellitus	11	0
Type 2 diabetes mellitus	2	0
<i><b>Diabetic complications NEC</b></i>		
Diabetic complication	2	0
Diabetic ketoacidosis	9	0
Diabetic ketosis	1	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	56	0
<i><b>Electrolyte imbalance NEC</b></i>		
Fluid imbalance	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	6	0
Cachexia	1	0
Feeding disorder	33	0
Food aversion	6	0
Neonatal insufficient breast milk syndrome	1	0
Overweight	1	0
Poor feeding infant	5	0
Weight loss poor	1	0
<i><b>Hyperglycaemic conditions NEC</b></i>		
Hyperglycaemia	57	0
Insulin resistance	4	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Glycopenia	1	0
Hypoglycaemia	62	0

## Case Series Drug Analysis Print

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Report Run Date: 14-Jun-2021

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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		
Postprandial hypoglycaemia	1	0
<b>Iron deficiencies</b>		
Iron deficiency	3	0
<b>Lipid metabolism and deposit disorders NEC</b>		
Body fat disorder	1	0
<b>Metabolic acidoses (excl diabetic acidoses)</b>		
Ketoacidosis	4	0
Metabolic acidosis	2	0
<b>Mixed acid-base disorders</b>		
Acidosis	3	0
<b>Potassium imbalance</b>		
Hyperkalaemia	2	0
Hypokalaemia	2	0
Hypokalaemic syndrome	1	0
<b>Sodium imbalance</b>		
Hyponatraemia	6	0
Hyponatraemic syndrome	2	0
<b>Sugar intolerance (excl glucose intolerance)</b>		
Lactose intolerance	1	0
<b>Total fluid volume decreased</b>		
Dehydration	97	0
<b>Total fluid volume increased</b>		
Fluid retention	25	0
Hypervolaemia	1	0
<b>Vitamin deficiencies NEC</b>		
Hypovitaminosis	2	0
<b>Metabolic disorders SOC TOTAL</b>	<b>1222</b>	<b>1</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>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	142	0
Arthropathy	17	0
Autoimmune arthritis	2	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	1	0
Polyarthritis	11	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	213	0
Bone swelling	4	0
Coccydynia	2	0
Pain in jaw	185	0
Pubic pain	1	0
Spinal pain	32	0
<i><b>Bursal disorders</b></i>		
Bursitis	34	0
<i><b>Cartilage disorders</b></i>		
Chondritis	1	0
Costochondritis	29	0
Osteochondritis	1	0
Polychondritis	2	0
<i><b>Connective tissue disorders NEC</b></i>		
Connective tissue disorder	1	0
Polymyalgia rheumatica	31	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
Foot deformity	1	0
Hand deformity	2	0
Knee deformity	1	0
Limb deformity	3	0
Musculoskeletal deformity	1	0
<i><b>Joint related disorders NEC</b></i>		
Chondromalacia	1	0
Joint destruction	1	0
Joint laxity	3	0
Joint lock	12	0
Patellofemoral pain syndrome	1	0
Periarthritis	70	0



## Case Series Drug Analysis Print

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Report Run Date: 14-Jun-2021

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Rotator cuff syndrome	6	0
Temporomandibular joint syndrome	4	0
<b>Joint related signs and symptoms</b>		
Arthralgia	5249	0
Jaw clicking	4	0
Joint effusion	12	0
Joint noise	16	0
Joint range of motion decreased	8	0
Joint stiffness	127	0
Joint swelling	257	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	14	0
Polymyositis	3	0
<b>Muscle pains</b>		
Fibromyalgia	53	0
Myalgia	6720	0
Myalgia intercostal	1	0
Myofascial pain syndrome	6	0
<b>Muscle related signs and symptoms NEC</b>		
Haematoma muscle	1	0
Muscle atrophy	8	0
Muscle discomfort	2	0
Muscle disorder	3	0
Muscle fatigue	206	0
Muscle mass	2	0
Muscle spasms	539	0
Muscle swelling	13	0
Muscle tightness	41	0
Muscle twitching	177	0
<b>Muscle tone abnormalities</b>		
Muscle rigidity	7	0
Nuchal rigidity	8	0
Torticollis	3	0
Trismus	17	0
<b>Muscle weakness conditions</b>		
Muscular weakness	464	0
<b>Musculoskeletal and connective tissue conditions NEC</b>		
Back disorder	1	0
Limb mass	8	0
Mandibular mass	2	0
Mastication disorder	1	0

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i>Muscle &amp; tissue disorders cont'd</i>		
Mobility decreased	41	0
Musculoskeletal disorder	7	0
Musculoskeletal stiffness	699	0
Posture abnormal	1	0
<b><i>Musculoskeletal and connective tissue deformities of skull, face and buccal cavity</i></b>		
Head deformity	1	0
<b><i>Musculoskeletal and connective tissue infections and inflammations NEC</i></b>		
Dactylitis	1	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	5	0
<b><i>Musculoskeletal and connective tissue pain and discomfort</i></b>		
Back pain	1198	0
Flank pain	22	0
Limb discomfort	818	0
Musculoskeletal chest pain	93	0
Musculoskeletal discomfort	51	0
Musculoskeletal pain	32	0
Neck pain	1018	0
Pain in extremity	6832	0
Rheumatic disorder	5	0
<b><i>Myopathies</i></b>		
Myopathy	4	0
Rhabdomyolysis	4	0
<b><i>Osteoarthropathies</i></b>		
Nodal osteoarthritis	1	0
Osteoarthritis	26	0
<b><i>Psoriatic arthropathies</i></b>		
Psoriatic arthropathy	11	0
<b><i>Rheumatoid arthropathies</i></b>		
Rheumatoid arthritis	71	0
<b><i>Soft tissue disorders NEC</i></b>		
Axillary mass	144	0
Fluctuance	1	0
Groin pain	61	0
Neck mass	16	0
Purple glove syndrome	1	0
Soft tissue disorder	1	0
Soft tissue swelling	3	0
<b><i>Spine and neck deformities</i></b>		
Kyphosis	1	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
<b><i>Spondyloarthropathies</i></b>		
Ankylosing spondylitis	6	0
Arthritis reactive	22	0
Spondylitis	1	0
<b><i>Synovial disorders</i></b>		
Synovial cyst	11	0
Synovitis	4	0
<b><i>Tendon disorders</i></b>		

