

COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 01-Apr-2021
Data Lock Date: 28-Mar-2021 19:00:03

All UK spontaneous reports received between 09/12/20 and 28/03/21 for mRNA
Pfizer/BioNTech vaccine analysis print

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia vitamin B12 deficiency	1	0
Deficiency anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	12	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	2	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	7	0
<i>Coagulation factor deficiencies</i>		
Acquired haemophilia	1	0
<i>Coagulopathies</i>		
Antiphospholipid syndrome	1	0
Coagulopathy	2	0
Hypercoagulation	1	0
<i>Haematological disorders</i>		
Mast cell activation syndrome	1	0
<i>Haemolyses NEC</i>		
Haemolysis	1	0
Intravascular haemolysis	1	0
<i>Leukocytoses NEC</i>		
Lymphocytosis	2	0
<i>Leukopenias NEC</i>		
Lymphopenia	2	0
<i>Lymphatic system disorders NEC</i>		
Abdominal lymphadenopathy	2	0
Granulomatous lymphadenitis	1	0
Lymph node pain	459	0
Lymphadenitis	69	0
Lymphadenopathy	3049	0
Lymphatic disorder	1	0
Pseudolymphoma	2	0
<i>Marrow depression and hypoplastic anaemias</i>		
Myelosuppression	1	0
Pancytopenia	2	0
<i>Neutropenias</i>		
Neutropenia	18	0
<i>Platelet disorders NEC</i>		
Platelet anisocytosis	1	0
<i>Spleen disorders</i>		
Spleen atrophy	1	0
Splenomegaly	2	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	23	0
Thrombocytopenia	29	1
Thrombotic thrombocytopenic purpura	1	0
<i>Thrombocytoses</i>		
Thrombocytosis	2	0
Blood disorders SOC TOTAL	3698	1

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	1	0
Bundle branch block right	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	2	0
Cardiac disorder	6	0
Cardiovascular disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	1	0
Palpitations	741	0
<i>Cardiomyopathies</i>		
Congestive cardiomyopathy	1	0
Stress cardiomyopathy	1	0
<i>Coronary artery disorders NEC</i>		
Coronary artery disease	2	1
<i>Heart failures NEC</i>		
Cardiac failure	12	1
Cardiac failure congestive	1	0
Cardiogenic shock	1	0
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	11	1
Angina pectoris	24	0
Angina unstable	1	0
Arteriospasm coronary	1	0
Microvascular coronary artery disease	2	0
Myocardial infarction	50	13
Myocardial ischaemia	1	0
<i>Left ventricular failures</i>		
Left ventricular failure	2	1
<i>Mitral valvular disorders</i>		
Mitral valve prolapse	1	0
<i>Myocardial disorders NEC</i>		
Cardiomegaly	1	0
Left ventricular dysfunction	1	0
Myocardial fibrosis	1	0
Myocardial oedema	2	0
Right ventricular enlargement	1	0
Ventricular hypertrophy	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	12	0
<i>Noninfectious pericarditis</i>		
Pericarditis	12	1
<i>Pericardial disorders NEC</i>		
Pericardial effusion	5	0
Pericardial haemorrhage	1	1
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	19	0
Bradycardia	17	0
Cardiac flutter	34	0
Extrasystoles	20	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	4	0

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Cardiac disorders Cardiac disorders cont'd		
Tachycardia	377	0
<i>Right ventricular failures</i>		
Cor pulmonale	1	0
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	6	0
Atrial fibrillation	69	0
Atrial flutter	4	0
Atrial tachycardia	3	0
Sinus bradycardia	2	0
Sinus tachycardia	29	0
Supraventricular tachycardia	15	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	49	21
Cardio-respiratory arrest	1	1
Pulseless electrical activity	2	0
Ventricular arrhythmia	2	1
Ventricular extrasystoles	5	0
Ventricular fibrillation	4	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	1567	43

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Reaction Name	Total	Fatal
Congenital disorders		
<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>Haematological disorders congenital NEC</i>		
Amegakaryocytic thrombocytopenia	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital multiplex arthrogyrosis	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
Familial periodic paralysis	1	0
<i>Pulmonary and bronchial disorders congenital</i>		
Congenital cystic lung	1	0
<i>Retinal disorders congenital</i>		
Retinitis pigmentosa	1	0
Congenital disorders SOC TOTAL	11	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	5	0
Ear discomfort	22	0
Ear disorder	6	0
Ear haemorrhage	1	0
Ear pain	294	0
Ear pruritus	5	0
Ear swelling	8	0
Otorrhoea	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	1	0
Eustachian tube dysfunction	4	0
Eustachian tube obstruction	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	1	0
External ear pain	1	0
Red ear syndrome	2	0
<i>External ear infections and inflammations</i>		
External ear inflammation	1	0
<i>Hearing disorders NEC</i>		
Auditory disorder	2	0
<i>Hearing losses</i>		
Deafness	42	0
Deafness bilateral	1	0
Deafness neurosensory	6	0
Deafness unilateral	7	0
Hypoacusis	39	0
Sudden hearing loss	7	0
<i>Hyperacusia</i>		
Hyperacusis	12	0
Misophonia	1	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	1	0
Inner ear disorder	4	0
Meniere's disease	3	0
Vestibular disorder	3	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	19	0
Tinnitus	339	0
Vertigo	361	0
Vertigo labyrinthine	4	0
Vertigo positional	28	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
Ear disorders SOC TOTAL	1235	0

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Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis subacute	1	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	1	0
Adrenocortical insufficiency acute	6	0
<i>Endocrine abnormalities of puberty</i>		
Premature menarche	1	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	2	0
<i>Thyroid disorders NEC</i>		
Goitre	3	0
Thyroid disorder	1	0
Thyroid pain	1	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	3	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	6	0
Endocrine disorders SOC TOTAL	25	0

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Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	2	0
<i>Choroid and vitreous haemorrhages and vascular disorders</i>		
Choroidal haemorrhage	1	0
Choroidal neovascularisation	1	0
Vitreous haemorrhage	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	2	0
Vitreous floaters	15	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	1	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	14	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	2	0
<i>Corneal infections, oedemas and inflammations</i>		
Keratitis	4	0
Ulcerative keratitis	4	0
<i>Eyelid movement disorders</i>		
Blepharospasm	35	0
Excessive eye blinking	1	0
Eyelid ptosis	14	0
<i>Glaucomas (excl congenital)</i>		
Glaucoma	2	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	1	0
Iridocyclitis	5	0
Iritis	2	0
Uveitis	12	0
<i>Lacrimation disorders</i>		
Dry eye	46	0
Lacrimation increased	53	0
<i>Lid bleeding and vascular disorders</i>		
Eyelid bleeding	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	3	0
Chalazion	1	0
Eczema eyelids	2	0
Erythema of eyelid	2	0
Eyelid cyst	1	0
Eyelid irritation	1	0
Eyelid margin crusting	1	0
Eyelid oedema	3	0
Eyelid rash	4	0
Swelling of eyelid	40	0
<i>Lid, lash and lacrimal structural disorders</i>		
Eyelid exfoliation	1	0
Lagophthalmos	1	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haematoma	1	0
Eye haemorrhage	4	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
<i>Ocular disorders NEC</i>		
Dark circles under eyes	1	0
Eye disorder	10	0
Eye oedema	4	0
Eye pain	327	0
Eye swelling	166	0
Eye ulcer	1	0
Eyelid disorder	2	0
Eyelid pain	4	0
Eyelids pruritus	3	0
Ocular discomfort	11	0
Periorbital oedema	13	0
Periorbital pain	1	0
Periorbital swelling	43	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	2	0
Eye discharge	10	0
Eye inflammation	7	0
Eye irritation	37	0
Eye pruritus	100	0
Limbal swelling	2	0
Ocular hyperaemia	68	0
<i>Ocular nerve and muscle disorders</i>		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Extraocular muscle paresis	1	0
Eye movement disorder	9	0
Ophthalmoplegia	2	0
Strabismus	2	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	7	0
Asthenopia	56	0
Eye paraesthesia	1	0
Foreign body sensation in eyes	10	0
Hypoaesthesia eye	4	0
Photophobia	137	0
<i>Optic disc abnormalities NEC</i>		
Papilloedema	1	0
<i>Orbital infections, inflammations and irritations</i>		
Parophthalmia	1	0
<i>Orbital structural change, deposit and degeneration</i>		
Orbital oedema	1	0
<i>Pupil disorders</i>		
Miosis	1	0
Mydriasis	7	0
Pupillary disorder	1	0
Pupils unequal	3	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal artery occlusion	1	0
Retinal haemorrhage	1	0
Retinal vein occlusion	3	0
<i>Retinal structural change, deposit and degeneration</i>		
Macular degeneration	1	0

