

COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 04-Mar-2021
Data Lock Date: 03-Mar-2021 19:00:03

All UK spontaneous reports received between 9/12/20 and 21/02/21 for mRNA Pfizer/BioNTech vaccine analysis print

Case Series Drug Analysis Print

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

Report Run Date: 04-Mar-2021

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

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemias NEC</i>		
Anaemia	4	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>Lymphatic system disorders NEC</i>		
Granulomatous lymphadenitis	1	0
Lymph node pain	242	0
Lymphadenitis	37	0
Lymphadenopathy	1706	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	8	0
<i>Platelet disorders NEC</i>		
Platelet anisocytosis	1	0
<i>Spleen disorders</i>		
Splenomegaly	1	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	5	0
Thrombocytopenia	12	1
<i>Thrombocytoses</i>		
Thrombocytosis	2	0
Blood disorders SOC TOTAL	2033	1

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Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Bundle branch block right	1	0
<i>Cardiac disorders NEC</i>		
Cardiac disorder	3	0
Cardiovascular disorder	1	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	471	0
<i>Coronary artery disorders NEC</i>		
Coronary artery disease	1	1
<i>Heart failures NEC</i>		
Cardiac failure	3	1
Cardiac failure congestive	1	0
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	7	0
Angina pectoris	11	0
Myocardial infarction	21	6
<i>Left ventricular failures</i>		
Left ventricular failure	1	0
<i>Myocardial disorders NEC</i>		
Left ventricular dysfunction	1	0
Myocardial fibrosis	1	0
Myocardial oedema	2	0
Right ventricular enlargement	1	0
<i>Noninfectious myocarditis</i>		
Myocarditis	5	0
<i>Noninfectious pericarditis</i>		
Pericarditis	6	0
<i>Rate and rhythm disorders NEC</i>		
Arrhythmia	17	0
Bradycardia	14	0
Cardiac flutter	21	0
Extrasystoles	12	0
Postural orthostatic tachycardia syndrome	2	0
Tachycardia	293	0
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	5	0
Atrial fibrillation	44	1
Atrial flutter	1	0
Atrial tachycardia	2	0
Sinus bradycardia	1	0
Sinus tachycardia	24	0
Supraventricular tachycardia	11	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	35	14
Cardio-respiratory arrest	1	1
Pulseless electrical activity	2	0
Ventricular arrhythmia	1	0
Ventricular extrasystoles	3	0
Ventricular fibrillation	4	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	1032	25

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Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
<i>Retinal disorders congenital</i>		
Retinitis pigmentosa	1	0
Congenital disorders SOC TOTAL	3	0

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Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	3	0
Ear discomfort	15	0
Ear disorder	2	0
Ear pain	186	0
Ear pruritus	1	0
Ear swelling	6	0
Otorrhoea	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	1	0
Eustachian tube dysfunction	2	0
<i>External ear disorders NEC</i>		
Red ear syndrome	1	0
<i>Hearing disorders NEC</i>		
Auditory disorder	1	0
<i>Hearing losses</i>		
Deafness	19	0
Deafness neurosensory	2	0
Deafness unilateral	2	0
Hypoacusis	25	0
Sudden hearing loss	6	0
<i>Hyperacusia</i>		
Hyperacusis	8	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	1	0
Inner ear disorder	2	0
Meniere's disease	2	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	13	0
Tinnitus	169	0
Vertigo	223	0
Vertigo labyrinthine	4	0
Vertigo positional	16	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
Ear disorders SOC TOTAL	713	0

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Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis subacute	1	0
<i>Adrenal cortical hypofunctions</i>		
Adrenocortical insufficiency acute	3	0
<i>Endocrine abnormalities of puberty</i>		
Premature menarche	1	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	1	0
<i>Thyroid disorders NEC</i>		
Goitre	2	0
Thyroid pain	1	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	1	0
Endocrine disorders SOC TOTAL	10	0

