

COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 11-Feb-2021
Data Lock Date: 10-Feb-2021 19:00:04

All UK spontaneous reports received between 9/12/20 and 31/01/21 for mRNA Pfizer- BioNTech vaccine analysis print

Case Series Drug Analysis Print

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

Report Run Date: 11-Feb-2021

Data Lock Date: 10-Feb-2021 19:00:04

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	2	0
<i>Bleeding tendencies</i>		
Increased tendency to bruise	2	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	182	0
Lymphadenitis	30	0
Lymphadenopathy	1204	0
Lymphatic disorder	1	0
Pseudolymphoma	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Myelosuppression	1	0
Pancytopenia	1	0
<i>Neutropenias</i>		
Neutropenia	4	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	2	0
Thrombocytopenia	6	0
<i>Thrombocytoses</i>		
Thrombocytosis	1	0
Blood disorders SOC TOTAL	1437	0

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Bundle branch block right	2	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	2	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	303	0
<i>Coronary artery disorders NEC</i>		
Coronary artery disease	1	1
<i>Heart failures NEC</i>		
Cardiac failure	1	0
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	6	0
Angina pectoris	5	0
Myocardial infarction	13	3
<i>Left ventricular failures</i>		
Left ventricular failure	1	0
<i>Myocardial disorders NEC</i>		
Right ventricular enlargement	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	5	0
<i>Noninfectious pericarditis</i>		
Pericarditis	2	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	9	0
Bradycardia	13	0
Cardiac flutter	12	0
Extrasystoles	9	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	230	0
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	2	0
Atrial fibrillation	29	1
Atrial tachycardia	1	0
Sinus bradycardia	1	0
Sinus tachycardia	20	0
Supraventricular tachycardia	10	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	23	10
Cardio-respiratory arrest	1	1
Pulseless electrical activity	2	0
Ventricular extrasystoles	2	0
Ventricular fibrillation	3	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	712	17

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
Congenital disorders SOC TOTAL	1	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	2	0
Ear discomfort	11	0
Ear disorder	2	0
Ear pain	122	0
Ear pruritus	1	0
Ear swelling	4	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	1	0
<i>Hearing losses</i>		
Deafness	12	0
Hypoacusis	17	0
Sudden hearing loss	2	0
<i>Hyperacusia</i>		
Hyperacusis	6	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	1	0
Inner ear disorder	2	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	9	0
Tinnitus	93	0
Vertigo	146	0
Vertigo labyrinthine	2	0
Vertigo positional	10	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
Ear disorders SOC TOTAL	445	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	1	0
<i>Endocrine abnormalities of puberty</i>		
Premature menarche	1	0
<i>Thyroid disorders NEC</i>		
Goitre	1	0
Endocrine disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	2	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	1	0
Vitreous floaters	6	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	6	0
<i>Corneal infections, oedemas and inflammations</i>		
Keratitis	1	0
Ulcerative keratitis	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	11	0
Eyelid ptosis	4	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	4	0
Iritis	1	0
Uveitis	3	0
<i>Lacrimation disorders</i>		
Dry eye	13	0
Lacrimation increased	22	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	1	0
Eczema eyelids	1	0
Erythema of eyelid	1	0
Eyelid irritation	1	0
Eyelid margin crusting	1	0
Eyelid rash	3	0
Swelling of eyelid	18	0
<i>Lid, lash and lacrimal structural disorders</i>		
Eyelid exfoliation	1	0
<i>Ocular bleeding and vascular disorders NEC</i>		
Eye haemorrhage	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	9	0
Eye oedema	3	0
Eye pain	145	0
Eye swelling	80	0
Eye ulcer	1	0
Eyelid pain	2	0
Eyelids pruritus	1	0
Ocular discomfort	6	0
Periorbital oedema	6	0
Periorbital pain	1	0
Periorbital swelling	19	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	1	0
Eye discharge	5	0
Eye inflammation	3	0
Eye irritation	16	0
Eye pruritus	46	0
Limbal swelling	1	0
Ocular hyperaemia	33	0
<i>Ocular nerve and muscle disorders</i>		

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Eye disorders Eye disorders cont'd		
Binocular eye movement disorder	1	0
Eye movement disorder	5	0
Ophthalmoplegia	1	0
Strabismus	1	0
Ocular sensation disorders		
Abnormal sensation in eye	5	0
Asthenopia	32	0
Eye paraesthesia	1	0
Foreign body sensation in eyes	6	0
Hypoaesthesia eye	1	0
Photophobia	61	0
Optic disc abnormalities NEC		
Papilloedema	1	0
Pupil disorders		
Miosis	1	0
Mydriasis	2	0
Pupillary disorder	1	0
Pupils unequal	2	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal vein occlusion	2	0
Retinal structural change, deposit and degeneration		
Maculopathy	1	0
Scleral infections, irritations and inflammations		
Episcleritis	2	0
Visual disorders NEC		
Diplopia	15	0
Halo vision	3	0
Metamorphopsia	2	0
Oscillopsia	1	0
Photopsia	15	0
Vision blurred	126	0
Visual brightness	1	0
Visual impairment and blindness (excl colour blindness)		
Blindness	5	0
Blindness transient	2	0
Central vision loss	1	0
Visual acuity reduced	1	0
Visual impairment	44	0
Eye disorders SOC TOTAL	823	0

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Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	1	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis necrotising	1	0
<i>Anal and rectal disorders NEC</i>		
Anal sphincter atony	1	0
<i>Anal and rectal pains</i>		
Proctalgia	2	0
<i>Anal and rectal signs and symptoms</i>		
Anal spasm	1	0
Anorectal discomfort	2	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	1	0
<i>Colitis (excl infective)</i>		
Colitis	2	0
Colitis microscopic	1	0
Colitis ulcerative	1	0
Crohn's disease	1	0
<i>Dental disorders NEC</i>		
Teething	1	0
<i>Dental pain and sensation disorders</i>		
Hyperaesthesia teeth	4	0
Toothache	9	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	924	1
Diarrhoea haemorrhagic	3	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	41	0
Epigastric discomfort	1	0
Eructation	9	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	3	0
Faeces discoloured	6	0
Faeces pale	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	27	0
Aerophagia	2	0
Flatulence	26	0
<i>Gastritis (excl infective)</i>		
Gastritis	8	0
Reflux gastritis	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	192	0
Abdominal pain lower	10	0
Abdominal pain upper	282	0
Abdominal rigidity	1	0
Abdominal tenderness	3	0
Gastrointestinal pain	16	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	17	0
Duodenogastric reflux	2	0

