

COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 22-Mar-2021
Data Lock Date: 14-Mar-2021 19:00:03

All UK spontaneous reports received between 9/12/20 and 14/03/21 for
mRNA Pfizer/BioNTech vaccine analysis print

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-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
<i>Anaemias NEC</i>		
Anaemia	10	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	7	0
<i>Coagulopathies</i>		
Coagulopathy	1	0
<i>Haematological disorders</i>		
Mast cell activation syndrome	1	0
<i>Haemolyses NEC</i>		
Haemolysis	1	0
<i>Leukocytoses NEC</i>		
Lymphocytosis	1	0
<i>Leukopenias NEC</i>		
Lymphopenia	2	0
<i>Lymphatic system disorders NEC</i>		
Abdominal lymphadenopathy	1	0
Granulomatous lymphadenitis	1	0
Lymph node pain	333	0
Lymphadenitis	52	0
Lymphadenopathy	2338	0
Lymphatic disorder	1	0
Pseudolymphoma	2	0
<i>Marrow depression and hypoplastic anaemias</i>		
Myelosuppression	1	0
Pancytopenia	1	0
<i>Neutropenias</i>		
Neutropenia	12	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	13	0
Thrombocytopenia	15	1
<i>Thrombocytoses</i>		
Thrombocytosis	2	0
Blood disorders SOC TOTAL	2801	1

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Bundle branch block right	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	1	0
Cardiac disorder	4	0
Cardiovascular disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	1	0
Palpitations	646	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	7	1
Cardiac failure congestive	1	0
Cardiogenic shock	1	0
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	8	0
Angina pectoris	18	0
Angina unstable	1	0
Arteriospasm coronary	1	0
Myocardial infarction	34	9
<i>Left ventricular failures</i>		
Left ventricular failure	1	0
<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
<i>Noninfectious myocarditis</i>		
Myocarditis	9	0
<i>Noninfectious pericarditis</i>		
Pericarditis	9	1
<i>Pericardial disorders NEC</i>		
Pericardial effusion	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	18	0
Bradycardia	16	0
Cardiac flutter	30	0
Extrasystoles	19	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	2	0
Tachycardia	345	0
<i>Right ventricular failures</i>		
Cor pulmonale	1	0
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	6	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Atrial fibrillation	61	0
Atrial flutter	1	0
Atrial tachycardia	3	0
Sinus bradycardia	2	0
Sinus tachycardia	26	0
Supraventricular tachycardia	13	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	44	18
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	1361	33

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	1	0
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	1	0
<i>Coagulation disorders congenital</i>		
Haemophilia	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	7	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	5	0
Ear discomfort	18	0
Ear disorder	3	0
Ear haemorrhage	1	0
Ear pain	257	0
Ear pruritus	3	0
Ear swelling	7	0
Otorrhoea	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	1	0
Eustachian tube dysfunction	4	0
<i>External ear disorders NEC</i>		
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	30	0
Deafness neurosensory	4	0
Deafness unilateral	3	0
Hypoacusis	32	0
Sudden hearing loss	7	0
<i>Hyperacusia</i>		
Hyperacusis	10	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	1	0
Inner ear disorder	3	0
Meniere's disease	3	0
Vestibular disorder	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	16	0
Tinnitus	246	0
Vertigo	296	0
Vertigo labyrinthine	4	0
Vertigo positional	23	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
Ear disorders SOC TOTAL	986	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
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	4	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 pain	1	0
<i>Thyroid hyperfunction disorders</i>		
Hyperthyroidism	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	3	0
Endocrine disorders SOC TOTAL	17	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
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
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	1	0
Vitreous floaters	14	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	11	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	1	0
Conjunctival oedema	1	0
<i>Corneal infections, oedemas and inflammations</i>		
Keratitis	4	0
Ulcerative keratitis	4	0
<i>Eyelid movement disorders</i>		
Blepharospasm	26	0
Excessive eye blinking	1	0
Eyelid ptosis	8	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	1	0
Iridocyclitis	5	0
Iritis	2	0
Uveitis	10	0
<i>Lacrimation disorders</i>		
Dry eye	39	0
Lacrimation increased	48	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	2	0
Chalazion	1	0
Eczema eyelids	1	0
Erythema of eyelid	1	0
Eyelid irritation	1	0
Eyelid margin crusting	1	0
Eyelid oedema	1	0
Eyelid rash	4	0
Swelling of eyelid	32	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
<i>Ocular disorders NEC</i>		
Dark circles under eyes	1	0
Eye disorder	10	0
Eye oedema	4	0
Eye pain	292	0
Eye swelling	148	0
Eye ulcer	1	0
Eyelid disorder	2	0
Eyelid pain	3	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Eyelids pruritus	1	0
Ocular discomfort	10	0
Periorbital oedema	11	0
Periorbital pain	1	0
Periorbital swelling	38	0
Ocular infections, inflammations and associated manifestations		
Eye allergy	2	0
Eye discharge	9	0
Eye inflammation	6	0
Eye irritation	31	0
Eye pruritus	92	0
Limbal swelling	1	0
Ocular hyperaemia	60	0
Ocular nerve and muscle disorders		
Binocular eye movement disorder	1	0
Extraocular muscle paresis	1	0
Eye movement disorder	6	0
Ophthalmoplegia	2	0
Strabismus	1	0
Ocular sensation disorders		
Abnormal sensation in eye	6	0
Asthenopia	54	0
Eye paraesthesia	1	0
Foreign body sensation in eyes	9	0
Hypoaesthesia eye	4	0
Photophobia	123	0
Optic disc abnormalities NEC		
Papilloedema	1	0
Pupil disorders		
Miosis	1	0
Mydriasis	5	0
Pupillary disorder	1	0
Pupils unequal	3	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal artery occlusion	1	0
Retinal haemorrhage	1	0
Retinal vein occlusion	2	0
Retinal structural change, deposit and degeneration		
Maculopathy	1	0
Retinal toxicity	1	0
Retinal, choroid and vitreous infections and inflammations		
Macular oedema	1	0
Scleral infections, irritations and inflammations		
Episcleritis	3	0
Visual colour distortions		
Cyanopsia	1	0
Erythropsia	2	0
Visual disorders NEC		
Diplopia	34	0
Halo vision	4	0
Metamorphopsia	4	0
Oscillopsia	1	0
Photopsia	33	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Scintillating scotoma	1	0
Vision blurred	259	0
Visual brightness	1	0
Visual impairment and blindness (excl colour blindness)		
Blindness	16	0
Blindness transient	5	0
Blindness unilateral	2	0
Central vision loss	1	0
Sudden visual loss	1	0
Visual acuity reduced	2	0
Visual impairment	79	0
Eye disorders SOC TOTAL	1629	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	4	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	1	0
Pancreatitis necrotising	1	0
<i>Anal and rectal disorders NEC</i>		
Anal sphincter atony	1	0
<i>Anal and rectal pains</i>		
Proctalgia	4	0
<i>Anal and rectal signs and symptoms</i>		
Anal spasm	1	0
Anorectal discomfort	3	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	2	0
<i>Colitis (excl infective)</i>		
Colitis	6	0
Colitis ulcerative	9	0
Crohn's disease	9	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	27	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1760	4
Diarrhoea haemorrhagic	5	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	95	0
Epigastric discomfort	6	0
Eructation	15	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	3	0
Faeces discoloured	12	0
Faeces pale	2	0
Faeces soft	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	66	0
Aerophagia	2	0
Flatulence	53	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	2	1
Oesophageal varices haemorrhage	1	1
<i>Gastric ulcers and perforation</i>		