## 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		
Enthesopathy	1	0
Tendon pain	8	0
Tendonitis	16	0
Tenosynovitis	2	0
Tenosynovitis stenosaurs	1	0
Trigger finger	12	0
<b>Trunk deformities</b>		
Drooping shoulder syndrome	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>26106</b>	<b>0</b>

## Case Series Drug Analysis Print

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Report Run Date: 14-Jun-2021

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MedDRA Version: MedDRA 24.0

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 malignant</i>		
Breast cancer	25	0
Breast cancer female	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>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	13	1
<i>Lymphoproliferative disorders NEC (excl leukaemias and lymphomas)</i>		
Lymphoproliferative disorder	1	0
<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 malignant site unspecified NEC</i>		
Neoplasm malignant	2	0
Second primary malignancy	1	0
Squamous cell carcinoma	3	0
<i>Neoplasms unspecified malignancy and site unspecified NEC</i>		
Neoplasm	1	0
Neoplasm recurrence	1	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Neoplasms</b> Neoplasms cont'd		
<b><i>Nervous system neoplasms benign NEC</i></b>		
Cranial nerve neoplasm benign	1	0
<b><i>Nervous system neoplasms unspecified malignancy NEC</i></b>		
Brain neoplasm	1	0
<b><i>Neuromas</i></b>		
Acoustic neuroma	1	0
<b><i>Non-Hodgkin's lymphomas NEC</i></b>		
Non-Hodgkin's lymphoma	1	0
<b><i>Oesophageal neoplasms malignant</i></b>		
Oesophageal cancer metastatic	1	0
<b><i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i></b>		
Tonsil cancer	2	0
<b><i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i></b>		
Pancreatic carcinoma	4	0
<b><i>Plasma cell myelomas</i></b>		
POEMS syndrome	1	0
Plasma cell myeloma	1	0
<b><i>Plasma cell neoplasms NEC</i></b>		
TEMPI syndrome	1	0
<b><i>Prostatic neoplasms malignant</i></b>		
Prostate cancer	2	0
<b><i>Renal neoplasms malignant</i></b>		
Renal cancer	2	0
<b><i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i></b>		
Lung neoplasm malignant	4	0
<b><i>Skin melanomas (excl ocular)</i></b>		
Malignant melanoma	1	0
<b><i>Skin neoplasms benign</i></b>		
Acrochordon	2	0
Anogenital warts	2	0
Haemangioma of skin	1	0
Melanocytic naevus	4	0
Skin papilloma	4	0
<b><i>Skin neoplasms malignant and unspecified (excl melanoma)</i></b>		
Basal cell carcinoma	2	0
Neoplasm skin	1	0
Squamous cell carcinoma of skin	1	0
<b><i>Soft tissue neoplasms benign NEC</i></b>		
Lipoma	2	0
Lymphangioma	1	0
<b><i>Soft tissue sarcomas histology unspecified</i></b>		
Sarcoma	1	0
<b><i>Thyroid neoplasms malignant</i></b>		
Papillary thyroid cancer	2	0
Thyroid cancer	1	0
<b><i>Uterine neoplasms benign</i></b>		
Uterine leiomyoma	5	0
<b>Neoplasms SOC TOTAL</b>	<b>133</b>	<b>2</b>

## Case Series Drug Analysis Print

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

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Abnormal reflexes</b></i>		
Areflexia	4	0
Extensor plantar response	1	0
Hyperreflexia	1	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	16	0
<i><b>Acute polyneuropathies</b></i>		
Guillain-Barre syndrome	38	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	28	6
Cerebral infarction	22	1
Cerebral thrombosis	5	0
Cerebrovascular accident	245	12
Embolic stroke	5	0
Haemorrhage intracranial	6	1
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	30	1
Lacunar infarction	2	0
Lacunar stroke	2	0
Lateral medullary syndrome	1	0
Subarachnoid haemorrhage	8	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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MedDRA Version: MedDRA 24.0

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	26	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	4	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
<b>Coordination and balance disturbances</b>		
Ataxia	6	0
Balance disorder	204	0
Coordination abnormal	26	0
Dysdiadochokinesis	1	0
Dysstasia	27	0
Nystagmus	8	0
<b>Cortical dysfunction NEC</b>		
Aphasia	38	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	3	0
Clinically isolated syndrome	1	0
Demyelination	7	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	23	1
Lethargy	1396	0
Loss of consciousness	258	0
Sedation	5	0
Somnolence	545	0
Stupor	3	0
Syncope	808	0
<b>Disturbances in sleep phase rhythm</b>		

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Irregular sleep wake rhythm disorder	1	0
<b>Dyskinesias and movement disorders NEC</b>		
Akathisia	2	0
Bradykinesia	7	0
Clumsiness	9	0
Dyskinesia	31	0
Extrapyramidal disorder	1	0
Fine motor skill dysfunction	7	0
Hyperkinesia	3	0
Hypokinesia	30	1
Motor dysfunction	2	0
Movement disorder	28	0
Psychomotor hyperactivity	13	0
Synkinesis	1	0
Tardive dyskinesia	2	0
<b>Dystonias</b>		
Dystonia	12	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	2	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	6	0
<b>Facial cranial nerve disorders</b>		
Bell's palsy	269	0
Facial nerve disorder	3	0
Facial paralysis	216	0
Facial paresis	57	0
Facial spasm	25	0
<b>Generalised tonic-clonic seizures</b>		
Generalised tonic-clonic seizure	21	0
<b>Headaches NEC</b>		
Cervicogenic headache	3	0
Cluster headache	125	0
Cold-stimulus headache	10	0
Drug withdrawal headache	2	0
Exertional headache	5	0
External compression headache	1	0
Headache	15739	0
Medication overuse headache	2	0
New daily persistent headache	4	0
Occipital neuralgia	6	0
Ophthalmoplegic migraine	1	0
Primary cough headache	3	0
Primary headache associated with sexual activity	1	0
Sinus headache	214	0