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Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Gastrooesophageal reflux disease	14	0
Gastrointestinal disorders NEC		
Functional gastrointestinal disorder	2	0
Gastric disorder	2	0
Gastrointestinal disorder	2	0
Gastrointestinal dyskinetic disorders		
Dyschezia	1	0
Gastrointestinal motility disorder	1	0
Gastrointestinal inflammatory disorders NEC		
Enteritis	1	0
Gastrointestinal mucosal dystrophies and secretion disorders		
Hyperchlorhydria	1	0
Gastrointestinal signs and symptoms NEC		
Abdominal discomfort	91	0
Anal incontinence	5	0
Breath odour	5	0
Dysphagia	31	0
Gastrointestinal spastic and hypermotility disorders		
Defaecation urgency	2	0
Frequent bowel movements	9	0
Irritable bowel syndrome	9	0
Oesophageal spasm	1	0
Pylorospasm	1	0
Gastrointestinal stenosis and obstruction NEC		
Intestinal obstruction	1	0
Gastrointestinal vascular occlusion and infarction		
Intestinal ischaemia	1	0
Gingival disorders, signs and symptoms NEC		
Gingival blister	2	0
Gingival discomfort	1	0
Gingival pain	14	0
Gingival swelling	3	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	1	0
Gingival haemorrhages		
Gingival bleeding	5	0
Haemorrhoids and gastrointestinal varices (excl oesophageal)		
Haemorrhoids	2	0
Intestinal haemorrhages		
Anal haemorrhage	2	0
Rectal haemorrhage	10	0
Intestinal ulcers and perforation NEC		
Intestinal perforation	2	2
Malabsorption syndromes		
Steatorrhoea	1	0
Nausea and vomiting symptoms		
Discoloured vomit	2	0
Nausea	2889	1
Regurgitation	1	0
Retching	22	0
Vomiting	775	2
Vomiting projectile	11	0
Non-site specific gastrointestinal haemorrhages		

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Gastrointestinal haemorrhage	2	0
Haematemesis	14	2
Haematochezia	3	0
Melaena	4	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	104	0
Lip dry	8	0
Salivary hypersecretion	9	0
Oral soft tissue disorders NEC		
Chapped lips	4	0
Cheilitis	6	0
Enlarged uvula	3	0
Lip blister	6	0
Lip disorder	2	0
Oral disorder	3	0
Oral papule	1	0
Uvulitis	1	0
Oral soft tissue haemorrhages		
Mouth haemorrhage	1	0
Oral blood blister	4	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	95	0
Lip discolouration	1	0
Lip erythema	1	0
Lip exfoliation	2	0
Lip pain	10	0
Lip pruritus	3	0
Lip scab	1	0
Odynophagia	2	0
Oral discomfort	11	0
Oral mucosal blistering	6	0
Oral mucosal eruption	4	0
Oral mucosal erythema	1	0
Oral mucosal exfoliation	2	0
Oral pain	26	0
Oral pruritus	4	0
Paraesthesia oral	291	0
Oral soft tissue swelling and oedema		
Lip oedema	1	0
Lip swelling	145	0
Mouth swelling	14	0
Oedema mouth	1	0
Peritoneal and retroperitoneal fibrosis and adhesions		
Abdominal adhesions	1	0
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	2	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	1	0
Submaxillary gland enlargement	4	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	7	0
Lip ulceration	2	0
Mouth ulceration	57	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	6	0
<i>Tongue disorders</i>		
Glossitis	3	0
Plicated tongue	2	0
Tongue disorder	7	0
Tongue haemorrhage	1	0
Tongue ulceration	7	0
<i>Tongue signs and symptoms</i>		
Glossodynia	35	0
Stiff tongue	1	0
Swollen tongue	105	0
Tongue blistering	2	0
Tongue coated	2	0
Tongue discolouration	2	0
Tongue discomfort	7	0
Tongue dry	4	0
Tongue eruption	3	0
Tongue erythema	1	0
Tongue movement disturbance	1	0
Tongue oedema	4	0
Tongue spasm	2	0
Gastrointestinal disorders SOC TOTAL	6605	8

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Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	1	0
Administration site erythema	1	0
Administration site pain	3	0
Administration site warmth	1	0
Puncture site bruise	4	0
Puncture site pain	3	0
Puncture site swelling	1	0
Vessel puncture site bruise	1	0
<i>Adverse effect absent</i>		
No adverse event	2	0
<i>Application and instillation site reactions</i>		
Application site bruise	1	0
Application site erythema	1	0
Application site haemorrhage	1	0
Application site pain	2	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	282	1
Chronic fatigue syndrome	2	0
Fatigue	4007	0
Malaise	948	0
Sluggishness	2	0
<i>Body temperature altered</i>		
Hypothermia	8	0
Temperature regulation disorder	4	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	61	66
Sudden death	9	9
<i>Febrile disorders</i>		
Hyperpyrexia	3	0
Pyrexia	3665	0
<i>Feelings and sensations NEC</i>		
Chills	2310	0
Feeling abnormal	181	0
Feeling cold	242	0
Feeling drunk	12	0
Feeling hot	262	0
Feeling jittery	5	0
Feeling of body temperature change	78	0
Hangover	5	0
Hunger	3	0
Sensation of foreign body	13	0
Temperature intolerance	2	0
Thirst	50	0
<i>Gait disturbances</i>		

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Gait disturbance	19	0
Gait inability	12	0
Loss of control of legs	1	0
General signs and symptoms NEC		
Condition aggravated	16	0
Crying	7	0
Disease recurrence	1	0
Energy increased	1	0
Exercise tolerance decreased	2	0
General physical health deterioration	2	0
Glassy eyes	2	0
Illness	259	0
Induration	2	0
Influenza like illness	491	0
Local reaction	27	0
Peripheral swelling	462	0
Pre-existing condition improved	1	0
Screaming	2	0
Secretion discharge	2	0
Swelling	396	0
Swelling face	132	0
Inflamations		
Inflammation	47	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		
Injected limb mobility decreased	8	0
Injection site bruising	13	0
Injection site discolouration	2	0
Injection site discomfort	3	0
Injection site erythema	107	0
Injection site haemorrhage	2	0
Injection site hypoaesthesia	5	0
Injection site induration	1	0
Injection site inflammation	8	0
Injection site joint pain	4	0
Injection site mass	88	0
Injection site necrosis	1	0
Injection site oedema	5	0
Injection site pain	773	0
Injection site paraesthesia	3	0
Injection site pruritus	52	0
Injection site rash	17	0
Injection site reaction	8	0
Injection site scab	1	0
Injection site scar	2	0
Injection site swelling	97	0
Injection site urticaria	5	0

