

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

Report Run Date: 26-Apr-2021  
Data Lock Date: 21-Apr-2021 19:00:03

All UK spontaneous reports received between 9/12/20 to 21/04/21 for COVID-19 mRNA Pfizer/BioNTech vaccine

## Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Blood disorders</b>		
<b><i>Anaemia deficiencies</i></b>		
Anaemia vitamin B12 deficiency	2	0
Deficiency anaemia	1	0
<b><i>Anaemias NEC</i></b>		
Anaemia	19	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	1	0
<b><i>Anaemias haemolytic immune</i></b>		
Autoimmune haemolytic anaemia	3	0
<b><i>Bleeding tendencies</i></b>		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	12	0
<b><i>Coagulation factor deficiencies</i></b>		
Acquired haemophilia	1	0
<b><i>Coagulopathies</i></b>		
Antiphospholipid syndrome	2	0
Coagulopathy	3	0
Disseminated intravascular coagulation	1	0
Hypercoagulation	1	0
Thrombotic microangiopathy	1	0
<b><i>Eosinophilic disorders</i></b>		
Eosinophilia	2	0
<b><i>Haematological disorders</i></b>		
Mast cell activation syndrome	1	0
<b><i>Haemolyses NEC</i></b>		
Haemolysis	2	0
Intravascular haemolysis	1	0
<b><i>Leukocytoses NEC</i></b>		
Lymphocytosis	3	0
Neutrophilia	2	0
<b><i>Leukopenias NEC</i></b>		
Leukopenia	2	0
Lymphopenia	2	0
<b><i>Lymphatic system disorders NEC</i></b>		
Abdominal lymphadenopathy	2	0
Granulomatous lymphadenitis	1	0
Lymph node pain	623	0
Lymphadenitis	86	0
Lymphadenopathy	4160	0
Lymphatic disorder	1	0
Pseudolymphoma	4	0
<b><i>Marrow depression and hypoplastic anaemias</i></b>		
Myelosuppression	1	0
Pancytopenia	3	0
<b><i>Neutropenias</i></b>		
Autoimmune neutropenia	2	0
Neutropenia	22	0
<b><i>Platelet disorders NEC</i></b>		
Platelet anisocytosis	1	0
<b><i>Spleen disorders</i></b>		
Spleen atrophy	1	0
Splenomegaly	4	0
<b><i>Thrombocytopenias</i></b>		

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<b>Blood disorders</b> Blood disorders cont'd		
Immune thrombocytopenia	36	0
Thrombocytopenia	53	1
Thrombotic thrombocytopenic purpura	5	0
<i><b>Thrombocytoses</b></i>		
Thrombocytosis	2	0
<b>Blood disorders SOC TOTAL</b>	<b>5071</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Cardiac disorders</b>		
<i><b>Cardiac conduction disorders</b></i>		
Atrioventricular block	3	0
Atrioventricular block complete	1	0
Atrioventricular block second degree	1	0
Bundle branch block	1	0
Bundle branch block right	1	0
<i><b>Cardiac disorders NEC</b></i>		
Acute cardiac event	2	0
Cardiac disorder	7	0
Cardiovascular disorder	1	0
<i><b>Cardiac hypertensive complications</b></i>		
Hypertensive heart disease	1	0
<i><b>Cardiac signs and symptoms NEC</b></i>		
Cardiac discomfort	2	0
Palpitations	890	0
<i><b>Cardiac valve disorders NEC</b></i>		
Cardiac valve disease	1	0
<i><b>Cardiomyopathies</b></i>		
Cardiomyopathy	1	0
Congestive cardiomyopathy	1	0
Stress cardiomyopathy	2	0
<i><b>Coronary artery disorders NEC</b></i>		
Coronary artery disease	3	1
<i><b>Heart failures NEC</b></i>		
Cardiac failure	17	2
Cardiac failure acute	2	0
Cardiac failure chronic	1	0
Cardiac failure congestive	2	1
Cardiogenic shock	1	0
Cardiopulmonary failure	1	1
<i><b>Ischaemic coronary artery disorders</b></i>		
Acute coronary syndrome	3	0
Acute myocardial infarction	13	1
Angina pectoris	32	0
Angina unstable	1	0
Arteriospasm coronary	1	0
Microvascular coronary artery disease	2	0
Myocardial infarction	74	14
Myocardial ischaemia	3	1
<i><b>Left ventricular failures</b></i>		
Left ventricular failure	2	1
<i><b>Mitral valvular disorders</b></i>		
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
<i><b>Myocardial disorders NEC</b></i>		
Cardiomegaly	1	0
Left ventricular dysfunction	2	0
Myocardial fibrosis	1	0
Myocardial haemorrhage	1	0
Myocardial oedema	2	0
Right ventricular enlargement	1	0
Ventricular hypertrophy	1	0
<i><b>Noninfectious myocarditis</b></i>		

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<b>Cardiac disorders</b> Cardiac disorders cont'd		
Myocarditis	16	0
<b>Noninfectious pericarditis</b>		
Pericarditis	13	1
<b>Pericardial disorders NEC</b>		
Pericardial effusion	6	0
Pericardial haemorrhage	2	2
<b>Rate and rhythm disorders NEC</b>		
Arrhythmia	25	0
Bradycardia	24	0
Cardiac flutter	49	0
Extrasystoles	27	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	4	0
Tachycardia	421	0
<b>Right ventricular failures</b>		
Cor pulmonale	1	0
<b>Supraventricular arrhythmias</b>		
Arrhythmia supraventricular	7	0
Atrial fibrillation	86	0
Atrial flutter	6	0
Atrial tachycardia	3	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus bradycardia	3	0
Sinus tachycardia	31	0
Supraventricular tachycardia	15	0
<b>Tricuspid valvular disorders</b>		
Tricuspid valve incompetence	1	0
<b>Ventricular arrhythmias and cardiac arrest</b>		
Cardiac arrest	55	20
Cardio-respiratory arrest	1	1
Pulseless electrical activity	2	0
Ventricular arrhythmia	2	0
Ventricular extrasystoles	6	0
Ventricular fibrillation	5	1
Ventricular tachycardia	3	0
<b>Cardiac disorders SOC TOTAL</b>	<b>1901</b>	<b>47</b>

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Reaction Name	Total	Fatal
<b>Congenital disorders</b>		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	2	0
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	1	0
<i>Coagulation disorders congenital</i>		
Haemophilia	1	0
<i>Congenital disorders NEC</i>		
Foetal malformation	1	0
<i>Gastrointestinal tract disorders congenital NEC</i>		
Gastroschisis	1	0
<i>Haematological disorders congenital NEC</i>		
Amegakaryocytic thrombocytopenia	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital multiplex arthrogyposis	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
Familial periodic paralysis	1	0
<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
<b>Congenital disorders SOC TOTAL</b>	<b>13</b>	<b>0</b>

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<b>Ear disorders</b>		
<i><b>Ear disorders NEC</b></i>		
Ear canal erythema	1	0
Ear congestion	7	0
Ear discomfort	25	0
Ear disorder	7	0
Ear haemorrhage	2	0
Ear pain	364	0
Ear pruritus	5	0
Ear swelling	9	0
Otorrhoea	1	0
<i><b>Eustachian tube disorders</b></i>		
Eustachian tube disorder	1	0
Eustachian tube dysfunction	5	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	1	0
<i><b>Hearing disorders NEC</b></i>		
Auditory disorder	3	0
<i><b>Hearing losses</b></i>		
Deafness	69	0
Deafness bilateral	2	0
Deafness neurosensory	8	0
Deafness transitory	3	0
Deafness unilateral	11	0
Hypoacusis	52	0
Sudden hearing loss	11	0
<i><b>Hyperacusia</b></i>		
Hyperacusis	15	0
Misophonia	1	0
<i><b>Inner ear disorders NEC</b></i>		
Acute vestibular syndrome	1	0
Inner ear disorder	4	0
Meniere's disease	5	0
Vestibular disorder	3	0
<i><b>Inner ear infections and inflammations</b></i>		
Inner ear inflammation	2	0
<i><b>Inner ear signs and symptoms</b></i>		
Motion sickness	23	0
Tinnitus	529	0
Vertigo	499	0
Vertigo labyrinthine	5	0
Vertigo positional	37	0
<i><b>Middle ear disorders NEC</b></i>		
Middle ear disorder	1	0
<i><b>Middle ear infections and inflammations</b></i>		
Middle ear inflammation	1	0
<b>Ear disorders SOC TOTAL</b>	<b>1719</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Endocrine disorders</b>		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	1	0
Thyroiditis subacute	1	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	1	0
Adrenocortical insufficiency acute	7	0
<i>Endocrine abnormalities of puberty</i>		
Premature menarche	2	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	2	0
<i>Thyroid disorders NEC</i>		
Goitre	5	0
Thyroid disorder	1	0
Thyroid pain	1	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	1	0
Hyperthyroidism	6	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	9	0
<b>Endocrine disorders SOC TOTAL</b>	<b>37</b>	<b>0</b>



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<b>Eye disorders</b>		
<i><b>Amblyopic vision impairment</b></i>		
Amblyopia	3	0
<i><b>Cataract conditions</b></i>		
Cataract	3	0
<i><b>Choroid and vitreous haemorrhages and vascular disorders</b></i>		
Choroidal haemorrhage	1	0
Choroidal neovascularisation	1	0
Vitreous haemorrhage	1	0
<i><b>Choroid and vitreous structural change, deposit and degeneration</b></i>		
Chorioretinopathy	1	0
Vitreous detachment	9	0
Vitreous floaters	23	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	17	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	43	0
Excessive eye blinking	1	0
Eyelid ptosis	16	0
<i><b>Glaucomas (excl congenital)</b></i>		
Glaucoma	2	0
<i><b>Iris and uveal tract infections, irritations and inflammations</b></i>		
Autoimmune uveitis	1	0
Iridocyclitis	5	0
Iritis	3	0
Uveitis	13	0
<i><b>Lacrimation disorders</b></i>		
Dry eye	54	0
Lacrimation increased	61	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	4	0
Chalazion	2	0
Eczema eyelids	2	0
Erythema of eyelid	2	0
Eyelid cyst	2	0
Eyelid irritation	1	0
Eyelid margin crusting	2	0
Eyelid oedema	3	0
Eyelid rash	5	0
Swelling of eyelid	48	0
<i><b>Lid, lash and lacrimal structural disorders</b></i>		
Eyelid exfoliation	1	0
Growth of eyelashes	1	0

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Reaction Name	Total	Fatal
<b>Eye disorders</b> Eye disorders cont'd		
Lagophthalmos	1	0
<b>Ocular bleeding and vascular disorders NEC</b>		
Eye haematoma	1	0
Eye haemorrhage	5	0
<b>Ocular disorders NEC</b>		
Dark circles under eyes	1	0
Eye disorder	11	0
Eye oedema	5	0
Eye pain	406	0
Eye swelling	195	0
Eye ulcer	1	0
Eyelid disorder	2	0
Eyelid pain	6	0
Eyelids pruritus	3	0
Ocular discomfort	14	0
Periorbital oedema	14	0
Periorbital pain	1	0
Periorbital swelling	50	0
Retinal disorder	1	0
<b>Ocular infections, inflammations and associated manifestations</b>		
Eye allergy	2	0
Eye discharge	11	0
Eye inflammation	8	0
Eye irritation	41	0
Eye pruritus	115	0
Limbal swelling	2	0
Ocular hyperaemia	87	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	9	0
Ocular myasthenia	1	0
Ophthalmoplegia	2	0
Strabismus	2	0
<b>Ocular sensation disorders</b>		
Abnormal sensation in eye	9	0
Asthenopia	66	0
Eye paraesthesia	1	0
Foreign body sensation in eyes	12	0
Hypoaesthesia eye	5	0
Photophobia	164	0
<b>Optic disc abnormalities NEC</b>		
Papilloedema	1	0
<b>Optic nerve bleeding and vascular disorders</b>		
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	1	0
<b>Pupil disorders</b>		
Miosis	2	0
Mydriasis	7	0

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<b>Eye disorders</b> Eye disorders cont'd		
Pupil fixed	1	0
Pupils unequal	3	0
<b><i>Retinal bleeding and vascular disorders (excl retinopathy)</i></b>		
Retinal artery occlusion	2	0
Retinal artery thrombosis	1	0
Retinal haemorrhage	2	0
Retinal vein occlusion	7	0
Retinal vein thrombosis	1	0
<b><i>Retinal structural change, deposit and degeneration</i></b>		
Macular degeneration	1	0
Macular hole	1	0
Macular rupture	1	0
Maculopathy	1	0
Retinal detachment	1	0
Retinal tear	1	0
Retinal toxicity	1	0
<b><i>Retinal, choroid and vitreous infections and inflammations</i></b>		
Macular oedema	2	0
Retinal vasculitis	1	0
<b><i>Retinopathies NEC</i></b>		
Retinal exudates	2	0
Retinopathy	1	0
<b><i>Scleral infections, irritations and inflammations</i></b>		
Episcleritis	4	0
Scleritis	1	0
<b><i>Scleral structural change, deposit and degeneration</i></b>		
Scleral discolouration	2	0
<b><i>Visual colour distortions</i></b>		
Cyanopsia	1	0
Erythropsia	2	0
<b><i>Visual disorders NEC</i></b>		
Diplopia	59	0
Halo vision	4	0
Metamorphopsia	6	0
Oscillopsia	2	0
Photopsia	49	0
Scintillating scotoma	2	0
Vision blurred	363	0
Visual brightness	1	0
Visual snow syndrome	1	0
<b><i>Visual impairment and blindness (excl colour blindness)</i></b>		
Blindness	31	0
Blindness transient	5	0
Blindness unilateral	6	0
Central vision loss	2	0
Sudden visual loss	1	0
Visual acuity reduced	8	0
Visual impairment	125	0
<b>Eye disorders SOC TOTAL</b>	<b>2322</b>	<b>0</b>