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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Tension headache	303	0
Thunderclap headache	3	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	1	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	41	0
<b>Memory loss (excl dementia)</b>		
Amnesia	77	0
Memory impairment	70	0
Transient global amnesia	6	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	45	0
Cognitive linguistic deficit	1	0
Disturbance in attention	155	0
Mental impairment	26	0
<b>Migraine headaches</b>		
Hemiplegic migraine	11	0
Migraine	1456	0
Migraine with aura	102	0
Migraine without aura	11	0
Ophthalmic migraine	4	0
Retinal migraine	19	0
Typical aura without headache	4	0
Vestibular migraine	11	0
<b>Mixed cranial nerve disorders</b>		
Bulbar palsy	1	0
<b>Mononeuropathies</b>		
Carpal tunnel syndrome	10	0
Cubital tunnel syndrome	1	0
Mononeuropathy	1	0
Nerve compression	9	0
Peripheral nerve lesion	1	0
Peroneal nerve palsy	6	0
Sciatic nerve neuropathy	2	0
Ulnar neuritis	1	0
<b>Multiple sclerosis acute and progressive</b>		
Band sensation	1	0
Multiple sclerosis	21	0
Multiple sclerosis relapse	16	0
Tumefactive multiple sclerosis	1	1
<b>Muscle tone abnormal</b>		
Hypotonia	11	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
Nervous system disorders cont'd		
Stiff leg syndrome	1	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	19	0
<b>Narcolepsy and hypersomnia</b>		
Cataplexy	1	0
Hypersomnia	52	0
Narcolepsy	3	0
<b>Nervous system disorders NEC</b>		
Central nervous system lesion	2	0
Nervous system disorder	6	0
<b>Neurologic visual problems NEC</b>		
Hemianopia	1	0
Hemianopia homonymous	1	0
Quadrantanopia	1	0
Tunnel vision	8	0
<b>Neurological signs and symptoms NEC</b>		
Clonus	1	0
Dizziness	5285	0
Dizziness exertional	28	0
Dizziness postural	453	0
Drooling	13	0
Fontanelle bulging	1	0
Head discomfort	157	0
Hyporesponsive to stimuli	2	0
Inability to crawl	2	0
Infant irritability	2	0
Myoclonus	12	0
Neurological symptom	25	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	9	0
Presyncope	302	0
Sensory overload	2	0
Slow response to stimuli	2	0
Tongue biting	2	0
Unresponsive to stimuli	27	1
<b>Neuromuscular disorders NEC</b>		
Muscle contractions involuntary	12	0
Muscle spasticity	8	0
Neuromuscular pain	2	0
<b>Neuromuscular junction dysfunction</b>		
Myasthenia gravis	6	0
Myasthenia gravis crisis	2	0
<b>Olfactory nerve disorders</b>		
Anosmia	126	0
Hyposmia	9	0
Parosmia	130	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	18	0
<b>Paraesthesias and dysaesthesias</b>		
Burning feet syndrome	5	0
Burning sensation	263	0
Dysaesthesia	5	0
Formication	28	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Hand-arm vibration syndrome	2	0
Hemiparaesthesia	1	0
Hyperaesthesia	48	0
Hypoaesthesia	1414	0
Paraesthesia	1997	0
Reversed hot-cold sensation	2	0
Synaesthesia	1	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Diplegia	6	1
Hemiparesis	23	0
Hemiplegia	19	0
Locked-in syndrome	1	0
Monoparesis	36	0
Monoplegia	31	0
Paralysis	68	0
Paraparesis	3	0
Paresis	4	0
<b>Parkinson's disease and parkinsonism</b>		
Freezing phenomenon	7	0
Parkinson's disease	3	0
Parkinsonian gait	1	0
Parkinsonism	4	0
Reduced facial expression	3	0
<b>Partial complex seizures</b>		
Dreamy state	6	0
Focal dyscognitive seizures	1	0
Temporal lobe epilepsy	1	0
<b>Peripheral neuropathies NEC</b>		
Neuralgic amyotrophy	1	0
Neuritis	5	0
Neuropathy peripheral	55	0
Peripheral sensory neuropathy	6	0
Thoracic outlet syndrome	1	0
<b>Seizures and seizure disorders NEC</b>		
Atonic seizures	4	0
Clonic convulsion	1	0
Epilepsy	105	0
Epileptic aura	2	0
Epileptic encephalopathy	1	0
Febrile convulsion	14	0
Partial seizures	12	0
Post stroke seizure	1	0
Psychogenic seizure	6	0
Seizure	289	0
Seizure anoxic	1	0
Seizure cluster	4	0
Seizure like phenomena	1	0
Status epilepticus	37	0
Tonic clonic movements	2	0
Tonic convulsion	12	0
Tonic posturing	1	0
<b>Sensory abnormalities NEC</b>		
Ageusia	285	0