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General disorders General disorders cont'd		
Injection site vesicles	2	0
Injection site warmth	34	0
Interactions		
Alcohol interaction	2	0
Drug interaction	2	0
Mass conditions NEC		
Cyst	1	0
Mass	3	0
Nodule	3	0
Necrosis NEC		
Fat necrosis	1	0
Oedema NEC		
Face oedema	5	0
Localised oedema	6	0
Oedema	6	0
Oedema peripheral	10	0
Pain and discomfort NEC		
Axillary pain	194	0
Chest discomfort	240	0
Chest pain	293	0
Discomfort	23	0
Facial discomfort	3	0
Facial pain	36	0
Non-cardiac chest pain	2	0
Pain	1383	0
Tenderness	118	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	46	0
Adverse reaction	1	0
Drug ineffective	64	0
Immediate post-injection reaction	1	0
No reaction on previous exposure to drug	4	0
Therapeutic product effect delayed	1	0
Therapeutic product effect increased	1	0
Therapeutic response unexpected	6	0
Treatment failure	1	0
Ulcers NEC		
Ulcer	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	31	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	5	0
Vaccination site discomfort	16	0
Vaccination site eczema	1	0
Vaccination site erythema	191	0
Vaccination site haemorrhage	4	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	27	0
Vaccination site inflammation	25	0
Vaccination site irritation	3	0
Vaccination site joint discomfort	2	0

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General disorders General disorders cont'd		
Vaccination site joint erythema	3	0
Vaccination site joint movement impairment	10	0
Vaccination site joint pain	19	0
Vaccination site joint swelling	2	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	1	0
Vaccination site mass	48	0
Vaccination site movement impairment	19	0
Vaccination site oedema	3	0
Vaccination site pain	741	0
Vaccination site paraesthesia	4	0
Vaccination site pruritus	49	0
Vaccination site rash	27	0
Vaccination site reaction	10	0
Vaccination site swelling	212	0
Vaccination site ulcer	1	0
Vaccination site urticaria	4	0
Vaccination site vesicles	2	0
Vaccination site warmth	109	0
<i>Withdrawal and rebound effects</i>		
Withdrawal syndrome	1	0
General disorders SOC TOTAL	19354	77

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Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Jaundice	1	0
<i>Hepatic vascular disorders</i>		
Hepatic artery embolism	1	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	5	0
Liver tenderness	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	1	0
Liver injury	1	0
Hepatic disorders SOC TOTAL	10	0

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Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	2	0
Allergy to arthropod bite	1	0
Hypersensitivity	146	0
Serum sickness	1	0
Type IV hypersensitivity reaction	2	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to chemicals	1	0
Allergy to vaccine	13	0
Drug hypersensitivity	2	0
Reaction to preservatives	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	116	0
Anaphylactic shock	4	0
Anaphylactoid reaction	8	0
Anaphylactoid shock	2	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	1	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	3	0
Immune system disorder	1	0
Immune-mediated adverse reaction	1	0
Immune system disorders SOC TOTAL	308	0

Case Series Drug Analysis Print

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

Report Run Date: 11-Feb-2021
 Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 10-Feb-2021 19:00:04
 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	3	0
Dysentery	1	0
Gastroenteritis	3	0
<i>Bacterial infections NEC</i>		
Bacterial diarrhoea	1	0
Cellulitis	43	0
Ear infection bacterial	1	0
Injection site cellulitis	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	3	0
<i>Candida infections</i>		
Anal candidiasis	1	0
Candida infection	2	0
Oral candidiasis	6	0
Vulvovaginal candidiasis	5	0
<i>Central nervous system and spinal infections</i>		
Myelitis	1	0
<i>Clostridia infections</i>		
Clostridium difficile infection	1	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	6	0
COVID-19	269	12
COVID-19 pneumonia	7	2
Coronavirus infection	4	0
Suspected COVID-19	22	0
<i>Coxiella infections</i>		
Q fever	4	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	2	0
Gingivitis	2	0
Parotitis	4	0
<i>Ear infections</i>		
Ear infection	8	0
Labyrinthitis	10	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	1	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	16	0
Eye abscess	1	0
Eye infection	1	0
Hordeolum	2	0
Periorbital infection	1	0
<i>Female reproductive tract infections</i>		
Vulval abscess	1	0
<i>Hepatobiliary and spleen infections</i>		
Biliary sepsis	1	0
<i>Herpes viral infections</i>		
Genital herpes	2	0

Case Series Drug Analysis Print

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

Report Run Date: 11-Feb-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 10-Feb-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Herpes simplex	1	0
Herpes simplex reactivation	1	0
Herpes virus infection	3	0
Herpes zoster	97	0
Herpes zoster oticus	1	0
Ophthalmic herpes zoster	1	0
Oral herpes	44	0
<i>Infections NEC</i>		
Abscess	2	0
Abscess limb	1	0
Infection	48	0
Injection site abscess	1	0
Injection site infection	2	0
Localised infection	3	0
Lymph gland infection	2	0
Respiratory tract infection	1	0
Vaccination site abscess	2	0
Vaccination site infection	6	0
<i>Influenza viral infections</i>		
Influenza	231	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	3	0
Lower respiratory tract infection	18	5
Pneumonia	10	3
Sputum purulent	1	0
<i>Male reproductive tract infections</i>		
Orchitis	1	0
<i>Muscle and soft tissue infections</i>		
Soft tissue infection	1	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Sepsis	7	0
Urosepsis	1	0
<i>Skin structures and soft tissue infections</i>		
Acne pustular	1	0
Folliculitis	2	0
Pustule	2	0
Rash pustular	1	0
Skin infection	2	0
Subcutaneous abscess	1	0
<i>Staphylococcal infections</i>		
Furuncle	2	0
Staphylococcal abscess	1	0
<i>Streptococcal infections</i>		
Pharyngitis streptococcal	2	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	1	0
<i>Upper respiratory tract infections</i>		
Nasopharyngitis	116	0
Pharyngitis	4	0
Rhinitis	12	0
Sinusitis	8	0
Tonsillitis	13	0
Tracheitis	1	0