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Gastric ulcer	1	0
Gastritis (excl infective)		
Gastritis	13	0
Reflux gastritis	3	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal migraine	1	0
Abdominal pain	348	0
Abdominal pain lower	17	0
Abdominal pain upper	553	0
Abdominal rigidity	3	0
Abdominal tenderness	3	0
Gastrointestinal pain	32	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	61	0
Duodenogastric reflux	2	0
Gastric dilatation	3	0
Gastroesophageal reflux disease	31	0
Infrequent bowel movements	1	0
Intestinal pseudo-obstruction	1	0
Gastrointestinal disorders NEC		
Functional gastrointestinal disorder	2	0
Gastric disorder	3	0
Gastrointestinal disorder	2	0
Gastrointestinal dyskinetic disorders		
Change of bowel habit	2	0
Dyschezia	1	0
Gastrointestinal motility disorder	1	0
Gastrointestinal inflammatory disorders NEC		
Duodenitis	1	0
Enteritis	1	0
Gastrointestinal mucosal dystrophies and secretion disorders		
Hyperchlorhydria	2	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	195	0
Abdominal symptom	1	0
Acute abdomen	1	0
Anal incontinence	7	0
Breath odour	7	0
Dysphagia	60	1
Gastrointestinal spastic and hypermotility disorders		
Defaecation urgency	2	0
Frequent bowel movements	10	0
Irritable bowel syndrome	22	0
Oesophageal spasm	2	0
Pylorospasm	1	0
Gastrointestinal stenosis and obstruction NEC		
Intestinal obstruction	1	0
Gastrointestinal vascular malformations		
Gastric antral vascular ectasia	1	0
Gastrointestinal vascular occlusion and infarction		
Intestinal ischaemia	1	0
Gingival disorders, signs and symptoms NEC		
Gingival blister	5	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Gingival discomfort	2	0
Gingival disorder	2	0
Gingival pain	30	0
Gingival swelling	7	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	1	0
Gingival haemorrhages		
Gingival bleeding	10	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)		
Gastric varices	1	0
Haemorrhoids	6	0
Intestinal haemorrhages		
Anal haemorrhage	4	0
Rectal haemorrhage	18	0
Small intestinal haemorrhage	3	0
Intestinal ulcers and perforation NEC		
Intestinal perforation	2	2
Malabsorption syndromes		
Coeliac disease	2	0
Steatorrhoea	1	0
Nausea and vomiting symptoms		
Discoloured vomit	4	0
Nausea	4972	1
Regurgitation	1	0
Retching	38	0
Vomiting	1345	2
Vomiting projectile	24	0
Non-site specific gastrointestinal haemorrhages		
Gastrointestinal haemorrhage	4	0
Haematemesis	15	2
Haematochezia	12	0
Melaena	5	0
Upper gastrointestinal haemorrhage	2	0
Oesophageal stenosis and obstruction		
Oesophageal stenosis	1	0
Oesophagitis (excl infective)		
Oesophagitis	1	0
Oral dryness and saliva altered		
Aptyalism	1	0
Dry mouth	195	0
Lip dry	14	0
Saliva altered	1	0
Salivary hypersecretion	15	0
Oral soft tissue disorders NEC		
Chapped lips	6	0
Cheilitis	10	0
Enlarged uvula	6	0
Lip blister	9	0
Lip disorder	3	0
Oral disorder	3	0
Oral lichen planus	1	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
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	181	0
Lip discolouration	1	0
Lip erythema	1	0
Lip exfoliation	3	0
Lip pain	20	0
Lip pruritus	5	0
Lip scab	1	0
Odynophagia	5	0
Oral discomfort	22	0
Oral dysaesthesia	1	0
Oral mucosal blistering	7	0
Oral mucosal eruption	8	0
Oral mucosal erythema	2	0
Oral mucosal exfoliation	2	0
Oral mucosal roughening	1	0
Oral pain	59	0
Oral pruritus	8	0
Paraesthesia oral	461	0
Oral soft tissue swelling and oedema		
Lip oedema	3	0
Lip swelling	264	0
Mouth swelling	29	0
Oedema mouth	1	0
Palatal oedema	2	0
Palatal swelling	1	0
Peptic ulcers and perforation		
Peptic ulcer haemorrhage	1	0
Peritoneal and retroperitoneal disorders		
Ascites	1	0
Peritoneal and retroperitoneal fibrosis and adhesions		
Abdominal adhesions	1	0
Rectal inflammations NEC		
Proctitis	1	0
Proctitis ulcerative	1	0
Salivary gland disorders NEC		
Salivary gland pain	3	0
Salivary gland enlargements		
Parotid gland enlargement	2	0
Salivary gland enlargement	1	0
Submaxillary gland enlargement	4	0
Stomatitis and ulceration		
Aphthous ulcer	13	0
Lip ulceration	2	0
Mouth ulceration	119	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Stomatitis	19	0
<i>Tongue disorders</i>		
Glossitis	3	0
Plicated tongue	2	0
Tongue disorder	15	0
Tongue haemorrhage	1	0
Tongue ulceration	9	0
<i>Tongue signs and symptoms</i>		
Glossodynia	75	0
Stiff tongue	1	0
Swollen tongue	196	0
Tongue blistering	6	0
Tongue coated	3	0
Tongue discolouration	7	0
Tongue discomfort	18	0
Tongue dry	5	0
Tongue eruption	6	0
Tongue erythema	1	0
Tongue movement disturbance	2	0
Tongue oedema	11	0
Tongue rough	2	0
Tongue spasm	3	0
Gastrointestinal disorders SOC TOTAL	11932	14

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-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	5	0
Administration site warmth	1	0
Puncture site bruise	7	0
Puncture site pain	3	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	1	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	1	0
Application site reaction	1	0
Application site vesicles	1	0
Instillation site warmth	1	0
<i>Asthenic conditions</i>		
Asthenia	494	1
Chronic fatigue syndrome	9	0
Fatigue	7397	0
Malaise	1684	0
Sluggishness	4	0
<i>Body temperature altered</i>		
Hyperthermia	4	0
Hypothermia	14	0
Temperature regulation disorder	4	0
<i>Breast complications associated with device</i>		
Capsular contracture associated with breast implant	1	0
<i>Complications associated with device NEC</i>		
Medical device pain	1	0
Medical device site swelling	1	0
<i>Death and sudden death</i>		
Clinical death	1	1
Death	105	105
Sudden death	15	15
<i>Febrile disorders</i>		
Hyperpyrexia	4	0
Pyrexia	5723	1
<i>Feelings and sensations NEC</i>		

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-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		
Chills	3775	0
Feeling abnormal	353	0
Feeling cold	423	0
Feeling drunk	19	0
Feeling hot	381	0
Feeling jittery	8	0
Feeling of body temperature change	109	0
Hangover	15	0
Hunger	6	0
Sensation of foreign body	19	0
Temperature intolerance	4	0
Thirst	98	0
Gait disturbances		
Gait disturbance	36	0
Gait inability	22	0
Loss of control of legs	3	0
General signs and symptoms NEC		
Condition aggravated	40	0
Crepitations	1	0
Crying	26	0
Disease recurrence	3	0
Energy increased	3	0
Exercise tolerance decreased	2	0
General physical health deterioration	4	1
Glassy eyes	2	0
Illness	509	1
Induration	2	0
Influenza like illness	881	0
Irritability postvaccinal	1	0
Local reaction	53	0
Moaning	1	0
Multiple organ dysfunction syndrome	1	1
Nonspecific reaction	1	0
Peripheral swelling	926	0
Pre-existing condition improved	3	0
Screaming	2	0
Secretion discharge	6	0
Swelling	677	0
Swelling face	278	0
Implant and catheter site reactions		
Implant site pain	1	0
Implant site rash	1	0
Inflammations		
Inflammation	86	0
Papillitis	1	0
Systemic inflammatory response syndrome	1	0
Infusion site reactions		
Infusion site coldness	1	0
Infusion site joint pain	2	0
Infusion site pain	1	0
Infusion site swelling	1	0
Infusion site urticaria	1	0
Injection site reactions		