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Allodynia	11	0
Aura	10	0
Complex regional pain syndrome	1	0
Dysgeusia	780	0
Electric shock sensation	15	0
Hypergeusia	1	0
Hypogeusia	1	0
Loss of proprioception	3	0
Neuralgia	274	0
Persistent genital arousal disorder	1	0
Phantom limb syndrome	3	0
Post herpetic neuralgia	12	0
Restless legs syndrome	58	0
Sensory disturbance	41	0
Sensory loss	39	0
Taste disorder	161	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	94	0
Incoherent	5	0
Language disorder	1	0
Repetitive speech	1	0
Slow speech	6	0
Speech disorder	27	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	95	1
<b>Tremor (excl congenital)</b>		
Action tremor	1	0
Essential tremor	2	0
Head titubation	5	0
Resting tremor	1	0
Tremor	893	0
<b>Trigeminal disorders</b>		
Facial neuralgia	12	0
Numb chin syndrome	1	0
Trigeminal nerve disorder	1	0
Trigeminal neuralgia	28	0
<b>Vertigos NEC</b>		
Vertigo CNS origin	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>37404</b>	<b>41</b>

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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	110	2
<i>Foetal complications NEC</i>		
Foetal hypokinesia	2	0
Hydrops foetalis	1	0
<i>Foetal growth complications</i>		
Foetal growth restriction	1	1
<i>Gestational age and weight conditions</i>		
Premature baby	1	1
<i>Labour onset and length abnormalities</i>		
Premature delivery	1	0
Premature labour	1	0
Premature rupture of membranes	1	0
<i>Maternal complications of pregnancy NEC</i>		
Ectopic pregnancy	1	0
Morning sickness	9	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	14	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	5	0
<i>Stillbirth and foetal death</i>		
Foetal death	4	0
Stillbirth	3	1
<i>Umbilical cord complications</i>		
Umbilical cord abnormality	1	0
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	2	0
Pregnancy on contraceptive	1	0
Pregnancy on oral contraceptive	1	0
Pregnancy with contraceptive device	2	0
Pregnancy with implant contraceptive	2	0
Unintended pregnancy	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>170</b>	<b>5</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	3	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	5	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	5	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>58</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<i><b>Abnormal behaviour NEC</b></i>		
Abnormal behaviour	8	0
Behaviour disorder	1	0
Breath holding	1	0
Staring	3	0
<i><b>Adjustment disorders</b></i>		
Adjustment disorder with depressed mood	2	0
<i><b>Affect alterations NEC</b></i>		
Affect lability	5	0
Constricted affect	1	0
Flat affect	4	0
Inappropriate affect	7	0
<i><b>Amnesic symptoms</b></i>		
Paramnesia	3	0
<i><b>Anxiety symptoms</b></i>		
Agitation	51	0
Anxiety	320	0
Immunisation anxiety related reaction	1	0
Nervousness	104	0
Stress	20	0
Tension	17	0
<i><b>Attention deficit and disruptive behaviour disorders</b></i>		
Attention deficit hyperactivity disorder	2	0
<i><b>Behaviour and socialisation disturbances</b></i>		
Aggression	5	0
Aversion	1	0
Homicidal ideation	1	0
Indifference	5	0
Paranoia	12	0
Personality change	3	0
Social avoidant behaviour	4	0
Soliloquy	1	0
Suspiciousness	1	0
<i><b>Bipolar disorders</b></i>		
Bipolar I disorder	1	0
Bipolar disorder	4	0
<i><b>Cognitive and attention disorders and disturbances NEC</b></i>		
Daydreaming	3	0
Distractibility	1	0
Mental fatigue	116	0
<i><b>Communications disorders</b></i>		
Communication disorder	4	0
Mutism	2	0
<i><b>Confusion and disorientation</b></i>		
Confusional state	484	0
Disorientation	153	0
<i><b>Decreased physical activity levels</b></i>		
Catatonia	1	0
<i><b>Deliria</b></i>		
Delirium	68	0
<i><b>Delusional symptoms</b></i>		
Delusion	6	0
<i><b>Depressive disorders</b></i>		

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Agitated depression	1	0
Depression	133	0
Depression suicidal	4	0
Major depression	3	0
Mixed anxiety and depressive disorder	1	0
<b>Dissociative states</b>		
Depersonalisation/derealisation disorder	5	0
Dissociation	18	0
Dissociative amnesia	2	0
Dissociative disorder	1	0
<b>Disturbances in initiating and maintaining sleep</b>		
Initial insomnia	10	0
Insomnia	622	0
Middle insomnia	14	0
Terminal insomnia	8	0
<b>Dyssomnias</b>		
Dyssomnia	1	0
Poor quality sleep	109	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	12	0
Dysphoria	2	0
Emotional disorder	22	0
Emotional distress	14	0
Emotional poverty	1	0
Euphoric mood	26	0
Frustration tolerance decreased	1	0
Irritability	95	0
Mood altered	24	0
<b>Factitious disorders</b>		
Factitious disorder	2	0
<b>Fear symptoms and phobic disorders (incl social phobia)</b>		
Agoraphobia	1	0
Fear	7	0
Fear of falling	3	0
Fear of injection	2	0
Osmophobia	1	0
Phobia	1	0
Phonophobia	1	0
Social fear	1	0
<b>Fluctuating mood symptoms</b>		
Mood swings	31	0
<b>Hallucinations (excl sleep-related)</b>		
Hallucination	111	0
Hallucination, auditory	8	0
Hallucination, olfactory	4	0
Hallucination, tactile	1	0
Hallucination, visual	17	0
Hallucinations, mixed	1	0
<b>Increased physical activity levels</b>		