Case Series Drug Analysis Print

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

Report Run Date: 11-Feb-2021

Data Lock Date: 10-Feb-2021 19:00:04

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Urinary tract infections</i>		
Cystitis	5	0
Kidney infection	2	0
Pyelonephritis	1	0
Urinary tract infection	15	0
<i>Vascular infections</i>		
Haematoma infection	1	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Eye infection viral	1	0
Gastroenteritis viral	3	0
Post viral fatigue syndrome	4	0
Sweating fever	27	0
Vestibular neuronitis	3	0
Viral infection	1	0
Viral labyrinthitis	2	0
Viral pharyngitis	3	0
Viral rash	8	0
Viral tonsillitis	1	0
Infections SOC TOTAL	1186	22

Case Series Drug Analysis Print

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

Report Run Date: 11-Feb-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 10-Feb-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Oral contusion	1	0
<i>Anaesthetic and allied procedural complications</i>		
Delayed recovery from anaesthesia	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Conditions caused by cold</i>		
Chillblains	6	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	4	0
Maternal exposure during breast feeding	9	0
Maternal exposure during pregnancy	12	0
<i>Eye injuries NEC</i>		
Eye contusion	3	0
Eye injury	2	0
Injury corneal	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	1	0
<i>Heat injuries (excl thermal burns)</i>		
Heat illness	1	0
Heat oedema	2	0
Heat stroke	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
Product use issue	1	0
Vaccination error	1	0
Wrong technique in product usage process	1	0
<i>Muscle, tendon and ligament injuries</i>		
Epicondylitis	1	0
Muscle injury	1	0
Muscle strain	3	0
<i>Musculoskeletal procedural complications</i>		
Post laminectomy syndrome	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	2	0
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	3	0
<i>Non-site specific injuries NEC</i>		
Bite	1	0
Electric shock	2	0
Fall	24	0
Wound	1	0
Wound complication	2	0
<i>Non-site specific procedural complications</i>		
Incision site pain	1	0
Infusion related reaction	2	0
Injection related reaction	8	0
Post procedural complication	1	0
<i>Off label uses</i>		
Off label use	1	0
<i>Overdoses NEC</i>		

Case Series Drug Analysis Print

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

Report Run Date: 11-Feb-2021
 Earliest Reaction Date: 19-Jan-2001

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 MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Overdose	7	0
Poisoning and toxicity		
Poisoning	1	0
Product administration errors and issues		
Accidental overdose	1	0
Contraindicated product administered	1	0
Inappropriate schedule of product administration	5	0
Product administered at inappropriate site	3	0
Product administered to patient of inappropriate age	1	0
Product administration error	1	0
Product dose omission issue	1	0
Product preparation errors and issues		
Product preparation issue	3	0
Radiation injuries		
Sunburn	1	0
Site specific injuries NEC		
Face crushing	1	0
Head injury	1	0
Limb injury	1	0
Skin injuries NEC		
Contusion	69	0
Scar	1	0
Skin abrasion	2	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		
Burns second degree	2	0
Thermal burn	2	0
Underdoses NEC		
Underdose	1	0
Vaccination related complications		
Vaccination complication	10	0
Injuries SOC TOTAL	224	0

Case Series Drug Analysis Print

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Report Run Date: 11-Feb-2021

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Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations		
Adrenal cortex tests		
Cortisol decreased	1	0
Blood gas and acid base analyses		
Blood lactic acid increased	2	0
Blood pH increased	1	0
Oxygen consumption decreased	1	0
Oxygen saturation	1	0
Oxygen saturation decreased	17	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose decreased	4	0
Blood glucose increased	17	0
Glycosylated haemoglobin increased	1	0
Cardiac function diagnostic procedures		
Central venous pressure	1	0
Central nervous system imaging procedures		
Magnetic resonance imaging brain	2	0
Chemistry analyses NEC		
Inflammatory marker increased	1	0
Coagulation and bleeding analyses		
Fibrin D dimer increased	1	0
International normalised ratio abnormal	1	0
International normalised ratio decreased	3	0
International normalised ratio increased	12	0
ECG investigations		
Electrocardiogram ST segment elevation	1	0
Haematological analyses NEC		
Red blood cell sedimentation rate increased	2	0
Heart rate and pulse investigations		
Heart rate	27	0
Heart rate abnormal	2	0
Heart rate decreased	7	0
Heart rate increased	114	0
Heart rate irregular	10	0
Pulse abnormal	5	0
Immunology analyses NEC		
Immunology test	1	0
Investigations NEC		
Blood test abnormal	2	0
Polymerase chain reaction positive	3	0
Systemic lupus erythematosus disease activity index increased	1	0
Liver function analyses		
Alanine aminotransferase increased	2	0
Gamma-glutamyltransferase increased	1	0
Hepatic enzyme increased	1	0
Liver function test increased	2	0
Transaminases increased	1	0
Metabolism tests NEC		
Blood ketone body increased	1	0
Microbiology and serology tests NEC		
Culture negative	1	0
Mineral and electrolyte analyses		
Blood potassium abnormal	1	0
Serum ferritin increased	1	0

Case Series Drug Analysis Print

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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	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Intraocular pressure increased	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	68	0
Body temperature abnormal	17	0
Body temperature decreased	6	0
Body temperature fluctuation	5	0
Body temperature increased	134	0
Body temperature normal	1	0
Breath sounds abnormal	1	0
Grip strength	2	0
Grip strength decreased	2	0
Lymph node palpable	4	0
Respiratory rate decreased	1	0
Respiratory rate increased	11	0
Skin temperature	7	0
Temperature difference of extremities	1	0
Weight	1	0
Weight decreased	6	0
Weight increased	1	0
<i>Pituitary analyses anterior</i>		
Blood growth hormone	2	0
<i>Platelet analyses</i>		
Platelet count decreased	1	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	4	0
<i>Red blood cell analyses</i>		
Haemoglobin decreased	3	0
<i>Respiratory and pulmonary function diagnostic procedures</i>		
Forced expiratory volume increased	1	0
Peak expiratory flow rate decreased	1	0
<i>Respiratory tract and thoracic histopathology procedures</i>		
Sputum abnormal	1	0
<i>Skeletal and cardiac muscle analyses</i>		
Blood creatine phosphokinase increased	1	0
Troponin increased	2	0
<i>Therapeutic drug monitoring analyses</i>		
Anticoagulation drug level increased	1	0
<i>Thyroid analyses</i>		
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	1	0
<i>Tissue enzyme analyses NEC</i>		
Blood alkaline phosphatase increased	1	0
<i>Urinalysis NEC</i>		
Blood urine present	4	0
pH urine	1	0
pH urine increased	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output	2	0
Urine output decreased	3	0
Urine output increased	1	0

Case Series Drug Analysis Print

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Report Run Date: 11-Feb-2021