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-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		
Injected limb mobility decreased	11	0
Injection site bruising	18	0
Injection site cyst	1	0
Injection site discolouration	2	0
Injection site discomfort	5	0
Injection site erythema	156	0
Injection site haemorrhage	2	0
Injection site hypoaesthesia	6	0
Injection site indentation	1	0
Injection site induration	2	0
Injection site inflammation	13	0
Injection site joint movement impairment	1	0
Injection site joint pain	9	0
Injection site mass	151	0
Injection site necrosis	2	0
Injection site oedema	10	0
Injection site pain	1228	0
Injection site paraesthesia	5	0
Injection site pruritus	73	0
Injection site rash	46	0
Injection site reaction	14	0
Injection site scab	2	0
Injection site scar	2	0
Injection site swelling	149	0
Injection site urticaria	9	0
Injection site vesicles	3	0
Injection site warmth	61	0
Interactions		
Alcohol interaction	2	0
Drug interaction	3	0
Mass conditions NEC		
Cyst	5	0
Mass	6	0
Nodule	5	0
Mucosal findings abnormal		
Mucosal haemorrhage	2	0
Oedema mucosal	1	0
Necrosis NEC		
Fat necrosis	1	0
Oedema NEC		
Face oedema	12	0
Localised oedema	12	0
Oedema	10	0
Oedema peripheral	19	0
Pain and discomfort NEC		
Axillary pain	410	0
Chest discomfort	435	0
Chest pain	597	0
Discomfort	46	0
Facial discomfort	6	0
Facial pain	68	0
Inflammatory pain	1	0
Non-cardiac chest pain	7	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-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		
Pain	2267	0
Suprapubic pain	1	0
Tenderness	222	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	21	0
Adverse reaction	1	0
Drug ineffective	86	0
Immediate post-injection reaction	2	0
No reaction on previous exposure to drug	13	0
Therapeutic product effect delayed	1	0
Therapeutic product effect increased	1	0
Therapeutic response unexpected	10	0
Treatment failure	5	0
Ulcers NEC		
Ulcer	6	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	3	0
Shoulder injury related to vaccine administration	3	0
Vaccination site bruising	39	0
Vaccination site cyst	1	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	6	0
Vaccination site discomfort	21	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	256	0
Vaccination site haemorrhage	6	0
Vaccination site hypersensitivity	2	0
Vaccination site hypoaesthesia	5	0
Vaccination site induration	41	0
Vaccination site inflammation	30	0
Vaccination site irritation	4	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	4	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	2	0
Vaccination site macule	1	0
Vaccination site mass	77	0
Vaccination site movement impairment	23	0
Vaccination site oedema	3	0
Vaccination site pain	929	0
Vaccination site paraesthesia	4	0
Vaccination site pruritus	57	0
Vaccination site rash	40	0
Vaccination site reaction	12	0
Vaccination site scab	1	0
Vaccination site swelling	268	0
Vaccination site ulcer	1	0
Vaccination site urticaria	6	0
Vaccination site vesicles	2	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-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 warmth	144	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	3	0
Withdrawal syndrome	4	0
General disorders SOC TOTAL	32603	126

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-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	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>		
Hepatic artery embolism	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	7	0
Liver tenderness	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Drug-induced liver injury	1	0
Hepatitis	2	0
Liver injury	3	0
Hepatic disorders SOC TOTAL	22	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-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	6	0
<i>Allergic conditions NEC</i>		
Allergic oedema	6	0
Allergy to arthropod bite	1	0
Hypersensitivity	291	0
Multiple allergies	1	0
Serum sickness	2	0
Serum sickness-like reaction	2	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	18	1
Contrast media reaction	1	0
Drug hypersensitivity	6	0
Food allergy	4	0
Oral allergy syndrome	1	0
Reaction to colouring	1	0
Reaction to excipient	1	0
Reaction to preservatives	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	212	0
Anaphylactic shock	13	0
Anaphylactoid reaction	10	0
Anaphylactoid shock	2	0
<i>Atopic disorders</i>		
Atopy	1	0
Seasonal allergy	3	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	6	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	6	0
Immune system disorder	5	0
Immune-mediated adverse reaction	1	0
Systemic immune activation	1	0
Immune system disorders SOC TOTAL	614	1

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-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	4	0
Diverticulitis	2	0
Dysentery	1	0
Gastroenteritis	9	0
<i>Aspergillus infections</i>		
Bronchopulmonary aspergillosis	1	0
<i>Bacterial infections NEC</i>		
Arthritis bacterial	1	0
Bacterial diarrhoea	1	0
Cellulitis	62	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
Injection site cellulitis	1	0
Meningitis bacterial	1	0
Tonsillitis bacterial	1	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	11	0
<i>Breast infections</i>		
Breast abscess	1	0
Mastitis	9	0
<i>Candida infections</i>		
Anal candidiasis	1	0
Candida infection	5	0
Oral candidiasis	13	0
Vulvovaginal candidiasis	9	0
<i>Central nervous system and spinal infections</i>		
Encephalitis	3	0
Meningitis	2	0
Meningitis aseptic	1	0
Myelitis	1	0
<i>Clostridia infections</i>		
Clostridium difficile infection	1	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	7	0
COVID-19	483	25
COVID-19 pneumonia	15	4
Coronavirus infection	5	0
Suspected COVID-19	30	1
<i>Coxiella infections</i>		
Q fever	5	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	3	0
Gingivitis	2	0
Parotitis	6	0
Pulpitis dental	1	0
Sialoadenitis	1	0
Tooth abscess	1	0
<i>Ear infections</i>		
Ear infection	15	0
Labyrinthitis	25	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	1	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Infectious mononucleosis	3	0
Eye and eyelid infections		
Conjunctivitis	29	0
Eye abscess	1	0
Eye infection	5	0
Hordeolum	5	0
Periorbital infection	1	0
Female reproductive tract infections		
Bartholinitis	1	0
Vulval abscess	1	0
Fungal infections NEC		
Fungal skin infection	1	0
Pneumonia fungal	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	10	0
Genital herpes simplex	1	0
Herpes ophthalmic	1	0
Herpes simplex	4	0
Herpes simplex reactivation	1	0
Herpes virus infection	3	0
Herpes zoster	303	0
Herpes zoster oticus	3	0
Nasal herpes	1	0
Ophthalmic herpes zoster	1	0
Oral herpes	97	0
Varicella	3	0
Varicella zoster virus infection	1	0
Infections NEC		
Abscess	5	0
Abscess limb	1	0
Abscess soft tissue	1	0
Infection	69	0
Injection site abscess	1	0
Injection site infection	3	0
Localised infection	8	0
Lymph gland infection	3	0
Lymph node abscess	1	0
Respiratory tract infection	2	0
Vaccination site abscess	2	0
Vaccination site infection	7	0
Vestibulitis	1	0
Influenza viral infections		
Influenza	489	0
Lower respiratory tract and lung infections		
Bronchitis	4	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	44	5
Pneumonia	25	6
Sputum purulent	1	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections		
<i>Infections cont'd</i>		
<i>Male reproductive tract infections</i>		
Epididymitis	2	0
Orchitis	2	0
<i>Mumps viral infections</i>		
Mumps	2	0
<i>Muscle and soft tissue infections</i>		
Soft tissue infection	1	0
<i>Neisseria infections</i>		
Gonorrhoea	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	15	1
Septic pulmonary embolism	1	0
Septic shock	1	0
Urosepsis	2	0
<i>Skin structures and soft tissue infections</i>		
Acne pustular	1	0
Dermatitis infected	1	0
Folliculitis	3	0
Paronychia	1	0
Pustule	5	0
Rash pustular	4	0
Skin infection	7	0
Subcutaneous abscess	2	0
Vaccination site pustule	1	0
<i>Staphylococcal infections</i>		
Furuncle	11	0
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	2	0
<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	226	0
Pharyngitis	5	0
Rhinitis	18	0
Sinusitis	28	0
Tonsillitis	23	0
Tracheitis	1	0
<i>Urinary tract infections</i>		
Cystitis	13	0
Kidney infection	6	0
Pyelonephritis	1	0
Urinary tract infection	42	0
<i>Vascular infections</i>		
Haematoma infection	1	0
Lymphangitis	2	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Eye infection viral	1	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name		Total	Fatal
Infections	Infections cont'd		
Gastroenteritis viral		6	0
Meningitis viral		1	0
Pneumonia viral		1	1
Post viral fatigue syndrome		11	0
Sweating fever		42	0
Vestibular neuronitis		6	0
Viral infection		4	0
Viral labyrinthitis		2	0
Viral pharyngitis		5	0
Viral rash		14	0
Viral tonsillitis		1	0
Infections SOC TOTAL		2429	43