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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Restlessness	75	0
<b>Infancy, childhood and adolescence psychiatric disorders NEC</b>		
Social (pragmatic) communication disorder	1	0
<b>Learning disorders</b>		
Learning disorder	1	0
<b>Mental disorders NEC</b>		
Mental disorder	7	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>		
Decreased interest	7	0
Depressed mood	159	0
Feeling of despair	1	0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Sense of a foreshortened future	2	0
Tearfulness	23	0
<b>Mood alterations with manic symptoms</b>		
Hypomania	1	0
Mania	7	0
<b>Mood disorders NEC</b>		
Apathy	15	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	67	0
Panic disorder	3	0
Panic reaction	14	0
<b>Parasomnias</b>		
Abnormal dreams	105	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Nightmare	113	0
Parasomnia	1	0
Sleep talking	2	0
Sleep terror	11	0
Somnambulism	2	0
<b>Perception disturbances NEC</b>		
Autoscopy	9	0
Deja vu	2	0
Derealisation	6	0
Flashback	2	0
Illusion	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

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>		
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	3	0
Psychiatric symptom	2	0
Psychological trauma	1	0
Trance	1	0
<b>Psychotic disorder NEC</b>		
Psychotic behaviour	1	0
Psychotic disorder	11	0
<b>Schizophrenia NEC</b>		
Schizophrenia	1	0
<b>Sexual arousal disorders</b>		
Disturbance in sexual arousal	1	0
<b>Sexual desire disorders</b>		
Libido decreased	4	0
Libido increased	2	0
Loss of libido	8	0
<b>Sleep disorders NEC</b>		
Sleep disorder	103	0
Sleep disorder due to general medical condition, insomnia type	1	0
<b>Somatic symptom disorders</b>		
Conversion disorder	4	0
Habit cough	11	0
Somatic symptom disorder	1	0
Vomiting psychogenic	1	0
<b>Speech and language usage disturbances</b>		
Disorganised speech	3	0
Logorrhoea	2	0
<b>Speech articulation and rhythm disturbances</b>		
Dysphemia	8	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
<b>Stereotypies and automatisms</b>		
Bruxism	7	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
<b>Suicidal and self-injurious behaviour</b>		
Intentional self-injury	4	0
Self-injurious ideation	2	0
Suicidal ideation	14	0
Suicide attempt	8	0

## Case Series Drug Analysis Print

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

Report Run Date: 14-Jun-2021

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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>		
<i>Thinking disturbances</i>		
Bradyphrenia	25	0
Intrusive thoughts	3	0
Morbid thoughts	1	0
Tachyphrenia	2	0
Thinking abnormal	10	0
<i>Tic disorders</i>		
Tic	4	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>3702</b>	<b>1</b>

## Case Series Drug Analysis Print

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

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

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	14	0
Dysuria	31	0
Incontinence	17	0
Lower urinary tract symptoms	2	0
Micturition disorder	1	0
Micturition urgency	20	0
Pollakiuria	55	0
Urethral pain	1	0
Urge incontinence	1	0
Urinary hesitation	1	0
Urinary incontinence	36	0
Urinary retention	28	0
Urine flow decreased	5	0
<i><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	13	0
<i><b>Myoneurogenic bladder disorders</b></i>		
Bladder dysfunction	3	0
Hypertonic bladder	1	0
Hypotonic urinary bladder	1	0
Loss of bladder sensation	1	0
Neurogenic bladder	1	0
<i><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	1
Anuria	3	0
Chronic kidney disease	1	0
Oliguria	1	0
Renal failure	11	1
Renal impairment	13	0
Renal injury	1	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>Renal &amp; urinary disorders</b>		
<i>Renal lithiasis</i>		
Nephrolithiasis	3	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	27	0
Haematuria	23	0
Proteinuria	4	0
Urine abnormality	8	0
Urine odour abnormal	4	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	9	0
Nocturia	2	0
Polyuria	3	0
Renal colic	1	0
Renal pain	145	0
Urinary tract pain	2	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>563</b>	<b>3</b>

## Case Series Drug Analysis Print

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Report Run Date: 14-Jun-2021