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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
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous detachment	1	0
Vitreous floaters	10	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	10	0
<i>Corneal infections, oedemas and inflammations</i>		
Keratitis	2	0
Ulcerative keratitis	3	0
<i>Eyelid movement disorders</i>		
Blepharospasm	18	0
Excessive eye blinking	1	0
Eyelid ptosis	5	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	1	0
Iridocyclitis	5	0
Iritis	1	0
Uveitis	7	0
<i>Lacrimation disorders</i>		
Dry eye	26	0
Lacrimation increased	36	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	26	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	3	0
<i>Ocular disorders NEC</i>		
Eye disorder	10	0
Eye oedema	3	0
Eye pain	219	0
Eye swelling	117	0
Eye ulcer	1	0
Eyelid disorder	2	0
Eyelid pain	3	0
Eyelids pruritus	1	0
Ocular discomfort	6	0
Periorbital oedema	9	0
Periorbital pain	1	0
Periorbital swelling	25	0

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Eye disorders Eye disorders cont'd		
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	1	0
Eye discharge	6	0
Eye inflammation	4	0
Eye irritation	23	0
Eye pruritus	71	0
Limbal swelling	1	0
Ocular hyperaemia	50	0
<i>Ocular nerve and muscle disorders</i>		
Binocular eye movement disorder	1	0
Extraocular muscle paresis	1	0
Eye movement disorder	5	0
Ophthalmoplegia	2	0
Strabismus	1	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	5	0
Asthenopia	41	0
Eye paraesthesia	1	0
Foreign body sensation in eyes	8	0
Hypoaesthesia eye	2	0
Photophobia	91	0
<i>Optic disc abnormalities NEC</i>		
Papilloedema	1	0
<i>Pupil disorders</i>		
Miosis	1	0
Mydriasis	4	0
Pupillary disorder	1	0
Pupils unequal	2	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal haemorrhage	1	0
Retinal vein occlusion	2	0
<i>Retinal structural change, deposit and degeneration</i>		
Maculopathy	1	0
Retinal toxicity	1	0
<i>Scleral infections, irritations and inflammations</i>		
Episcleritis	3	0
<i>Visual colour distortions</i>		
Cyanopsia	1	0
Erythroptisia	2	0
<i>Visual disorders NEC</i>		
Diplopia	26	0
Halo vision	4	0
Metamorphopsia	2	0
Oscillopsia	1	0
Photopsia	25	0
Vision blurred	200	0
Visual brightness	1	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Blindness	12	0
Blindness transient	2	0
Blindness unilateral	1	0
Central vision loss	1	0
Sudden visual loss	1	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Visual acuity reduced	1	0
Visual impairment	61	0
Eye disorders SOC TOTAL	1242	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	2	0
<i>Acute and chronic pancreatitis</i>		
Pancreatitis	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	3	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	4	0
Colitis ulcerative	2	0
Crohn's disease	6	0
<i>Dental disorders NEC</i>		
Teething	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	1	0
Dental paraesthesia	1	0
Hyperaesthesia teeth	7	0
Toothache	17	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	1	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	1342	3
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	68	0
Epigastric discomfort	3	0
Eructation	13	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	3	0
Faeces discoloured	8	0
Faeces pale	2	0
Faeces soft	2	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	42	0
Aerophagia	2	0
Flatulence	42	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	2	1
<i>Gastritis (excl infective)</i>		
Gastritis	9	0
Reflux gastritis	3	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	275	0
Abdominal pain lower	15	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Abdominal pain upper	426	0
Abdominal rigidity	2	0
Abdominal tenderness	3	0
Gastrointestinal pain	27	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	34	0