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Eye disorders Eye disorders cont'd		
Macular rupture	1	0
Maculopathy	1	0
Retinal tear	1	0
Retinal toxicity	1	0
<i>Retinal, choroid and vitreous infections and inflammations</i>		
Macular oedema	1	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	4	0
Scleritis	1	0
<i>Scleral structural change, deposit and degeneration</i>		
Scleral discolouration	1	0
<i>Visual colour distortions</i>		
Cyanopsia	1	0
Erythropsia	2	0
<i>Visual disorders NEC</i>		
Diplopia	46	0
Halo vision	4	0
Metamorphopsia	6	0
Oscillopsia	2	0
Photopsia	38	0
Scintillating scotoma	1	0
Vision blurred	297	0
Visual brightness	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	19	0
Blindness transient	5	0
Blindness unilateral	4	0
Central vision loss	2	0
Sudden visual loss	1	0
Visual acuity reduced	5	0
Visual impairment	101	0
Eye disorders SOC TOTAL	1897	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	6	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	1	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	0
Pancreatitis	3	0
Pancreatitis acute	2	0
Pancreatitis necrotising	1	0
<i>Anal and rectal disorders NEC</i>		
Anal sphincter atony	1	0
<i>Anal and rectal pains</i>		
Proctalgia	5	0
<i>Anal and rectal signs and symptoms</i>		
Anal spasm	1	0
Anorectal discomfort	3	0
Anorectal swelling	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	3	0
<i>Colitis (excl infective)</i>		
Colitis	9	0
Colitis ulcerative	15	0
Crohn's disease	11	0
<i>Dental disorders NEC</i>		
Teething	2	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	2	0
Dental paraesthesia	1	0
Hyperaesthesia teeth	9	0
Toothache	34	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1962	4
Diarrhoea haemorrhagic	6	0
<i>Diverticula</i>		
Diverticulum	1	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	1	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer haemorrhage	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	105	0
Epigastric discomfort	7	0
Eructation	17	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	3	0
Faeces discoloured	14	0
Faeces hard	1	0
Faeces pale	2	0
Faeces soft	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	77	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Aerophagia	2	0
Flatulence	57	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	2	1
Oesophageal varices haemorrhage	1	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	1	0
<i>Gastritis (excl infective)</i>		
Chronic gastritis	1	0
Gastritis	16	0
Reflux gastritis	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	1	0
Abdominal pain	401	0
Abdominal pain lower	21	0
Abdominal pain upper	638	0
Abdominal rigidity	3	0
Abdominal tenderness	3	0
Gastrointestinal pain	39	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	81	0
Duodenogastric reflux	2	0
Gastric dilatation	3	0
Gastrooesophageal reflux disease	35	0
Infrequent bowel movements	1	0
Intestinal pseudo-obstruction	1	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	4	0
Gastric disorder	3	0
Gastrointestinal disorder	4	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	2	0
Dyschezia	1	0
Gastrointestinal motility disorder	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Duodenitis	1	0
Enteritis	2	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	214	0
Abdominal symptom	1	0
Acute abdomen	1	0
Anal incontinence	7	0
Breath odour	9	0
Dysphagia	64	1
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	2	0
Frequent bowel movements	11	0
Irritable bowel syndrome	27	0
Oesophageal spasm	2	0
Pylorospasm	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Intestinal obstruction	2	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	2	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	2	1
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	6	0
Gingival discomfort	2	0
Gingival disorder	2	0
Gingival pain	35	0
Gingival pruritus	1	0
Gingival swelling	8	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	2	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	11	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Gastric varices	1	0
Haemorrhoids	7	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	6	0
Rectal haemorrhage	18	0
Small intestinal haemorrhage	3	0
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	2	2
<i>Malabsorption syndromes</i>		
Coeliac disease	4	0
Steatorrhoea	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	6	0
Nausea	5525	1
Regurgitation	1	0
Retching	42	0
Vomiting	1537	2
Vomiting projectile	24	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	4	0
Haematemesis	15	2
Haematochezia	14	0
Melaena	6	0
Upper gastrointestinal haemorrhage	2	0
<i>Oesophageal stenosis and obstruction</i>		
Oesophageal stenosis	1	0
<i>Oesophagitis (excl infective)</i>		
Oesophagitis	1	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	1	0
Dry mouth	215	0
Lip dry	20	0
Saliva altered	1	0
Salivary hypersecretion	17	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	9	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Cheilitis	11	0
Enlarged uvula	6	0
Lip blister	9	0
Lip disorder	3	0
Oral disorder	3	0
Oral lichen planus	3	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	1	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	2	0
Oral blood blister	6	0
Oral soft tissue signs and symptoms		
Anaesthesia oral	1	0
Burning mouth syndrome	1	0
Hypoaesthesia oral	194	0
Lip discolouration	1	0
Lip erythema	1	0
Lip exfoliation	4	0
Lip pain	24	0
Lip pruritus	5	0
Lip scab	1	0
Odynophagia	6	0
Oral discomfort	25	0
Oral dysaesthesia	1	0
Oral mucosal blistering	7	0
Oral mucosal eruption	8	0
Oral mucosal erythema	2	0
Oral mucosal exfoliation	3	0
Oral mucosal roughening	2	0
Oral pain	66	0
Oral pruritus	11	0
Paraesthesia oral	503	0
Pigmentation lip	1	0
Oral soft tissue swelling and oedema		
Lip oedema	3	0
Lip swelling	290	0
Mouth swelling	34	0
Oedema mouth	3	0
Palatal oedema	2	0
Palatal swelling	1	0
Peptic ulcers and perforation		
Peptic ulcer haemorrhage	2	0
Peritoneal and retroperitoneal disorders		
Ascites	1	0
Peritoneal and retroperitoneal fibrosis and adhesions		
Abdominal adhesions	1	0
Peritoneal and retroperitoneal haemorrhages		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	1
Rectal inflammations NEC		
Proctitis	1	0
Proctitis ulcerative	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<i>Salivary gland disorders NEC</i>		
Salivary gland pain	6	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	3	0
Salivary gland enlargement	2	0
Submaxillary gland enlargement	4	0
<i>Salivary gland infections and inflammations</i>		
Noninfective sialoadenitis	1	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	15	0
Lip ulceration	3	0
Mouth ulceration	137	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	21	0
<i>Tongue disorders</i>		
Glossitis	4	0
Plicated tongue	2	0
Tongue disorder	15	0
Tongue haemorrhage	1	0
Tongue ulceration	9	0
Trichoglossia	1	0
<i>Tongue signs and symptoms</i>		
Glossodynia	84	0
Scalloped tongue	1	0
Stiff tongue	1	0
Swollen tongue	214	0
Tongue blistering	6	0
Tongue coated	3	0
Tongue discolouration	7	0
Tongue discomfort	20	0
Tongue dry	6	0
Tongue eruption	6	0
Tongue erythema	2	0
Tongue movement disturbance	2	0
Tongue oedema	11	0
Tongue rough	2	0
Tongue spasm	3	0
Gastrointestinal disorders SOC TOTAL	13387	15

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	2	0
Administration site erythema	1	0
Administration site extravasation	1	0
Administration site haematoma	1	0
Administration site inflammation	1	0
Administration site joint discomfort	1	0
Administration site joint movement impairment	1	0
Administration site pain	7	0
Administration site warmth	1	0
Puncture site bruise	7	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
<i>Adverse effect absent</i>		
No adverse event	4	0
<i>Application and instillation site reactions</i>		
Application site acne	1	0
Application site bruise	2	0
Application site erythema	3	0
Application site haemorrhage	1	0
Application site joint pain	1	0
Application site mass	1	0
Application site pain	3	0
Application site pruritus	2	0
Application site rash	1	0
Application site reaction	1	0
Application site vesicles	2	0
Instillation site warmth	1	0
<i>Asthenic conditions</i>		
Asthenia	559	1
Chronic fatigue syndrome	17	0
Fatigue	8333	0
Malaise	1914	0
Sluggishness	4	0
<i>Body temperature altered</i>		
Hyperthermia	4	0
Hypothermia	14	0
Temperature regulation disorder	5	0
<i>Breast complications associated with device</i>		
Capsular contracture associated with breast implant	1	0
<i>Complications associated with device NEC</i>		
Injury associated with device	1	0
Medical device pain	1	0
Medical device site swelling	1	0
<i>Death and sudden death</i>		
Clinical death	1	1
Death	104	104
Sudden death	17	17
<i>Febrile disorders</i>		
Hyperpyrexia	4	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Pyrexia	6344	1
Feelings and sensations NEC		
Chills	4216	0
Feeling abnormal	407	0
Feeling cold	463	0
Feeling drunk	20	0
Feeling hot	417	0
Feeling jittery	8	0
Feeling of body temperature change	122	0
Hangover	18	0
Hunger	6	0
Sensation of foreign body	20	0
Temperature intolerance	6	0
Thirst	110	0
Gait disturbances		
Gait disturbance	46	0
Gait inability	26	0
Loss of control of legs	4	0
General signs and symptoms NEC		
Condition aggravated	48	0
Crepitations	1	0
Crying	29	0
Disease progression	1	0
Disease recurrence	4	0
Effusion	2	0
Energy increased	6	0
Exercise tolerance decreased	2	0
General physical health deterioration	5	1
General symptom	1	0
Glassy eyes	2	0
Illness	586	1
Induration	2	0
Influenza like illness	1011	0
Irritability postvaccinal	1	0
Local reaction	53	0
Moaning	1	0
Multiple organ dysfunction syndrome	2	1
Nonspecific reaction	1	0
Peripheral swelling	1067	0
Pre-existing condition improved	5	0
Screaming	4	0
Secretion discharge	6	0
Swelling	805	0
Swelling face	315	0
Implant and catheter site reactions		
Implant site pain	1	0
Implant site rash	1	0
Inflammations		
Inflammation	103	0
Papillitis	1	0
Systemic inflammatory response syndrome	1	0
Infusion site reactions		
Infusion site coldness	1	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021
 Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 28-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Infusion site joint pain	2	0
Infusion site pain	1	0
Infusion site swelling	1	0
Infusion site urticaria	1	0
Injection site reactions		
Injected limb mobility decreased	12	0
Injection site bruising	21	0
Injection site cyst	1	0
Injection site discolouration	2	0
Injection site discomfort	7	0
Injection site erythema	172	0
Injection site haemorrhage	2	0
Injection site hypoaesthesia	6	0
Injection site indentation	2	0
Injection site induration	2	0
Injection site inflammation	14	0
Injection site joint movement impairment	1	0
Injection site joint pain	9	0
Injection site mass	176	0
Injection site necrosis	2	0
Injection site oedema	11	0
Injection site pain	1344	0
Injection site paraesthesia	5	0
Injection site pruritus	79	0
Injection site rash	55	0
Injection site reaction	15	0
Injection site scab	2	0
Injection site scar	2	0
Injection site swelling	160	0
Injection site urticaria	10	0
Injection site vesicles	3	0
Injection site warmth	70	0
Interactions		
Alcohol interaction	2	0
Drug interaction	5	0
Mass conditions NEC		
Cyst	5	0
Mass	10	0
Nodule	8	0
Mucosal findings abnormal		
Mucosal haemorrhage	2	0
Oedema mucosal	1	0
Necrosis NEC		
Fat necrosis	1	0
Oedema NEC		
Face oedema	14	0
Localised oedema	12	0
Oedema	15	0
Oedema peripheral	25	0
Pain and discomfort NEC		
Axillary pain	589	0
Chest discomfort	478	0
Chest pain	688	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021
 Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 28-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Discomfort	68	0
Facial discomfort	7	0
Facial pain	77	0
Inflammatory pain	1	0
Non-cardiac chest pain	7	0
Pain	2618	0
Suprapubic pain	1	0
Tenderness	255	0
Visceral pain	1	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	60	0
Adverse event	1	0
Adverse reaction	2	0
Drug ineffective	92	0
Immediate post-injection reaction	2	0
No reaction on previous exposure to drug	17	0
Therapeutic product effect delayed	2	0
Therapeutic product effect increased	1	0
Therapeutic product ineffective	1	0
Therapeutic response unexpected	14	0
Treatment failure	5	0
Ulcers NEC		
Ulcer	7	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	4	0
Shoulder injury related to vaccine administration	3	0
Vaccination site bruising	44	0
Vaccination site cyst	1	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	6	0
Vaccination site discomfort	23	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	274	0
Vaccination site haemorrhage	7	0
Vaccination site hypersensitivity	2	0
Vaccination site hypoaesthesia	6	0
Vaccination site induration	44	0
Vaccination site inflammation	31	0
Vaccination site irritation	4	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	5	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	83	0
Vaccination site movement impairment	28	0
Vaccination site oedema	3	0
Vaccination site pain	989	0
Vaccination site paraesthesia	4	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site pruritus	60	0
Vaccination site rash	46	0
Vaccination site reaction	14	0
Vaccination site scab	1	0
Vaccination site swelling	284	0
Vaccination site ulcer	1	0
Vaccination site urticaria	7	0
Vaccination site vesicles	2	0
Vaccination site warmth	150	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	3	0
Withdrawal syndrome	4	0
General disorders SOC TOTAL	36796	127