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<b>Gastrointestinal disorders</b>		
<i><b>Abdominal findings abnormal</b></i>		
Abdominal mass	1	0
Gastrointestinal sounds abnormal	7	0
<i><b>Abdominal hernias NEC</b></i>		
Abdominal hernia	1	0
<i><b>Acute and chronic pancreatitis</b></i>		
Obstructive pancreatitis	1	0
Pancreatitis	3	0
Pancreatitis acute	4	0
Pancreatitis necrotising	1	0
<i><b>Anal and rectal disorders NEC</b></i>		
Anal sphincter atony	1	0
<i><b>Anal and rectal pains</b></i>		
Proctalgia	5	0
<i><b>Anal and rectal signs and symptoms</b></i>		
Anal spasm	1	0
Anorectal discomfort	3	0
Anorectal swelling	1	0
<i><b>Benign oral cavity neoplasms</b></i>		
Mouth cyst	3	0
Tongue cyst	1	0
<i><b>Colitis (excl infective)</b></i>		
Colitis	14	0
Colitis ischaemic	1	0
Colitis microscopic	1	0
Colitis ulcerative	21	0
Crohn's disease	14	0
<i><b>Dental and periodontal infections and inflammations</b></i>		
Dental caries	1	0
<i><b>Dental disorders NEC</b></i>		
Teething	2	0
<i><b>Dental pain and sensation disorders</b></i>		
Dental discomfort	2	0
Dental paraesthesia	1	0
Hyperaesthesia teeth	11	0
Toothache	44	0
<i><b>Diaphragmatic hernias</b></i>		
Hiatus hernia	1	0
<i><b>Diarrhoea (excl infective)</b></i>		
Diarrhoea	2245	3
Diarrhoea haemorrhagic	10	0
<i><b>Diverticula</b></i>		
Diverticulum	1	0
Diverticulum intestinal	1	0
<i><b>Duodenal and small intestinal stenosis and obstruction</b></i>		
Small intestinal obstruction	1	0
<i><b>Duodenal ulcers and perforation</b></i>		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	1	0
<i><b>Dyspeptic signs and symptoms</b></i>		
Dyspepsia	127	0
Epigastric discomfort	8	0
Eructation	23	0

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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
<b><i>Faecal abnormalities NEC</i></b>		
Abnormal faeces	4	0
Faeces discoloured	19	0
Faeces hard	1	0
Faeces pale	2	0
Faeces soft	4	0
Mucous stools	1	0
<b><i>Flatulence, bloating and distension</i></b>		
Abdominal distension	97	0
Aerophagia	2	0
Flatulence	70	0
<b><i>Gastric and oesophageal haemorrhages</i></b>		
Gastric haemorrhage	2	1
Oesophageal varices haemorrhage	1	0
<b><i>Gastric ulcers and perforation</i></b>		
Gastric ulcer	2	0
<b><i>Gastritis (excl infective)</i></b>		
Chronic gastritis	1	0
Gastritis	20	0
Reflux gastritis	4	0
<b><i>Gastrointestinal and abdominal pains (excl oral and throat)</i></b>		
Abdominal migraine	2	0
Abdominal pain	489	0
Abdominal pain lower	30	0
Abdominal pain upper	763	0
Abdominal rigidity	3	0
Abdominal tenderness	4	0
Gastrointestinal pain	45	0
Oesophageal pain	1	0
<b><i>Gastrointestinal atonic and hypomotility disorders NEC</i></b>		
Constipation	97	0
Duodenogastric reflux	2	0
Gastric dilatation	3	0
Gastrooesophageal reflux disease	40	0
Impaired gastric emptying	1	0
Infrequent bowel movements	1	0
Intestinal pseudo-obstruction	2	0
<b><i>Gastrointestinal disorders NEC</i></b>		
Functional gastrointestinal disorder	5	0
Gastric disorder	3	0
Gastrointestinal disorder	5	0
<b><i>Gastrointestinal dyskinetic disorders</i></b>		
Change of bowel habit	3	0
Dyschezia	1	0
Gastrointestinal motility disorder	1	0
<b><i>Gastrointestinal inflammatory disorders NEC</i></b>		
Duodenitis	1	0
Enteritis	3	0
<b><i>Gastrointestinal mucosal dystrophies and secretion disorders</i></b>		
Hyperchlorhydria	2	0
<b><i>Gastrointestinal signs and symptoms NEC</i></b>		
Abdominal discomfort	259	0
Abdominal symptom	1	0

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<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Acute abdomen	3	0
Anal incontinence	8	0
Breath odour	8	0
Dysphagia	78	1
<b><i>Gastrointestinal spastic and hypermotility disorders</i></b>		
Defaecation urgency	3	0
Frequent bowel movements	11	0
Irritable bowel syndrome	29	0
Oesophageal spasm	2	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	3	0
<b><i>Gastrointestinal vascular occlusion and infarction</i></b>		
Intestinal ischaemia	3	2
Mesenteric vein thrombosis	3	0
<b><i>Gingival disorders, signs and symptoms NEC</i></b>		
Gingival blister	6	0
Gingival discomfort	2	0
Gingival disorder	2	0
Gingival pain	43	0
Gingival pruritus	1	0
Gingival swelling	9	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	3	0
<b><i>Gingival haemorrhages</i></b>		
Gingival bleeding	16	0
<b><i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i></b>		
Gastric varices	1	0
Haemorrhoids	10	0
<b><i>Intestinal haemorrhages</i></b>		
Anal haemorrhage	7	0
Rectal haemorrhage	26	0
Small intestinal haemorrhage	3	0
<b><i>Intestinal ulcers and perforation NEC</i></b>		
Intestinal perforation	3	2
<b><i>Malabsorption syndromes</i></b>		
Bile acid malabsorption	1	0
Coeliac disease	6	0
Steatorrhoea	1	0
<b><i>Nausea and vomiting symptoms</i></b>		
Discoloured vomit	7	0
Nausea	6385	1
Regurgitation	1	0
Retching	44	0
Vomiting	1802	2
Vomiting projectile	29	0
<b><i>Non-mechanical ileus</i></b>		
Ileus paralytic	1	0
<b><i>Non-site specific gastrointestinal haemorrhages</i></b>		
Gastrointestinal haemorrhage	6	0
Haematemesis	16	2

## Case Series Drug Analysis Print

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

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Haematochezia	16	0
Melaena	6	0
Upper gastrointestinal haemorrhage	2	0
<b><i>Oesophageal stenosis and obstruction</i></b>		
Oesophageal stenosis	1	0
<b><i>Oesophagitis (excl infective)</i></b>		
Oesophagitis	1	0
<b><i>Oral dryness and saliva altered</i></b>		
Aptyalism	1	0
Dry mouth	242	0
Lip dry	24	0
Saliva altered	1	0
Salivary hypersecretion	20	0
<b><i>Oral soft tissue disorders NEC</i></b>		
Angina bullosa haemorrhagica	1	0
Chapped lips	9	0
Cheilitis	13	0
Enlarged uvula	7	0
Lip blister	14	0
Lip disorder	3	0
Oral disorder	6	0
Oral lichen planus	3	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	1	0
<b><i>Oral soft tissue haemorrhages</i></b>		
Mouth haemorrhage	3	0
Oral blood blister	6	0
Oral purpura	1	0
<b><i>Oral soft tissue infections</i></b>		
Angular cheilitis	1	0
<b><i>Oral soft tissue signs and symptoms</i></b>		
Anaesthesia oral	1	0
Burning mouth syndrome	2	0
Coating in mouth	1	0
Hypoaesthesia oral	215	0
Lip discolouration	2	0
Lip erythema	1	0
Lip exfoliation	4	0
Lip pain	29	0
Lip pruritus	5	0
Lip scab	1	0
Odynophagia	7	0
Oral discomfort	32	0
Oral dysaesthesia	1	0
Oral mucosal blistering	8	0
Oral mucosal eruption	10	0
Oral mucosal erythema	3	0
Oral mucosal exfoliation	4	0
Oral mucosal roughening	2	0
Oral pain	80	0
Oral pruritus	14	0
Paraesthesia oral	554	0

## Case Series Drug Analysis Print

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

Report Run Date: 26-Apr-2021  
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 21-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
<i>Gastrointestinal disorders cont'd</i>		
Pigmentation lip	1	0
<b>Oral soft tissue swelling and oedema</b>		
Lip oedema	3	0
Lip swelling	333	0
Mouth swelling	40	0
Oedema mouth	3	0
Palatal oedema	2	0
Palatal swelling	1	0
<b>Peptic ulcers and perforation</b>		
Peptic ulcer haemorrhage	3	0
<b>Peritoneal and retroperitoneal disorders</b>		
Ascites	1	0
<b>Peritoneal and retroperitoneal fibrosis and adhesions</b>		
Abdominal adhesions	1	0
<b>Peritoneal and retroperitoneal haemorrhages</b>		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	1
<b>Rectal inflammations NEC</b>		
Proctitis	1	0
Proctitis ulcerative	1	0
<b>Salivary gland disorders NEC</b>		
Salivary gland pain	6	0
<b>Salivary gland enlargements</b>		
Parotid gland enlargement	4	0
Salivary gland enlargement	2	0
Submaxillary gland enlargement	4	0
<b>Salivary gland infections and inflammations</b>		
Noninfective sialoadenitis	1	0
<b>Stomatitis and ulceration</b>		
Aphthous ulcer	19	0
Lip ulceration	3	0
Mouth ulceration	173	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	27	0
<b>Tongue disorders</b>		
Glossitis	5	0
Plicated tongue	2	0
Tongue disorder	16	0
Tongue haemorrhage	1	0
Tongue ulceration	12	0
Trichoglossia	1	0
<b>Tongue signs and symptoms</b>		
Glossodynia	104	0
Scalloped tongue	1	0
Stiff tongue	1	0
Swollen tongue	238	0
Tongue blistering	7	0
Tongue coated	4	0
Tongue discolouration	11	0
Tongue discomfort	24	0
Tongue dry	7	0
Tongue eruption	7	0



## Case Series Drug Analysis Print

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

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Gastrointestinal disorders</b>		
Gastrointestinal disorders cont'd		
Tongue erythema	3	0
Tongue movement disturbance	3	0
Tongue oedema	15	0
Tongue rough	2	0
Tongue spasm	4	0
<b>Gastrointestinal disorders SOC TOTAL</b>	<b>15608</b>	<b>15</b>

## Case Series Drug Analysis Print

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

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>General disorders</b>		
<b><i>Administration site reactions NEC</i></b>		
Administration site bruise	3	0
Administration site erythema	1	0
Administration site extravasation	2	0
Administration site haematoma	3	0
Administration site inflammation	1	0
Administration site joint discomfort	1	0
Administration site joint movement impairment	1	0
Administration site pain	8	0
Administration site swelling	2	0
Administration site warmth	1	0
Puncture site bruise	13	0
Puncture site pain	4	0
Puncture site swelling	1	0
Vessel puncture site bruise	1	0
Vessel puncture site erythema	1	0
Vessel puncture site pain	1	0
<b><i>Adverse effect absent</i></b>		
No adverse event	12	0
<b><i>Application and instillation site reactions</i></b>		
Application site acne	1	0
Application site bruise	2	0
Application site burn	1	0
Application site erythema	3	0
Application site haemorrhage	1	0
Application site hypoaesthesia	1	0
Application site joint pain	1	0
Application site mass	1	0
Application site pain	3	0
Application site pruritus	3	0
Application site rash	1	0
Application site reaction	1	0
Application site vesicles	3	0
Instillation site warmth	1	0
<b><i>Asthenic conditions</i></b>		
Asthenia	652	1
Chronic fatigue syndrome	26	0
Decreased activity	1	0
Fatigue	9679	0
Malaise	2272	0
Sluggishness	4	0
<b><i>Body temperature altered</i></b>		
Hyperthermia	4	0
Hypothermia	17	0
Temperature regulation disorder	5	0
<b><i>Breast complications associated with device</i></b>		
Capsular contracture associated with breast implant	1	0
<b><i>Complications associated with device NEC</i></b>		
Injury associated with device	1	0
Medical device pain	1	0
Medical device site swelling	1	0
<b><i>Death and sudden death</i></b>		
Clinical death	1	1

## Case Series Drug Analysis Print

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

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Death	112	112
Sudden death	21	21
<b>Febrile disorders</b>		
Hyperpyrexia	4	0
Pyrexia	7200	1
<b>Feelings and sensations NEC</b>		
Chills	4855	0
Feeling abnormal	491	0
Feeling cold	555	0
Feeling drunk	25	0
Feeling hot	490	0
Feeling jittery	10	0
Feeling of body temperature change	139	0
Hangover	21	0
Hunger	6	0
Sensation of foreign body	23	0
Temperature intolerance	13	0
Thirst	133	0
<b>Gait disturbances</b>		
Gait disturbance	56	0
Gait inability	28	0
Loss of control of legs	6	0
<b>General signs and symptoms NEC</b>		
Adhesion	1	0
Condition aggravated	56	0
Crepitations	1	0
Crying	36	0
Discharge	1	0
Disease progression	1	0
Disease recurrence	6	0
Effusion	2	0
Energy increased	6	0
Exercise tolerance decreased	3	0
Foaming at mouth	1	0
General physical health deterioration	7	1
General symptom	1	0
Glassy eyes	2	0
High-pitched crying	1	0
Illness	694	1
Induration	2	0
Influenza like illness	1186	0
Irritability postvaccinal	1	0
Local reaction	58	0
Moaning	1	0
Multiple organ dysfunction syndrome	2	1
Nonspecific reaction	1	0
Peripheral swelling	1359	0
Pre-existing condition improved	5	0
Prolapse	1	0
Screaming	5	0
Secretion discharge	6	0
Swelling	1001	0
Swelling face	368	0