Duodenogastric reflux	2	0
Gastric dilatation	1	0
Gastrooesophageal reflux disease	21	0
Intestinal pseudo-obstruction	1	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	2	0
Gastric disorder	3	0
Gastrointestinal disorder	2	0
<i>Gastrointestinal dyskinetic disorders</i>		
Dyschezia	1	0
Gastrointestinal motility disorder	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Enteritis	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	1	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	145	0
Anal incontinence	6	0
Breath odour	5	0
Dysphagia	43	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	2	0
Frequent bowel movements	9	0
Irritable bowel syndrome	13	0
Oesophageal spasm	2	0
Pylorospasm	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	1	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	5	0
Gingival discomfort	2	0
Gingival pain	21	0
Gingival swelling	6	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	5	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Gastric varices	1	0
Haemorrhoids	4	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	4	0
Rectal haemorrhage	14	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Small intestinal haemorrhage	1	0
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	2	2
<i>Malabsorption syndromes</i>		
Coeliac disease	1	0
Steatorrhoea	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	3	0
Nausea	3975	1
Regurgitation	1	0
Retching	33	0
Vomiting	1075	2
Vomiting projectile	18	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	3	0
Haematemesis	15	2
Haematochezia	6	0
Melaena	5	0
Upper gastrointestinal haemorrhage	2	0
<i>Oesophageal stenosis and obstruction</i>		
Oesophageal stenosis	1	0
<i>Oesophagitis (excl infective)</i>		
Oesophagitis	1	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	1	0
Dry mouth	155	0
Lip dry	12	0
Salivary hypersecretion	11	0
<i>Oral soft tissue disorders NEC</i>		
Chapped lips	5	0
Cheilitis	9	0
Enlarged uvula	4	0
Lip blister	7	0
Lip disorder	2	0
Oral disorder	3	0
Oral lichen planus	1	0
Oral papule	1	0
Uvulitis	1	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	1	0
Oral blood blister	4	0
<i>Oral soft tissue signs and symptoms</i>		
Anaesthesia oral	1	0
Hypoaesthesia oral	135	0
Lip discolouration	1	0
Lip erythema	1	0
Lip exfoliation	3	0
Lip pain	16	0
Lip pruritus	5	0
Lip scab	1	0
Odynophagia	2	0
Oral discomfort	19	0
Oral mucosal blistering	6	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Oral mucosal eruption	7	0
Oral mucosal erythema	1	0
Oral mucosal exfoliation	2	0
Oral pain	45	0
Oral pruritus	5	0
Paraesthesia oral	378	0
<i>Oral soft tissue swelling and oedema</i>		
Lip oedema	3	0
Lip swelling	206	0
Mouth swelling	22	0
Oedema mouth	1	0
Palatal oedema	1	0
Palatal swelling	1	0
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	1	0
<i>Peritoneal and retroperitoneal fibrosis and adhesions</i>		
Abdominal adhesions	1	0
<i>Rectal inflammations NEC</i>		
Proctitis	1	0
Proctitis ulcerative	1	0
<i>Salivary gland disorders NEC</i>		
Salivary gland pain	2	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	2	0
Submaxillary gland enlargement	4	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	10	0
Lip ulceration	2	0
Mouth ulceration	91	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	12	0
<i>Tongue disorders</i>		
Glossitis	3	0
Plicated tongue	2	0
Tongue disorder	12	0
Tongue haemorrhage	1	0
Tongue ulceration	7	0
<i>Tongue signs and symptoms</i>		
Glossodynia	60	0
Stiff tongue	1	0
Swollen tongue	162	0
Tongue blistering	3	0
Tongue coated	3	0
Tongue discolouration	5	0
Tongue discomfort	12	0
Tongue dry	5	0
Tongue eruption	4	0
Tongue erythema	1	0
Tongue movement disturbance	2	0
Tongue oedema	11	0
Tongue rough	2	0
Tongue spasm	3	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders cont'd		
Gastrointestinal disorders SOC TOTAL	9360	11