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	2	0
<i>Cholecystitis and cholelithiasis</i>		
Cholelithiasis	1	0
<i>Cholestasis and jaundice</i>		
Jaundice	4	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	1	0
<i>Hepatic failure and associated disorders</i>		
Hepatic failure	1	0
<i>Hepatic vascular disorders</i>		
Congestive hepatopathy	1	0
Hepatic artery embolism	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	8	0
Liver tenderness	2	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Drug-induced liver injury	1	0
Hepatitis	4	0
Liver injury	5	0
Hepatic disorders SOC TOTAL	31	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	7	0
<i>Allergic conditions NEC</i>		
Allergic oedema	6	0
Allergy to arthropod bite	1	0
Hypersensitivity	323	0
Multiple allergies	1	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	3	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	4	0
Allergy to chemicals	1	0
Allergy to vaccine	19	1
Contrast media reaction	1	0
Drug hypersensitivity	11	0
Food allergy	6	0
Oral allergy syndrome	1	0
Reaction to colouring	1	0
Reaction to excipient	3	0
Reaction to preservatives	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	230	0
Anaphylactic shock	14	0
Anaphylactoid reaction	12	0
Anaphylactoid shock	3	0
<i>Atopic disorders</i>		
Atopy	1	0
Seasonal allergy	5	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	8	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	8	0
Immune system disorder	7	0
Immune-mediated adverse reaction	1	0
Sensitisation	1	0
Systemic immune activation	1	0
Immune system disorders SOC TOTAL	689	1

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	7	0
Diverticulitis	2	0
Dysentery	1	0
Gastroenteritis	12	0
Mesenteric abscess	1	0
<i>Aspergillus infections</i>		
Bronchopulmonary aspergillosis	1	0
<i>Bacterial infections NEC</i>		
Arthritis bacterial	1	0
Bacterial diarrhoea	1	0
Cellulitis	73	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	1	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	12	0
<i>Bone and joint infections</i>		
Abscess jaw	1	0
<i>Borrelial infections</i>		
Relapsing fever	1	0
<i>Breast infections</i>		
Breast abscess	1	0
Mastitis	12	0
<i>Caliciviral infections</i>		
Gastroenteritis norovirus	1	0
<i>Candida infections</i>		
Anal candidiasis	1	0
Candida infection	7	0
Oral candidiasis	15	0
Systemic candida	1	0
Vulvovaginal candidiasis	11	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	5	0
Meningitis	3	0
Meningitis aseptic	1	0
Myelitis	2	0
<i>Clostridia infections</i>		
Clostridium difficile infection	2	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	8	0
COVID-19	531	31
COVID-19 pneumonia	17	6
Coronavirus infection	6	0
Severe acute respiratory syndrome	1	0
Suspected COVID-19	33	1
<i>Coxiella infections</i>		
Q fever	5	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	3	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Gingivitis	3	0
Parotitis	6	0
Pulpitis dental	1	0
Sialoadenitis	1	0
Tooth abscess	2	0
Ear infections		
Ear infection	21	0
Labyrinthitis	32	0
Ectoparasitic infestations		
Acarodermatitis	1	0
Epstein-Barr viral infections		
Epstein-Barr virus infection	1	0
Infectious mononucleosis	3	0
Eye and eyelid infections		
Conjunctivitis	29	0
Eye abscess	1	0
Eye infection	7	0
Hordeolum	6	0
Periorbital infection	1	0
Female reproductive tract infections		
Bartholinitis	1	0
Vulval abscess	1	0
Fungal infections NEC		
Fungal infection	1	0
Fungal skin infection	1	0
Pneumonia fungal	1	0
Hepatitis viral infections		
Hepatitis A	1	0
Hepatobiliary and spleen infections		
Biliary sepsis	1	0
Herpes viral infections		
Disseminated varicella zoster virus infection	1	0
Eczema herpeticum	1	0
Genital herpes	13	0
Genital herpes simplex	1	0
Herpes ophthalmic	2	0
Herpes simplex	5	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	1	0
Herpes virus infection	3	0
Herpes zoster	353	0
Herpes zoster oticus	3	0
Nasal herpes	1	0
Ophthalmic herpes zoster	1	0
Oral herpes	109	0
Varicella	4	0
Varicella zoster virus infection	1	0
Infections NEC		
Abscess	10	0
Abscess limb	1	0
Abscess soft tissue	1	0
Infection	90	0
Injection site abscess	1	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Injection site infection	4	0
Localised infection	9	0
Lymph gland infection	5	0
Lymph node abscess	1	0
Respiratory tract infection	2	0
Vaccination site abscess	2	0
Vaccination site infection	10	0
Vaccine breakthrough infection	8	0
Vestibulitis	1	0
<i>Infectious transmissions</i>		
Secondary transmission	1	0
<i>Influenza viral infections</i>		
Influenza	577	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	4	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	60	7
Pneumonia	33	6
Sputum purulent	1	0
<i>Male reproductive tract infections</i>		
Epididymitis	2	0
Orchitis	2	0
<i>Mumps viral infections</i>		
Mumps	3	0
<i>Muscle and soft tissue infections</i>		
Necrotising fasciitis	1	0
Soft tissue infection	1	0
<i>Neisseria infections</i>		
Gonorrhoea	1	0
<i>Prion-associated disorders</i>		
Creutzfeldt-Jakob disease	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Neutropenic sepsis	2	0
Sepsis	16	2
Sepsis syndrome	1	0
Septic shock	2	0
Urosepsis	2	0
<i>Skin structures and soft tissue infections</i>		
Acne pustular	1	0
Dermatitis infected	1	0
Folliculitis	3	0
Injection site pustule	1	0
Paronychia	1	0
Pustule	5	0
Rash pustular	4	0
Skin infection	9	0
Subcutaneous abscess	3	0
Vaccination site pustule	1	0
<i>Staphylococcal infections</i>		
Furuncle	13	0
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	2	0

Case Series Drug Analysis Print

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Report Run Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Streptococcal infections</i>		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	3	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	1	0
<i>Upper respiratory tract infections</i>		
Laryngitis	4	0
Nasopharyngitis	261	0
Pharyngitis	7	0
Rhinitis	21	0
Sinusitis	32	0
Tonsillitis	28	0
Tracheitis	2	0
<i>Urinary tract infections</i>		
Cystitis	18	0
Kidney infection	8	0
Pyelonephritis	1	0
Urinary tract infection	48	0
<i>Vascular infections</i>		
Haematoma infection	1	0
Lymphangitis	3	0
<i>Viral infections NEC</i>		
Arthritis viral	1	0
Conjunctivitis viral	1	0
Eye infection viral	1	0
Gastroenteritis viral	7	0
Hepatitis viral	1	0
Meningitis viral	2	0
Pneumonia viral	1	1
Post viral fatigue syndrome	15	0
Sweating fever	45	0
Vestibular neuronitis	7	0
Viral infection	7	0
Viral labyrinthitis	3	0
Viral pericarditis	1	0
Viral pharyngitis	5	0
Viral rash	16	0
Viral tonsillitis	1	0
Infections SOC TOTAL	2864	55