## Case Series Drug Analysis Print

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

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
<b><i>Implant and catheter site reactions</i></b>		
Implant site pain	1	0
Implant site rash	1	0
Implant site swelling	1	0
<b><i>Inflamations</i></b>		
Granuloma	1	0
Inflammation	130	0
Papillitis	1	0
Serositis	1	0
Systemic inflammatory response syndrome	1	0
<b><i>Infusion site reactions</i></b>		
Infusion site coldness	1	0
Infusion site joint pain	2	0
Infusion site pain	1	0
Infusion site swelling	1	0
Infusion site urticaria	1	0
Infusion site warmth	1	0
<b><i>Injection site reactions</i></b>		
Injected limb mobility decreased	14	0
Injection site bruising	25	0
Injection site coldness	1	0
Injection site cyst	2	0
Injection site discolouration	3	0
Injection site discomfort	7	0
Injection site erythema	187	0
Injection site haemorrhage	3	0
Injection site hypoaesthesia	6	0
Injection site indentation	2	0
Injection site induration	2	0
Injection site inflammation	18	0
Injection site joint movement impairment	1	0
Injection site joint pain	10	0
Injection site lymphadenopathy	1	0
Injection site mass	222	0
Injection site necrosis	3	0
Injection site oedema	11	0
Injection site pain	1506	0
Injection site paraesthesia	5	0
Injection site pruritus	85	0
Injection site rash	70	0
Injection site reaction	17	0
Injection site scab	2	0
Injection site scar	2	0
Injection site swelling	165	0
Injection site urticaria	14	0
Injection site vesicles	3	0
Injection site warmth	79	0
<b><i>Interactions</i></b>		
Alcohol interaction	2	0
Drug interaction	8	0
<b><i>Mass conditions NEC</i></b>		
Cyst	8	0
Mass	13	0

## Case Series Drug Analysis Print

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

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Nodule	15	0
<b><i>Mucosal findings abnormal</i></b>		
Mucosal haemorrhage	2	0
Oedema mucosal	1	0
<b><i>Necrosis NEC</i></b>		
Fat necrosis	1	0
<b><i>Oedema NEC</i></b>		
Face oedema	18	0
Generalised oedema	1	0
Localised oedema	12	0
Oedema	22	0
Oedema peripheral	38	0
<b><i>Pain and discomfort NEC</i></b>		
Axillary pain	905	0
Chest discomfort	550	0
Chest pain	871	0
Discomfort	95	0
Facial discomfort	8	0
Facial pain	93	0
Inflammatory pain	1	0
Non-cardiac chest pain	9	0
Pain	3106	0
Suprapubic pain	1	0
Tenderness	298	0
Visceral pain	1	0
<b><i>Therapeutic and nontherapeutic responses</i></b>		
Adverse drug reaction	108	0
Adverse event	3	0
Adverse reaction	3	0
Drug ineffective	103	1
Immediate post-injection reaction	2	0
Inadequate analgesia	2	0
No reaction on previous exposure to drug	26	0
Therapeutic product effect delayed	2	0
Therapeutic product effect increased	1	0
Therapeutic product ineffective	1	0
Therapeutic response unexpected	20	0
Treatment failure	5	0
<b><i>Ulcers NEC</i></b>		
Ulcer	8	0
<b><i>Vaccination site reactions</i></b>		
Extensive swelling of vaccinated limb	5	0
Shoulder injury related to vaccine administration	5	0
Vaccination site bruising	50	0
Vaccination site cyst	1	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	7	0
Vaccination site discomfort	25	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	309	0
Vaccination site granuloma	1	0
Vaccination site haemorrhage	8	0

## Case Series Drug Analysis Print

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

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>General disorders</b> General disorders cont'd		
Vaccination site hypersensitivity	2	0
Vaccination site hypoaesthesia	7	0
Vaccination site induration	49	0
Vaccination site inflammation	33	0
Vaccination site irritation	5	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	6	0
Vaccination site joint movement impairment	12	0
Vaccination site joint pain	20	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	96	0
Vaccination site movement impairment	35	0
Vaccination site oedema	3	0
Vaccination site pain	1088	0
Vaccination site paraesthesia	4	0
Vaccination site pruritus	66	0
Vaccination site rash	50	0
Vaccination site reaction	15	0
Vaccination site scab	1	0
Vaccination site swelling	315	0
Vaccination site ulcer	1	0
Vaccination site urticaria	7	0
Vaccination site vesicles	2	0
Vaccination site warmth	156	0
<b>Withdrawal and rebound effects</b>		
Drug withdrawal syndrome	3	0
Withdrawal syndrome	7	0
<b>General disorders SOC TOTAL</b>	<b>43126</b>	<b>140</b>

## Case Series Drug Analysis Print

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

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Hepatic disorders</b>		
<i><b>Bile duct infections and inflammations</b></i>		
Biliary colic	2	0
Cholangitis	1	0
<i><b>Cholecystitis and cholelithiasis</b></i>		
Cholelithiasis	4	0
<i><b>Cholestasis and jaundice</b></i>		
Jaundice	9	0
<i><b>Gallbladder disorders NEC</b></i>		
Gallbladder disorder	1	0
<i><b>Hepatic and hepatobiliary disorders NEC</b></i>		
Liver disorder	1	0
<i><b>Hepatic enzymes and function abnormalities</b></i>		
Hepatic function abnormal	1	0
<i><b>Hepatic failure and associated disorders</b></i>		
Hepatic failure	1	0
<i><b>Hepatic vascular disorders</b></i>		
Congestive hepatopathy	1	0
Hepatic artery embolism	1	0
Hepatic vein thrombosis	3	0
Portal vein thrombosis	1	0
<i><b>Hepatobiliary signs and symptoms</b></i>		
Hepatic pain	9	0
Liver tenderness	2	0
<i><b>Hepatocellular damage and hepatitis NEC</b></i>		
Drug-induced liver injury	1	0
Hepatitis	6	0
Immune-mediated hepatic disorder	1	0
Liver injury	5	0
<b>Hepatic disorders SOC TOTAL</b>	<b>50</b>	<b>0</b>

## Case Series Drug Analysis Print

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

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Immune system disorders</b>		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	8	0
<i>Allergic conditions NEC</i>		
Allergic oedema	9	0
Allergy to arthropod bite	1	0
Allergy to arthropod sting	1	0
Hypersensitivity	389	0
Mite allergy	1	0
Multiple allergies	2	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	22	0
Contrast media reaction	1	0
Drug hypersensitivity	11	0
Food allergy	8	0
Oral allergy syndrome	1	0
Reaction to colouring	1	0
Reaction to excipient	4	0
Reaction to preservatives	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	240	1
Anaphylactic shock	17	0
Anaphylactoid reaction	14	0
Anaphylactoid shock	3	0
<i>Atopic disorders</i>		
Atopy	1	0
Seasonal allergy	12	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	11	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	11	0
Graft versus host disease	1	0
Immune system disorder	8	0
Immune-mediated adverse reaction	2	0
Immunisation reaction	1	0
Sensitisation	2	0
Systemic immune activation	2	0
<i>Transplant rejections</i>		
Kidney transplant rejection	1	0
<b>Immune system disorders SOC TOTAL</b>	<b>807</b>	<b>1</b>



## Case Series Drug Analysis Print

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

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Infections</b>		
<b><i>Abdominal and gastrointestinal infections</i></b>		
Appendicitis	8	0
Diverticulitis	3	0
Dysentery	1	0
Gastroenteritis	15	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	1	0
Bacterial diarrhoea	1	0
Bacterial infection	1	0
Cellulitis	97	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
Injection site cellulitis	2	0
Meningitis bacterial	1	0
Periorbital cellulitis	1	0
Tonsillitis bacterial	2	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	12	0
<b><i>Bone and joint infections</i></b>		
Abscess jaw	1	0
<b><i>Borrelial infections</i></b>		
Relapsing fever	1	0
<b><i>Breast infections</i></b>		
Breast abscess	2	0
Mastitis	15	0
<b><i>Caliciviral infections</i></b>		
Gastroenteritis norovirus	1	0
<b><i>Candida infections</i></b>		
Anal candidiasis	2	0
Candida infection	14	0
Oral candidiasis	18	0
Systemic candida	1	0
Vulvovaginal candidiasis	12	0
<b><i>Central nervous system and spinal infections</i></b>		
Cavernous sinus thrombosis	1	0
Encephalitis	7	0
Meningitis	3	0
Meningitis aseptic	1	0
Myelitis	2	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	579	32
COVID-19 pneumonia	20	8
Coronavirus infection	6	0
Severe acute respiratory syndrome	1	0
Suspected COVID-19	34	1

## Case Series Drug Analysis Print

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

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
<i><b>Coxiella infections</b></i>		
Q fever	6	0
<i><b>Dental and oral soft tissue infections</b></i>		
Abscess oral	3	0
Gingivitis	3	0
Parotitis	6	0
Pulpitis dental	1	0
Sialoadenitis	2	0
Tooth abscess	2	0
Tooth infection	2	0
<i><b>Ear infections</b></i>		
Ear infection	27	0
Labyrinthitis	41	0
Mastoiditis	1	0
Otitis media	1	0
Otitis media acute	1	0
<i><b>Ectoparasitic infestations</b></i>		
Acarodermatitis	1	0
Bed bug infestation	1	0
<i><b>Epstein-Barr viral infections</b></i>		
Epstein-Barr virus infection	1	0
Infectious mononucleosis	5	0
<i><b>Eye and eyelid infections</b></i>		
Conjunctivitis	33	0
Eye abscess	1	0
Eye infection	9	0
Hordeolum	8	0
Periorbital infection	1	0
<i><b>Female reproductive tract infections</b></i>		
Bartholinitis	1	0
Vulval abscess	1	0
<i><b>Fungal infections NEC</b></i>		
Fungal infection	2	0
Fungal skin infection	1	0
Pneumonia fungal	1	0
<i><b>Hepatitis viral infections</b></i>		
Hepatitis A	1	0
<i><b>Hepatobiliary and spleen infections</b></i>		
Biliary sepsis	1	0
<i><b>Herpes viral infections</b></i>		
Disseminated varicella zoster virus infection	1	0
Eczema herpeticum	2	0
Genital herpes	20	0
Genital herpes simplex	3	0
Herpes ophthalmic	2	0
Herpes simplex	9	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	2	0
Herpes virus infection	3	0
Herpes zoster	492	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	4	0
Nasal herpes	1	0

## Case Series Drug Analysis Print

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Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Ophthalmic herpes zoster	1	0
Oral herpes	139	0
Varicella	7	0
Varicella zoster virus infection	1	0
<b><i>Infections NEC</i></b>		
Abscess	14	0
Abscess limb	2	0
Abscess soft tissue	1	0
Infection	106	0
Injection site abscess	1	0
Injection site infection	4	0
Localised infection	12	0
Lymph gland infection	5	0
Lymph node abscess	1	0
Respiratory tract infection	3	0
Vaccination site abscess	2	0
Vaccination site infection	11	0
Vaccine breakthrough infection	22	0
Vestibulitis	2	0
<b><i>Infectious transmissions</i></b>		
Secondary transmission	1	0
<b><i>Influenza viral infections</i></b>		
Influenza	687	0
<b><i>Lower respiratory tract and lung infections</i></b>		
Bronchitis	4	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	78	7
Pneumonia	45	6
Sputum purulent	1	0
<b><i>Male reproductive tract infections</i></b>		
Epididymitis	2	0
Orchitis	2	0
<b><i>Mumps viral infections</i></b>		
Mumps	3	0
<b><i>Muscle and soft tissue infections</i></b>		
Necrotising fasciitis	1	0
Soft tissue infection	1	0
<b><i>Neisseria infections</i></b>		
Gonorrhoea	1	0
<b><i>Rotaviral infections</i></b>		
Gastroenteritis rotavirus	1	0
<b><i>Rubeola viral infections</i></b>		
Measles	2	0
<b><i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i></b>		
Neutropenic sepsis	2	0
Sepsis	22	3
Sepsis syndrome	1	0
Septic shock	3	0
Urosepsis	2	0
<b><i>Skin structures and soft tissue infections</i></b>		
Abscess sweat gland	1	0
Acne pustular	1	0
Dermatitis infected	1	0

## Case Series Drug Analysis Print

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

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Infections</b>		
Infections cont'd		
Folliculitis	4	0
Injection site pustule	1	0
Paronychia	1	0
Pustule	5	0
Rash pustular	6	0
Skin infection	14	0
Subcutaneous abscess	5	0
Vaccination site pustule	2	0
<b>Staphylococcal infections</b>		
Furuncle	18	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	3	0
Streptococcal abscess	1	0
<b>Trypanosomal infections</b>		
African trypanosomiasis	1	0
<b>Tuberculous infections</b>		
Pulmonary tuberculosis	1	0
<b>Upper respiratory tract infections</b>		
Epiglottitis	1	0
Laryngitis	7	0
Nasopharyngitis	325	0
Pharyngitis	8	0
Rhinitis	22	0
Sinusitis	45	0
Tonsillitis	35	0
Tracheitis	2	0
Upper respiratory tract infection	2	0
<b>Urinary tract infections</b>		
Cystitis	24	0
Kidney infection	9	0
Pyelonephritis	1	0
Urinary tract infection	52	0
<b>Vascular infections</b>		
Haematoma infection	1	0
Lymphangitis	5	0
<b>Viral infections NEC</b>		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Encephalitis viral	1	0
Eye infection viral	2	0
Gastroenteritis viral	9	0
Hepatitis viral	2	0
Meningitis viral	2	0
Oral viral infection	1	0
Pneumonia viral	1	1
Post viral fatigue syndrome	20	0
Sweating fever	55	0
Vestibular neuronitis	9	0

## Case Series Drug Analysis Print

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

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Infections</b> Infections cont'd		
Viral infection	15	0
Viral labyrinthitis	3	0
Viral pericarditis	1	0
Viral pharyngitis	5	0
Viral rash	21	0
Viral tonsillitis	1	0
<b>Infections SOC TOTAL</b>	<b>3545</b>	<b>60</b>