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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><b>Benign and malignant breast neoplasms</b></i>		
Breast cyst	5	0
<i><b>Breast disorders NEC</b></i>		
Breast enlargement	1	0
Breast mass	44	0
Gynaecomastia	2	0
<i><b>Breast signs and symptoms</b></i>		
Breast discharge	2	0
Breast discomfort	5	0
Breast engorgement	1	0
Breast haematoma	1	0
Breast oedema	4	0
Breast pain	240	0
Breast swelling	50	0
Breast tenderness	23	0
Nipple pain	12	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	1	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	26	0
Erection increased	2	0
Organic erectile dysfunction	2	0
Painful ejaculation	1	0
<i><b>Lactation disorders</b></i>		
Galactorrhoea	2	0
Lactation puerperal increased	1	0
Suppressed lactation	7	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	58	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Abnormal uterine bleeding	4	0
Dysmenorrhoea	254	0
Intermenstrual bleeding	149	0
Menstrual discomfort	1	0
Menstrual disorder	241	0
Menstruation irregular	341	0
Premenstrual dysphoric disorder	2	0
Premenstrual headache	1	0
Premenstrual pain	11	0
Premenstrual syndrome	6	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>		
Reproductive & breast disorders cont'd		
Withdrawal bleed	3	0
<b>Menstruation with decreased bleeding</b>		
Amenorrhoea	90	0
Hypomenorrhoea	71	0
Menstruation delayed	367	0
Oligomenorrhoea	12	0
<b>Menstruation with increased bleeding</b>		
Heavy menstrual bleeding	640	0
Menometrorrhagia	3	0
Polymenorrhoea	95	0
<b>Ovarian and fallopian tube cysts and neoplasms</b>		
Ovarian cyst	2	0
Polycystic ovaries	8	0
<b>Ovarian and fallopian tube disorders NEC</b>		
Adnexal torsion	1	0
Ovarian haemorrhage	1	0
Ovulation pain	7	0
Premature ovulation	2	0
<b>Pelvis and broad ligament disorders NEC</b>		
Adnexa uteri pain	10	0
Pelvic haemorrhage	6	0
<b>Penile disorders NEC (excl erection and ejaculation)</b>		
Penile discomfort	1	0
Penile erythema	1	0
Penile swelling	4	0
Penis disorder	3	0
<b>Prostate and seminal vesicles infections and inflammations</b>		
Prostatitis	2	0
<b>Prostatic signs, symptoms and disorders NEC</b>		
Prostatomegaly	3	0
<b>Reproductive tract disorders NEC (excl neoplasms)</b>		
Genital haemorrhage	6	0
Genital lesion	1	0
Genital ulceration	3	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	1
Genital swelling	1	0
Pelvic discomfort	3	0
Pelvic pain	36	0
Perineal pain	1	0
Pruritus genital	1	0
<b>Scrotal disorders NEC</b>		
Scrotal discomfort	1	0
Scrotal erythema	1	0
Scrotal exfoliation	1	0
Scrotal pain	4	0
Scrotal swelling	4	0
<b>Sexual function and fertility disorders NEC</b>		
Dyspareunia	2	0
Infertility	1	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
<b><i>Spermatogenesis and semen disorders</i></b>		
Aspermia	2	0
Haematospermia	4	0
Semen discolouration	1	0
<b><i>Testicular and epididymal disorders NEC</i></b>		
Testicular disorder	1	0
Testicular pain	17	0
Testicular swelling	5	0
<b><i>Uterine disorders NEC</i></b>		
Adenomyosis	1	0
Endometrial thickening	1	0
Endometriosis	19	0
Uterine haemorrhage	5	0
Uterine pain	5	0
<b><i>Uterine tone disorders</i></b>		
Uterine spasm	6	0
<b><i>Vulvovaginal cysts and neoplasms</i></b>		
Vaginal cyst	2	0
<b><i>Vulvovaginal disorders NEC</i></b>		
Vaginal haemorrhage	293	0
Vulval haemorrhage	9	0
Vulval ulceration	3	0
Vulvovaginal ulceration	3	0
<b><i>Vulvovaginal signs and symptoms</i></b>		
Coital bleeding	1	0
Vaginal discharge	12	0
Vaginal odour	1	0
Vulval oedema	1	0
Vulvovaginal burning sensation	2	0
Vulvovaginal dryness	2	0
Vulvovaginal pain	8	0
Vulvovaginal pruritus	2	0
Vulvovaginal swelling	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>3335</b>	<b>1</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>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	3	0
Apnoeic attack	1	0
Dyspnoea	1956	6
Dyspnoea at rest	6	0
Dyspnoea exertional	18	1
Hyperventilation	24	0
Hypopnoea	51	0
Irregular breathing	9	0
Mouth breathing	3	0
Nocturnal dyspnoea	1	0
Orthopnoea	3	0
Respiration abnormal	28	0
Respiratory arrest	8	0
Respiratory depression	1	0
Respiratory distress	11	0
Sleep apnoea syndrome	6	0
Tachypnoea	21	0
<i><b>Bronchial conditions NEC</b></i>		
Bronchial secretion retention	1	0
Bronchiectasis	10	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	175	0
Asthma late onset	2	0
Bronchospasm	12	0
Chronic obstructive pulmonary disease	13	0
Cough variant asthma	3	0
Obstructive airways disorder	4	0
Reversible airways obstruction	1	0
Wheezing	245	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	1297	2
Cough decreased	2	0
Haemoptysis	22	0
Productive cough	83	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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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Stridor	15	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	14	0
Increased bronchial secretion	1	0
Lung opacity	2	0
Pleuritic pain	9	0
Pulmonary pain	50	0
Rales	4	0
<b>Nasal congestion and inflammations</b>		
Nasal congestion	131	0
Nasal inflammation	1	0
Rhinitis allergic	7	0
<b>Nasal disorders NEC</b>		
Epistaxis	514	0
Intranasal hypoaesthesia	1	0
Intranasal paraesthesia	1	0
Nasal crusting	1	0
Nasal disorder	1	0
Nasal dryness	18	0
Nasal odour	6	0
Nasal oedema	4	0
Nasal pruritus	8	0
<b>Neonatal hypoxic conditions</b>		
Dry lung 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	7	0
Sinus congestion	33	0
Sinus disorder	4	0
<b>Parenchymal lung disorders NEC</b>		
Atelectasis	1	0
Emphysema	2	0
Interstitial lung disease	4	0
Lung infiltration	1	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	3	0
<b>Pharyngeal disorders (excl infections and neoplasms)</b>		
Pharyngeal erythema	5	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	21	0
Pharyngeal inflammation	4	0
Pharyngeal oedema	8	0
Pharyngeal paraesthesia	40	0
Pharyngeal swelling	137	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>Respiratory disorders</b> Respiratory disorders cont'd		
Pharyngeal ulceration	10	0
Tonsillar erythema	3	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	40	0
Tonsillar inflammation	3	0
Tonsillar ulcer	1	0
<b>Pleural infections and inflammations</b>		
Pleurisy	16	0
<b>Pneumothorax and pleural effusions NEC</b>		
Pleural effusion	11	0
Pneumothorax	3	0
Pneumothorax spontaneous	1	0
<b>Pulmonary hypertensions</b>		
Pulmonary hypertension	2	0
<b>Pulmonary oedemas</b>		
Acute respiratory distress syndrome	1	0
Pulmonary congestion	5	0
Pulmonary oedema	14	1
<b>Pulmonary thrombotic and embolic conditions</b>		
Pulmonary embolism	246	18
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	5	0
Respiratory symptom	7	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 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	60	0
Catarrh	12	0
Choking	10	1
Choking sensation	2	0
Dry throat	109	0