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021
Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 28-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Oral contusion	1	0
Tongue injury	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	9	0
<i>Anaesthetic and allied procedural complications</i>		
Delayed recovery from anaesthesia	1	0
<i>Atmospheric pressure injuries</i>		
Hypobarism	1	0
<i>Bone and joint injuries NEC</i>		
Joint injury	1	0
<i>Cardiovascular injuries</i>		
Heart injury	2	0
Vascular injury	1	0
<i>Cerebral injuries NEC</i>		
Traumatic intracranial haemorrhage	1	1
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	2	0
<i>Conditions caused by cold</i>		
Chillblains	19	0
<i>Cranial nerve injuries</i>		
Vth nerve injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	4	0
Exposure via breast milk	4	0
Foetal exposure during pregnancy	3	0
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	96	0
Maternal exposure during pregnancy	58	0
<i>Eye injuries NEC</i>		
Eye contusion	5	0
Eye injury	3	0
Injury corneal	1	0
Periorbital haematoma	1	0
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	4	0
<i>Heat injuries (excl thermal burns)</i>		
Heat illness	1	0
Heat oedema	5	0
Heat stroke	2	0
<i>Limb fractures and dislocations</i>		
Atypical femur fracture	1	0
Clavicle fracture	5	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	6	0
Product use issue	5	0
Vaccination error	1	0
Wrong drug	2	0
Wrong technique in product usage process	2	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	4	0
Ligament sprain	1	0
Muscle injury	2	0
Muscle rupture	1	0
Muscle strain	7	0
Tendon injury	2	0
<i>Musculoskeletal procedural complications</i>		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	11	0
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	6	0
<i>Non-occupational environmental exposures</i>		
Exposure to extreme temperature	1	0
<i>Non-site specific injuries NEC</i>		
Bite	1	0
Electric shock	7	0
Fall	52	1
Injury	2	0
Wound	2	0
Wound complication	4	0
Wound haemorrhage	1	0
Wound secretion	1	0
<i>Non-site specific procedural complications</i>		
Incision site pain	2	0
Infusion related reaction	4	0
Injection related reaction	24	0
Post procedural complication	3	0
<i>Occupational exposures</i>		
Occupational exposure to SARS-CoV-2	1	0
<i>Off label uses</i>		
Off label use	7	0
<i>Overdoses NEC</i>		
Overdose	2	0
<i>Peripheral nerve injuries</i>		
Ulnar nerve injury	3	0
<i>Poisoning and toxicity</i>		
Poisoning	2	0
Toxicity to various agents	1	0
<i>Product administration errors and issues</i>		
Accidental overdose	1	0
Contraindicated product administered	1	0
Expired product administered	2	0
Inappropriate schedule of product administration	10	0
Incomplete course of vaccination	1	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	1	0
<i>Product confusion errors and issues</i>		

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Product label confusion	1	0
Product dispensing errors and issues		
Product dispensing error	2	0
Product monitoring errors and issues		
Drug monitoring procedure incorrectly performed	1	0
Product preparation errors and issues		
Product preparation issue	2	0
Radiation injuries		
Sunburn	3	0
Site specific injuries NEC		
Face crushing	1	0
Head injury	4	0
Limb injury	12	0
Skin injuries NEC		
Contusion	218	0
Nail avulsion	1	0
Scar	2	0
Scratch	1	0
Skin abrasion	4	0
Skin injury	1	0
Skull fractures, facial bone fractures and dislocations		
Fractured skull depressed	1	0
Stoma complications		
Gastrointestinal stoma complication	1	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
Thermal burns		
Airway burns	1	0
Burn oesophageal	1	0
Burn of internal organs	1	0
Burn oral cavity	1	0
Burns second degree	2	0
Thermal burn	5	0
Thermal burns of eye	4	0
Underdoses NEC		
Underdose	2	0
Vaccination related complications		
Vaccination complication	25	0
Vaccination failure	1	0
Injuries SOC TOTAL	738	2

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021
Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 28-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Cortisol decreased	2	0
<i>Auditory function diagnostic procedures</i>		
Acoustic stimulation tests	1	0
<i>Autoimmunity analyses</i>		
Rheumatoid factor	2	0
<i>Blood counts NEC</i>		
Blood count	2	0
Blood count abnormal	1	0
<i>Blood gas and acid base analyses</i>		
Blood lactic acid	1	0
Blood lactic acid increased	2	0
Blood pH	2	0
Blood pH increased	3	0
Oxygen consumption decreased	1	0
Oxygen saturation	5	0
Oxygen saturation decreased	29	0
<i>Bone marrow and immune tissue histopathology procedures</i>		
Biopsy lymph gland	1	0
<i>Bone marrow and immune tissue imaging procedures</i>		
Lymph nodes scan abnormal	1	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	5	0
Blood glucose abnormal	5	0
Blood glucose decreased	11	0
Blood glucose fluctuation	10	0
Blood glucose increased	52	0
Glycosylated haemoglobin increased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	2	0
Heart sounds abnormal	1	0
<i>Cardiac function diagnostic procedures</i>		
Cardiac output	1	0
Central venous pressure	1	0
<i>Central nervous system imaging procedures</i>		
Magnetic resonance imaging brain	8	0
<i>Chemistry analyses NEC</i>		
Inflammatory marker increased	3	0
<i>Cholesterol analyses</i>		
Blood cholesterol increased	1	0
<i>Coagulation and bleeding analyses</i>		
Bleeding time abnormal	1	0
Clot retraction	1	1
Coagulation time prolonged	2	0
Fibrin D dimer increased	3	0
International normalised ratio abnormal	1	0
International normalised ratio decreased	12	0
International normalised ratio increased	31	0
<i>ECG investigations</i>		
Electrocardiogram ST segment elevation	2	0
Electrocardiogram abnormal	1	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	2	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021
 Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 28-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Faecal analyses NEC</i>		
Faecal calprotectin	1	0
Faecal calprotectin increased	1	0
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	4	0
<i>Heart rate and pulse investigations</i>		
Heart rate	90	0
Heart rate abnormal	5	0
Heart rate decreased	17	0
Heart rate increased	219	0
Heart rate irregular	29	0
Pulse abnormal	8	0
Radial pulse abnormal	1	0
<i>Imaging procedures NEC</i>		
Magnetic resonance imaging	1	0
<i>Immunoglobulin analyses</i>		
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	1	0
<i>Immunology analyses NEC</i>		
Antibody test	1	0
Antibody test abnormal	2	0
Immunology test	3	0
<i>Immunology skin tests NEC</i>		
Skin test positive	1	0
<i>Investigations NEC</i>		
Blood test	2	0
Blood test abnormal	5	0
False positive investigation result	1	0
Polymerase chain reaction positive	30	0
Systemic lupus erythematosus disease activity index increased	1	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	5	0
Aspartate aminotransferase increased	1	0
Gamma-glutamyltransferase increased	1	0
Hepatic enzyme increased	2	0
Liver function test abnormal	6	0
Liver function test increased	9	0
Transaminases increased	1	0
<i>Metabolism tests NEC</i>		
Blood ketone body	2	0
Blood ketone body increased	1	0
<i>Microbiology and serology tests NEC</i>		
Culture negative	1	0
<i>Mineral and electrolyte analyses</i>		
Blood copper increased	1	0
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	3	0
Serum ferritin increased	1	0
<i>Musculoskeletal and soft tissue tests NEC</i>		
Swollen joint count increased	1	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021
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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Neurologic diagnostic procedures</i>		
Coma scale abnormal	2	0
Temperature perception test increased	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Corneal reflex decreased	1	0
Intraocular pressure increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	120	0
Body temperature abnormal	19	0
Body temperature decreased	15	0
Body temperature fluctuation	9	0
Body temperature increased	198	0
Body temperature normal	1	0
Breath sounds abnormal	1	0
Grip strength	2	0
Grip strength decreased	3	0
Lymph node palpable	15	0
Palpatory finding abnormal	1	0
Product residue present	1	0
Respiratory rate	3	0
Respiratory rate decreased	3	0
Respiratory rate increased	18	0
Skin temperature	16	0
Temperature difference of extremities	4	0
Weight	1	0
Weight decreased	16	0
Weight increased	4	0
<i>Pituitary analyses anterior</i>		
Blood growth hormone	2	0
Blood thyroid stimulating hormone increased	2	0
<i>Platelet analyses</i>		
Platelet count decreased	10	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	6	0
<i>Red blood cell analyses</i>		
Haematocrit	1	0
Haemoglobin decreased	4	0
<i>Reproductive hormone analyses</i>		
False negative pregnancy test	1	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Forced expiratory volume increased	2	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	4	0
Pulmonary function test	1	0
Vital capacity	1	0
<i>Respiratory tract and thoracic histopathology procedures</i>		
Sputum abnormal	3	0
<i>Respiratory tract and thoracic imaging procedures</i>		
Chest X-ray	4	0
<i>Skeletal and cardiac muscle analyses</i>		
Blood creatine phosphokinase increased	3	0
Troponin increased	4	0
<i>Therapeutic drug monitoring analyses</i>		

Case Series Drug Analysis Print

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Earliest Reaction Date: 03-Apr-1990

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Analgesic drug level	1	0
Anticoagulation drug level below therapeutic	4	0
Anticoagulation drug level increased	1	0
Drug level decreased	1	0
Thyroid analyses		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	1	0
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	2	0
Tissue enzyme analyses NEC		
Blood alkaline phosphatase increased	1	0
Urinalysis NEC		
Blood urine	4	0
Blood urine present	10	0
Glucose urine present	1	0
Urine analysis abnormal	1	0
pH urine	3	0
pH urine increased	1	0
Urinary tract function analyses NEC		
Urine output	6	0
Urine output decreased	4	0
Urine output increased	1	0
Urinary tract imaging procedures		
Cystoscopy	1	0
Vascular imaging procedures NEC		
Venogram	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	3	0
Blood pressure decreased	13	0
Blood pressure diastolic	1	0
Blood pressure increased	93	0
Blood pressure measurement	11	0
Blood pressure systolic decreased	1	0
Blood pressure systolic increased	1	0
Virus identification and serology		
Coronavirus test	3	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	14	0
SARS-CoV-2 antibody test positive	2	0
SARS-CoV-2 test	16	0
SARS-CoV-2 test false negative	1	0
SARS-CoV-2 test false positive	1	0
SARS-CoV-2 test negative	3	0
SARS-CoV-2 test positive	41	0
Viral test	2	0
Vitamin analyses		
Blood folate decreased	1	0
White blood cell analyses		
Lymphocyte count decreased	1	0
White blood cell count decreased	2	0
White blood cell count increased	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Investigations SOC TOTAL	1440	1