## Case Series Drug Analysis Print

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

Report Run Date: 26-Apr-2021  
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 21-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
<b><i>Abdominal and gastrointestinal injuries NEC</i></b>		
Mouth injury	1	0
Oral contusion	1	0
Rectal injury	1	0
Splenic rupture	2	0
Tongue injury	1	0
<b><i>Accidental exposures to product</i></b>		
Accidental exposure to product	10	0
<b><i>Anaesthetic and allied procedural complications</i></b>		
Delayed recovery from anaesthesia	2	0
Sedation complication	1	0
<b><i>Atmospheric pressure injuries</i></b>		
Hypobarism	1	0
<b><i>Bone and joint injuries NEC</i></b>		
Joint injury	2	0
<b><i>Cardiovascular injuries</i></b>		
Heart injury	2	0
Vascular injury	2	0
<b><i>Cerebral injuries NEC</i></b>		
Subdural haematoma	2	0
Subdural haemorrhage	1	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	3	0
<b><i>Conditions caused by cold</i></b>		
Chillblains	25	0
<b><i>Cranial nerve injuries</i></b>		
Vth nerve injury	1	0
<b><i>Exposures associated with pregnancy, delivery and lactation</i></b>		
Exposure during pregnancy	4	0
Exposure via breast milk	15	0
Foetal exposure during pregnancy	5	0
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	152	0
Maternal exposure during pregnancy	95	0
Paternal exposure before pregnancy	1	0
Paternal exposure during pregnancy	1	0
<b><i>Exposures to agents or circumstances NEC</i></b>		
Exposure to SARS-CoV-2	1	0
<b><i>Eye and ear procedural complications</i></b>		
Toxic anterior segment syndrome	1	0
<b><i>Eye injuries NEC</i></b>		
Eye contusion	7	0
Eye injury	3	0
Injury corneal	1	0
Periorbital haematoma	1	0
Retinal injury	2	0
<b><i>Fractures and dislocations NEC</i></b>		
Joint dislocation	1	0
<b><i>Gastrointestinal and hepatobiliary procedural complications</i></b>		
Post procedural constipation	1	0

## Case Series Drug Analysis Print

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Report Run Date: 26-Apr-2021  
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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Injuries</b> <span style="float: right;">Injuries cont'd</span>		
Postoperative ileus	1	0
Procedural nausea	4	0
Procedural vomiting	1	0
<b>Heat injuries (excl thermal burns)</b>		
Heat illness	1	0
Heat oedema	6	0
Heat stroke	2	0
<b>Limb fractures and dislocations</b>		
Atypical femur fracture	1	0
Clavicle fracture	12	0
<b>Medication errors, product use errors and issues NEC</b>		
Circumstance or information capable of leading to medication error	1	0
Medication error	8	0
Prescription drug used without a prescription	1	0
Product use complaint	1	0
Product use issue	6	0
Vaccination error	2	0
Wrong drug	3	0
Wrong technique in product usage process	3	0
<b>Muscle, tendon and ligament injuries</b>		
Epicondylitis	4	0
Ligament sprain	2	0
Mallet finger	1	0
Muscle injury	2	0
Muscle rupture	2	0
Muscle strain	11	0
Tendon injury	2	0
<b>Musculoskeletal procedural complications</b>		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
<b>Nerve injuries NEC</b>		
Nerve injury	16	0
<b>Neurological and psychiatric procedural complications</b>		
Procedural dizziness	7	0
<b>Non-occupational environmental exposures</b>		
Exposure to extreme temperature	1	0
<b>Non-site specific injuries NEC</b>		
Bite	1	0
Electric shock	8	0
Fall	68	1
Foreign body	1	0
Injury	4	0
Wound	4	0
Wound complication	4	0
Wound haemorrhage	1	0
Wound secretion	2	0
<b>Non-site specific procedural complications</b>		
Incision site pain	2	0
Infusion related reaction	5	0
Injection related reaction	29	0
Post procedural complication	3	0
<b>Occupational exposures</b>		
Occupational exposure to SARS-CoV-2	1	0

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Injuries</b>		
Injuries cont'd		
Occupational exposure to product	1	0
<b>Off label uses</b>		
Off label use	11	0
<b>Overdoses NEC</b>		
Overdose	6	0
<b>Peripheral nerve injuries</b>		
Brachial plexus injury	1	0
Ulnar nerve injury	4	0
<b>Poisoning and toxicity</b>		
Poisoning	3	0
Toxicity to various agents	1	0
<b>Product administration errors and issues</b>		
Accidental overdose	1	0
Contraindicated product administered	1	0
Expired product administered	5	0
Inappropriate schedule of product administration	14	0
Incomplete course of vaccination	1	0
Incorrect product formulation administered	2	0
Product administered at inappropriate site	6	0
Product administered to patient of inappropriate age	1	0
Product administration error	2	0
Product dose omission issue	3	0
Wrong product administered	8	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 issue	2	0
<b>Product prescribing errors and issues</b>		
Contraindicated product prescribed	1	0
<b>Radiation injuries</b>		
Sunburn	6	0
<b>Site specific injuries NEC</b>		
Face crushing	1	0
Head injury	7	0
Limb crushing injury	1	0
Limb injury	22	0
<b>Skin injuries NEC</b>		
Contusion	316	0
Nail avulsion	1	0
Scar	2	0
Scratch	1	0
Skin abrasion	4	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>Stoma complications</b>		
Gastrointestinal stoma complication	1	0



## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Injuries</b> Injuries cont'd		
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
<b><i>Thermal burns</i></b>		
Airway burns	1	0
Burn oesophageal	1	0
Burn of internal organs	1	0
Burn oral cavity	1	0
Burns second degree	3	0
Thermal burn	6	0
Thermal burns of eye	6	0
<b><i>Underdoses NEC</i></b>		
Underdose	2	0
<b><i>Vaccination related complications</i></b>		
Vaccination complication	34	0
Vaccination failure	3	0
<b>Injuries SOC TOTAL</b>	<b>1094</b>	<b>2</b>

## Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Investigations</b>		
<b><i>Adrenal cortex tests</i></b>		
Cortisol decreased	2	0
<b><i>Auditory function diagnostic procedures</i></b>		
Acoustic stimulation tests	2	0
<b><i>Autoimmunity analyses</i></b>		
Rheumatoid factor	2	0
<b><i>Blood counts NEC</i></b>		
Blood count	2	0
Blood count abnormal	1	0
<b><i>Blood gas and acid base analyses</i></b>		
Blood lactic acid	2	0
Blood lactic acid increased	2	0
Blood pH	3	0
Blood pH increased	4	0
Oxygen consumption decreased	1	0
Oxygen saturation	5	0
Oxygen saturation decreased	33	0
<b><i>Bone marrow and immune tissue histopathology procedures</i></b>		
Biopsy lymph gland	1	0
<b><i>Bone marrow and immune tissue imaging procedures</i></b>		
Lymph nodes scan abnormal	1	0
<b><i>Carbohydrate tolerance analyses (incl diabetes)</i></b>		
Blood glucose	6	0
Blood glucose abnormal	6	0
Blood glucose decreased	14	0
Blood glucose fluctuation	11	0
Blood glucose increased	59	0
Glycosylated haemoglobin increased	1	0
<b><i>Cardiac auscultatory investigations</i></b>		
Cardiac murmur	6	0
Heart sounds abnormal	2	0
<b><i>Cardiac function diagnostic procedures</i></b>		
Cardiac output	1	0
Central venous pressure	1	0
<b><i>Central nervous system imaging procedures</i></b>		
Computerised tomogram head	1	0
Magnetic resonance imaging brain	10	0
Magnetic resonance imaging brain abnormal	1	0
<b><i>Chemistry analyses NEC</i></b>		
Inflammatory marker increased	3	0
<b><i>Cholesterol analyses</i></b>		
Blood cholesterol increased	2	0
<b><i>Coagulation and bleeding analyses</i></b>		
Activated partial thromboplastin time prolonged	4	0
Bleeding time abnormal	1	0
Blood thromboplastin	1	0
Clot retraction	1	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	2	0
Fibrin D dimer increased	3	0
International normalised ratio abnormal	3	0
International normalised ratio decreased	16	0
International normalised ratio increased	37	0

## Case Series Drug Analysis Print

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Report Run Date: 26-Apr-2021  
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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
<b><i>ECG investigations</i></b>		
Electrocardiogram ST segment elevation	2	0
Electrocardiogram abnormal	2	0
<b><i>Endocrine analyses and imaging NEC</i></b>		
Hormone level abnormal	2	0
<b><i>Faecal analyses NEC</i></b>		
Faecal calprotectin	2	0
Faecal calprotectin increased	1	0
<b><i>Haematological analyses NEC</i></b>		
Plasma viscosity	1	0
Red blood cell sedimentation rate increased	4	0
<b><i>Heart rate and pulse investigations</i></b>		
Heart rate	109	0
Heart rate abnormal	7	0
Heart rate decreased	17	0
Heart rate increased	251	0
Heart rate irregular	38	0
Pulse abnormal	8	0
Radial pulse abnormal	1	0
<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
Antibody test abnormal	1	0
Immunology test	4	0
<b><i>Immunology skin tests NEC</i></b>		
Skin test positive	1	0
<b><i>Investigations NEC</i></b>		
Blood test	4	0
Blood test abnormal	10	0
False positive investigation result	1	0
Polymerase chain reaction positive	30	0
Systemic lupus erythematosus disease activity index increased	1	0
<b><i>Liver function analyses</i></b>		
Alanine aminotransferase increased	8	0
Aspartate aminotransferase increased	1	0
Gamma-glutamyltransferase increased	1	0
Hepatic enzyme increased	3	0
Liver function test abnormal	8	0
Liver function test increased	10	0
Transaminases increased	1	0
<b><i>Metabolism tests NEC</i></b>		
Blood ketone body	2	0
Blood ketone body increased	1	0
Ubiquinone	1	0
<b><i>Microbiology and serology tests NEC</i></b>		
Culture negative	1	0

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
<b><i>Mineral and electrolyte analyses</i></b>		
Blood copper increased	1	0
Blood iron	1	0
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	3	0
Blood sodium decreased	1	0
Serum ferritin increased	1	0
<b><i>Musculoskeletal and soft tissue tests NEC</i></b>		
Swollen joint count increased	1	0
<b><i>Neurologic diagnostic procedures</i></b>		
Coma scale abnormal	2	0
Temperature perception test increased	1	0
<b><i>Ophthalmic function diagnostic procedures</i></b>		
Corneal reflex decreased	1	0
Intraocular pressure increased	2	0
<b><i>Physical examination procedures and organ system status</i></b>		
Body temperature	135	0
Body temperature abnormal	20	0
Body temperature decreased	17	0
Body temperature fluctuation	13	0
Body temperature increased	220	0
Body temperature normal	1	0
Breath sounds abnormal	1	0
Grip strength	2	0
Grip strength decreased	6	0
Lymph node palpable	19	0
Ophthalmological examination	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	19	0
Skin temperature	21	0
Temperature difference of extremities	6	0
Weight	1	0
Weight decreased	22	0
Weight increased	4	0
<b><i>Pituitary analyses anterior</i></b>		
Blood growth hormone	2	0
Blood thyroid stimulating hormone increased	2	0
<b><i>Platelet analyses</i></b>		
Mean platelet volume decreased	1	0
Platelet count decreased	25	0
Platelet count increased	1	0
<b><i>Protein analyses NEC</i></b>		
C-reactive protein increased	6	0
<b><i>Red blood cell analyses</i></b>		
Haematocrit	1	0
Haemoglobin decreased	5	0
<b><i>Reproductive hormone analyses</i></b>		

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
False negative pregnancy test	1	0
Pregnancy test	1	0
Pregnancy test false positive	1	0
Pregnancy test positive	1	0
<b><i>Respiratory and pulmonary function diagnostic procedures</i></b>		
Forced expiratory volume increased	2	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	4	0
Pulmonary function test	2	0
Vital capacity	1	0
<b><i>Respiratory tract and thoracic histopathology procedures</i></b>		
Sputum abnormal	3	0
<b><i>Respiratory tract and thoracic imaging procedures</i></b>		
Chest X-ray	7	0
<b><i>Skeletal and cardiac muscle analyses</i></b>		
Blood creatine phosphokinase increased	3	0
Troponin increased	4	0
<b><i>Therapeutic drug monitoring analyses</i></b>		
Analgesic drug level	1	0
Anticoagulation drug level below therapeutic	5	0
Anticoagulation drug level increased	1	0
Drug level decreased	1	0
<b><i>Thyroid analyses</i></b>		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	1	0
Thyroxine free increased	2	0
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	2	0
<b><i>Tissue enzyme analyses NEC</i></b>		
Blood alkaline phosphatase increased	1	0
<b><i>Toxicology laboratory analyses</i></b>		
Opiates	1	0
<b><i>Urinalysis NEC</i></b>		
Blood urine	5	0
Blood urine present	12	0
Cells in urine	1	0
Glucose urine present	1	0
Urine analysis abnormal	2	0
pH urine	3	0
pH urine increased	1	0
<b><i>Urinary tract function analyses NEC</i></b>		
Urine output	6	0
Urine output decreased	5	0
Urine output increased	2	0
<b><i>Urinary tract imaging procedures</i></b>		
Cystoscopy	2	0
<b><i>Vascular imaging procedures NEC</i></b>		
Venogram	1	0
<b><i>Vascular tests NEC (incl blood pressure)</i></b>		
Blood pressure abnormal	3	0
Blood pressure decreased	20	0
Blood pressure diastolic	1	0
Blood pressure diastolic increased	1	0