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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 pain	4	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	3	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 joint pain	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	384	1
Chronic fatigue syndrome	3	0
Fatigue	5761	1
Malaise	1356	0
Sluggishness	3	0
<i>Body temperature altered</i>		
Hypothermia	12	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	93	93
Sudden death	14	14
<i>Febrile disorders</i>		
Hyperpyrexia	3	0
Pyrexia	4786	0
<i>Feelings and sensations NEC</i>		
Chills	3107	0
Feeling abnormal	273	0
Feeling cold	335	0
Feeling drunk	14	0
Feeling hot	332	0

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General disorders General disorders cont'd		
Feeling jittery	7	0
Feeling of body temperature change	92	0
Hangover	13	0
Hunger	5	0
Sensation of foreign body	17	0
Temperature intolerance	4	0
Thirst	72	0
Gait disturbances		
Gait disturbance	30	0
Gait inability	19	0
Loss of control of legs	2	0
General signs and symptoms NEC		
Condition aggravated	27	0
Crepitations	1	0
Crying	17	0
Disease recurrence	1	0
Energy increased	2	0
Exercise tolerance decreased	2	0
General physical health deterioration	2	0
Glassy eyes	2	0
Illness	389	0
Induration	2	0
Influenza like illness	710	0
Irritability postvaccinal	1	0
Local reaction	39	0
Multiple organ dysfunction syndrome	1	1
Peripheral swelling	718	0
Pre-existing condition improved	3	0
Screaming	2	0
Secretion discharge	4	0
Swelling	540	0
Swelling face	205	0
Inflamations		
Inflammation	67	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		
Injected limb mobility decreased	10	0
Injection site bruising	15	0
Injection site discolouration	2	0
Injection site discomfort	4	0
Injection site erythema	137	0
Injection site haemorrhage	2	0
Injection site hypoaesthesia	6	0
Injection site indentation	1	0
Injection site induration	1	0
Injection site inflammation	10	0

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General disorders General disorders cont'd		
Injection site joint pain	8	0
Injection site mass	120	0
Injection site necrosis	2	0
Injection site oedema	7	0
Injection site pain	1031	0
Injection site paraesthesia	4	0
Injection site pruritus	63	0
Injection site rash	33	0
Injection site reaction	11	0
Injection site scab	2	0
Injection site scar	2	0
Injection site swelling	128	0
Injection site urticaria	7	0
Injection site vesicles	3	0
Injection site warmth	42	0
Interactions		
Alcohol interaction	2	0
Drug interaction	2	0
Mass conditions NEC		
Cyst	2	0
Mass	4	0
Nodule	4	0
Necrosis NEC		
Fat necrosis	1	0
Oedema NEC		
Face oedema	10	0
Localised oedema	9	0
Oedema	6	0
Oedema peripheral	14	0
Pain and discomfort NEC		
Axillary pain	268	0
Chest discomfort	346	0
Chest pain	453	0
Discomfort	34	0
Facial discomfort	6	0
Facial pain	52	0
Inflammatory pain	1	0
Non-cardiac chest pain	7	0
Pain	1860	0
Suprapubic pain	1	0
Tenderness	172	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	3	0
Drug ineffective	80	0
Immediate post-injection reaction	2	0
No reaction on previous exposure to drug	9	0
Therapeutic product effect delayed	1	0
Therapeutic product effect increased	1	0
Therapeutic response unexpected	10	0
Treatment failure	3	0
Ulcers NEC		
Ulcer	3	0
Vaccination site reactions		

Case Series Drug Analysis Print

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

Report Run Date: 04-Mar-2021

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

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Extensive swelling of vaccinated limb	2	0
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	34	0
Vaccination site cyst	1	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	5	0
Vaccination site discomfort	19	0
Vaccination site eczema	1	0
Vaccination site erythema	235	0
Vaccination site haemorrhage	5	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	32	0
Vaccination site inflammation	27	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	1	0
Vaccination site mass	62	0
Vaccination site movement impairment	22	0
Vaccination site oedema	3	0
Vaccination site pain	852	0
Vaccination site paraesthesia	4	0
Vaccination site pruritus	53	0
Vaccination site rash	36	0
Vaccination site reaction	12	0
Vaccination site swelling	253	0
Vaccination site ulcer	1	0
Vaccination site urticaria	5	0
Vaccination site vesicles	2	0
Vaccination site warmth	133	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	2	0
Withdrawal syndrome	1	0
General disorders SOC TOTAL	26391	111