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

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	10	0
<i>Anaesthetic and allied procedural complications</i>		
Delayed recovery from anaesthesia	1	0
<i>Bone and joint injuries NEC</i>		
Joint injury	1	0
<i>Cardiovascular injuries</i>		
Heart injury	2	0
<i>Cerebral injuries NEC</i>		
Traumatic intracranial haemorrhage	1	1
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Conditions caused by cold</i>		
Chillblains	17	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	3	0
Foetal exposure during pregnancy	3	0
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	67	0
Maternal exposure during pregnancy	46	0
<i>Eye injuries NEC</i>		
Eye contusion	5	0
Eye injury	2	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	4	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	4	0
Product use issue	5	0
Vaccination error	1	0
Wrong drug	1	0
Wrong technique in product usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	3	0
Ligament sprain	1	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Muscle injury	2	0
Muscle rupture	1	0
Muscle strain	6	0
Tendon injury	2	0
Musculoskeletal procedural complications		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
Nerve injuries NEC		
Nerve injury	7	0
Neurological and psychiatric procedural complications		
Procedural dizziness	6	0
Non-site specific injuries NEC		
Bite	1	0
Electric shock	5	0
Fall	43	1
Wound	2	0
Wound complication	4	0
Wound secretion	1	0
Non-site specific procedural complications		
Incision site pain	2	0
Infusion related reaction	3	0
Injection related reaction	22	0
Post procedural complication	3	0
Off label uses		
Off label use	7	0
Overdoses NEC		
Overdose	7	0
Peripheral nerve injuries		
Ulnar nerve injury	3	0
Poisoning and toxicity		
Poisoning	2	0
Toxicity to various agents	1	0
Product administration errors and issues		
Accidental overdose	1	0
Contraindicated product administered	1	0
Inappropriate schedule of product administration	10	0
Incomplete course of vaccination	1	0
Product administered at inappropriate site	4	0
Product administered to patient of inappropriate age	1	0
Product administration error	1	0
Product dose omission issue	3	0
Product confusion errors and issues		
Product label confusion	1	0
Product preparation errors and issues		
Product preparation issue	3	0
Radiation injuries		
Sunburn	3	0
Site specific injuries NEC		
Face crushing	1	0
Head injury	4	0
Limb injury	9	0
Skin injuries NEC		
Contusion	156	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
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
Spinal fractures and dislocations		
Spinal fracture	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	3	0
Thermal burns of eye	4	0
Underdoses NEC		
Underdose	1	0
Vaccination related complications		
Vaccination complication	21	0
Vaccination failure	1	0
Injuries SOC TOTAL	587	2

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Cortisol decreased	2	0
<i>Autoimmunity analyses</i>		
Rheumatoid factor	2	0
<i>Blood counts NEC</i>		
Blood count	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	4	0
Oxygen saturation decreased	27	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	8	0
Blood glucose fluctuation	7	0
Blood glucose increased	46	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>		
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	2	0
<i>Coagulation and bleeding analyses</i>		
Bleeding time abnormal	1	0
Coagulation time prolonged	1	0
Fibrin D dimer increased	3	0
International normalised ratio abnormal	1	0
International normalised ratio decreased	9	0
International normalised ratio increased	25	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
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	3	0
<i>Heart rate and pulse investigations</i>		
Heart rate	70	0
Heart rate abnormal	4	0
Heart rate decreased	13	0
Heart rate increased	191	0
Heart rate irregular	22	0
Pulse abnormal	7	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Radial pulse abnormal	1	0
Immunoglobulin analyses		
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M increased	1	0
Immunology analyses NEC		
Antibody test	1	0
Antibody test abnormal	2	0
Immunology test	3	0
Immunology skin tests NEC		
Skin test positive	1	0
Investigations NEC		
Blood test	1	0
Blood test abnormal	3	0
Polymerase chain reaction positive	27	0
Systemic lupus erythematosus disease activity index increased	1	0
Liver function analyses		
Alanine aminotransferase increased	5	0
Aspartate aminotransferase increased	1	0
Gamma-glutamyltransferase increased	1	0
Hepatic enzyme increased	1	0
Liver function test abnormal	3	0
Liver function test increased	6	0
Transaminases increased	1	0
Metabolism tests NEC		
Blood ketone body	2	0
Blood ketone body increased	1	0
Microbiology and serology tests NEC		
Culture negative	1	0
Mineral and electrolyte analyses		
Blood copper increased	1	0
Blood magnesium decreased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	2	0
Serum ferritin increased	1	0
Musculoskeletal and soft tissue tests NEC		
Swollen joint count increased	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	2	0
Temperature perception test increased	1	0
Ophthalmic function diagnostic procedures		
Intraocular pressure increased	1	0
Physical examination procedures and organ system status		
Body temperature	105	0
Body temperature abnormal	19	0
Body temperature decreased	15	0
Body temperature fluctuation	9	0
Body temperature increased	179	0
Body temperature normal	1	0
Breath sounds abnormal	1	0
Grip strength	2	0
Grip strength decreased	3	0
Lymph node palpable	10	0
Palpatory finding abnormal	1	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Product residue present	1	0
Respiratory rate	2	0
Respiratory rate decreased	2	0
Respiratory rate increased	16	0
Skin temperature	15	0
Temperature difference of extremities	3	0
Weight	1	0
Weight decreased	13	0
Weight increased	3	0
Pituitary analyses anterior		
Blood growth hormone	2	0
Blood thyroid stimulating hormone increased	2	0
Platelet analyses		
Platelet count decreased	6	0
Protein analyses NEC		
C-reactive protein increased	4	0
Red blood cell analyses		
Haematocrit	1	0
Haemoglobin decreased	4	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume increased	2	0
Peak expiratory flow rate abnormal	1	0
Peak expiratory flow rate decreased	1	0
Vital capacity	1	0
Respiratory tract and thoracic histopathology procedures		
Sputum abnormal	2	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	2	0
Troponin increased	3	0
Therapeutic drug monitoring analyses		
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		
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	3	0
Blood urine present	10	0
Glucose urine present	1	0
Urine analysis abnormal	1	0
pH urine	2	0
pH urine increased	1	0
Urinary tract function analyses NEC		
Urine output	5	0
Urine output decreased	4	0
Urine output increased	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	3	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Blood pressure decreased	12	0
Blood pressure diastolic	1	0
Blood pressure increased	85	0
Blood pressure measurement	8	0
Blood pressure systolic decreased	1	0
Blood pressure systolic increased	1	0
<i>Virus identification and serology</i>		
Coronavirus test	1	0
Coronavirus test positive	2	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	2	0
SARS-CoV-2 antibody test negative	13	0
SARS-CoV-2 antibody test positive	2	0
SARS-CoV-2 test	13	0
SARS-CoV-2 test false positive	1	0
SARS-CoV-2 test negative	2	0
SARS-CoV-2 test positive	38	0
Viral test	1	0
<i>Vitamin analyses</i>		
Blood folate decreased	1	0
<i>White blood cell analyses</i>		
White blood cell count decreased	2	0
White blood cell count increased	1	0
Investigations SOC TOTAL	1225	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	3	0
Decreased appetite	430	0
Eating disorder symptom	1	0
Food craving	3	0
Food refusal	4	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	9	0
Diabetes mellitus inadequate control	3	1
Increased insulin requirement	1	0
Latent autoimmune diabetes in adults	1	0
Type 1 diabetes mellitus	6	0
<i>Diabetic complications NEC</i>		
Diabetic complication	1	0
Diabetic ketoacidosis	4	0
<i>Disorders of purine metabolism</i>		
Gout	21	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>		
Gluten sensitivity	1	0
Histamine intolerance	2	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	1	0
Abnormal weight gain	4	0
Feeding disorder	14	0
Food aversion	2	0
Overweight	1	0
Poor feeding infant	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	31	0
Insulin resistance	2	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	35	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
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Ketoacidosis	4	0
Metabolic acidosis	2	0
<i>Mixed acid-base disorders</i>		
Acidosis	2	0
<i>Potassium imbalance</i>		