Case Series Drug Analysis Print

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Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 28-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	3	0
Decreased appetite	474	0
Eating disorder symptom	1	0
Food craving	4	0
Food refusal	4	0
Hyperphagia	1	0
Hypophagia	5	0
Increased appetite	3	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	2	0
Tetany	2	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	14	0
Diabetes mellitus inadequate control	4	1
Increased insulin requirement	1	0
Latent autoimmune diabetes in adults	1	0
Type 1 diabetes mellitus	6	0
Type 2 diabetes mellitus	1	0
<i>Diabetic complications NEC</i>		
Diabetic complication	2	0
Diabetic ketoacidosis	5	0
<i>Disorders of purine metabolism</i>		
Gout	27	0
<i>Electrolyte imbalance NEC</i>		
Fluid imbalance	1	0
<i>Fluid intake increased</i>		
Polydipsia	3	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Dairy intolerance	1	0
Food intolerance	1	0
Gluten sensitivity	1	0
Histamine intolerance	2	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	2	0
Abnormal weight gain	5	0
Cachexia	1	0
Feeding disorder	18	0
Food aversion	3	0
Overweight	1	0
Poor feeding infant	3	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	38	0
Insulin resistance	3	0
<i>Hypoglycaemic conditions NEC</i>		
Glycopenia	1	0
Hypoglycaemia	41	0
Postprandial hypoglycaemia	1	0
<i>Iron deficiencies</i>		
Iron deficiency	1	0
<i>Lipid metabolism and deposit disorders NEC</i>		
Body fat disorder	1	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Ketoacidosis	4	0
Metabolic acidosis	2	0
<i>Mixed acid-base disorders</i>		
Acidosis	3	0
<i>Potassium imbalance</i>		
Hyperkalaemia	2	0
Hypokalaemia	2	0
Hypokalaemic syndrome	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	5	0
Hyponatraemic syndrome	1	0
<i>Sugar intolerance (excl glucose intolerance)</i>		
Lactose intolerance	1	0
<i>Total fluid volume decreased</i>		
Dehydration	56	0
<i>Total fluid volume increased</i>		
Fluid retention	8	0
Hypervolaemia	1	0
<i>Vitamin deficiencies NEC</i>		
Hypovitaminosis	1	0
Metabolic disorders SOC TOTAL	777	1

Case Series Drug Analysis Print

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

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	82	0
Arthropathy	8	0
Haemarthrosis	1	0
Joint microhaemorrhage	1	0
Polyarthritis	4	0
Sacroiliitis	1	0
<i>Bone disorders NEC</i>		
Medial tibial stress syndrome	2	0
Spinal disorder	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	127	0
Bone swelling	3	0
Coccydynia	1	0
Pain in jaw	114	0
Spinal pain	18	0
<i>Bursal disorders</i>		
Bursitis	15	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	18	0
Polychondritis	1	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	15	0
Sjogren's syndrome	1	0
<i>Crystal arthropathic disorders</i>		
Crystal arthropathy	1	0
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		
Foot deformity	1	0
Musculoskeletal deformity	1	0
<i>Joint related disorders NEC</i>		
Joint destruction	1	0
Joint laxity	1	0
Joint lock	5	0
Periarthritis	23	0
Temporomandibular joint syndrome	2	0
<i>Joint related signs and symptoms</i>		
Arthralgia	3494	0
Jaw clicking	2	0
Joint effusion	10	0
Joint noise	5	0
Joint range of motion decreased	2	0
Joint stiffness	78	0
Joint swelling	130	0
Joint vibration	1	0
Joint warmth	6	0
<i>Ligament disorders</i>		
Symphysiolysis	1	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	6	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
<i>Muscle infections and inflammations</i>		
Antisynthetase syndrome	1	0
Myositis	6	0
Polymyositis	1	0
<i>Muscle pains</i>		
Fibromyalgia	23	0
Myalgia	4843	0
Myalgia intercostal	1	0
Myofascial pain syndrome	6	0
<i>Muscle related signs and symptoms NEC</i>		
Haematoma muscle	1	0
Muscle atrophy	2	0
Muscle discomfort	2	0
Muscle disorder	2	0
Muscle fatigue	143	0
Muscle spasms	242	0
Muscle swelling	10	0
Muscle tightness	23	0
Muscle twitching	106	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	7	0
Nuchal rigidity	5	0
Torticollis	2	0
Trismus	9	0
<i>Muscle weakness conditions</i>		
Muscular weakness	289	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Limb mass	4	0
Mandibular mass	2	0
Mastication disorder	1	0
Mobility decreased	22	0
Musculoskeletal disorder	4	0
Musculoskeletal stiffness	408	0
Posture abnormal	1	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Fasciitis	1	0
Plantar fasciitis	4	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	761	0
Flank pain	11	0
Limb discomfort	513	0
Musculoskeletal chest pain	50	0
Musculoskeletal discomfort	28	0
Musculoskeletal pain	21	0
Neck pain	624	0
Pain in extremity	4123	0
Rheumatic disorder	3	0
<i>Myopathies</i>		
Myopathy	1	0
Rhabdomyolysis	3	0
<i>Osteoarthropathies</i>		
Osteoarthritis	11	0
<i>Psoriatic arthropathies</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Psoriatic arthropathy	6	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	35	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	78	0
Groin pain	33	0
Neck mass	11	0
Purple glove syndrome	1	0
Soft tissue swelling	1	0
<i>Spine and neck deformities</i>		
Kyphosis	1	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	4	0
Arthritis reactive	12	0
<i>Synovial disorders</i>		
Synovial cyst	6	0
Synovitis	4	0
<i>Tendon disorders</i>		
Enthesopathy	1	0
Tendon pain	3	0
Tendonitis	10	0
Tenosynovitis	1	0
Tenosynovitis stenosaurs	1	0
Trigger finger	3	0
<i>Trunk deformities</i>		
Drooping shoulder syndrome	1	0
Muscle & tissue disorders SOC TOTAL	16718	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma	2	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	7	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>Leukaemias acute NEC</i>		
Acute leukaemia	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	7	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>Nervous system neoplasms unspecified malignancy NEC</i>		
Brain neoplasm	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	1	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Lung neoplasm malignant	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	1	0
Anogenital warts	1	0
Melanocytic naevus	2	0
Skin papilloma	2	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	1	0
Neoplasm skin	1	0
Squamous cell carcinoma of skin	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	1	0
Lymphangioma	1	0

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Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Soft tissue sarcomas histology unspecified</i>		
Sarcoma	1	0
Neoplasms SOC TOTAL	53	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	2	0
Extensor plantar response	1	0
Hyperreflexia	1	0
Hyporeflexia	4	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	4	0
<i>Absence seizures</i>		
Petit mal epilepsy	10	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	15	1
Subacute inflammatory demyelinating polyneuropathy	1	0
<i>Autonomic nervous system disorders</i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	2	0
Horner's syndrome	1	0
<i>Central nervous system aneurysms and dissections</i>		
Vertebral artery dissection	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	1
Cerebellar haemorrhage	1	0
Cerebellar infarction	2	0
Cerebellar stroke	3	0
Cerebral artery occlusion	1	0
Cerebral haemorrhage	13	5
Cerebral infarction	11	0
Cerebral thrombosis	1	0
Cerebrovascular accident	108	5
Embolic stroke	2	0
Haemorrhage intracranial	4	0
Haemorrhagic stroke	1	1
Ischaemic cerebral infarction	1	0
Ischaemic stroke	17	1
Lacunar infarction	2	0
Lacunar stroke	1	0
Lateral medullary syndrome	1	0
Subarachnoid haemorrhage	4	1
<i>Central nervous system inflammatory disorders NEC</i>		
Gliosis	1	0
<i>Central nervous system vascular disorders NEC</i>		
Reversible cerebral vasoconstriction syndrome	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	3	0
Cerebral venous thrombosis	1	0
<i>Cervical spinal cord and nerve root disorders</i>		
Cervicobrachial syndrome	2	0
<i>Choreiform movements</i>		
Chorea	2	0
<i>Coma states</i>		
Coma	2	0
Hypoglycaemic coma	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	3	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Balance disorder	114	0
Coordination abnormal	15	0
Dysdiadochokinesis	1	0
Dysstasia	17	0
Nystagmus	3	0
Cortical dysfunction NEC		
Aphasia	19	0
Apraxia	1	0
Neurologic neglect syndrome	1	0
Cranial nerve disorders NEC		
Cranial nerve disorder	2	0
Dementia (excl Alzheimer's type)		
Dementia	5	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
Demyelinating disorders NEC		
Demyelination	1	0
Disturbances in consciousness NEC		
Altered state of consciousness	4	0
Consciousness fluctuating	2	0
Depressed level of consciousness	12	1
Lethargy	964	0
Loss of consciousness	132	0
Sedation	3	0
Somnolence	328	0
Stupor	2	0
Syncope	397	0
Disturbances in sleep phase rhythm		
Irregular sleep wake rhythm disorder	1	0
Dyskinesias and movement disorders NEC		
Akathisia	1	0
Bradykinesia	4	0
Clumsiness	3	0
Dyskinesia	14	0
Extrapyramidal disorder	1	0
Fine motor skill dysfunction	3	0
Hyperkinesia	1	0
Hypokinesia	12	1
Motor dysfunction	1	0
Movement disorder	14	0
Psychomotor hyperactivity	7	0
Dystonias		
Dystonia	7	0
Opisthotonus	1	0
Writer's cramp	1	0
Encephalitis NEC		
Noninfective encephalitis	1	0
Encephalopathies NEC		
Encephalopathy	1	0
Posterior reversible encephalopathy syndrome	1	0
Eye movement disorders		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	2	0