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Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	2	0
Blood pressure decreased	9	0
Blood pressure increased	48	0
Blood pressure measurement	6	0
Blood pressure systolic decreased	1	0
Blood pressure systolic increased	1	0
<i>Virus identification and serology</i>		
Coronavirus test positive	2	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 test	6	0
SARS-CoV-2 test false positive	1	0
SARS-CoV-2 test positive	19	0
Viral test	1	0
<i>White blood cell analyses</i>		
White blood cell count decreased	1	0
White blood cell count increased	1	0
Investigations SOC TOTAL	653	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	1	0
Decreased appetite	252	0
Eating disorder symptom	1	0
Food craving	1	0
Food refusal	2	0
Hypophagia	2	0
Increased appetite	2	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus inadequate control	2	1
Type 1 diabetes mellitus	2	0
<i>Diabetic complications NEC</i>		
Diabetic complication	1	0
Diabetic ketoacidosis	3	0
<i>Disorders of purine metabolism</i>		
Gout	8	0
<i>Electrolyte imbalance NEC</i>		
Fluid imbalance	1	0
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Gluten sensitivity	1	0
<i>General nutritional disorders NEC</i>		
Abnormal weight gain	2	0
Feeding disorder	7	0
Food aversion	1	0
Poor feeding infant	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	12	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	18	0
Postprandial hypoglycaemia	1	0
<i>Lipid metabolism and deposit disorders NEC</i>		
Body fat disorder	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Ketoacidosis	2	0
<i>Mixed acid-base disorders</i>		
Acidosis	2	0
<i>Sodium imbalance</i>		
Hyponatraemia	2	0
<i>Total fluid volume decreased</i>		
Dehydration	26	0
<i>Total fluid volume increased</i>		
Fluid retention	2	0
Metabolic disorders SOC TOTAL	357	1

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	23	0
Arthropathy	2	0
Sacroiliitis	1	0
<i>Bone disorders NEC</i>		
Medial tibial stress syndrome	1	0
Spinal disorder	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	53	0
Bone swelling	1	0
Coccydynia	1	0
Pain in jaw	46	0
Spinal pain	7	0
<i>Bursal disorders</i>		
Bursitis	2	0
<i>Cartilage disorders</i>		
Costochondritis	3	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	3	0
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		
Foot deformity	1	0
<i>Joint related disorders NEC</i>		
Joint lock	1	0
Periarthritis	4	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	1704	0
Jaw clicking	2	0
Joint effusion	4	0
Joint noise	2	0
Joint range of motion decreased	2	0
Joint stiffness	31	0
Joint swelling	41	0
Joint warmth	2	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	1	0
<i>Muscle infections and inflammations</i>		
Antisynthetase syndrome	1	0
Myositis	2	0
<i>Muscle pains</i>		
Fibromyalgia	9	0
Myalgia	2678	0
Myofascial pain syndrome	3	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle discomfort	1	0
Muscle disorder	2	0
Muscle fatigue	61	0
Muscle spasms	102	0
Muscle swelling	5	0
Muscle tightness	7	0
Muscle twitching	41	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 tone abnormalities</i>		
Muscle rigidity	6	0
Nuchal rigidity	2	0
Torticollis	1	0
Trismus	3	0
<i>Muscle weakness conditions</i>		
Muscular weakness	121	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Limb mass	2	0
Mastication disorder	1	0
Mobility decreased	11	0
Musculoskeletal disorder	3	0
Musculoskeletal stiffness	184	0
<i>Musculoskeletal and connective tissue infections and inflammations NEC</i>		
Fasciitis	1	0
Plantar fasciitis	1	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	367	0
Flank pain	7	0
Limb discomfort	262	0
Musculoskeletal chest pain	18	0
Musculoskeletal discomfort	14	0
Musculoskeletal pain	13	0
Neck pain	307	0
Pain in extremity	1876	0
Rheumatic disorder	1	0
<i>Myopathies</i>		
Rhabdomyolysis	3	0
<i>Osteoarthropathies</i>		
Osteoarthritis	3	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	7	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	25	0
Groin pain	18	0
Neck mass	5	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	2	0
Arthritis reactive	4	0
<i>Synovial disorders</i>		
Synovial cyst	1	0
Synovitis	2	0
<i>Tendon disorders</i>		
Tendon pain	1	0
Tendonitis	2	0
<i>Trunk deformities</i>		
Drooping shoulder syndrome	1	0
Muscle & tissue disorders SOC TOTAL	8129	0

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Neoplasms		
<i>Lymphomas unspecified NEC</i>		
Lymphoma	3	0
<i>Metastases to specified sites</i>		
Metastases to lymph nodes	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Neoplasm malignant	1	0
<i>Skin neoplasms benign</i>		
Melanocytic naevus	1	0
Neoplasms SOC TOTAL	6	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Extensor plantar response	1	0
Hyperreflexia	1	0
Hyporeflexia	3	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	2	0
<i>Absence seizures</i>		
Petit mal epilepsy	3	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	1	0
<i>Autonomic nervous system disorders</i>		
Anticholinergic 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 infarction	2	0
Cerebellar stroke	1	0
Cerebral artery occlusion	1	0
Cerebral haemorrhage	6	2
Cerebral infarction	5	0
Cerebrovascular accident	32	3
Haemorrhage intracranial	2	0
Haemorrhagic stroke	1	1
Ischaemic cerebral infarction	1	0
Ischaemic stroke	6	1
Lacunar infarction	2	0
Lacunar stroke	1	0
Subarachnoid haemorrhage	2	1
<i>Central nervous system inflammatory disorders NEC</i>		
Gliosis	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	1	0
Balance disorder	51	0
Coordination abnormal	9	0
Dysstasia	10	0
<i>Cortical dysfunction NEC</i>		
Aphasia	9	0
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	1	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	2	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	4	0
Consciousness fluctuating	2	0
Depressed level of consciousness	4	0
Lethargy	487	0
Loss of consciousness	49	0
Sedation	3	0
Somnolence	130	0
Stupor	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Syncope	196	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	2	0
Dyskinesia	1	0
Extrapyramidal disorder	1	0
Fine motor skill dysfunction	1	0
Hypokinesia	2	0
Motor dysfunction	1	0
Movement disorder	5	0
Psychomotor hyperactivity	3	0
<i>Dystonias</i>		
Dystonia	5	0
Writer's cramp	1	0
<i>Encephalopathies NEC</i>		
Posterior reversible encephalopathy syndrome	1	0
<i>Eye movement disorders</i>		
VIth nerve paralysis	2	0
<i>Facial cranial nerve disorders</i>		
Facial nerve disorder	1	0
Facial paralysis	84	0
Facial paresis	15	0
Facial spasm	7	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	4	0
<i>Headaches NEC</i>		
Cervicogenic headache	1	0
Cluster headache	32	0
Cold-stimulus headache	1	0
Exertional headache	3	0
Headache	5506	0
Medication overuse headache	2	0
New daily persistent headache	2	0
Occipital neuralgia	1	0
Ophthalmoplegic migraine	1	0
Primary cough headache	1	0
Primary headache associated with sexual activity	1	0
Sinus headache	70	0
Tension headache	91	0
Thunderclap headache	1	0
Vascular headache	1	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	8	0
<i>Memory loss (excl dementia)</i>		
Amnesia	8	0
Memory impairment	17	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	7	0
Disturbance in attention	43	0
Mental impairment	5	0
<i>Migraine headaches</i>		
Migraine	361	0
Migraine with aura	24	0
Retinal migraine	2	0