Case Series Drug Analysis Print

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

Report Run Date: 04-Mar-2021

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

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Cholestasis and jaundice</i>		
Jaundice	3	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	6	0
Liver tenderness	1	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	2	0
Liver injury	2	0
Hepatic disorders SOC TOTAL	17	0

Case Series Drug Analysis Print

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

Report Run Date: 04-Mar-2021

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

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	5	0
<i>Allergic conditions NEC</i>		
Allergic oedema	4	0
Allergy to arthropod bite	1	0
Hypersensitivity	216	0
Multiple allergies	1	0
Serum sickness	2	0
Serum sickness-like reaction	2	0
Type I hypersensitivity	1	0
Type IV hypersensitivity reaction	3	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	2	0
Allergy to chemicals	1	0
Allergy to vaccine	15	0
Contrast media reaction	1	0
Drug hypersensitivity	5	0
Food allergy	2	0
Reaction to preservatives	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	173	0
Anaphylactic shock	7	0
Anaphylactoid reaction	8	0
Anaphylactoid shock	2	0
<i>Atopic disorders</i>		
Seasonal allergy	1	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	4	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	4	0
Immune system disorder	2	0
Immune-mediated adverse reaction	1	0
Immune system disorders SOC TOTAL	466	0

Case Series Drug Analysis Print

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

Report Run Date: 04-Mar-2021
Earliest Reaction Date: 19-Jan-2001

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

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	3	0
Diverticulitis	1	0
Dysentery	1	0
Gastroenteritis	7	0
<i>Aspergillus infections</i>		
Bronchopulmonary aspergillosis	1	0
<i>Bacterial infections NEC</i>		
Arthritis bacterial	1	0
Bacterial diarrhoea	1	0
Cellulitis	52	0
Conjunctivitis bacterial	1	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	6	0
<i>Candida infections</i>		
Anal candidiasis	1	0
Candida infection	5	0
Oral candidiasis	10	0
Vulvovaginal candidiasis	8	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	6	0
COVID-19	402	19
COVID-19 pneumonia	10	3
Coronavirus infection	4	0
Suspected COVID-19	27	0
<i>Coxiella infections</i>		
Q fever	6	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	3	0
Gingivitis	2	0
Parotitis	5	0
Pulpitis dental	1	0
Sialoadenitis	1	0
Tooth abscess	1	0
<i>Ear infections</i>		
Ear infection	11	0
Labyrinthitis	18	0
<i>Epstein-Barr viral infections</i>		
Infectious mononucleosis	1	0
<i>Eye and eyelid infections</i>		

Case Series Drug Analysis Print

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

Report Run Date: 04-Mar-2021

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

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Conjunctivitis	21	0
Eye abscess	1	0
Eye infection	3	0
Hordeolum	4	0
Periorbital infection	1	0
Female reproductive tract infections		
Vulval abscess	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	5	0
Herpes ophthalmic	1	0
Herpes simplex	3	0
Herpes simplex reactivation	1	0
Herpes virus infection	3	0
Herpes zoster	200	0
Herpes zoster oticus	2	0
Ophthalmic herpes zoster	1	0
Oral herpes	74	0
Infections NEC		
Abscess	3	0
Abscess limb	1	0
Abscess soft tissue	1	0
Infection	62	0
Injection site abscess	1	0
Injection site infection	3	0
Localised infection	5	0
Lymph gland infection	2	0
Respiratory tract infection	1	0
Vaccination site abscess	2	0
Vaccination site infection	7	0
Vestibulitis	1	0
Influenza viral infections		
Influenza	375	0
Lower respiratory tract and lung infections		
Bronchitis	4	0
Lower respiratory tract infection	35	5
Pneumonia	17	5
Sputum purulent	1	0
Male reproductive tract infections		
Epididymitis	1	0
Orchitis	2	0
Mumps viral infections		
Mumps	1	0
Muscle and soft tissue infections		
Soft tissue infection	1	0
Neisseria infections		
Gonorrhoea	1	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Sepsis	11	0
Urosepsis	2	0