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Reaction Name	Total	Fatal
<b>Investigations</b> Investigations cont'd		
Blood pressure increased	108	0
Blood pressure measurement	15	0
Blood pressure systolic decreased	2	0
Blood pressure systolic increased	1	0
<b><i>Virus identification and serology</i></b>		
Coronavirus test	5	0
Coronavirus test positive	2	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	3	0
SARS-CoV-2 antibody test negative	13	0
SARS-CoV-2 antibody test positive	1	0
SARS-CoV-2 test	18	0
SARS-CoV-2 test false negative	1	0
SARS-CoV-2 test false positive	1	0
SARS-CoV-2 test negative	4	0
SARS-CoV-2 test positive	41	0
Viral test	3	0
<b><i>Vitamin analyses</i></b>		
Blood folate decreased	1	0
Vitamin D	2	0
<b><i>Water and electrolyte analyses NEC</i></b>		
Volume blood	1	0
<b><i>White blood cell analyses</i></b>		
Lymphocyte count	1	0
Lymphocyte count decreased	1	0
Neutrophil count decreased	1	0
White blood cell count	1	0
White blood cell count decreased	5	0
White blood cell count increased	1	0
<b>Investigations SOC TOTAL</b>	<b>1721</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Metabolic disorders</b>		
<i><b>Appetite disorders</b></i>		
Appetite disorder	4	0
Decreased appetite	559	0
Eating disorder symptom	1	0
Food craving	4	0
Food refusal	4	0
Hyperphagia	1	0
Hypophagia	6	0
Increased appetite	5	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	20	0
Diabetes mellitus inadequate control	6	1
Increased insulin requirement	1	0
Latent autoimmune diabetes in adults	1	0
Type 1 diabetes mellitus	10	0
Type 2 diabetes mellitus	1	0
<i><b>Diabetic complications NEC</b></i>		
Diabetic complication	2	0
Diabetic ketoacidosis	6	0
<i><b>Disorders of purine metabolism</b></i>		
Gout	36	0
<i><b>Electrolyte imbalance NEC</b></i>		
Fluid imbalance	1	0
<i><b>Fluid intake increased</b></i>		
Polydipsia	4	0
<i><b>Food malabsorption and intolerance syndromes (excl sugar intolerance)</b></i>		
Alcohol intolerance	2	0
Dairy intolerance	1	0
Food intolerance	3	0
Gluten sensitivity	1	0
Histamine intolerance	2	0
<i><b>General nutritional disorders NEC</b></i>		
Abnormal loss of weight	3	0
Abnormal weight gain	5	0
Cachexia	1	0
Feeding disorder	21	0
Food aversion	5	0
Overweight	1	0
Poor feeding infant	3	0
Weight loss poor	1	0
<i><b>Hyperglycaemic conditions NEC</b></i>		
Hyperglycaemia	52	0
Insulin resistance	4	0
<i><b>Hypoglycaemic conditions NEC</b></i>		
Glycopenia	1	0
Hypoglycaemia	49	0
Postprandial hypoglycaemia	1	0
<i><b>Iron deficiencies</b></i>		
Iron deficiency	1	0

## Case Series Drug Analysis Print

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Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Metabolic disorders</b> Metabolic disorders cont'd		
<i><b>Lipid metabolism and deposit disorders NEC</b></i>		
Body fat disorder	1	0
<i><b>Metabolic acidoses (excl diabetic acidoses)</b></i>		
Ketoacidosis	4	0
Metabolic acidosis	2	0
<i><b>Mixed acid-base disorders</b></i>		
Acidosis	3	0
<i><b>Potassium imbalance</b></i>		
Hyperkalaemia	2	0
Hypokalaemia	2	0
Hypokalaemic syndrome	1	0
<i><b>Sodium imbalance</b></i>		
Hyponatraemia	5	0
Hyponatraemic syndrome	2	0
<i><b>Sugar intolerance (excl glucose intolerance)</b></i>		
Lactose intolerance	1	0
<i><b>Total fluid volume decreased</b></i>		
Dehydration	64	0
<i><b>Total fluid volume increased</b></i>		
Fluid retention	13	0
Hypervolaemia	1	0
<i><b>Vitamin deficiencies NEC</b></i>		
Hypovitaminosis	2	0
<b>Metabolic disorders SOC TOTAL</b>	<b>939</b>	<b>1</b>



## Case Series Drug Analysis Print

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

Report Run Date: 26-Apr-2021  
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 21-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
<i><b>Arthropathies NEC</b></i>		
Arthritis	108	0
Arthropathy	13	0
Haemarthrosis	3	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	1	0
Polyarthritis	8	0
Sacroiliitis	3	0
<i><b>Bone disorders NEC</b></i>		
Medial tibial stress syndrome	2	0
Osteitis	1	0
Osteonecrosis of jaw	2	0
Spinal disorder	1	0
<i><b>Bone related signs and symptoms</b></i>		
Bone pain	160	0
Bone swelling	3	0
Coccydynia	1	0
Pain in jaw	137	0
Spinal pain	23	0
<i><b>Bursal disorders</b></i>		
Bursitis	18	0
<i><b>Cartilage disorders</b></i>		
Chondritis	1	0
Costochondritis	20	0
Osteochondritis	1	0
Polychondritis	2	0
<i><b>Connective tissue disorders NEC</b></i>		
Polymyalgia rheumatica	22	0
Sjogren's syndrome	2	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
Knee deformity	1	0
Musculoskeletal deformity	1	0
<i><b>Joint related disorders NEC</b></i>		
Joint destruction	1	0
Joint laxity	2	0
Joint lock	8	0
Patellofemoral pain syndrome	1	0
Periarthritis	38	0
Rotator cuff syndrome	3	0
Temporomandibular joint syndrome	2	0
<i><b>Joint related signs and symptoms</b></i>		
Arthralgia	4130	0
Jaw clicking	3	0
Joint effusion	11	0
Joint noise	10	0
Joint range of motion decreased	2	0
Joint stiffness	95	0

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Joint swelling	181	0
Joint vibration	1	0
Joint warmth	7	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	7	0
<b>Metabolic bone disorders</b>		
Osteopenia	1	0
<b>Muscle infections and inflammations</b>		
Antisynthetase syndrome	1	0
Myositis	10	0
Polymyositis	1	0
<b>Muscle pains</b>		
Fibromyalgia	35	0
Myalgia	5553	0
Myalgia intercostal	1	0
Myofascial pain syndrome	6	0
<b>Muscle related signs and symptoms NEC</b>		
Haematoma muscle	1	0
Muscle atrophy	4	0
Muscle discomfort	2	0
Muscle disorder	2	0
Muscle fatigue	163	0
Muscle mass	1	0
Muscle spasms	311	0
Muscle swelling	11	0
Muscle tightness	25	0
Muscle twitching	122	0
<b>Muscle tone abnormalities</b>		
Muscle rigidity	7	0
Nuchal rigidity	6	0
Torticollis	2	0
Trismus	12	0
<b>Muscle weakness conditions</b>		
Muscular weakness	349	0
<b>Musculoskeletal and connective tissue conditions NEC</b>		
Limb mass	5	0
Mandibular mass	2	0
Mastication disorder	1	0
Mobility decreased	27	0
Musculoskeletal disorder	4	0
Musculoskeletal stiffness	483	0
Posture abnormal	1	0
<b>Musculoskeletal and connective tissue infections and inflammations NEC</b>		
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	4	0
<b>Musculoskeletal and connective tissue pain and discomfort</b>		
Back pain	918	0
Flank pain	15	0

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Muscle &amp; tissue disorders</b>		
Muscle & tissue disorders cont'd		
Limb discomfort	588	0
Musculoskeletal chest pain	61	0
Musculoskeletal discomfort	33	0
Musculoskeletal pain	25	0
Neck pain	747	0
Pain in extremity	4812	0
Rheumatic disorder	3	0
<b>Myopathies</b>		
Myopathy	1	0
Rhabdomyolysis	3	0
<b>Osteoarthropathies</b>		
Nodal osteoarthritis	1	0
Osteoarthritis	13	0
<b>Psoriatic arthropathies</b>		
Psoriatic arthropathy	8	0
<b>Rheumatoid arthropathies</b>		
Rheumatoid arthritis	53	0
<b>Soft tissue disorders NEC</b>		
Axillary mass	119	0
Fluctuance	1	0
Groin pain	42	0
Neck mass	12	0
Purple glove syndrome	1	0
Soft tissue swelling	3	0
<b>Spine and neck deformities</b>		
Kyphosis	1	0
Neck deformity	1	0
<b>Spondyloarthropathies</b>		
Ankylosing spondylitis	4	0
Arthritis reactive	14	0
<b>Synovial disorders</b>		
Synovial cyst	8	0
Synovitis	4	0
<b>Tendon disorders</b>		
Enthesopathy	1	0
Tendon pain	3	0
Tendonitis	13	0
Tenosynovitis	1	0
Tenosynovitis stenosaurs	1	0
Trigger finger	6	0
<b>Trunk deformities</b>		
Drooping shoulder syndrome	1	0
<b>Muscle &amp; tissue disorders SOC TOTAL</b>	<b>19716</b>	<b>0</b>

## Case Series Drug Analysis Print

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Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Neoplasms</b>		
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma	3	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	13	0
Breast cancer stage III	1	0
Triple negative breast cancer	1	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	1	0
<i>Follicle centre lymphomas, follicular grade I, II, III</i>		
Primary gastrointestinal follicular lymphoma	1	0
<i>Gastric neoplasms malignant</i>		
Gastric cancer	1	1
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	1	0
<i>Leukaemias acute NEC</i>		
Acute leukaemia	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	9	0
<i>Metastases to specified sites</i>		
Metastases to liver	1	0
Metastases to lymph nodes	4	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	1	0
<i>Neoplasms unspecified malignancy and site unspecified NEC</i>		
Neoplasm recurrence	1	0
<i>Nervous system neoplasms unspecified malignancy NEC</i>		
Brain neoplasm	1	0
<i>Non-Hodgkin's lymphomas NEC</i>		
Non-Hodgkin's lymphoma	1	0
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	1	0
<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>		
Pancreatic carcinoma	4	0
<i>Plasma cell myelomas</i>		
Plasma cell myeloma	1	0
<i>Plasma cell neoplasms NEC</i>		
TEMPI syndrome	1	0
<i>Renal neoplasms malignant</i>		
Renal cancer	2	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Lung neoplasm malignant	3	0
<i>Skin neoplasms benign</i>		
Acrochordon	2	0

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Reaction Name	Total	Fatal
<b>Neoplasms</b> Neoplasms cont'd		
Anogenital warts	1	0
Melanocytic naevus	4	0
Skin papilloma	3	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	1	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	1	0
<b>Neoplasms SOC TOTAL</b>	<b>77</b>	<b>1</b>

## Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i><b>Abnormal reflexes</b></i>		
Areflexia	2	0
Extensor plantar response	1	0
Hyperreflexia	1	0
Hyporeflexia	4	0
<i><b>Abnormal sleep-related events</b></i>		
Sleep paralysis	5	0
<i><b>Absence seizures</b></i>		
Petit mal epilepsy	12	0
<i><b>Acute polyneuropathies</b></i>		
Guillain-Barre syndrome	25	1
Subacute inflammatory demyelinating polyneuropathy	1	0
<i><b>Autonomic nervous system disorders</b></i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	3	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
Cerebellar haemorrhage	1	0
Cerebellar infarction	2	0
Cerebellar stroke	3	0
Cerebral artery embolism	2	1
Cerebral artery occlusion	1	0
Cerebral artery thrombosis	2	0
Cerebral haemorrhage	18	6
Cerebral infarction	15	0
Cerebral thrombosis	1	0
Cerebrovascular accident	176	10
Embolic stroke	4	0
Haemorrhage intracranial	4	0
Haemorrhagic stroke	5	3
Ischaemic cerebral infarction	1	0
Ischaemic stroke	24	1
Lacunar infarction	2	0
Lacunar stroke	1	0
Lateral medullary syndrome	1	0
Subarachnoid haemorrhage	5	2
Thrombotic stroke	1	0
<i><b>Central nervous system inflammatory disorders NEC</b></i>		
Gliosis	1	0
<i><b>Central nervous system vascular disorders NEC</b></i>		
Carotid artery disease	1	0
Reversible cerebral vasoconstriction syndrome	1	0
<i><b>Cerebrovascular venous and sinus thrombosis</b></i>		
Cerebral venous sinus thrombosis	14	0
Cerebral venous thrombosis	1	0
Superior sagittal sinus thrombosis	1	0
<i><b>Cervical spinal cord and nerve root disorders</b></i>		
Cervicobrachial syndrome	2	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
<b><i>Choreiform movements</i></b>		
Chorea	2	0
<b><i>Coma states</i></b>		
Coma	3	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
<b><i>Coordination and balance disturbances</i></b>		
Ataxia	5	0
Balance disorder	135	0
Coordination abnormal	20	0
Dysdiadochokinesis	1	0
Dysstasia	20	0
Nystagmus	7	0
<b><i>Cortical dysfunction NEC</i></b>		
Aphasia	29	0
Apraxia	1	0
Neurologic neglect syndrome	1	0
<b><i>Cranial nerve disorders NEC</i></b>		
Cranial nerve disorder	2	0
<b><i>Dementia (excl Alzheimer's type)</i></b>		
Dementia	6	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
<b><i>Demyelinating disorders NEC</i></b>		
Acute disseminated encephalomyelitis	2	0
Demyelination	5	0
<b><i>Disturbances in consciousness NEC</i></b>		
Altered state of consciousness	6	0
Consciousness fluctuating	2	0
Depressed level of consciousness	19	1
Lethargy	1124	0
Loss of consciousness	163	0
Sedation	4	0
Somnolence	365	0
Stupor	2	0
Syncope	476	0
<b><i>Disturbances in sleep phase rhythm</i></b>		
Irregular sleep wake rhythm disorder	1	0
<b><i>Dyskinesias and movement disorders NEC</i></b>		
Akathisia	1	0
Bradykinesia	5	0
Clumsiness	5	0
Dyskinesia	22	0
Extrapyramidal disorder	1	0
Fine motor skill dysfunction	4	0
Hyperkinesia	1	0
Hypokinesia	17	1
Motor dysfunction	2	0
Movement disorder	19	0
Psychomotor hyperactivity	8	0
Tardive dyskinesia	1	0
<b><i>Dystonias</i></b>		
Dystonia	9	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
Writer's cramp	1	0
<b>Encephalitis NEC</b>		
Encephalitis autoimmune	1	0
Noninfective encephalitis	1	0
<b>Encephalopathies NEC</b>		
Encephalopathy	1	0
Posterior reversible encephalopathy syndrome	1	0
<b>Eye movement disorders</b>		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	2	0
IVth nerve paralysis	1	0
VIth nerve paralysis	4	0
<b>Facial cranial nerve disorders</b>		
Facial nerve disorder	1	0
Facial paralysis	341	0
Facial paresis	43	0
Facial spasm	17	0
<b>Generalised tonic-clonic seizures</b>		
Generalised tonic-clonic seizure	16	0
<b>Headaches NEC</b>		
Cervicogenic headache	2	0
Cluster headache	89	0
Cold-stimulus headache	7	0
Drug withdrawal headache	1	0
Exertional headache	5	0
Headache	12576	0
Medication overuse headache	2	0
New daily persistent headache	4	0
Occipital neuralgia	4	0
Ophthalmoplegic migraine	1	0
Primary cough headache	2	0
Primary headache associated with sexual activity	1	0
Sinus headache	171	0
Tension headache	234	0
Thunderclap headache	1	0
Vascular headache	7	0
<b>Hypoglossal nerve disorders</b>		
Tongue paralysis	1	0
<b>Increased intracranial pressure disorders</b>		
Brain oedema	1	0
Idiopathic intracranial hypertension	1	0
<b>Lumbar spinal cord and nerve root disorders</b>		
Sciatica	22	0
<b>Memory loss (excl dementia)</b>		
Amnesia	47	0
Memory impairment	49	0
Transient global amnesia	6	0
<b>Mental impairment (excl dementia and memory loss)</b>		
Cognitive disorder	29	0
Disturbance in attention	111	0
Mental impairment	14	0
<b>Migraine headaches</b>		
Hemiplegic migraine	5	0