Case Series Drug Analysis Print

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

Report Run Date: 11-Feb-2021

Data Lock Date: 10-Feb-2021 19:00:04

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Typical aura without headache	1	0
Vestibular migraine	1	0
Mononeuropathies		
Carpal tunnel syndrome	2	0
Mononeuropathy	1	0
Nerve compression	2	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	1	0
Multiple sclerosis relapse	5	0
Muscle tone abnormal		
Hypotonia	1	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
Myelitis (incl infective)		
Myelitis transverse	1	0
Narcolepsy and hypersomnia		
Hypersomnia	16	0
Narcolepsy	1	0
Nervous system disorders NEC		
Nervous system disorder	1	0
Neurologic visual problems NEC		
Tunnel vision	4	0
Visual field defect	1	0
Neurological signs and symptoms NEC		
Dizziness	1546	0
Dizziness exertional	5	0
Dizziness postural	127	0
Head discomfort	36	0
Hyporesponsive to stimuli	1	0
Inability to crawl	1	0
Myoclonus	1	0
Neurological symptom	2	0
Persistent postural-perceptual dizziness	1	0
Presyncope	114	0
Slow response to stimuli	1	0
Unresponsive to stimuli	13	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	4	0
Neuromuscular junction dysfunction		
Myasthenia gravis	1	0
Olfactory nerve disorders		
Anosmia	45	0
Hyposmia	4	0
Parosmia	22	0
Optic nerve disorders NEC		
Optic neuritis	3	0
Paraesthesias and dysaesthesias		
Burning sensation	61	0
Dysaesthesia	2	0
Formication	4	0
Hemiparaesthesia	1	0
Hyperaesthesia	16	0

Case Series Drug Analysis Print

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

Report Run Date: 11-Feb-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 10-Feb-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Hypoaesthesia	329	0
Paraesthesia	490	0
<i>Paralysis and paresis (excl cranial nerve)</i>		
Hemiparesis	11	0
Hemiplegia	2	0
Locked-in syndrome	1	0
Monoparesis	7	0
Monoplegia	5	0
Paralysis	15	0
Paraparesis	1	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	1	0
Parkinsonian gait	1	0
Parkinsonism	2	0
<i>Partial complex seizures</i>		
Dreamy state	1	0
Temporal lobe epilepsy	1	0
<i>Peripheral neuropathies NEC</i>		
Neuropathy peripheral	10	0
Peripheral sensory neuropathy	2	0
<i>Seizures and seizure disorders NEC</i>		
Clonic convulsion	1	0
Epilepsy	8	0
Febrile convulsion	2	0
Partial seizures	1	0
Psychogenic seizure	3	0
Seizure	45	0
Status epilepticus	3	0
Tonic convulsion	3	0
<i>Sensory abnormalities NEC</i>		
Ageusia	91	0
Allodynia	3	0
Aura	7	0
Dysgeusia	243	0
Neuralgia	39	0
Restless legs syndrome	15	0
Sensory disturbance	10	0
Sensory loss	6	0
Taste disorder	43	0
<i>Sleep disturbances NEC</i>		
Poor quality sleep	26	0
<i>Speech and language abnormalities</i>		
Dysarthria	19	0
Repetitive speech	1	0
Speech disorder	6	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculitis brachial	1	0
Radiculopathy	1	0
<i>Structural brain disorders NEC</i>		
Brain injury	2	2
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	14	0
<i>Tremor (excl congenital)</i>		

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Essential tremor	1	0
Resting tremor	1	0
Tremor	261	0
Trigeminal disorders		
Facial neuralgia	5	0
Trigeminal nerve disorder	1	0
Trigeminal neuralgia	5	0
Nervous system disorders SOC TOTAL	11160	11

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	5	0
<i>Maternal complications of pregnancy NEC</i>		
Morning sickness	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	2	0
Pregnancy conditions SOC TOTAL	8	0

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Reaction Name	Total	Fatal
<i>Device malfunction events NEC</i>		
Device stimulation issue	1	0
Oversensing	5	0
<i>Product contamination and sterility issues</i>		
Product contamination physical	1	0
<i>Product physical issues</i>		
Product taste abnormal	1	0
null SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Agitation	18	0
Anxiety	73	0
Nervousness	39	0
Tension	11	0
<i>Behaviour and socialisation disturbances</i>		
Indifference	2	0
Paranoia	2	0
Social avoidant behaviour	2	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Mental fatigue	24	0
<i>Communications disorders</i>		
Communication disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	112	0
Disorientation	36	0
<i>Deliria</i>		
Delirium	25	0
<i>Depressive disorders</i>		
Depression	12	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	2	0
Dissociation	3	0
Dissociative amnesia	1	0
Dissociative disorder	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	3	0
Insomnia	162	0
Middle insomnia	3	0
<i>Dyssomnias</i>		
Dyssomnia	1	0
<i>Eating disorders NEC</i>		
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	2	0
Emotional disorder	5	0
Emotional distress	2	0
Euphoric mood	3	0
Irritability	21	0
Mood altered	3	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Phonophobia	1	0
Social fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	2	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	38	0
Hallucination, auditory	2	0
Hallucination, olfactory	1	0
Hallucination, tactile	1	0
Hallucination, visual	5	0
<i>Increased physical activity levels</i>		
Restlessness	22	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Mental disorders NEC</i>		
Mental disorder	1	0
<i>Mood alterations with depressive symptoms</i>		
Decreased interest	3	0
Depressed mood	30	0
Negative thoughts	1	0
Tearfulness	2	0
<i>Mood disorders NEC</i>		
Apathy	2	0
Laziness	1	0
Listless	2	0
<i>Narcolepsy and associated conditions</i>		
Sleep attacks	2	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	14	0
Panic disorder	1	0
Panic reaction	4	0
<i>Parasomnias</i>		
Abnormal dreams	31	0
Nightmare	28	0
Sleep terror	2	0
<i>Perception disturbances NEC</i>		
Autoscopy	1	0
Derealisation	2	0
Flashback	1	0
Illusion	1	0
<i>Psychiatric elimination disorders</i>		
Enuresis	4	0
<i>Psychiatric symptoms NEC</i>		
Hypervigilance	1	0
Trance	1	0
<i>Psychotic disorder NEC</i>		
Psychotic behaviour	1	0
Psychotic disorder	2	0
<i>Sleep disorders NEC</i>		
Sleep disorder	26	0
<i>Somatic symptom disorders</i>		
Habit cough	2	0
Vomiting psychogenic	1	0
<i>Speech and language usage disturbances</i>		
Disorganised speech	2	0
Logorrhoea	1	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	1	0
<i>Stereotypies and automatisms</i>		
Head banging	2	0
Stereotypy	1	0
<i>Suicidal and self-injurious behaviour</i>		
Intentional self-injury	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Thinking disturbances</i>		
Bradyphrenia	7	0
Thinking abnormal	3	0
Psychiatric disorders SOC TOTAL	830	0