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
Respiratory disorders cont'd		
Dysphonia	97	0
Increased upper airway secretion	4	0
Increased viscosity of upper respiratory secretion	15	0
Nasal discharge discolouration	2	0
Nasal discomfort	32	0
Nasal obstruction	2	0
Oropharyngeal blistering	9	0
Oropharyngeal discomfort	37	0
Oropharyngeal pain	1592	0
Oropharyngeal plaque	1	0
Paranasal sinus discomfort	23	0
Rhinalgia	6	0
Rhinorrhoea	475	0
Sinus pain	119	0
Sneezing	199	0
Snoring	4	0
Throat clearing	5	0
Throat irritation	143	0
Throat tightness	158	0
Upper airway obstruction	2	0
Upper-airway cough syndrome	4	0
Yawning	11	0
<b>Vascular pulmonary disorders NEC</b>		
Acute chest syndrome	1	0
<b>Respiratory disorders SOC TOTAL</b>	<b>8709</b>	<b>40</b>

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	43	0
Acne cystic	3	0
Dermatitis acneiform	3	0
<b><i>Alopecias</i></b>		
Alopecia	91	0
Alopecia areata	7	0
Alopecia totalis	1	0
Androgenetic alopecia	1	0
Madarosis	1	0
<b><i>Angioedemas</i></b>		
Angioedema	124	0
Circumoral swelling	1	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Anhidrosis	1	0
Cold sweat	386	0
Hidradenitis	1	0
Hyperhidrosis	1093	0
Miliaria	49	0
Night sweats	355	0
<b><i>Bullous conditions</i></b>		
Blister	260	0
Blister rupture	1	0
Blood blister	19	0
Dermatitis bullous	9	0
Erythema multiforme	21	0
Fracture blisters	1	0
Pemphigoid	13	0
Pemphigus	5	0
Stevens-Johnson syndrome	4	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	130	0
Macule	2	0
Pain of skin	163	0
Papule	42	0
Pathergy reaction	1	0
Peau d'orange	2	0
Scab	11	0
Scar pain	10	0
Sensitive skin	88	0
Skin burning sensation	130	0
Skin degenerative disorder	1	0
Skin discolouration	63	0
Skin discomfort	2	0
Skin disorder	6	0
Skin fissures	3	0
Skin indentation	2	0
Skin induration	3	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		
Skin lesion	28	0
Skin lesion inflammation	1	0
Skin necrosis	1	0
Skin odour abnormal	10	0
Skin plaque	1	0
Skin reaction	81	0
Skin sensitisation	16	0
Skin swelling	46	0
Skin tightness	21	0
Skin warm	172	0
Skin weeping	5	0
Sticky skin	1	0
Transient acantholytic dermatosis	1	0
Yellow skin	8	0
<b>Dermatitis and eczema</b>		
Dermatitis	65	0
Dermatitis allergic	141	0
Dermatitis atopic	14	0
Dermatitis contact	6	0
Dermatitis diaper	1	0
Dyshidrotic eczema	10	0
Eczema	115	0
Eczema asteatotic	6	0
Eczema nummular	4	0
Eczema weeping	1	0
Perioral dermatitis	1	0
Seborrhoeic dermatitis	2	0
Skin irritation	59	0
<b>Dermatitis ascribed to specific agent</b>		
Drug eruption	22	0
Drug reaction with eosinophilia and systemic symptoms	1	0
Fixed eruption	1	0
Toxic skin eruption	1	0
<b>Erythemas</b>		
Erythema	1344	0
Palmar erythema	4	0
Red man syndrome	1	0
<b>Exfoliative conditions</b>		
Dermatitis exfoliative	1	0
Dermatitis exfoliative generalised	2	0
Exfoliative rash	12	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	52	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>		
Argyria	1	0
Chloasma	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 14-Jun-2021

Data Lock Date: 09-Jun-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
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	3	0
<b>Lipodystrophies</b>		
Lipoatrophy	2	0
Lipodystrophy acquired	1	0
<b>Nail and nail bed conditions (excl infections and infestations)</b>		
Nail discolouration	5	0
Nail disorder	2	0
Nail pigmentation	2	0
Onychalgia	6	0
Onychoclasia	3	0
Onychomadesis	2	0
Splinter haemorrhages	1	0
<b>Panniculitides</b>		
Erythema nodosum	14	0
<b>Papulosquamous conditions</b>		
Erythema annulare	2	0
Lichen planus	6	0
Lichen sclerosus	2	0
Parapsoriasis	2	0
Pityriasis rosea	53	0
<b>Photosensitivity and photodermatosis conditions</b>		
Photosensitivity reaction	29	0
Polymorphic light eruption	1	0
<b>Pigmentation changes NEC</b>		
Haemosiderin stain	1	0
Pigmentation disorder	4	0
<b>Pilar disorders NEC</b>		
Hair colour changes	7	0
Hair disorder	1	0
Hair growth abnormal	1	0
Hair texture abnormal	4	0
Piloerection	11	0
Pseudofolliculitis	1	0
<b>Pruritus NEC</b>		
Itching scar	5	0
Pruritus	2964	0
<b>Psoriatic conditions</b>		
Dermatitis psoriasiform	2	0
Guttate psoriasis	10	0
Nail psoriasis	1	0
Palmoplantar pustulosis	1	0
Psoriasis	86	0
Pustular psoriasis	1	0
<b>Purpura and related conditions</b>		
Henoch-Schonlein purpura	2	0