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
IVth nerve paralysis	1	0
VIth nerve paralysis	4	0
Facial cranial nerve disorders		
Facial nerve disorder	1	0
Facial paralysis	269	0
Facial paresis	36	0
Facial spasm	16	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	12	0
Headaches NEC		
Cervicogenic headache	2	0
Cluster headache	75	0
Cold-stimulus headache	4	0
Drug withdrawal headache	1	0
Exertional headache	5	0
Headache	10819	0
Medication overuse headache	2	0
New daily persistent headache	4	0
Occipital neuralgia	3	0
Ophthalmoplegic migraine	1	0
Primary cough headache	2	0
Primary headache associated with sexual activity	1	0
Sinus headache	146	0
Tension headache	197	0
Thunderclap headache	1	0
Vascular headache	6	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Increased intracranial pressure disorders		
Brain oedema	1	0
Lumbar spinal cord and nerve root disorders		
Sciatica	21	0
Memory loss (excl dementia)		
Amnesia	34	0
Memory impairment	37	0
Transient global amnesia	5	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	24	0
Disturbance in attention	91	0
Mental impairment	13	0
Migraine headaches		
Hemiplegic migraine	4	0
Migraine	860	0
Migraine with aura	58	0
Migraine without aura	5	0
Retinal migraine	11	0
Typical aura without headache	1	0
Vestibular migraine	5	0
Mononeuropathies		
Carpal tunnel syndrome	6	0
Mononeuropathy	1	0
Nerve compression	4	0
Peroneal nerve palsy	3	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Sciatic nerve neuropathy	1	0
Ulnar neuritis	1	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	12	0
Multiple sclerosis relapse	10	0
Muscle tone abnormal		
Hypotonia	4	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
Myelitis (incl infective)		
Myelitis transverse	13	0
Narcolepsy and hypersomnia		
Cataplexy	1	0
Hypersomnia	30	0
Narcolepsy	2	0
Nervous system disorders NEC		
Nervous system disorder	2	0
Neurologic visual problems NEC		
Hemianopia	1	0
Tunnel vision	5	0
Visual field defect	6	0
Neurological signs and symptoms NEC		
Dizziness	3212	0
Dizziness exertional	17	0
Dizziness postural	294	0
Drooling	3	0
Head discomfort	79	0
Hyporesponsive to stimuli	1	0
Inability to crawl	2	0
Myoclonus	8	0
Neurological symptom	15	0
Persistent postural-perceptual dizziness	5	0
Presyncope	192	0
Slow response to stimuli	2	0
Tongue biting	1	0
Unresponsive to stimuli	22	1
Neuromuscular disorders NEC		
Muscle contractions involuntary	6	0
Muscle spasticity	5	0
Neuromuscular pain	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	3	0
Myasthenia gravis crisis	1	0
Olfactory nerve disorders		
Anosmia	86	0
Hyposmia	6	0
Parosmia	77	0
Optic nerve disorders NEC		
Optic neuritis	7	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	2	0
Burning sensation	137	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021
Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 28-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Dysaesthesia	3	0
Formication	13	0
Hand-arm vibration syndrome	2	0
Hemiparaesthesia	1	0
Hyperaesthesia	32	0
Hypoaesthesia	770	0
Paraesthesia	1123	0
Reversed hot-cold sensation	1	0
Synaesthesia	1	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	3	1
Hemiparesis	13	0
Hemiplegia	10	0
Locked-in syndrome	1	0
Monoparesis	20	0
Monoplegia	18	0
Paralysis	33	0
Paraparesis	1	0
Paresis	2	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	4	0
Parkinson's disease	1	0
Parkinsonian gait	1	0
Parkinsonism	4	0
Reduced facial expression	2	0
Partial complex seizures		
Dreamy state	2	0
Focal dyscognitive seizures	1	0
Temporal lobe epilepsy	1	0
Peripheral neuropathies NEC		
Neuritis	2	0
Neuropathy peripheral	32	0
Peripheral sensory neuropathy	5	0
Seizures and seizure disorders NEC		
Atonic seizures	4	0
Clonic convulsion	1	0
Epilepsy	50	0
Epileptic aura	2	0
Epileptic encephalopathy	1	0
Febrile convulsion	2	0
Partial seizures	6	0
Post stroke seizure	1	0
Psychogenic seizure	4	0
Seizure	159	0
Seizure cluster	4	0
Seizure like phenomena	1	0
Status epilepticus	10	0
Tonic clonic movements	2	0
Tonic convulsion	7	0
Sensory abnormalities NEC		
Ageusia	179	0
Allodynia	6	0
Aura	7	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021
 Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 28-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Dysgeusia	475	0
Hypergeusia	1	0
Loss of proprioception	1	0
Neuralgia	132	0
Phantom limb syndrome	3	0
Post herpetic neuralgia	3	0
Restless legs syndrome	33	0
Sensory disturbance	20	0
Sensory loss	14	0
Taste disorder	94	0
<i>Sleep disturbances NEC</i>		
Poor quality sleep	66	0
Sleep deficit	2	0
<i>Speech and language abnormalities</i>		
Dysarthria	51	0
Incoherent	1	0
Repetitive speech	1	0
Speech disorder	11	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculitis brachial	2	0
Radiculopathy	2	0
<i>Structural brain disorders NEC</i>		
Brain injury	2	2
Hyperintensity in brain deep nuclei	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	36	0
<i>Tremor (excl congenital)</i>		
Essential tremor	1	0
Head titubation	1	0
Resting tremor	1	0
Tremor	600	0
<i>Trigeminal disorders</i>		
Facial neuralgia	10	0
Numb chin syndrome	1	0
Trigeminal nerve disorder	1	0
Trigeminal neuralgia	17	0
Nervous system disorders SOC TOTAL	23534	21

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	40	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	5	0
Preterm premature rupture of membranes	2	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	5	0
Pregnancy conditions SOC TOTAL	55	3

Case Series Drug Analysis Print

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

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Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device issue	1	0
<i>Device malfunction events NEC</i>		
Device infusion issue	1	0
Device pacing issue	1	0
Device stimulation issue	1	0
Oversensing	8	0
Thrombosis in device	1	0
<i>Device physical property and chemical issues</i>		
Device kink	1	0
Needle issue	2	0
<i>Product physical issues</i>		
Liquid product physical issue	2	0
Product odour abnormal	1	0
Product physical issue	1	0
Product taste abnormal	5	0
<i>Product quality issues NEC</i>		
Product origin unknown	2	0
null SOC TOTAL	27	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021
Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 28-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	3	0
Staring	1	0
<i>Affect alterations NEC</i>		
Affect lability	1	0
Constricted affect	1	0
Flat affect	3	0
Inappropriate affect	2	0
<i>Amnesic symptoms</i>		
Paramnesia	2	0
<i>Anxiety symptoms</i>		
Agitation	31	0
Anxiety	174	0
Immunisation anxiety related reaction	1	0
Nervousness	71	0
Stress	5	0
Tension	13	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	1	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	1	0
Indifference	3	0
Paranoia	7	0
Personality change	1	0
Social avoidant behaviour	2	0
Soliloquy	1	0
<i>Bipolar disorders</i>		
Bipolar I disorder	1	0
Bipolar disorder	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	2	0
Mental fatigue	71	0
<i>Communications disorders</i>		
Communication disorder	2	0
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	266	0
Disorientation	88	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	44	0
<i>Delusional symptoms</i>		
Delusion	2	0
<i>Depressive disorders</i>		
Agitated depression	1	0
Depression	64	0
Depression suicidal	1	0
Major depression	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	3	0
Dissociation	6	0
Dissociative amnesia	1	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Dissociative disorder	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	4	0
Insomnia	338	0
Middle insomnia	9	0
Terminal insomnia	3	0
<i>Dyssomnias</i>		
Dyssomnia	1	0
<i>Eating disorders NEC</i>		
Bulimia nervosa	1	0
Eating disorder	2	0
Selective eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	4	0
Dysphoria	1	0
Emotional disorder	10	0
Emotional distress	7	0
Euphoric mood	10	0
Irritability	51	0
Mood altered	13	0
<i>Factitious disorders</i>		
Factitious disorder	1	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	1	0
Fear of falling	1	0
Osmophobia	1	0
Phonophobia	1	0
Social fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	11	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	70	0
Hallucination, auditory	4	0
Hallucination, olfactory	3	0
Hallucination, tactile	1	0
Hallucination, visual	7	0
Hallucinations, mixed	1	0
<i>Increased physical activity levels</i>		
Restlessness	37	0
<i>Learning disorders</i>		
Learning disorder	1	0
<i>Mental disorders NEC</i>		
Mental disorder	4	0
<i>Mental disorders due to a general medical condition NEC</i>		
Neuropsychiatric symptoms	1	0
<i>Mood alterations with depressive symptoms</i>		
Decreased interest	5	0
Depressed mood	82	0
Feeling of despair	1	0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Sense of a foreshortened future	2	0
Tearfulness	10	0

Case Series Drug Analysis Print

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Report Run Date: 01-Apr-2021