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	1	0
Dysuria	8	0
Incontinence	4	0
Micturition disorder	1	0
Micturition urgency	2	0
Pollakiuria	7	0
Urinary incontinence	12	0
Urinary retention	10	0
Urine flow decreased	1	0
<i>Bladder disorders NEC</i>		
Bladder disorder	3	0
<i>Genital and urinary tract disorders NEC</i>		
Urinary tract disorder	2	0
<i>Myoneurogenic bladder disorders</i>		
Hypertonic bladder	1	0
Loss of bladder sensation	1	0
<i>Nephritis NEC</i>		
Nephritis	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	4	0
Anuria	1	0
Renal failure	2	0
<i>Urinary abnormalities</i>		
Chromaturia	11	0
Haematuria	4	0
Proteinuria	1	0
Urine abnormality	2	0
Urine odour abnormal	2	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0
Haemorrhage urinary tract	1	0
Nocturia	1	0
Polyuria	1	0
Renal pain	35	0
Renal & urinary disorders SOC TOTAL	120	0

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	1	0
<i>Breast disorders NEC</i>		
Breast mass	4	0
<i>Breast signs and symptoms</i>		
Breast discomfort	2	0
Breast pain	31	0
Breast swelling	9	0
Breast tenderness	3	0
Nipple pain	3	0
Nipple swelling	2	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	4	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	2	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	1	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	11	0
Menstrual disorder	7	0
Menstruation irregular	7	0
Metrorrhagia	5	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	2	0
Hypomenorrhoea	4	0
Menstruation delayed	11	0
Oligomenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	22	0
Polymenorrhoea	3	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovulation pain	2	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	2	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile swelling	1	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatomegaly	1	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital ulceration	2	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital pain	1	0
Pelvic discomfort	2	0
Pelvic pain	5	0
Perineal pain	1	0
<i>Scrotal disorders NEC</i>		
Scrotal erythema	1	0
Scrotal exfoliation	1	0
Scrotal pain	2	0
Scrotal swelling	1	0
<i>Spermatogenesis and semen disorders</i>		
Haematospermia	1	0
<i>Testicular and epididymal disorders NEC</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Testicular pain	2	0
Testicular swelling	2	0
<i>Uterine disorders NEC</i>		
Uterine pain	1	0
<i>Uterine tone disorders</i>		
Uterine spasm	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	20	0
Vulval ulceration	2	0
<i>Vulvovaginal signs and symptoms</i>		
Vulvovaginal pruritus	1	0
Reproductive & breast disorders SOC TOTAL	187	0

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Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	520	0
Dyspnoea exertional	6	1
Hyperventilation	5	0
Hypopnoea	9	0
Irregular breathing	5	0
Mouth breathing	1	0
Orthopnoea	2	0
Respiration abnormal	10	0
Respiratory arrest	3	0
Respiratory distress	2	0
Tachypnoea	11	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	1	0
Bronchiectasis	2	0
<i>Bronchospasm and obstruction</i>		
Asthma	43	0
Bronchospasm	6	0
Chronic obstructive pulmonary disease	2	0
Obstructive airways disorder	1	0
Wheezing	67	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	5	1
<i>Coughing and associated symptoms</i>		
Cough	426	0
Haemoptysis	7	0
Productive cough	24	0
Sputum discoloured	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Epiglottic oedema	1	0
Stridor	2	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Hypersensitivity pneumonitis	1	0
Pneumonia aspiration	3	2
Pneumonitis	4	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	2	0
Pleuritic pain	4	0
Pulmonary pain	16	0
Rales	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	35	0
Rhinitis allergic	2	0
<i>Nasal disorders NEC</i>		
Epistaxis	102	0
Intranasal hyposaesthesia	1	0
Intranasal paraesthesia	1	0
Nasal disorder	1	0
Nasal dryness	3	0
Nasal odour	2	0
Nasal oedema	1	0
Nasal pruritus	2	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Paranasal sinus inflammation	1	0
Sinonasal obstruction	2	0
Sinus congestion	7	0
Sinus disorder	1	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	3	0
Pharyngeal haemorrhage	1	0
Pharyngeal hypoaesthesia	8	0
Pharyngeal inflammation	2	0
Pharyngeal oedema	3	0
Pharyngeal paraesthesia	18	0
Pharyngeal swelling	51	0
Pharyngeal ulceration	5	0
Tonsillar hypertrophy	12	0
Tonsillar inflammation	3	0
<i>Pleural infections and inflammations</i>		
Pleurisy	2	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
<i>Pulmonary oedemas</i>		
Pulmonary congestion	2	0
Pulmonary oedema	2	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	6	1
Pulmonary infarction	1	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	2	1
<i>Respiratory signs and symptoms NEC</i>		
Painful respiration	2	0
Respiratory symptom	1	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	1	0
Respiratory disorder	1	0
Respiratory tract irritation	1	0
Respiratory tract oedema	1	0
<i>Upper respiratory tract neoplasms</i>		
Tonsillar cyst	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	12	0
Catarrh	4	0
Choking	2	0
Dry throat	37	0
Dysphonia	25	0
Increased upper airway secretion	3	0
Increased viscosity of upper respiratory secretion	2	0
Nasal discharge discolouration	1	0
Nasal discomfort	7	0
Nasal obstruction	2	0
Oropharyngeal blistering	5	0
Oropharyngeal discomfort	17	0
Oropharyngeal pain	483	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Paranasal sinus discomfort	6	0
Rhinalgia	5	0
Rhinorrhoea	97	0
Sinus pain	31	0
Sneezing	56	0
Snoring	2	0
Throat clearing	2	0
Throat irritation	49	0
Throat tightness	64	0
Respiratory disorders SOC TOTAL	2397	6