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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Migraine	1065	0
Migraine with aura	77	0
Migraine without aura	8	0
Retinal migraine	14	0
Typical aura without headache	3	0
Vestibular migraine	9	0
<b>Mixed cranial nerve disorders</b>		
Bulbar palsy	1	0
<b>Mononeuropathies</b>		
Carpal tunnel syndrome	7	0
Mononeuropathy	1	0
Nerve compression	7	0
Peroneal nerve palsy	3	0
Sciatic nerve neuropathy	1	0
Ulnar neuritis	1	0
<b>Multiple sclerosis acute and progressive</b>		
Multiple sclerosis	12	0
Multiple sclerosis relapse	11	0
Tumefactive multiple sclerosis	1	1
<b>Muscle tone abnormal</b>		
Hypotonia	6	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
<b>Myelitis (incl infective)</b>		
Myelitis transverse	17	0
<b>Narcolepsy and hypersomnia</b>		
Cataplexy	1	0
Hypersomnia	38	0
Narcolepsy	2	0
<b>Nervous system disorders NEC</b>		
Nervous system disorder	4	0
<b>Neurologic visual problems NEC</b>		
Hemianopia	1	0
Hemianopia homonymous	1	0
Tunnel vision	5	0
Visual field defect	7	0
<b>Neurological signs and symptoms NEC</b>		
Dizziness	3787	0
Dizziness exertional	20	0
Dizziness postural	352	0
Drooling	7	0
Fontanelle bulging	1	0
Head discomfort	101	0
Hyporesponsive to stimuli	1	0
Inability to crawl	2	0
Infant irritability	1	0
Myoclonus	9	0
Neurological symptom	19	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	6	0
Presyncope	215	0
Slow response to stimuli	2	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>		
Tongue biting	1	0
Unresponsive to stimuli	23	1
<b>Neuromuscular disorders NEC</b>		
Muscle contractions involuntary	9	0
Muscle spasticity	5	0
Neuromuscular pain	2	0
<b>Neuromuscular junction dysfunction</b>		
Myasthenia gravis	5	0
Myasthenia gravis crisis	2	0
<b>Olfactory nerve disorders</b>		
Anosmia	100	0
Hyposmia	8	0
Parosmia	97	0
<b>Optic nerve disorders NEC</b>		
Optic neuritis	10	0
<b>Paraesthesias and dysaesthesias</b>		
Burning feet syndrome	2	0
Burning sensation	179	0
Dysaesthesia	4	0
Formication	17	0
Hand-arm vibration syndrome	2	0
Hemiparaesthesia	1	0
Hyperaesthesia	41	0
Hypoaesthesia	923	0
Paraesthesia	1351	0
Reversed hot-cold sensation	1	0
Synaesthesia	1	0
<b>Paralysis and paresis (excl cranial nerve)</b>		
Diplegia	4	1
Hemiparesis	19	0
Hemiplegia	13	0
Locked-in syndrome	1	0
Monoparesis	26	0
Monoplegia	22	0
Paralysis	39	0
Paraparesis	1	0
Paresis	3	0
<b>Parkinson's disease and parkinsonism</b>		
Freezing phenomenon	6	0
Parkinson's disease	2	0
Parkinsonian gait	1	0
Parkinsonism	4	0
Reduced facial expression	2	0
<b>Partial complex seizures</b>		
Dreamy state	2	0
Focal dyscognitive seizures	1	0
Temporal lobe epilepsy	1	0
<b>Peripheral neuropathies NEC</b>		
Neuritis	3	0
Neuropathy peripheral	41	0
Peripheral sensory neuropathy	5	0
<b>Seizures and seizure disorders NEC</b>		
Atonic seizures	4	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b>		
<i>Nervous system disorders cont'd</i>		
Clonic convulsion	1	0
Epilepsy	64	0
Epileptic aura	2	0
Epileptic encephalopathy	1	0
Febrile convulsion	9	0
Partial seizures	6	0
Post stroke seizure	1	0
Psychogenic seizure	5	0
Seizure	191	0
Seizure cluster	4	0
Seizure like phenomena	1	0
Status epilepticus	16	0
Tonic clonic movements	2	0
Tonic convulsion	8	0
<b>Sensory abnormalities NEC</b>		
Ageusia	214	0
Allodynia	8	0
Aura	8	0
Dysgeusia	556	0
Hypergeusia	1	0
Hypogeusia	1	0
Loss of proprioception	2	0
Neuralgia	181	0
Phantom limb syndrome	3	0
Post herpetic neuralgia	4	0
Restless legs syndrome	41	0
Sensory disturbance	27	0
Sensory loss	25	0
Taste disorder	120	0
Visual perseveration	1	0
<b>Sleep disturbances NEC</b>		
Poor quality sleep	77	0
Sleep deficit	2	0
Sudden onset of sleep	1	0
<b>Speech and language abnormalities</b>		
Dysarthria	67	0
Incoherent	2	0
Repetitive speech	1	0
Slow speech	3	0
Speech disorder	13	0
<b>Spinal cord and nerve root disorders NEC</b>		
Radiculitis brachial	2	0
Radiculopathy	3	0
<b>Structural brain disorders NEC</b>		
Brain injury	2	2
Hyperintensity in brain deep nuclei	1	0
<b>Transient cerebrovascular events</b>		
Transient ischaemic attack	63	0
<b>Tremor (excl congenital)</b>		
Essential tremor	2	0
Head titubation	1	0
Resting tremor	1	0
Tremor	685	0

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Reaction Name	Total	Fatal
<b>Nervous system disorders</b> <small>Nervous system disorders cont'd</small>		
<i><b>Trigeminal disorders</b></i>		
Facial neuralgia	10	0
Numb chin syndrome	1	0
Trigeminal nerve disorder	1	0
Trigeminal neuralgia	19	0
<i><b>Vertigos NEC</b></i>		
Vertigo CNS origin	1	0
<b>Nervous system disorders SOC TOTAL</b>	<b>27949</b>	<b>32</b>

## Case Series Drug Analysis Print

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

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Pregnancy conditions</b>		
<i>Abortions not specified as induced or spontaneous</i>		
Abortion missed	1	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	57	2
<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
<i>Maternal complications of pregnancy NEC</i>		
Morning sickness	6	0
Preterm premature rupture of membranes	2	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	8	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	2	0
<i>Stillbirth and foetal death</i>		
Foetal death	2	0
Stillbirth	1	0
<i>Unintended pregnancies</i>		
Pregnancy with contraceptive device	2	0
Pregnancy with implant contraceptive	1	0
Unintended pregnancy	1	0
<b>Pregnancy conditions SOC TOTAL</b>	<b>86</b>	<b>3</b>

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Reaction Name	Total	Fatal
<b><i>Device issues NEC</i></b>		
Device issue	1	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	11	0
Thrombosis in device	2	0
<b><i>Device physical property and chemical issues</i></b>		
Device kink	1	0
Needle issue	2	0
<b><i>Product contamination and sterility issues</i></b>		
Product contamination	1	0
<b><i>Product physical issues</i></b>		
Liquid product physical issue	3	0
Product odour abnormal	1	0
Product physical issue	1	0
Product taste abnormal	5	0
<b><i>Product quality issues NEC</i></b>		
Product origin unknown	3	0
<b>null SOC TOTAL</b>	<b>34</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b>		
<b><i>Abnormal behaviour NEC</i></b>		
Abnormal behaviour	4	0
Behaviour disorder	1	0
Staring	2	0
<b><i>Adjustment disorders</i></b>		
Adjustment disorder with depressed mood	1	0
<b><i>Affect alterations NEC</i></b>		
Affect lability	1	0
Constricted affect	1	0
Flat affect	4	0
Inappropriate affect	2	0
<b><i>Amnesic symptoms</i></b>		
Paramnesia	2	0
<b><i>Anxiety symptoms</i></b>		
Agitation	36	0
Anxiety	215	0
Immunisation anxiety related reaction	1	0
Nervousness	84	0
Stress	11	0
Tension	14	0
<b><i>Attention deficit and disruptive behaviour disorders</i></b>		
Attention deficit hyperactivity disorder	2	0
<b><i>Behaviour and socialisation disturbances</i></b>		
Aggression	4	0
Aversion	1	0
Indifference	4	0
Paranoia	8	0
Personality change	2	0
Social avoidant behaviour	2	0
Soliloquy	1	0
Suspiciousness	1	0
<b><i>Bipolar disorders</i></b>		
Bipolar I disorder	1	0
Bipolar disorder	1	0
<b><i>Cognitive and attention disorders and disturbances NEC</i></b>		
Daydreaming	2	0
Mental fatigue	78	0
<b><i>Communications disorders</i></b>		
Communication disorder	4	0
Mutism	1	0
<b><i>Confusion and disorientation</i></b>		
Confusional state	339	0
Disorientation	105	0
<b><i>Decreased physical activity levels</i></b>		
Catatonia	1	0
<b><i>Deliria</i></b>		
Delirium	53	0
<b><i>Delusional symptoms</i></b>		
Delusion	4	0
<b><i>Depressive disorders</i></b>		
Agitated depression	1	0
Depression	80	0
Depression suicidal	2	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Major depression	3	0
Perinatal depression	1	0
<b><i>Dissociative states</i></b>		
Depersonalisation/derealisation disorder	3	0
Dissociation	8	0
Dissociative amnesia	1	0
Dissociative disorder	1	0
<b><i>Disturbances in initiating and maintaining sleep</i></b>		
Initial insomnia	5	0
Insomnia	424	0
Middle insomnia	11	0
Terminal insomnia	4	0
<b><i>Dyssomnias</i></b>		
Dyssomnia	1	0
<b><i>Eating disorders NEC</i></b>		
Bulimia nervosa	1	0
Eating disorder	5	0
Selective eating disorder	1	0
<b><i>Emotional and mood disturbances NEC</i></b>		
Anger	5	0
Dysphoria	2	0
Emotional disorder	11	0
Emotional distress	9	0
Euphoric mood	12	0
Irritability	62	0
Mood altered	15	0
<b><i>Factitious disorders</i></b>		
Factitious disorder	1	0
<b><i>Fear symptoms and phobic disorders (incl social phobia)</i></b>		
Fear	1	0
Fear of falling	2	0
Osmophobia	1	0
Phobia	1	0
Phonophobia	1	0
Social fear	1	0
<b><i>Fluctuating mood symptoms</i></b>		
Mood swings	11	0
<b><i>Hallucinations (excl sleep-related)</i></b>		
Hallucination	86	0
Hallucination, auditory	6	0
Hallucination, olfactory	4	0
Hallucination, tactile	1	0
Hallucination, visual	9	0
Hallucinations, mixed	1	0
<b><i>Increased physical activity levels</i></b>		
Restlessness	53	0
<b><i>Learning disorders</i></b>		
Learning disorder	1	0
<b><i>Mental disorders NEC</i></b>		
Mental disorder	5	0
<b><i>Mental disorders due to a general medical condition NEC</i></b>		
Neuropsychiatric symptoms	1	0
<b><i>Mood alterations with depressive symptoms</i></b>		



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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Decreased interest	6	0
Depressed mood	95	0
Feeling of despair	1	0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Sense of a foreshortened future	2	0
Tearfulness	16	0
<b>Mood alterations with manic symptoms</b>		
Hypomania	1	0
Mania	4	0
<b>Mood disorders NEC</b>		
Apathy	9	0
Laziness	1	0
Listless	11	0
<b>Narcolepsy and associated conditions</b>		
Hypnagogic 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	1	0
<b>Panic attacks and disorders</b>		
Panic attack	40	0
Panic disorder	3	0
Panic reaction	7	0
<b>Parasomnias</b>		
Abnormal dreams	80	0
Confusional arousal	1	0
Nightmare	74	0
Parasomnia	1	0
Sleep talking	1	0
Sleep terror	8	0
Somnambulism	1	0
<b>Perception disturbances NEC</b>		
Autoscopy	5	0
Deja vu	1	0
Derealisation	6	0
Flashback	2	0
Illusion	1	0
<b>Psychiatric elimination disorders</b>		
Enuresis	5	0
<b>Psychiatric symptoms NEC</b>		
Hypervigilance	3	0
Psychiatric symptom	1	0
Trance	1	0
<b>Psychotic disorder NEC</b>		
Psychotic behaviour	1	0
Psychotic disorder	9	0
<b>Schizophrenia NEC</b>		
Schizophrenia	1	0
<b>Sexual desire disorders</b>		
Libido decreased	3	0
Libido increased	1	0