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Hyperkalaemia	2	0
Hypokalaemia	2	0
Hypokalaemic syndrome	1	0
Sodium imbalance		
Hyponatraemia	5	0
Hyponatraemic syndrome	1	0
Total fluid volume decreased		
Dehydration	52	0
Total fluid volume increased		
Fluid retention	6	0
Hypervolaemia	1	0
Vitamin deficiencies NEC		
Hypovitaminosis	1	0
Metabolic disorders SOC TOTAL	681	1

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	69	0
Arthropathy	7	0
Joint microhaemorrhage	1	0
Polyarthritis	3	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	109	0
Bone swelling	3	0
Coccydynia	1	0
Pain in jaw	104	0
Spinal pain	15	0
<i>Bursal disorders</i>		
Bursitis	11	0
<i>Cartilage disorders</i>		
Costochondritis	13	0
Polychondritis	1	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	8	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	19	0
Temporomandibular joint syndrome	2	0
<i>Joint related signs and symptoms</i>		
Arthralgia	3070	0
Jaw clicking	2	0
Joint effusion	8	0
Joint noise	5	0
Joint range of motion decreased	2	0
Joint stiffness	72	0
Joint swelling	98	0
Joint vibration	1	0
Joint warmth	5	0
<i>Ligament disorders</i>		
Symphysiolysis	1	0
<i>Lupus erythematosus (incl subtypes)</i>		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	3	0
<i>Muscle infections and inflammations</i>		
Antisynthetase syndrome	1	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Myositis	5	0
Polymyositis	1	0
Muscle pains		
Fibromyalgia	22	0
Myalgia	4346	0
Myofascial pain syndrome	5	0
Muscle related signs and symptoms NEC		
Muscle atrophy	2	0
Muscle discomfort	1	0
Muscle disorder	2	0
Muscle fatigue	119	0
Muscle spasms	202	0
Muscle swelling	9	0
Muscle tightness	22	0
Muscle twitching	95	0
Muscle tone abnormalities		
Muscle rigidity	7	0
Nuchal rigidity	5	0
Torticollis	2	0
Trismus	9	0
Muscle weakness conditions		
Muscular weakness	241	0
Musculoskeletal and connective tissue conditions NEC		
Limb mass	2	0
Mandibular mass	2	0
Mastication disorder	1	0
Mobility decreased	19	0
Musculoskeletal disorder	4	0
Musculoskeletal stiffness	354	0
Posture abnormal	1	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Fasciitis	1	0
Plantar fasciitis	3	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	663	0
Flank pain	10	0
Limb discomfort	462	0
Musculoskeletal chest pain	45	0
Musculoskeletal discomfort	24	0
Musculoskeletal pain	19	0
Neck pain	543	0
Pain in extremity	3602	0
Rheumatic disorder	1	0
Myopathies		
Rhabdomyolysis	3	0
Osteoarthropathies		
Osteoarthritis	7	0
Psoriatic arthropathies		
Psoriatic arthropathy	5	0
Rheumatoid arthropathies		
Rheumatoid arthritis	28	0
Soft tissue disorders NEC		
Axillary mass	58	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Groin pain	30	0
Neck mass	11	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	4	0
Arthritis reactive	11	0
<i>Synovial disorders</i>		
Synovial cyst	5	0
Synovitis	3	0
<i>Tendon disorders</i>		
Enthesopathy	1	0
Tendon pain	3	0
Tendonitis	8	0
Tenosynovitis	1	0
Tenosynovitis stenosaurs	1	0
Trigger finger	1	0
<i>Trunk deformities</i>		
Drooping shoulder syndrome	1	0
Muscle & tissue disorders SOC TOTAL	14683	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Neoplasms		
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	5	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	6	0
<i>Metastases to specified sites</i>		
Metastases to liver	1	0
Metastases to lymph nodes	4	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	1	0
Second primary malignancy	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	1	0
<i>Plasma cell myelomas</i>		
Plasma cell myeloma	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	1	0
Anogenital warts	1	0
Melanocytic naevus	2	0
Skin papilloma	1	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Neoplasm skin	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	1	0
Lymphangioma	1	0
<i>Soft tissue sarcomas histology unspecified</i>		
Sarcoma	1	0
Neoplasms SOC TOTAL	32	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	1	0
Extensor plantar response	1	0
Hyperreflexia	1	0
Hyporeflexia	4	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	3	0
<i>Absence seizures</i>		
Petit mal epilepsy	7	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	11	1
<i>Autonomic nervous system disorders</i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	2	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 infarction	2	0
Cerebellar stroke	2	0
Cerebral artery occlusion	1	0
Cerebral haemorrhage	10	3
Cerebral infarction	7	0
Cerebrovascular accident	71	3
Embolic stroke	1	0
Haemorrhage intracranial	3	0
Haemorrhagic stroke	1	1
Ischaemic cerebral infarction	1	0
Ischaemic stroke	12	1
Lacunar infarction	2	0
Lacunar stroke	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	2	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	2	0
Balance disorder	104	0
Coordination abnormal	13	0
Dysstasia	15	0
Nystagmus	3	0
<i>Cortical dysfunction NEC</i>		
Aphasia	17	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
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	11	1
Lethargy	828	0
Loss of consciousness	113	0
Sedation	3	0
Somnolence	279	0
Stupor	1	0
Syncope	349	0
Dyskinesias and movement disorders NEC		
Akathisia	1	0
Bradykinesia	4	0
Clumsiness	1	0
Dyskinesia	9	0
Extrapyramidal disorder	1	0
Fine motor skill dysfunction	3	0
Hypokinesia	8	1
Motor dysfunction	1	0
Movement disorder	13	0
Psychomotor hyperactivity	5	0
Dystonias		
Dystonia	7	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 paralysis	2	0
IVth nerve paralysis	1	0
VIth nerve paralysis	3	0
Facial cranial nerve disorders		
Facial nerve disorder	1	0
Facial paralysis	220	0
Facial paresis	32	0
Facial spasm	15	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	9	0
Headaches NEC		
Cervicogenic headache	2	0
Cluster headache	66	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Cold-stimulus headache	3	0
Drug withdrawal headache	1	0
Exertional headache	5	0
Headache	9636	0
Medication overuse headache	2	0
New daily persistent headache	2	0
Occipital neuralgia	2	0
Ophthalmoplegic migraine	1	0
Primary cough headache	2	0
Primary headache associated with sexual activity	1	0
Sinus headache	127	0
Tension headache	163	0
Thunderclap headache	1	0
Vascular headache	6	0
Hypoglossal nerve disorders		
Tongue paralysis	1	0
Lumbar spinal cord and nerve root disorders		
Sciatica	19	0
Memory loss (excl dementia)		
Amnesia	25	0
Memory impairment	33	0
Transient global amnesia	4	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	18	0
Disturbance in attention	77	0
Mental impairment	12	0
Migraine headaches		
Hemiplegic migraine	3	0
Migraine	723	0
Migraine with aura	44	0
Migraine without aura	2	0
Retinal migraine	10	0
Typical aura without headache	1	0
Vestibular migraine	5	0
Mononeuropathies		
Carpal tunnel syndrome	5	0
Mononeuropathy	1	0
Nerve compression	3	0
Peroneal nerve palsy	2	0
Sciatic nerve neuropathy	1	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	7	0
Multiple sclerosis relapse	9	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	11	0
Narcolepsy and hypersomnia		
Hypersomnia	23	0
Narcolepsy	2	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Nervous system disorders NEC</i>		
Nervous system disorder	1	0
<i>Neurologic visual problems NEC</i>		
Hemianopia	1	0
Tunnel vision	4	0
Visual field defect	5	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	2863	0
Dizziness exertional	14	0
Dizziness postural	255	0
Drooling	3	0
Head discomfort	68	0
Hyporesponsive to stimuli	1	0
Inability to crawl	1	0
Myoclonus	6	0
Neurological symptom	11	0
Persistent postural-perceptual dizziness	5	0
Presyncope	183	0
Slow response to stimuli	2	0
Tongue biting	1	0
Unresponsive to stimuli	19	1
<i>Neuromuscular disorders NEC</i>		
Muscle contractions involuntary	6	0
Muscle spasticity	4	0
Neuromuscular pain	1	0
<i>Neuromuscular junction dysfunction</i>		
Myasthenia gravis	2	0
Myasthenia gravis crisis	1	0
<i>Olfactory nerve disorders</i>		
Anosmia	76	0
Hyposmia	6	0
Parosmia	68	0
<i>Optic nerve disorders NEC</i>		
Optic neuritis	6	0
<i>Paraesthesias and dysaesthesias</i>		
Burning feet syndrome	2	0
Burning sensation	122	0
Dysaesthesia	3	0
Formication	12	0
Hand-arm vibration syndrome	1	0
Hemiparaesthesia	1	0
Hyperaesthesia	27	0
Hypoaesthesia	669	0
Paraesthesia	974	0
Reversed hot-cold sensation	1	0
Synaesthesia	1	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Diplegia	2	1
Hemiparesis	12	0
Hemiplegia	7	0
Locked-in syndrome	1	0
Monoparesis	18	0
Monoplegia	18	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-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		
Paralysis	23	0
Paraparesis	1	0
Paresis	1	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	3	0
Parkinsonian gait	1	0
Parkinsonism	4	0
Partial complex seizures		
Dreamy state	2	0
Temporal lobe epilepsy	1	0
Peripheral neuropathies NEC		
Neuritis	2	0
Neuropathy peripheral	27	0
Peripheral sensory neuropathy	3	0
Seizures and seizure disorders NEC		
Atonic seizures	3	0
Clonic convulsion	1	0
Epilepsy	39	0
Epileptic encephalopathy	1	0
Febrile convulsion	1	0
Partial seizures	6	0
Post stroke seizure	1	0
Psychogenic seizure	4	0
Seizure	131	1
Seizure cluster	4	0
Seizure like phenomena	1	0
Status epilepticus	4	0
Tonic clonic movements	1	0
Tonic convulsion	7	0
Sensory abnormalities NEC		
Ageusia	164	0
Allodynia	5	0
Aura	7	0
Dysgeusia	427	0
Hypergeusia	1	0
Loss of proprioception	1	0
Neuralgia	100	0
Phantom limb syndrome	3	0
Post herpetic neuralgia	3	0
Restless legs syndrome	27	0
Sensory disturbance	17	0
Sensory loss	11	0
Taste disorder	84	0
Sleep disturbances NEC		
Poor quality sleep	57	0
Sleep deficit	2	0
Speech and language abnormalities		
Dysarthria	45	0
Incoherent	1	0
Repetitive speech	1	0
Speech disorder	7	0
Spinal cord and nerve root disorders NEC		
Radiculitis brachial	1	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-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		
Radiculopathy	1	0
Structural brain disorders NEC		
Brain injury	2	2
Transient cerebrovascular events		
Transient ischaemic attack	23	0
Tremor (excl congenital)		
Essential tremor	1	0
Resting tremor	1	0
Tremor	530	0
Trigeminal disorders		
Facial neuralgia	10	0
Numb chin syndrome	1	0
Trigeminal nerve disorder	2	0
Trigeminal neuralgia	15	0
Nervous system disorders SOC TOTAL	20632	18