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Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Mood alterations with manic symptoms</i>		
Hypomania	1	0
Mania	4	0
<i>Mood disorders NEC</i>		
Apathy	7	0
Laziness	1	0
Listless	7	0
<i>Narcolepsy and associated conditions</i>		
Hypnagogic hallucination	2	0
Sleep attacks	3	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive symptom	1	0
<i>Orgasmic disorders and disturbances</i>		
Anorgasmia	1	0
<i>Panic attacks and disorders</i>		
Panic attack	35	0
Panic disorder	3	0
Panic reaction	6	0
<i>Parasomnias</i>		
Abnormal dreams	65	0
Confusional arousal	1	0
Nightmare	57	0
Parasomnia	1	0
Sleep talking	1	0
Sleep terror	5	0
<i>Perception disturbances NEC</i>		
Autoscopy	3	0
Deja vu	1	0
Derealisation	4	0
Flashback	1	0
Illusion	1	0
<i>Psychiatric elimination disorders</i>		
Enuresis	4	0
<i>Psychiatric symptoms NEC</i>		
Hypervigilance	2	0
Psychiatric symptom	1	0
Trance	1	0
<i>Psychotic disorder NEC</i>		
Psychotic behaviour	1	0
Psychotic disorder	7	0
<i>Schizophrenia NEC</i>		
Schizophrenia	1	0
<i>Sexual desire disorders</i>		
Libido decreased	2	0
Libido increased	1	0
Loss of libido	5	0
<i>Sleep disorders NEC</i>		
Sleep disorder	61	0
<i>Somatic symptom disorders</i>		
Conversion disorder	1	0
Habit cough	8	0
Somatic symptom disorder	1	0
Vomiting psychogenic	1	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Speech and language usage disturbances</i>		
Disorganised speech	3	0
Logorrhoea	2	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	2	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
<i>Stereotypies and automatisms</i>		
Bruxism	5	0
Head banging	2	0
Stereotypy	1	0
<i>Stress disorders</i>		
Post-traumatic stress disorder	1	0
<i>Substance related and addictive disorders</i>		
Alcoholic hangover	1	0
<i>Suicidal and self-injurious behaviour</i>		
Intentional self-injury	3	0
Self-injurious ideation	1	0
Suicidal ideation	5	0
Suicide attempt	2	0
<i>Thinking disturbances</i>		
Bradyphrenia	14	0
Intrusive thoughts	1	0
Tachyphrenia	1	0
Thinking abnormal	4	0
Psychiatric disorders SOC TOTAL	1942	0

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	1	0
Bladder irritation	1	0
Bladder pain	3	0
Dysuria	15	0
Incontinence	11	0
Micturition disorder	1	0
Micturition urgency	8	0
Pollakiuria	22	0
Urethral pain	1	0
Urinary incontinence	25	0
Urinary retention	20	0
Urine flow decreased	2	0
<i>Bladder disorders NEC</i>		
Bladder disorder	3	0
Urinary bladder haemorrhage	1	0
<i>Bladder infections and inflammations</i>		
Cystitis interstitial	1	0
<i>Genital and urinary tract disorders NEC</i>		
Urinary tract disorder	2	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Glomerulonephritis	1	0
Glomerulonephritis minimal lesion	3	0
Glomerulonephritis rapidly progressive	1	0
Nephrotic syndrome	6	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	2	0
Hypertonic bladder	1	0
Loss of bladder sensation	1	0
Neurogenic bladder	1	0
<i>Nephritis NEC</i>		
Nephritis	1	0
Tubulointerstitial nephritis	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	18	0
Anuria	2	0
Chronic kidney disease	1	0
Oliguria	1	0
Renal failure	7	1
Renal impairment	5	0
<i>Renal lithiasis</i>		
Nephrolithiasis	1	0
<i>Renal structural abnormalities and trauma</i>		
Kidney small	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal vasculitis	1	1
<i>Structural and obstructive urethral disorders (excl congenital)</i>		
Urethral stenosis	1	0
<i>Ureteric disorders NEC</i>		
Ureteric stenosis	1	0
<i>Urinary abnormalities</i>		
Chromaturia	15	0
Haematuria	15	0

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Proteinuria	3	0
Urine abnormality	5	0
Urine odour abnormal	4	0
Urinary tract signs and symptoms NEC		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	5	0
Nocturia	1	0
Polyuria	2	0
Renal pain	84	0
Urinary tract pain	1	0
Renal & urinary disorders SOC TOTAL	311	2

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Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	3	0
<i>Breast disorders NEC</i>		
Breast mass	22	0
Gynaecomastia	1	0
<i>Breast signs and symptoms</i>		
Breast discharge	1	0
Breast discomfort	2	0
Breast engorgement	1	0
Breast haematoma	1	0
Breast oedema	1	0
Breast pain	99	0
Breast swelling	27	0
Breast tenderness	10	0
Nipple pain	6	0
Nipple swelling	2	0
<i>Cervix disorders NEC</i>		
Cervical dysplasia	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	14	0
Erection increased	1	0
<i>Lactation disorders</i>		
Suppressed lactation	1	0
<i>Menopausal effects NEC</i>		
Artificial menopause	1	0
Menopausal symptoms	2	0
Premature menopause	1	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	4	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysfunctional uterine bleeding	1	0
Dysmenorrhoea	32	0
Menstrual discomfort	1	0
Menstrual disorder	39	0
Menstruation irregular	32	0
Metrorrhagia	18	0
Premenstrual pain	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	18	0
Hypomenorrhoea	18	0
Menstruation delayed	69	0
Oligomenorrhoea	2	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	73	0
Polymenorrhoea	12	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovulation pain	3	0
Premature ovulation	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	6	0
Pelvic haemorrhage	3	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile swelling	3	0

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Earliest Reaction Date: 03-Apr-1990

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Penis disorder	2	0
Prostate and seminal vesicles infections and inflammations		
Prostatitis	1	0
Prostatic signs, symptoms and disorders NEC		
Prostatomegaly	3	0
Reproductive tract disorders NEC (excl neoplasms)		
Genital haemorrhage	1	0
Genital ulceration	2	0
Reproductive tract infections and inflammations NEC		
Genital tract inflammation	1	0
Reproductive tract signs and symptoms NEC		
Genital pain	2	0
Pelvic discomfort	2	0
Pelvic pain	12	0
Perineal pain	1	0
Pruritus genital	1	0
Scrotal disorders NEC		
Scrotal erythema	1	0
Scrotal exfoliation	1	0
Scrotal pain	3	0
Scrotal swelling	3	0
Sexual function and fertility disorders NEC		
Infertility	1	0
Spermatogenesis and semen disorders		
Haemospermia	1	0
Testicular and epididymal disorders NEC		
Testicular pain	8	0
Testicular swelling	3	0
Uterine disorders NEC		
Endometriosis	4	0
Uterine pain	1	0
Uterine tone disorders		
Uterine spasm	1	0
Vulvovaginal cysts and neoplasms		
Vaginal cyst	2	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	64	0
Vulval haemorrhage	2	0
Vulval ulceration	3	0
Vulvovaginal ulceration	1	0
Vulvovaginal signs and symptoms		
Vaginal discharge	3	0
Vulval oedema	1	0
Vulvovaginal burning sensation	2	0
Vulvovaginal pain	3	0
Vulvovaginal pruritus	1	0
Vulvovaginal swelling	1	0
Reproductive & breast disorders SOC TOTAL	672	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 28-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	2	0
Dyspnoea	1186	4
Dyspnoea at rest	1	0
Dyspnoea exertional	9	1
Hyperventilation	16	0
Hypopnoea	22	0
Irregular breathing	8	0
Mouth breathing	3	0
Orthopnoea	3	0
Respiration abnormal	21	0
Respiratory arrest	6	0
Respiratory depression	1	0
Respiratory distress	8	0
Sleep apnoea syndrome	4	0
Tachypnoea	18	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	1	0
Bronchiectasis	6	0
<i>Bronchospasm and obstruction</i>		
Asthma	117	0
Asthma late onset	2	0
Bronchospasm	7	0
Chronic obstructive pulmonary disease	8	0
Cough variant asthma	1	0
Obstructive airways disorder	1	0
Reversible airways obstruction	1	0
Wheezing	161	0
<i>Conditions associated with abnormal gas exchange</i>		
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	13	1
Respiratory acidosis	1	0
<i>Coughing and associated symptoms</i>		
Allergic cough	4	0
Cough	838	1
Cough decreased	2	0
Haemoptysis	8	0
Productive cough	45	0
Sputum discoloured	1	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Laryngeal disorder	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngospasm	1	0
Stridor	9	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Hypersensitivity pneumonitis	1	0
Pneumonia aspiration	6	4
Pneumonitis	11	3
Pulmonary sarcoidosis	1	0

Case Series Drug Analysis Print

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

Report Run Date: 01-Apr-2021
Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 28-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	4	0
Increased bronchial secretion	1	0
Pleuritic pain	6	0
Pulmonary pain	35	0
Rales	2	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	76	0
Nasal inflammation	1	0
Rhinitis allergic	4	0
<i>Nasal disorders NEC</i>		
Epistaxis	240	0
Intranasal hyposaesthesia	1	0
Intranasal paraesthesia	1	0
Nasal crusting	1	0
Nasal disorder	1	0
Nasal dryness	11	0
Nasal odour	5	0
Nasal oedema	1	0
Nasal pruritus	4	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Allergic sinusitis	1	0
Paranasal sinus inflammation	1	0
Sinonasal obstruction	4	0
Sinus congestion	16	0
Sinus disorder	2	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	1	0
Emphysema	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	3	0
Pharyngeal haemorrhage	1	0
Pharyngeal hyposaesthesia	13	0
Pharyngeal inflammation	3	0
Pharyngeal oedema	5	0
Pharyngeal paraesthesia	29	0
Pharyngeal swelling	92	0
Pharyngeal ulceration	7	0
Tonsillar erythema	1	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	27	0
Tonsillar inflammation	3	0
<i>Pleural infections and inflammations</i>		
Pleurisy	12	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	4	0
Pneumothorax	1	0
Pneumothorax spontaneous	1	0
<i>Pulmonary hypertension</i>		
Pulmonary hypertension	2	0
<i>Pulmonary oedemas</i>		
Pulmonary congestion	3	0
Pulmonary oedema	5	0

Case Series Drug Analysis Print

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Report Run Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	65	7
Pulmonary infarction	1	0
Pulmonary thrombosis	1	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	2	1
Respiratory failure	6	0
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	1	0
Diaphragmalgia	1	0
Painful respiration	3	0
Respiratory symptom	4	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	3	2
Respiratory disorder	3	0
Respiratory tract irritation	1	0
Respiratory tract oedema	1	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	1	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal pain	1	0
<i>Upper respiratory tract neoplasms</i>		
Tonsillar cyst	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	26	0
Catarrh	9	0
Choking	6	1
Choking sensation	1	0
Dry throat	71	0
Dysphonia	55	0
Increased upper airway secretion	3	0
Increased viscosity of upper respiratory secretion	6	0
Nasal discharge discolouration	1	0
Nasal discomfort	18	0
Nasal obstruction	2	0
Oropharyngeal blistering	6	0
Oropharyngeal discomfort	25	0
Oropharyngeal pain	990	0
Paranasal sinus discomfort	13	0
Rhinalgia	6	0
Rhinorrhoea	272	0
Sinus pain	67	0
Sneezing	124	0
Snoring	2	0
Throat clearing	3	0
Throat irritation	93	0
Throat tightness	106	0
Upper airway obstruction	2	0
Upper-airway cough syndrome	2	0
Yawning	4	0
Respiratory disorders SOC TOTAL	5200	25