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Reaction Name	Total	Fatal
<b>Psychiatric disorders</b> <small>Psychiatric disorders cont'd</small>		
Loss of libido	5	0
<b>Sleep disorders NEC</b>		
Sleep disorder	75	0
<b>Somatic symptom disorders</b>		
Conversion disorder	1	0
Habit cough	10	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	4	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
<b>Stereotypies and automatisms</b>		
Bruxism	6	0
Head banging	4	0
Stereotypy	1	0
<b>Stress disorders</b>		
Post-traumatic stress disorder	1	0
<b>Substance related and addictive disorders</b>		
Alcohol problem	1	0
Alcoholic hangover	1	0
<b>Suicidal and self-injurious behaviour</b>		
Completed suicide	1	0
Intentional self-injury	3	0
Self-injurious ideation	2	0
Suicidal behaviour	1	0
Suicidal ideation	6	0
Suicide attempt	3	0
<b>Thinking disturbances</b>		
Bradyphrenia	16	0
Intrusive thoughts	2	0
Tachyphrenia	2	0
Thinking abnormal	4	0
<b>Tic disorders</b>		
Tic	1	0
<b>Psychiatric disorders SOC TOTAL</b>	<b>2417</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<i><b>Bladder and urethral symptoms</b></i>		
Bladder discomfort	1	0
Bladder irritation	1	0
Bladder pain	6	0
Dysuria	19	0
Incontinence	14	0
Micturition disorder	1	0
Micturition urgency	14	0
Pollakiuria	30	0
Urethral pain	1	0
Urinary incontinence	29	0
Urinary retention	22	0
Urine flow decreased	3	0
<i><b>Bladder disorders NEC</b></i>		
Bladder disorder	3	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>		
Urinary tract disorder	2	0
<i><b>Glomerulonephritis and nephrotic syndrome</b></i>		
Glomerulonephritis	1	0
Glomerulonephritis minimal lesion	3	0
Glomerulonephritis rapidly progressive	1	0
IgA nephropathy	1	0
Nephrotic syndrome	8	0
<i><b>Myoneurogenic bladder disorders</b></i>		
Bladder dysfunction	3	0
Hypertonic bladder	1	0
Loss of bladder sensation	1	0
Neurogenic bladder	1	0
<i><b>Nephritis NEC</b></i>		
Nephritis	1	0
Tubulointerstitial nephritis	1	0
<i><b>Renal disorders NEC</b></i>		
Renal disorder	1	0
Renal haemorrhage	1	0
<i><b>Renal failure and impairment</b></i>		
Acute kidney injury	21	0
Anuria	3	0
Oliguria	1	0
Renal failure	10	1
Renal impairment	8	0
<i><b>Renal lithiasis</b></i>		
Nephrolithiasis	1	0
<i><b>Renal neoplasms</b></i>		
Renal cyst	1	0
<i><b>Renal structural abnormalities and trauma</b></i>		
Kidney small	1	0
<i><b>Renal vascular and ischaemic conditions</b></i>		
Renal vasculitis	1	1
<i><b>Structural and obstructive urethral disorders (excl congenital)</b></i>		
Urethral stenosis	1	0

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Reaction Name	Total	Fatal
<b>Renal &amp; urinary disorders</b>		
<small>Renal &amp; urinary disorders cont'd</small>		
<b><i>Ureteric disorders NEC</i></b>		
Ureteric stenosis	1	0
<b><i>Urinary abnormalities</i></b>		
Albuminuria	1	0
Chromaturia	18	0
Haematuria	19	0
Proteinuria	4	0
Urine abnormality	6	0
Urine odour abnormal	4	0
<b><i>Urinary tract signs and symptoms NEC</i></b>		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	8	0
Nocturia	1	0
Polyuria	2	0
Renal pain	105	0
Urinary tract pain	2	0
<b>Renal &amp; urinary disorders SOC TOTAL</b>	<b>394</b>	<b>2</b>

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i><b>Benign and malignant breast neoplasms</b></i>		
Breast cyst	4	0
<i><b>Breast disorders NEC</b></i>		
Breast mass	29	0
Gynaecomastia	1	0
<i><b>Breast signs and symptoms</b></i>		
Breast discharge	1	0
Breast discomfort	4	0
Breast engorgement	1	0
Breast haematoma	1	0
Breast oedema	4	0
Breast pain	158	0
Breast swelling	36	0
Breast tenderness	14	0
Nipple pain	8	0
Nipple swelling	3	0
<i><b>Cervix disorders NEC</b></i>		
Cervical dysplasia	2	0
<i><b>Erection and ejaculation conditions and disorders</b></i>		
Ejaculation disorder	1	0
Erectile dysfunction	18	0
Erection increased	2	0
Organic erectile dysfunction	1	0
<i><b>Lactation disorders</b></i>		
Galactorrhoea	1	0
Suppressed lactation	3	0
<i><b>Menopausal effects NEC</b></i>		
Artificial menopause	1	0
Menopausal symptoms	5	0
Premature menopause	2	0
<i><b>Menopausal effects on the genitourinary tract</b></i>		
Postmenopausal haemorrhage	8	0
<i><b>Menstruation and uterine bleeding NEC</b></i>		
Dysfunctional uterine bleeding	1	0
Dysmenorrhoea	45	0
Menstrual discomfort	1	0
Menstrual disorder	62	0
Menstruation irregular	56	0
Metrorrhagia	34	0
Premenstrual pain	2	0
<i><b>Menstruation with decreased bleeding</b></i>		
Amenorrhoea	33	0
Hypomenorrhoea	21	0
Menstruation delayed	116	0
Oligomenorrhoea	2	0
<i><b>Menstruation with increased bleeding</b></i>		
Menorrhagia	116	0
Polymenorrhoea	16	0
<i><b>Ovarian and fallopian tube cysts and neoplasms</b></i>		
Ovarian cyst	1	0
<i><b>Ovarian and fallopian tube disorders NEC</b></i>		
Ovulation pain	3	0
Premature ovulation	1	0

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Reaction Name	Total	Fatal
<b>Reproductive &amp; breast disorders</b>		
<i>Reproductive &amp; breast disorders cont'd</i>		
<b><i>Pelvis and broad ligament disorders NEC</i></b>		
Adnexa uteri pain	6	0
Pelvic haemorrhage	3	0
<b><i>Penile disorders NEC (excl erection and ejaculation)</i></b>		
Penile swelling	3	0
Penis disorder	2	0
<b><i>Prostate and seminal vesicles infections and inflammations</i></b>		
Prostatitis	2	0
<b><i>Prostatic signs, symptoms and disorders NEC</i></b>		
Prostatomegaly	3	0
<b><i>Reproductive tract disorders NEC (excl neoplasms)</i></b>		
Genital haemorrhage	2	0
Genital ulceration	2	0
<b><i>Reproductive tract infections and inflammations NEC</i></b>		
Genital tract inflammation	1	0
<b><i>Reproductive tract signs and symptoms NEC</i></b>		
Genital pain	2	0
Pelvic discomfort	2	0
Pelvic pain	17	0
Perineal pain	1	0
Pruritus genital	1	0
<b><i>Scrotal disorders NEC</i></b>		
Scrotal erythema	1	0
Scrotal exfoliation	1	0
Scrotal pain	3	0
Scrotal swelling	3	0
<b><i>Sexual function and fertility disorders NEC</i></b>		
Infertility	1	0
<b><i>Spermatogenesis and semen disorders</i></b>		
Haemospermia	2	0
Semen discolouration	1	0
<b><i>Testicular and epididymal disorders NEC</i></b>		
Testicular disorder	1	0
Testicular pain	8	0
Testicular swelling	4	0
<b><i>Uterine disorders NEC</i></b>		
Endometriosis	5	0
Uterine haemorrhage	3	0
Uterine pain	1	0
<b><i>Uterine tone disorders</i></b>		
Uterine spasm	1	0
<b><i>Vulvovaginal cysts and neoplasms</i></b>		
Vaginal cyst	2	0
<b><i>Vulvovaginal disorders NEC</i></b>		
Vaginal haemorrhage	89	0
Vulval haemorrhage	4	0
Vulval ulceration	3	0
Vulvovaginal ulceration	3	0
<b><i>Vulvovaginal signs and symptoms</i></b>		
Vaginal discharge	3	0
Vulval oedema	1	0
Vulvovaginal burning sensation	2	0
Vulvovaginal pain	3	0

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<b>Reproductive &amp; breast disorders</b>		
Reproductive & breast disorders cont'd		
Vulvovaginal pruritus	1	0
Vulvovaginal swelling	1	0
<b>Reproductive &amp; breast disorders SOC TOTAL</b>	<b>1012</b>	<b>0</b>

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b>		
<i><b>Breathing abnormalities</b></i>		
Apnoea	2	0
Dyspnoea	1421	6
Dyspnoea at rest	3	0
Dyspnoea exertional	14	1
Hyperventilation	19	0
Hypopnoea	33	0
Irregular breathing	9	0
Mouth breathing	3	0
Orthopnoea	3	0
Respiration abnormal	23	0
Respiratory arrest	6	0
Respiratory depression	1	0
Respiratory distress	9	0
Sleep apnoea syndrome	5	0
Tachypnoea	20	0
<i><b>Bronchial conditions NEC</b></i>		
Bronchial secretion retention	1	0
Bronchiectasis	7	0
<i><b>Bronchospasm and obstruction</b></i>		
Asthma	134	0
Asthma late onset	2	0
Bronchospasm	10	0
Chronic obstructive pulmonary disease	10	0
Cough variant asthma	1	0
Obstructive airways disorder	1	0
Reversible airways obstruction	1	0
Wheezing	188	0
<i><b>Conditions associated with abnormal gas exchange</b></i>		
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	15	1
Respiratory acidosis	1	0
<i><b>Coughing and associated symptoms</b></i>		
Allergic cough	4	0
Cough	970	1
Cough decreased	2	0
Haemoptysis	12	0
Productive cough	60	0
Sputum discoloured	3	0
<i><b>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</b></i>		
Laryngeal disorder	1	0
<i><b>Laryngeal spasm, oedema and obstruction</b></i>		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngospasm	1	0
Stridor	12	0
<i><b>Lower respiratory tract inflammatory and immunologic conditions</b></i>		
Alveolitis	1	0
Hypersensitivity pneumonitis	1	0
Pneumonia aspiration	6	4
Pneumonitis	14	3



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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
Pulmonary sarcoidosis	1	0
<b>Lower respiratory tract signs and symptoms</b>		
Hiccups	6	0
Increased bronchial secretion	1	0
Lung opacity	1	0
Pleuritic pain	6	0
Pulmonary pain	45	0
Rales	2	0
<b>Nasal congestion and inflammations</b>		
Nasal congestion	91	0
Nasal inflammation	1	0
Rhinitis allergic	4	0
<b>Nasal disorders NEC</b>		
Epistaxis	352	0
Intranasal hyposaesthesia	1	0
Intranasal paraesthesia	1	0
Nasal crusting	1	0
Nasal disorder	1	0
Nasal dryness	13	0
Nasal odour	5	0
Nasal oedema	2	0
Nasal pruritus	4	0
<b>Paranasal sinus disorders (excl infections and neoplasms)</b>		
Allergic sinusitis	1	0
Paranasal sinus inflammation	1	0
Sinonasal obstruction	5	0
Sinus congestion	21	0
Sinus disorder	3	0
<b>Parenchymal lung disorders NEC</b>		
Atelectasis	1	0
Emphysema	1	0
Interstitial lung disease	2	0
Pulmonary fibrosis	3	0
<b>Pharyngeal disorders (excl infections and neoplasms)</b>		
Pharyngeal erythema	3	0
Pharyngeal haemorrhage	1	0
Pharyngeal hyposaesthesia	14	0
Pharyngeal inflammation	3	0
Pharyngeal oedema	6	0
Pharyngeal paraesthesia	31	0
Pharyngeal swelling	106	0
Pharyngeal ulceration	7	0
Tonsillar erythema	1	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	29	0
Tonsillar inflammation	3	0
Tonsillar ulcer	1	0
<b>Pleural infections and inflammations</b>		
Pleurisy	13	0
<b>Pneumothorax and pleural effusions NEC</b>		
Pleural effusion	9	0
Pneumothorax	1	0
Pneumothorax spontaneous	1	0

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Reaction Name	Total	Fatal
<b>Respiratory disorders</b> <small>Respiratory disorders cont'd</small>		
<b><i>Pulmonary hypertensions</i></b>		
Pulmonary hypertension	2	0
<b><i>Pulmonary oedemas</i></b>		
Acute respiratory distress syndrome	1	0
Pulmonary congestion	4	0
Pulmonary oedema	7	0
<b><i>Pulmonary thrombotic and embolic conditions</i></b>		
Pulmonary embolism	145	12
Pulmonary infarction	1	0
Pulmonary thrombosis	1	0
<b><i>Respiratory failures (excl neonatal)</i></b>		
Acute respiratory failure	2	1
Respiratory failure	6	1
<b><i>Respiratory signs and symptoms NEC</i></b>		
Allergic respiratory symptom	1	0
Diaphragmalgia	3	0
Painful respiration	5	0
Respiratory symptom	4	0
<b><i>Respiratory tract disorders NEC</i></b>		
Aspiration	3	2
Lung disorder	1	0
Pulmonary mass	1	0
Respiratory disorder	3	0
Respiratory tract congestion	1	0
Respiratory tract irritation	3	0
Respiratory tract oedema	2	0
<b><i>Thoracic musculoskeletal disorders</i></b>		
Respiratory muscle weakness	1	0
<b><i>Tracheal disorders (excl infections and neoplasms)</i></b>		
Tracheal pain	1	0
<b><i>Upper respiratory tract neoplasms</i></b>		
Tonsillar cyst	1	0
<b><i>Upper respiratory tract signs and symptoms</i></b>		
Aphonia	33	0
Catarrh	9	0
Choking	6	1
Choking sensation	1	0
Dry throat	80	0
Dysphonia	69	0
Increased upper airway secretion	4	0
Increased viscosity of upper respiratory secretion	7	0
Nasal discharge discolouration	1	0
Nasal discomfort	23	0
Nasal obstruction	2	0
Oropharyngeal blistering	6	0
Oropharyngeal discomfort	27	0
Oropharyngeal pain	1165	0
Paranasal sinus discomfort	14	0
Rhinalgia	6	0
Rhinorrhoea	321	0
Sinus pain	78	0
Sneezing	141	0
Snoring	2	0

# Case Series Drug Analysis Print

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

Report Run Date: 26-Apr-2021

Data Lock Date: 21-Apr-2021 19:00:03

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Respiratory disorders</b> Respiratory disorders cont'd		
Throat clearing	3	0
Throat irritation	102	0
Throat tightness	121	0
Upper airway obstruction	2	0
Upper-airway cough syndrome	4	0
Yawning	6	0
<b>Respiratory disorders SOC TOTAL</b>	<b>6271</b>	<b>33</b>