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MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Petechiae	76	0
Purpura	29	0
<b>Pustular conditions</b>		
Acute generalised exanthematous pustulosis	1	0
<b>Rashes, eruptions and exanthems NEC</b>		
Butterfly rash	3	0
Rash	3130	1
Rash erythematous	676	0
Rash macular	293	0
Rash maculo-papular	38	0
Rash morbilliform	24	0
Rash papular	196	0
Rash pruritic	685	0
Rash vesicular	37	0
Systemic lupus erythematosus rash	5	0
<b>Rosaceas</b>		
Rosacea	16	0
<b>Scaly conditions</b>		
Dandruff	3	0
Pityriasis	11	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	9	0
<b>Skin and subcutaneous tissue ulcerations</b>		
Mucocutaneous ulceration	1	0
Scleroderma associated digital ulcer	1	0
Skin erosion	17	0
Skin ulcer	7	0
<b>Skin cysts and polyps</b>		
Dermal cyst	4	0
<b>Skin dystrophies</b>		
Skin wrinkling	2	0
<b>Skin haemorrhages</b>		
Haemorrhage subcutaneous	4	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
<b>Skin preneoplastic conditions NEC</b>		
Actinic keratosis	1	0
<b>Skin vasculitides</b>		
Cutaneous vasculitis	7	0
Vasculitic rash	12	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	17	0
<b>Urticarias</b>		
Chronic spontaneous urticaria	3	0



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Reaction Name		Total	Fatal
<b>Skin disorders</b>	Skin disorders cont'd		
Cold urticaria		2	0
Idiopathic urticaria		1	0
Mechanical urticaria		3	0
Solar urticaria		2	0
Urticaria		976	0
Urticaria chronic		6	0
Urticaria contact		1	0
Urticaria papular		2	0
Urticaria thermal		3	0
Urticarial vasculitis		2	0
<b>Skin disorders SOC TOTAL</b>		<b>15005</b>	<b>2</b>

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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	18	0
Breast prosthesis user	1	0
Hearing disability	1	0
Housebound	1	0
Immobile	8	0
Impaired driving ability	1	0
Impaired work ability	5	0
Loss of personal independence in daily activities	6	0
Physical disability	2	0
Sight disability	4	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	2	0
<i><b>Non-occupational and unspecified environmental problems</b></i>		
Water pollution	2	0
<i><b>Pregnancy related circumstances</b></i>		
Breast feeding	5	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>82</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
<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	1	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	61	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	2	0
<i>Nail therapeutic procedures</i>		
Nail operation	1	0
<i>Nervous system therapeutic procedures NEC</i>		
Multiple sclerosis relapse prophylaxis	2	0
<i>Phototherapies</i>		

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
Surgical & medical procedures cont'd		
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	6	0
Injection	12	0
Interchange of vaccine products	2	0
Mass excision	1	0
Medication dilution	1	0
Product used for unknown indication	2	0
Therapeutic procedure	1	0
Therapy change	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>178</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	0
Aortic dissection	1	0
<i><b>Aortic embolism and thrombosis</b></i>		
Aortic embolus	3	0
Aortic thrombosis	1	0
<i><b>Arterial infections and inflammations</b></i>		
Arteritis	1	0
Giant cell arteritis	8	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	42	0
Hypoperfusion	1	0
Neurogenic shock	19	0
Peripheral circulatory failure	3	0
Shock	9	0
Shock symptom	1	0
<i><b>Haemorrhages NEC</b></i>		
Bloody discharge	3	0
Haematoma	22	0
Haemorrhage	227	2
Internal haemorrhage	5	0
Venous haemorrhage	1	0
<i><b>Lymphangiopathies</b></i>		
Lymphangiopathy	1	0
Lymphocele	3	0
<i><b>Lymphoedemas</b></i>		
Lymphoedema	131	0
<i><b>Non-site specific embolism and thrombosis</b></i>		
Arterial thrombosis	2	0
Embolism	60	0
Embolism venous	3	0
Microembolism	1	0
Thrombosis	173	7
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	3	0
Vasospasm	1	0

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Reaction Name	Total	Fatal
<b>Vascular disorders</b> Vascular disorders cont'd		
<b><i>Non-site specific vascular disorders NEC</i></b>		
Superficial vein prominence	1	0
Vascular pain	10	0
Vasodilatation	16	0
Vein discolouration	4	0
Vein disorder	5	0
Vein rupture	3	0
<b><i>Peripheral embolism and thrombosis</i></b>		
Blue toe syndrome	18	0
Deep vein thrombosis	156	0
Femoral artery embolism	1	0
Jugular vein thrombosis	2	0
Pelvic venous thrombosis	4	0
Peripheral embolism	1	0
Subclavian vein thrombosis	1	0
Thrombophlebitis	14	0
Thrombophlebitis superficial	7	0
<b><i>Peripheral vascular disorders NEC</i></b>		
Cyanosis	27	0
Erythromelalgia	1	0
Flushing	316	0
Hot flush	616	0
<b><i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i></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	191	0
Peripheral ischaemia	9	0
Poor peripheral circulation	7	0
Raynaud's phenomenon	42	0
Vasoconstriction	2	0
<b><i>Phlebitis NEC</i></b>		
Phlebitis	18	0
Phlebitis superficial	3	0
<b><i>Site specific vascular disorders NEC</i></b>		
Pallor	159	0
<b><i>Varicose veins NEC</i></b>		
Spider vein	2	0
Varicophlebitis	1	0
Varicose vein	8	0
<b><i>Vascular hypertensive disorders NEC</i></b>		
Diastolic hypertension	1	0
Essential hypertension	3	0
Hypertension	328	1
Labile hypertension	1	0
Orthostatic hypertension	1	0
Secondary hypertension	1	0
Systolic hypertension	2	0
<b><i>Vascular hypotensive disorders</i></b>		
Capillary leak syndrome	1	0
Hypotension	231	0

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Reaction Name	Total	Fatal
<b>Vascular disorders</b> Vascular disorders cont'd		
Orthostatic hypotension	16	0
<b>Vasculitides NEC</b>		
Behcet's syndrome	4	0
Granulomatosis with polyangiitis	1	0
MAGIC syndrome	1	0
Vasculitis	32	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>3038</b>	<b>10</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>202036</b>	<b>421</b>
<b>TOTAL REPORTS</b>	<b>70950</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>421</b>