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-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	26	0
<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	3	0
Pregnancy conditions SOC TOTAL	39	1

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

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 stimulation issue	1	0
Oversensing	6	0
Thrombosis in device	1	0
<i>Device physical property and chemical issues</i>		
Needle issue	1	0
<i>Product physical issues</i>		
Product odour abnormal	1	0
Product taste abnormal	4	0
<i>Product quality issues NEC</i>		
Product origin unknown	1	0
null SOC TOTAL	17	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	2	0
<i>Affect alterations NEC</i>		
Affect lability	1	0
Constricted affect	1	0
Flat affect	2	0
Inappropriate affect	2	0
<i>Amnesic symptoms</i>		
Paramnesia	1	0
<i>Anxiety symptoms</i>		
Agitation	29	0
Anxiety	149	0
Immunisation anxiety related reaction	1	0
Nervousness	65	0
Stress	4	0
Tension	13	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 disorder	1	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	2	0
Mental fatigue	61	0
<i>Communications disorders</i>		
Communication disorder	2	0
<i>Confusion and disorientation</i>		
Confusional state	223	0
Disorientation	77	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	38	0
<i>Delusional symptoms</i>		
Delusion	2	0
<i>Depressive disorders</i>		
Agitated depression	1	0
Depression	50	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	2	0
Dissociation	5	0
Dissociative amnesia	1	0
Dissociative disorder	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	4	0
Insomnia	293	0
Middle insomnia	6	0
Terminal insomnia	2	0
<i>Dyssomnias</i>		

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Dyssomnia	1	0
Eating disorders NEC		
Eating disorder	2	0
Selective eating disorder	1	0
Emotional and mood disturbances NEC		
Anger	3	0
Dysphoria	1	0
Emotional disorder	8	0
Emotional distress	6	0
Euphoric mood	8	0
Irritability	46	0
Mood altered	10	0
Fear symptoms and phobic disorders (incl social phobia)		
Fear of falling	1	0
Osmophobia	1	0
Phonophobia	1	0
Social fear	1	0
Fluctuating mood symptoms		
Mood swings	9	0
Hallucinations (excl sleep-related)		
Hallucination	61	0
Hallucination, auditory	3	0
Hallucination, olfactory	3	0
Hallucination, tactile	1	0
Hallucination, visual	6	0
Hallucinations, mixed	1	0
Increased physical activity levels		
Restlessness	28	0
Mental disorders NEC		
Mental disorder	3	0
Mental disorders due to a general medical condition NEC		
Neuropsychiatric symptoms	1	0
Mood alterations with depressive symptoms		
Decreased interest	4	0
Depressed mood	69	0
Feeling of despair	1	0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Sense of a foreshortened future	2	0
Tearfulness	8	0
Mood alterations with manic symptoms		
Hypomania	1	0
Mania	2	0
Mood disorders NEC		
Apathy	7	0
Laziness	1	0
Listless	6	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	2	0
Sleep attacks	3	0
Obsessive-compulsive disorders and symptoms		
Obsessive-compulsive symptom	1	0
Orgasmic disorders and disturbances		