Case Series Drug Analysis Print

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Report Run Date: 01-Apr-2021

Data Lock Date: 28-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	17	0
Acne cystic	1	0
Dermatitis acneiform	2	0
<i>Alopecias</i>		
Alopecia	27	0
Alopecia totalis	1	0
Madarosis	1	0
<i>Angioedemas</i>		
Angioedema	87	0
Circumoral swelling	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	245	0
Hidradenitis	1	0
Hyperhidrosis	684	0
Miliaria	30	0
Night sweats	245	0
<i>Bullous conditions</i>		
Blister	104	0
Blister rupture	1	0
Blood blister	5	0
Dermatitis bullous	6	0
Erythema multiforme	13	0
Fracture blisters	1	0
Pemphigoid	9	0
Pemphigus	2	0
Stevens-Johnson syndrome	1	0
Toxic epidermal necrolysis	2	1
<i>Connective tissue disorders</i>		
Dermatomyositis	3	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	72	0
Macule	2	0
Pain of skin	107	0
Papule	25	0
Pathergy reaction	1	0
Peau d'orange	2	0
Scab	4	0
Scar pain	7	0
Sensitive skin	61	0
Skin burning sensation	77	0
Skin discolouration	38	0
Skin discomfort	1	0
Skin disorder	2	0
Skin fissures	2	0
Skin indentation	2	0
Skin induration	2	0
Skin lesion	15	0
Skin necrosis	1	0
Skin odour abnormal	3	0
Skin reaction	45	0

Case Series Drug Analysis Print

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Report Run Date: 01-Apr-2021
 Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 28-Mar-2021 19:00:03
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin sensitisation	8	0
Skin swelling	34	0
Skin tightness	14	0
Skin warm	113	0
Skin weeping	2	0
Sticky skin	1	0
Yellow skin	7	0
<i>Dermatitis and eczema</i>		
Dermatitis	37	0
Dermatitis allergic	88	0
Dermatitis atopic	10	0
Dermatitis diaper	1	0
Dyshidrotic eczema	5	0
Eczema	54	0
Eczema asteatotic	3	0
Eczema nummular	2	0
Eczema weeping	1	0
Perioral dermatitis	1	0
Skin irritation	41	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	13	0
Fixed eruption	1	0
Toxic skin eruption	1	0
<i>Erythemas</i>		
Erythema	889	0
Palmar erythema	3	0
Red man syndrome	1	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	1	0
Exfoliative rash	5	0
Skin exfoliation	28	0
<i>Hyperkeratoses</i>		
Lichenoid keratosis	1	0
<i>Hyperpigmentation disorders</i>		
Ephelides	1	0
Skin hyperpigmentation	2	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	1	0
Skin hypopigmentation	1	0
Vitiligo	1	0
<i>Lipodystrophies</i>		
Lipoatrophy	2	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	4	0
Nail disorder	1	0
Onychalgia	4	0
Onychoclasia	2	0
Splinter haemorrhages	1	0
<i>Panniculitides</i>		
Erythema nodosum	6	0
<i>Papulosquamous conditions</i>		
Erythema annulare	1	0
Lichen planus	2	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Parapsoriasis	1	0
Pityriasis rosea	29	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	15	0
Pigmentation changes NEC		
Haemosiderin stain	1	0
Pigmentation disorder	3	0
Pilar disorders NEC		
Hair colour changes	1	0
Hair growth abnormal	1	0
Hair texture abnormal	1	0
Piloerection	8	0
Pseudofolliculitis	1	0
Pruritus NEC		
Itching scar	5	0
Pruritus	1791	0
Psoriatic conditions		
Dermatitis psoriasiform	1	0
Guttate psoriasis	4	0
Psoriasis	42	0
Pustular psoriasis	1	0
Purpura and related conditions		
Petechiae	34	0
Purpura	13	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	2	0
Rash	1813	0
Rash erythematous	408	0
Rash macular	173	0
Rash maculo-papular	28	0
Rash morbilliform	10	0
Rash papular	109	0
Rash pruritic	402	0
Rash vesicular	16	0
Systemic lupus erythematosus rash	4	0
Rosaceas		
Rosacea	3	0
Scaly conditions		
Dandruff	1	0
Pityriasis	7	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	1	0
Skin mass	4	0
Skin and subcutaneous tissue ulcerations		
Scleroderma associated digital ulcer	1	0
Skin erosion	11	0
Skin ulcer	3	0
Skin cysts and polyps		
Dermal cyst	2	0
Skin haemorrhages		
Haemorrhage subcutaneous	2	0
Skin haemorrhage	2	0
Skin hyperplasias and hypertrophies		

Case Series Drug Analysis Print

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Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin hypertrophy	1	0
<i>Skin hypoplasias and atrophies</i>		
Skin striae	2	0
<i>Skin injuries and mechanical dermatoses</i>		
Decubitus ulcer	1	0
<i>Skin vasculitides</i>		
Cutaneous vasculitis	2	0
Vasculitic rash	8	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	15	0
<i>Urticarias</i>		
Chronic spontaneous urticaria	1	0
Cold urticaria	1	0
Idiopathic urticaria	1	0
Mechanical urticaria	2	0
Urticaria	627	0
Urticaria chronic	1	0
Urticaria papular	2	0
Urticaria thermal	2	0
Skin disorders SOC TOTAL	8974	1

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Infant	1	0
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Disability issues</i>		
Bedridden	11	0
Breast prosthesis user	1	0
Immobile	4	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
<i>Economic circumstances</i>		
High income	1	0
Low income	1	0
<i>Educational issues</i>		
Illiteracy	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	2	0
<i>Tobacco use</i>		
Non-tobacco user	2	0
Social circumstances SOC TOTAL	36	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Blood and blood product treatment</i>		
Transfusion	1	0
<i>Bronchial and pulmonary therapeutic procedures</i>		
Airway secretion clearance therapy	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Cardiac operation	1	0
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	1	0
Nothing by mouth order	1	0
<i>Fertility and fertilisation interventions female</i>		
Endometrial scratching	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	9	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	29	0
Immunisation	9	0
<i>Joint therapeutic procedures</i>		
Joint surgery	1	0
Knee arthroplasty	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	3	0
Limb operation	3	0
<i>Lymphoid tissue therapeutic procedures</i>		
Lymphadenectomy	1	0
<i>Mastectomies</i>		
Breast conserving surgery	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	1	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>Therapeutic procedures NEC</i>		
Abscess drainage	1	0
Anaphylaxis treatment	3	0
Bed rest	2	0
Fatigue management	1	0
Hospitalisation	2	0
Injection	7	0
Medication dilution	1	0
Product used for unknown indication	1	0
Therapy change	1	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
Surgical & medical procedures SOC TOTAL	92	0

Case Series Drug Analysis Print

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Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	1	0
<i>Aneurysms and dissections non-site specific</i>		
Artery dissection	1	0
<i>Aortic aneurysms and dissections</i>		
Aortic dissection	1	0
<i>Aortic necrosis and vascular insufficiency</i>		
Aortic stenosis	1	0
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	3	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	3	0
Labile blood pressure	2	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	1	0
<i>Circulatory collapse and shock</i>		
CT hypotension complex	2	0
Circulatory collapse	32	0
Hypoperfusion	1	0
Neurogenic shock	16	0
Peripheral circulatory failure	3	0
Shock	7	0
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haematoma	13	0
Haemorrhage	43	2
Venous haemorrhage	1	0
<i>Lymphangiopathies</i>		
Lymphocele	2	0
<i>Lymphoedemas</i>		
Lymphoedema	73	0
<i>Non-site specific embolism and thrombosis</i>		
Embolism	1	0
Thrombosis	53	1
Venous thrombosis	2	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Haemorrhagic infarction	1	0
Vasospasm	1	0
<i>Non-site specific vascular disorders NEC</i>		
Superficial vein prominence	1	0
Vascular pain	4	0
Vasodilatation	5	0
Vein discolouration	1	0
Vein disorder	2	0
Vein rupture	2	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	5	0
Deep vein thrombosis	50	0
Pelvic venous thrombosis	2	0
Peripheral embolism	1	0
Thrombophlebitis	8	0
Thrombophlebitis superficial	3	0

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Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	18	0
Flushing	229	0
Hot flush	392	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	111	0
Peripheral ischaemia	3	0
Poor peripheral circulation	3	0
Raynaud's phenomenon	25	0
Vasoconstriction	2	0
<i>Phlebitis NEC</i>		
Phlebitis	10	0
<i>Site specific vascular disorders NEC</i>		
Pallor	91	0
<i>Varicose veins NEC</i>		
Spider vein	1	0
Varicose vein	3	0
<i>Vascular hypertensive disorders NEC</i>		
Diastolic hypertension	1	0
Essential hypertension	2	0
Hypertension	191	1
Systolic hypertension	2	0
<i>Vascular hypotensive disorders</i>		
Hypotension	138	0
Orthostatic hypotension	12	0
<i>Vasculitides NEC</i>		
Behcet's syndrome	2	0
MAGIC syndrome	1	0
Vasculitis	12	0
<i>Vena caval embolism and thrombosis</i>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	1601	4
TOTAL REACTIONS FOR DRUG	124371	302
TOTAL REPORTS	43491	
TOTAL FATAL OUTCOME REPORTS		302