## Case Series Drug Analysis Print

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Data Lock Date: 21-Apr-2021 19:00:03  
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Skin disorders</b>		
<b><i>Acnes</i></b>		
Acne	25	0
Acne cystic	1	0
Dermatitis acneiform	3	0
<b><i>Alopecias</i></b>		
Alopecia	45	0
Alopecia areata	2	0
Alopecia totalis	1	0
Androgenetic alopecia	1	0
Madarosis	1	0
<b><i>Angioedemas</i></b>		
Angioedema	98	0
Circumoral swelling	1	0
<b><i>Apocrine and eccrine gland disorders</i></b>		
Cold sweat	282	0
Hidradenitis	1	0
Hyperhidrosis	816	0
Miliaria	36	0
Night sweats	292	0
<b><i>Bullous conditions</i></b>		
Blister	152	0
Blister rupture	1	0
Blood blister	8	0
Dermatitis bullous	8	0
Erythema multiforme	16	0
Fracture blisters	1	0
Pemphigoid	9	0
Pemphigus	3	0
Stevens-Johnson syndrome	2	0
Toxic epidermal necrolysis	2	1
<b><i>Connective tissue disorders</i></b>		
Dermatomyositis	3	0
<b><i>Dermal and epidermal conditions NEC</i></b>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	86	0
Macule	2	0
Pain of skin	126	0
Papule	30	0
Pathergy reaction	1	0
Peau d'orange	2	0
Scab	6	0
Scar pain	8	0
Sensitive skin	68	0
Skin burning sensation	96	0
Skin discolouration	46	0
Skin discomfort	1	0
Skin disorder	5	0
Skin fissures	2	0
Skin indentation	2	0
Skin induration	3	0
Skin lesion	18	0
Skin necrosis	1	0

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Skin odour abnormal	4	0
Skin plaque	1	0
Skin reaction	58	0
Skin sensitisation	13	0
Skin swelling	38	0
Skin tightness	16	0
Skin warm	133	0
Skin weeping	3	0
Sticky skin	1	0
Transient acantholytic dermatosis	1	0
Yellow skin	8	0
<b><i>Dermatitis and eczema</i></b>		
Dermatitis	50	0
Dermatitis allergic	106	0
Dermatitis atopic	11	0
Dermatitis contact	3	0
Dermatitis diaper	1	0
Dyshidrotic eczema	5	0
Eczema	72	0
Eczema asteatotic	3	0
Eczema nummular	3	0
Eczema weeping	1	0
Perioral dermatitis	1	0
Skin irritation	50	0
<b><i>Dermatitis ascribed to specific agent</i></b>		
Drug eruption	15	0
Fixed eruption	1	0
Toxic skin eruption	1	0
<b><i>Erythemas</i></b>		
Erythema	1045	0
Palmar erythema	4	0
Red man syndrome	1	0
<b><i>Exfoliative conditions</i></b>		
Dermatitis exfoliative	1	0
Dermatitis exfoliative generalised	2	0
Exfoliative rash	6	0
Keratolysis exfoliativa acquired	1	0
Skin exfoliation	37	0
<b><i>Granulomatous and deep cutaneous inflammatory conditions</i></b>		
Cutaneous sarcoidosis	1	0
<b><i>Hyperkeratoses</i></b>		
Lichenoid keratosis	2	0
<b><i>Hyperpigmentation disorders</i></b>		
Argyria	1	0
Ephelides	1	0
Skin hyperpigmentation	2	0
<b><i>Hypopigmentation disorders</i></b>		
Skin depigmentation	1	0
Skin hypopigmentation	1	0
Vitiligo	2	0
<b><i>Lipodystrophies</i></b>		
Lipoatrophy	2	0
<b><i>Nail and nail bed conditions (excl infections and infestations)</i></b>		

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Nail discolouration	5	0
Nail disorder	1	0
Nail pigmentation	2	0
Onychalgia	5	0
Onychoclasia	2	0
Splinter haemorrhages	1	0
<b>Panniculitides</b>		
Erythema nodosum	11	0
<b>Papulosquamous conditions</b>		
Erythema annulare	1	0
Lichen planus	4	0
Parapsoriasis	1	0
Pityriasis rosea	40	0
<b>Photosensitivity and photodermatosis conditions</b>		
Photosensitivity reaction	16	0
Polymorphic light eruption	1	0
<b>Pigmentation changes NEC</b>		
Haemosiderin stain	1	0
Pigmentation disorder	3	0
<b>Pilar disorders NEC</b>		
Hair colour changes	3	0
Hair growth abnormal	1	0
Hair texture abnormal	3	0
Piloerection	10	0
Pseudofolliculitis	1	0
<b>Pruritus NEC</b>		
Itching scar	5	0
Pruritus	2164	0
<b>Psoriatic conditions</b>		
Dermatitis psoriasiform	2	0
Guttate psoriasis	6	0
Psoriasis	60	0
Pustular psoriasis	1	0
<b>Purpura and related conditions</b>		
Petechiae	50	0
Purpura	17	0
<b>Rashes, eruptions and exanthems NEC</b>		
Butterfly rash	2	0
Rash	2237	0
Rash erythematous	499	0
Rash macular	209	0
Rash maculo-papular	34	0
Rash morbilliform	18	0
Rash papular	141	0
Rash pruritic	488	0
Rash vesicular	25	0
Systemic lupus erythematosus rash	4	0
<b>Rosaceas</b>		
Rosacea	6	0
<b>Scaly conditions</b>		
Dandruff	1	0
Pityriasis	9	0
<b>Sebaceous gland disorders</b>		

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Reaction Name	Total	Fatal
<b>Skin disorders</b> Skin disorders cont'd		
Seborrhoea	1	0
<b>Skin and subcutaneous conditions NEC</b>		
Cutaneous symptom	1	0
Reactive perforating collagenosis	1	0
Skin mass	7	0
<b>Skin and subcutaneous tissue ulcerations</b>		
Scleroderma associated digital ulcer	1	0
Skin erosion	14	0
Skin ulcer	4	0
<b>Skin cysts and polyps</b>		
Dermal cyst	3	0
<b>Skin dystrophies</b>		
Skin wrinkling	1	0
<b>Skin haemorrhages</b>		
Haemorrhage subcutaneous	4	0
Skin haemorrhage	4	0
<b>Skin hyperplasias and hypertrophies</b>		
Skin hypertrophy	1	0
<b>Skin hypoplasias and atrophies</b>		
Skin striae	2	0
<b>Skin injuries and mechanical dermatoses</b>		
Decubitus ulcer	1	0
<b>Skin preneoplastic conditions NEC</b>		
Actinic keratosis	1	0
<b>Skin vasculitides</b>		
Cutaneous vasculitis	2	0
Vasculitic rash	12	0
<b>Skin vasomotor conditions</b>		
Livedo reticularis	17	0
<b>Urticarias</b>		
Chronic spontaneous urticaria	1	0
Cold urticaria	1	0
Idiopathic urticaria	1	0
Mechanical urticaria	2	0
Solar urticaria	1	0
Urticaria	731	0
Urticaria chronic	4	0
Urticaria papular	2	0
Urticaria thermal	3	0
<b>Skin disorders SOC TOTAL</b>	<b>10937</b>	<b>1</b>

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<b>Social circumstances</b>		
<i><b>Age related issues</b></i>		
Infant	1	0
Menopause	3	0
<i><b>Criminal activity</b></i>		
Verbal abuse	1	0
<i><b>Disability issues</b></i>		
Bedridden	13	0
Breast prosthesis user	1	0
Hearing disability	1	0
Housebound	1	0
Immobile	6	0
Impaired driving ability	1	0
Impaired work ability	1	0
Loss of personal independence in daily activities	3	0
Physical disability	1	0
Sight disability	2	0
Sitting disability	1	0
Walking aid user	1	0
<i><b>Economic circumstances</b></i>		
High income	1	0
Low income	1	0
<i><b>Non-occupational and unspecified environmental problems</b></i>		
Water pollution	2	0
<i><b>Pregnancy related circumstances</b></i>		
Breast feeding	2	0
<i><b>Social issues NEC</b></i>		
Hair dye user	1	0
<i><b>Tobacco use</b></i>		
Non-tobacco user	3	0
<b>Social circumstances SOC TOTAL</b>	<b>47</b>	<b>0</b>



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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
<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
Antitussive therapy	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Cardiac operation	1	0
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	2	0
Nothing by mouth order	1	0
Wheat-free diet	1	0
<i>Fertility and fertilisation interventions female</i>		
Endometrial scratching	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	11	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	42	1
Immunisation	14	0
<i>Joint therapeutic procedures</i>		
Joint surgery	1	0
Knee arthroplasty	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	4	0
Limb operation	3	0
<i>Lymphoid tissue therapeutic procedures</i>		
Lymphadenectomy	1	0
<i>Mastectomies</i>		
Breast conserving surgery	1	0
<i>Nail therapeutic procedures</i>		
Nail operation	1	0
<i>Nervous system therapeutic procedures NEC</i>		
Multiple sclerosis relapse prophylaxis	1	0
<i>Phototherapies</i>		
UV light therapy	1	0
<i>Prophylactic procedures NEC</i>		
Anaphylaxis prophylaxis	2	0
Immune tolerance induction	1	0
<i>Psychiatric therapies</i>		
Electroconvulsive therapy	1	0
<i>Renal therapeutic procedures</i>		
Dialysis	1	0
<i>Respiratory tract therapeutic procedures NEC</i>		
Asthma prophylaxis	2	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	1	0
<i>Therapeutic procedures NEC</i>		
Abscess drainage	1	0

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Reaction Name	Total	Fatal
<b>Surgical &amp; medical procedures</b>		
Surgical & medical procedures cont'd		
Anaphylaxis treatment	3	0
Bed rest	2	0
Fatigue management	1	0
Hospitalisation	3	0
Injection	8	0
Mass excision	1	0
Medication dilution	1	0
Product used for unknown indication	2	0
Therapy change	1	0
<b>Surgical &amp; medical procedures SOC TOTAL</b>	<b>124</b>	<b>1</b>

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Reaction Name	Total	Fatal
<b>Vascular disorders</b>		
<b><i>Accelerated and malignant hypertension</i></b>		
Hypertensive crisis	5	0
Hypertensive urgency	1	0
Malignant hypertension	2	0
<b><i>Aneurysms and dissections non-site specific</i></b>		
Artery dissection	1	0
<b><i>Aortic aneurysms and dissections</i></b>		
Aortic dissection	1	0
<b><i>Aortic embolism and thrombosis</i></b>		
Aortic embolus	3	0
<b><i>Aortic necrosis and vascular insufficiency</i></b>		
Aortic stenosis	1	0
<b><i>Arterial infections and inflammations</i></b>		
Arteritis	1	0
Giant cell arteritis	5	0
<b><i>Blood pressure disorders NEC</i></b>		
Blood pressure fluctuation	4	0
Labile blood pressure	2	0
<b><i>Bruising, ecchymosis and purpura</i></b>		
Achenbach syndrome	1	0
<b><i>Circulatory collapse and shock</i></b>		
CT hypotension complex	2	0
Circulatory collapse	35	0
Hypoperfusion	1	0
Neurogenic shock	16	0
Peripheral circulatory failure	3	0
Shock	8	0
Shock symptom	1	0
<b><i>Haemorrhages NEC</i></b>		
Bloody discharge	1	0
Haematoma	18	0
Haemorrhage	66	2
Venous haemorrhage	1	0
<b><i>Lymphangiopathies</i></b>		
Lymphangiopathy	1	0
Lymphocele	3	0
<b><i>Lymphoedemas</i></b>		
Lymphoedema	110	0
<b><i>Non-site specific embolism and thrombosis</i></b>		
Arterial thrombosis	1	0
Embolism	35	0
Microembolism	1	0
Thrombosis	93	3
Venous thrombosis	3	0
<b><i>Non-site specific necrosis and vascular insufficiency NEC</i></b>		
Haemorrhagic infarction	1	0
Infarction	3	0
Ischaemia	1	0
Vasospasm	1	0
<b><i>Non-site specific vascular disorders NEC</i></b>		
Superficial vein prominence	1	0
Vascular pain	5	0
Vasodilatation	8	0

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Reaction Name	Total	Fatal
<b>Vascular disorders</b> <small>Vascular disorders cont'd</small>		
Vein discolouration	1	0
Vein disorder	4	0
Vein rupture	2	0
<b><i>Peripheral embolism and thrombosis</i></b>		
Blue toe syndrome	8	0
Deep vein thrombosis	92	0
Jugular vein thrombosis	1	0
Pelvic venous thrombosis	2	0
Peripheral embolism	1	0
Subclavian vein thrombosis	1	0
Thrombophlebitis	9	0
Thrombophlebitis superficial	5	0
<b><i>Peripheral vascular disorders NEC</i></b>		
Cyanosis	21	0
Flushing	264	0
Hot flush	456	0
<b><i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i></b>		
Extremity necrosis	1	0
Peripheral coldness	133	0
Peripheral ischaemia	6	0
Poor peripheral circulation	4	0
Raynaud's phenomenon	33	0
Vasoconstriction	2	0
<b><i>Phlebitis NEC</i></b>		
Phlebitis	14	0
Phlebitis superficial	1	0
<b><i>Site specific vascular disorders NEC</i></b>		
Pallor	104	0
<b><i>Varicose veins NEC</i></b>		
Spider vein	2	0
Varicose vein	3	0
<b><i>Vascular hypertensive disorders NEC</i></b>		
Diastolic hypertension	1	0
Essential hypertension	2	0
Hypertension	234	1
Orthostatic hypertension	1	0
Secondary hypertension	1	0
Systolic hypertension	2	0
<b><i>Vascular hypotensive disorders</i></b>		
Hypotension	168	0
Orthostatic hypotension	13	0
<b><i>Vasculitides NEC</i></b>		
Behcet's syndrome	2	0
MAGIC syndrome	1	0
Vasculitis	22	0
<b><i>Vena caval embolism and thrombosis</i></b>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
<b>Vascular disorders SOC TOTAL</b>	<b>2065</b>	<b>6</b>
<b>TOTAL REACTIONS FOR DRUG</b>	<b>149082</b>	<b>347</b>
<b>TOTAL REPORTS</b>	<b>52130</b>	
<b>TOTAL FATAL OUTCOME REPORTS</b>		<b>347</b>