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
Anorgasmia	1	0
Panic attacks and disorders		
Panic attack	28	0
Panic disorder	3	0
Panic reaction	6	0
Parasomnias		
Abnormal dreams	59	0
Confusional arousal	1	0
Nightmare	47	0
Parasomnia	1	0
Sleep terror	3	0
Perception disturbances NEC		
Autoscopy	3	0
Derealisation	4	0
Flashback	1	0
Illusion	1	0
Psychiatric elimination disorders		
Enuresis	4	0
Psychiatric symptoms NEC		
Hypervigilance	2	0
Trance	1	0
Psychotic disorder NEC		
Psychotic behaviour	1	0
Psychotic disorder	7	0
Sexual desire disorders		
Libido decreased	1	0
Libido increased	1	0
Loss of libido	3	0
Sleep disorders NEC		
Sleep disorder	49	0
Somatic symptom disorders		
Habit cough	6	0
Somatic symptom disorder	1	0
Vomiting psychogenic	1	0
Speech and language usage disturbances		
Disorganised speech	2	0
Logorrhoea	2	0
Speech articulation and rhythm disturbances		
Dysphemia	2	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
Stereotypies and automatisms		
Bruxism	4	0
Head banging	2	0
Stereotypy	1	0
Stress disorders		
Post-traumatic stress disorder	1	0
Substance related and addictive disorders		
Alcoholic hangover	1	0
Suicidal and self-injurious behaviour		
Intentional self-injury	2	0
Suicidal ideation	2	0
Suicide attempt	1	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Psychiatric disorders Psychiatric disorders cont'd		
<i>Thinking disturbances</i>		
Bradyphrenia	12	0
Tachyphrenia	1	0
Thinking abnormal	3	0
Psychiatric disorders SOC TOTAL	1645	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	1	0
Bladder pain	3	0
Dysuria	11	0
Incontinence	11	0
Micturition disorder	1	0
Micturition urgency	7	0
Pollakiuria	20	0
Urethral pain	1	0
Urinary incontinence	23	0
Urinary retention	18	0
Urine flow decreased	1	0
<i>Bladder disorders NEC</i>		
Bladder disorder	3	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	2	0
Glomerulonephritis rapidly progressive	1	0
Nephrotic syndrome	5	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	1	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	15	0
Anuria	2	0
Chronic kidney disease	1	0
Renal failure	5	0
Renal impairment	4	0
<i>Renal vascular and ischaemic conditions</i>		
Renal vasculitis	1	1
<i>Urinary abnormalities</i>		
Chromaturia	15	0
Haematuria	11	0
Proteinuria	3	0
Urine abnormality	5	0
Urine odour abnormal	4	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	5	0
Nocturia	1	0
Polyuria	2	0
Renal pain	69	0
Urinary tract pain	1	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Renal & urinary disorders SOC TOTAL	264	1

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

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	2	0
<i>Breast disorders NEC</i>		
Breast mass	15	0
Gynaecomastia	1	0
<i>Breast signs and symptoms</i>		
Breast discomfort	2	0
Breast haematoma	1	0
Breast oedema	1	0
Breast pain	76	0
Breast swelling	17	0
Breast tenderness	8	0
Nipple pain	5	0
Nipple swelling	2	0
<i>Cervix disorders NEC</i>		
Cervical dysplasia	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	11	0
Erection increased	1	0
<i>Menopausal effects NEC</i>		
Artificial menopause	1	0
Menopausal symptoms	2	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	3	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysfunctional uterine bleeding	1	0
Dysmenorrhoea	25	0
Menstrual disorder	33	0
Menstruation irregular	23	0
Metrorrhagia	14	0
Premenstrual pain	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	14	0
Hypomenorrhoea	16	0
Menstruation delayed	55	0
Oligomenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	60	0
Polymenorrhoea	9	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	3	0
Pelvic haemorrhage	3	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile swelling	3	0
Penis disorder	2	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	1	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatomegaly	2	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
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	10	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	7	0
Testicular swelling	3	0
Uterine disorders NEC		
Endometriosis	3	0
Uterine pain	1	0
Uterine tone disorders		
Uterine spasm	1	0
Vulvovaginal cysts and neoplasms		
Vaginal cyst	1	0
Vulvovaginal disorders NEC		
Vaginal haemorrhage	49	0
Vulval haemorrhage	2	0
Vulval ulceration	2	0
Vulvovaginal ulceration	1	0
Vulvovaginal signs and symptoms		
Vaginal discharge	2	0
Vulval oedema	1	0
Vulvovaginal burning sensation	1	0
Vulvovaginal pain	2	0
Vulvovaginal pruritus	1	0
Reproductive & breast disorders SOC TOTAL	527	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021
Earliest Reaction Date: 03-Apr-1990

Data Lock Date: 14-Mar-2021 19:00:03
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Dyspnoea	1056	2
Dyspnoea at rest	1	0
Dyspnoea exertional	9	1
Hyperventilation	14	0
Hypopnoea	20	0
Irregular breathing	8	0
Mouth breathing	3	0
Orthopnoea	3	0
Respiration abnormal	21	0
Respiratory arrest	5	0
Respiratory depression	1	0
Respiratory distress	5	0
Sleep apnoea syndrome	3	0
Tachypnoea	17	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	1	0
Bronchiectasis	4	0
<i>Bronchospasm and obstruction</i>		
Asthma	105	0
Asthma late onset	2	0
Bronchospasm	6	0
Chronic obstructive pulmonary disease	7	0
Obstructive airways disorder	1	0
Reversible airways obstruction	1	0
Wheezing	145	0
<i>Conditions associated with abnormal gas exchange</i>		
Cyanosis central	1	0
Hypoxia	14	1
Respiratory acidosis	1	0
<i>Coughing and associated symptoms</i>		
Allergic cough	2	0
Cough	754	1
Cough decreased	2	0
Haemoptysis	8	0
Productive cough	42	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	5	3
Pneumonitis	9	3
Pulmonary sarcoidosis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	3	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Increased bronchial secretion	1	0
Pleuritic pain	6	0
Pulmonary pain	32	0
Rales	2	0
Nasal congestion and inflammations		
Nasal congestion	68	0
Nasal inflammation	1	0
Rhinitis allergic	4	0
Nasal disorders NEC		
Epistaxis	190	0
Intranasal hypoaesthesia	1	0
Intranasal paraesthesia	1	0
Nasal disorder	1	0
Nasal dryness	9	0
Nasal odour	4	0
Nasal oedema	1	0
Nasal pruritus	4	0
Paranasal sinus disorders (excl infections and neoplasms)		
Allergic sinusitis	1	0
Paranasal sinus inflammation	1	0
Sinonasal obstruction	4	0
Sinus congestion	14	0
Sinus disorder	2	0
Parenchymal lung disorders NEC		
Atelectasis	1	0
Emphysema	1	0
Pharyngeal disorders (excl infections and neoplasms)		
Pharyngeal erythema	3	0
Pharyngeal haemorrhage	1	0
Pharyngeal hypoaesthesia	12	0
Pharyngeal inflammation	3	0
Pharyngeal oedema	5	0
Pharyngeal paraesthesia	27	0
Pharyngeal swelling	86	0
Pharyngeal ulceration	7	0
Tonsillar erythema	1	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	25	0
Tonsillar inflammation	3	0
Pleural infections and inflammations		
Pleurisy	10	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	1	0
Pneumothorax	1	0
Pulmonary hypertensions		
Pulmonary hypertension	1	0
Pulmonary oedemas		
Pulmonary congestion	3	0
Pulmonary oedema	3	0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	32	1
Pulmonary infarction	1	0
Pulmonary thrombosis	1	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	2	1
Respiratory failure	5	0
<i>Respiratory signs and symptoms NEC</i>		
Diaphragmalgia	1	0
Painful respiration	3	0
Respiratory symptom	4	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	2	1
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	23	0
Catarrh	9	0
Choking	4	1
Choking sensation	1	0
Dry throat	65	0
Dysphonia	49	0
Increased upper airway secretion	3	0
Increased viscosity of upper respiratory secretion	3	0
Nasal discharge discolouration	1	0
Nasal discomfort	16	0
Nasal obstruction	2	0
Oropharyngeal blistering	6	0
Oropharyngeal discomfort	24	0
Oropharyngeal pain	904	0
Paranasal sinus discomfort	12	0
Rhinalgia	6	0
Rhinorrhoea	237	0
Sinus pain	58	0
Sneezing	111	0
Snoring	2	0
Throat clearing	3	0
Throat irritation	85	0
Throat tightness	103	0
Upper airway obstruction	2	0
Upper-airway cough syndrome	2	0
Yawning	4	0
Respiratory disorders SOC TOTAL	4632	15