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	4	0
<i>Alopecias</i>		
Alopecia	8	0
<i>Angioedemas</i>		
Angioedema	35	0
Circumoral swelling	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	123	0
Hyperhidrosis	308	0
Miliaria	13	0
Night sweats	125	0
<i>Bullous conditions</i>		
Blister	37	0
Blood blister	1	0
Dermatitis bullous	3	0
Erythema multiforme	5	0
Pemphigoid	1	0
Stevens-Johnson syndrome	1	0
Toxic epidermal necrolysis	1	1
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	24	0
Macule	1	0
Pain of skin	54	0
Papule	13	0
Peau d'orange	2	0
Scar pain	4	0
Sensitive skin	35	0
Skin burning sensation	31	0
Skin discolouration	21	0
Skin discomfort	1	0
Skin disorder	1	0
Skin induration	1	0
Skin lesion	3	0
Skin odour abnormal	2	0
Skin reaction	21	0
Skin sensitisation	4	0
Skin swelling	12	0
Skin tightness	11	0
Skin warm	52	0
Sticky skin	1	0
Yellow skin	3	0
<i>Dermatitis and eczema</i>		
Dermatitis	17	0
Dermatitis allergic	36	0
Dyshidrotic eczema	1	0
Eczema	15	0
Eczema asteatotic	1	0
Eczema nummular	1	0
Eczema weeping	1	0
Perioral dermatitis	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin irritation	15	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	2	0
Fixed eruption	1	0
Toxic skin eruption	1	0
<i>Erythemas</i>		
Erythema	457	0
Red man syndrome	1	0
<i>Exfoliative conditions</i>		
Skin exfoliation	13	0
<i>Hyperpigmentation disorders</i>		
Ephelides	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	3	0
Nail disorder	1	0
Onychalgia	2	0
<i>Panniculitides</i>		
Erythema nodosum	1	0
<i>Papulosquamous conditions</i>		
Erythema annulare	1	0
Lichen planus	1	0
Pityriasis rosea	8	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	6	0
<i>Pigmentation changes NEC</i>		
Pigmentation disorder	1	0
<i>Pilar disorders NEC</i>		
Piloerection	3	0
<i>Pruritus NEC</i>		
Itching scar	3	0
Pruritus	776	0
<i>Psoriatic conditions</i>		
Psoriasis	6	0
<i>Purpura and related conditions</i>		
Petechiae	18	0
Purpura	6	0
<i>Rashes, eruptions and exanthems NEC</i>		
Rash	796	0
Rash erythematous	166	0
Rash macular	81	0
Rash maculo-papular	15	0
Rash morbilliform	6	0
Rash papular	53	0
Rash pruritic	139	0
Rash vesicular	4	0
<i>Rosaceas</i>		
Rosacea	1	0
<i>Scaly conditions</i>		
Pityriasis	3	0
<i>Skin and subcutaneous conditions NEC</i>		
Skin mass	3	0
<i>Skin and subcutaneous tissue ulcerations</i>		
Scleroderma associated digital ulcer	1	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin erosion	4	0
Skin ulcer	1	0
<i>Skin cysts and polyps</i>		
Dermal cyst	1	0
<i>Skin haemorrhages</i>		
Haemorrhage subcutaneous	2	0
Skin haemorrhage	2	0
<i>Skin hyperplasias and hypertrophies</i>		
Skin hypertrophy	1	0
<i>Skin vasculitides</i>		
Vasculitic rash	1	0
<i>Skin vasomotor conditions</i>		
Livedo reticularis	9	0
<i>Urticarias</i>		
Cold urticaria	1	0
Idiopathic urticaria	1	0
Mechanical urticaria	1	0
Urticaria	287	0
Urticaria papular	1	0
Urticaria thermal	2	0
Skin disorders SOC TOTAL	3947	1

Case Series Drug Analysis Print

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

Report Run Date: 11-Feb-2021

Data Lock Date: 10-Feb-2021 19:00:04

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Social circumstances		
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Disability issues</i>		
Bedridden	7	0
Breast prosthesis user	1	0
Immobile	2	0
Social circumstances SOC TOTAL	11	0

Case Series Drug Analysis Print

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

Report Run Date: 11-Feb-2021

Data Lock Date: 10-Feb-2021 19:00:04

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	4	0
<i>Immunisations</i>		
COVID-19 immunisation	3	0
Immunisation	2	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	1	0
<i>Respiratory tract therapeutic procedures NEC</i>		
Asthma prophylaxis	2	0
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	1	0
<i>Therapeutic procedures NEC</i>		
Bed rest	1	0
Fatigue management	1	0
Hospitalisation	1	0
Injection	1	0
Surgical & medical procedures SOC TOTAL	17	0

Case Series Drug Analysis Print

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

Report Run Date: 11-Feb-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 10-Feb-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Vascular disorders		
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	2	0
<i>Circulatory collapse and shock</i>		
Circulatory collapse	23	0
Neurogenic shock	9	0
Peripheral circulatory failure	2	0
<i>Haemorrhages NEC</i>		
Haematoma	6	0
Haemorrhage	7	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	19	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	6	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Haemorrhagic infarction	1	0
<i>Non-site specific vascular disorders NEC</i>		
Superficial vein prominence	1	0
Vasodilatation	2	0
Vein discolouration	1	0
Vein disorder	2	0
Vein rupture	1	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	3	0
Deep vein thrombosis	5	0
Thrombophlebitis	1	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	8	0
Flushing	128	0
Hot flush	182	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	50	0
Peripheral ischaemia	1	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	3	0
Vasoconstriction	1	0
<i>Site specific vascular disorders NEC</i>		
Pallor	36	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	90	0
<i>Vascular hypotensive disorders</i>		
Hypotension	75	0
Orthostatic hypotension	3	0
<i>Vasculitides NEC</i>		
Vasculitis	4	0
<i>Vena caval embolism and thrombosis</i>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	676	0
TOTAL REACTIONS FOR DRUG	59614	143
TOTAL REPORTS	20319	