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-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	10	0
Acne cystic	1	0
Dermatitis acneiform	2	0
<i>Alopecias</i>		
Alopecia	17	0
Madarosis	1	0
<i>Angioedemas</i>		
Angioedema	75	0
Circumoral swelling	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	220	0
Hidradenitis	1	0
Hyperhidrosis	599	0
Miliaria	27	0
Night sweats	216	0
<i>Bullous conditions</i>		
Blister	88	0
Blood blister	5	0
Dermatitis bullous	4	0
Erythema multiforme	12	0
Fracture blisters	1	0
Pemphigoid	6	0
Pemphigus	2	0
Stevens-Johnson syndrome	2	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	56	0
Macule	2	0
Pain of skin	89	0
Papule	21	0
Pathergy reaction	1	0
Peau d'orange	2	0
Scab	2	0
Scar pain	5	0
Sensitive skin	54	0
Skin burning sensation	69	0
Skin discolouration	30	0
Skin discomfort	1	0
Skin disorder	1	0
Skin fissures	2	0
Skin indentation	2	0
Skin induration	2	0
Skin lesion	13	0
Skin necrosis	1	0
Skin odour abnormal	3	0
Skin reaction	39	0
Skin sensitisation	6	0
Skin swelling	30	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin tightness	13	0
Skin warm	104	0
Skin weeping	2	0
Sticky skin	1	0
Yellow skin	6	0
<i>Dermatitis and eczema</i>		
Dermatitis	36	0
Dermatitis allergic	75	0
Dermatitis atopic	9	0
Dermatitis diaper	1	0
Dyshidrotic eczema	4	0
Eczema	42	0
Eczema asteatotic	1	0
Eczema nummular	2	0
Eczema weeping	1	0
Perioral dermatitis	1	0
Skin irritation	32	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	12	0
Fixed eruption	1	0
Toxic skin eruption	1	0
<i>Erythemas</i>		
Erythema	812	0
Red man syndrome	1	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	1	0
Exfoliative rash	5	0
Skin exfoliation	23	0
<i>Hyperkeratoses</i>		
Lichenoid keratosis	1	0
<i>Hyperpigmentation disorders</i>		
Ephelides	1	0
Skin hyperpigmentation	1	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	1	0
Skin hypopigmentation	1	0
<i>Lipodystrophies</i>		
Lipoatrophy	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	4	0
Nail disorder	1	0
Onychalgia	4	0
Splinter haemorrhages	1	0
<i>Panniculitides</i>		
Erythema nodosum	6	0
<i>Papulosquamous conditions</i>		
Erythema annulare	1	0
Lichen planus	2	0
Parapsoriasis	1	0
Pityriasis rosea	22	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	13	0
<i>Pigmentation changes NEC</i>		

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Haemosiderin stain	1	0
Pigmentation disorder	2	0
Pilar disorders NEC		
Hair colour changes	1	0
Piloerection	4	0
Pseudofolliculitis	1	0
Pruritus NEC		
Itching scar	5	0
Pruritus	1582	0
Psoriatic conditions		
Guttate psoriasis	1	0
Psoriasis	32	0
Pustular psoriasis	1	0
Purpura and related conditions		
Petechiae	29	0
Purpura	10	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	1	0
Rash	1591	0
Rash erythematous	366	0
Rash macular	151	0
Rash maculo-papular	26	0
Rash morbilliform	8	0
Rash papular	93	0
Rash pruritic	347	0
Rash vesicular	16	0
Systemic lupus erythematosus rash	3	0
Rosaceas		
Rosacea	3	0
Scaly conditions		
Dandruff	1	0
Pityriasis	6	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	1	0
Skin mass	3	0
Skin and subcutaneous tissue ulcerations		
Scleroderma associated digital ulcer	1	0
Skin erosion	10	0
Skin ulcer	2	0
Skin cysts and polyps		
Dermal cyst	2	0
Skin haemorrhages		
Haemorrhage subcutaneous	2	0
Skin haemorrhage	2	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	1	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	1	0
Skin vasculitides		
Cutaneous vasculitis	1	0
Vasculitic rash	5	0
Skin vasomotor conditions		
Livedo reticularis	15	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name		Total	Fatal
Skin disorders	Skin disorders cont'd		
<i>Urticarias</i>			
Chronic spontaneous urticaria		1	0
Cold urticaria		1	0
Idiopathic urticaria		1	0
Mechanical urticaria		1	0
Urticaria		551	0
Urticaria chronic		1	0
Urticaria papular		2	0
Urticaria thermal		2	0
Skin disorders SOC TOTAL		7862	1

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Social circumstances		
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Disability issues</i>		
Bedridden	9	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	1	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>Pregnancy related circumstances</i>		
Breast feeding	3	0
<i>Tobacco use</i>		
Non-tobacco user	2	0
Social circumstances SOC TOTAL	31	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

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	8	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	23	0
Immunisation	7	0
<i>Joint therapeutic procedures</i>		
Joint surgery	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	3	0
Limb operation	1	0
<i>Mastectomies</i>		
Breast conserving surgery	1	0
<i>Prophylactic procedures NEC</i>		
Anaphylaxis prophylaxis	1	0
<i>Psychiatric therapies</i>		
Electroconvulsive therapy	1	0
<i>Renal therapeutic procedures</i>		
Dialysis	1	0
<i>Respiratory tract therapeutic procedures NEC</i>		
Asthma prophylaxis	2	0
<i>Therapeutic procedures NEC</i>		
Abscess drainage	1	0
Anaphylaxis treatment	2	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
Surgical & medical procedures SOC TOTAL	75	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

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>Aortic necrosis and vascular insufficiency</i>		
Aortic stenosis	1	0
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	2	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	31	0
Neurogenic shock	16	0
Peripheral circulatory failure	2	0
Shock	5	0
<i>Haemorrhages NEC</i>		
Haematoma	10	0
Haemorrhage	29	1
Venous haemorrhage	1	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	53	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	16	0
Venous thrombosis	1	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	4	0
Deep vein thrombosis	15	0
Pelvic venous thrombosis	1	0
Thrombophlebitis	5	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	16	0
Flushing	212	0
Hot flush	342	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	93	0
Peripheral ischaemia	3	0
Poor peripheral circulation	2	0
Raynaud's phenomenon	20	0

Case Series Drug Analysis Print

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

Report Run Date: 22-Mar-2021

Data Lock Date: 14-Mar-2021 19:00:03

Earliest Reaction Date: 03-Apr-1990

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Vasoconstriction	1	0
Phlebitis NEC		
Phlebitis	5	0
Site specific vascular disorders NEC		
Pallor	85	0
Vascular hypertensive disorders NEC		
Diastolic hypertension	1	0
Essential hypertension	1	0
Hypertension	171	1
Systolic hypertension	1	0
Vascular hypotensive disorders		
Hypotension	117	0
Orthostatic hypotension	11	0
Vasculitides NEC		
Behcet's syndrome	2	0
MAGIC syndrome	1	0
Vasculitis	10	0
Vena caval embolism and thrombosis		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	1316	2
TOTAL REACTIONS FOR DRUG	108649	259
TOTAL REPORTS	38084	
TOTAL FATAL OUTCOME REPORTS		259