Case Series Drug Analysis Print

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

Report Run Date: 04-Mar-2021

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

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
<i>Skin structures and soft tissue infections</i>		
Acne pustular	1	0
Folliculitis	3	0
Pustule	4	0
Rash pustular	2	0
Skin infection	5	0
Subcutaneous abscess	1	0
Vaccination site pustule	1	0
<i>Staphylococcal infections</i>		
Furuncle	5	0
Pneumonia staphylococcal	1	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>		
Laryngitis	1	0
Nasopharyngitis	175	0
Pharyngitis	5	0
Rhinitis	14	0
Sinusitis	18	0
Tonsillitis	20	0
Tracheitis	1	0
<i>Urinary tract infections</i>		
Cystitis	11	0
Kidney infection	4	0
Pyelonephritis	1	0
Urinary tract infection	30	0
<i>Vascular infections</i>		
Haematoma infection	1	0
Lymphangitis	1	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0
Eye infection viral	1	0
Gastroenteritis viral	5	0
Pneumonia viral	1	1
Post viral fatigue syndrome	5	0
Sweating fever	32	0
Vestibular neuronitis	4	0
Viral infection	1	0
Viral labyrinthitis	2	0
Viral pharyngitis	4	0
Viral rash	13	0
Viral tonsillitis	1	0
Infections SOC TOTAL	1863	33

Case Series Drug Analysis Print

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

Report Run Date: 04-Mar-2021
Earliest Reaction Date: 19-Jan-2001

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

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Oral contusion	1	0
Tongue injury	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	2	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>Chest and respiratory tract injuries NEC</i>		
Chest crushing	1	0
<i>Conditions caused by cold</i>		
Chillblains	14	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	4	0
Exposure via breast milk	1	0
Foetal exposure during pregnancy	2	0
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	9	0
Maternal exposure during pregnancy	37	0
<i>Eye injuries NEC</i>		
Eye contusion	5	0
Eye injury	2	0
Injury corneal	1	0
Periorbital haematoma	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	3	0
<i>Heat injuries (excl thermal burns)</i>		
Heat illness	1	0
Heat oedema	3	0
Heat stroke	1	0
<i>Limb fractures and dislocations</i>		
Atypical femur fracture	1	0
Clavicle fracture	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	3	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	2	0
Ligament sprain	1	0
Muscle injury	1	0
Muscle rupture	1	0
Muscle strain	3	0
Tendon injury	1	0
<i>Musculoskeletal procedural complications</i>		
Post laminectomy syndrome	1	0
<i>Nerve injuries NEC</i>		
Nerve injury	4	0

Case Series Drug Analysis Print

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

Report Run Date: 04-Mar-2021
Earliest Reaction Date: 19-Jan-2001

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

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	4	0
<i>Non-site specific injuries NEC</i>		
Bite	1	0
Electric shock	3	0
Fall	36	1
Wound	1	0
Wound complication	3	0
Wound secretion	1	0
<i>Non-site specific procedural complications</i>		
Incision site pain	2	0
Infusion related reaction	3	0
Injection related reaction	18	0
Post procedural complication	2	0
<i>Off label uses</i>		
Off label use	6	0
<i>Overdoses NEC</i>		
Overdose	7	0
<i>Peripheral nerve injuries</i>		
Ulnar nerve injury	2	0
<i>Poisoning and toxicity</i>		
Poisoning	1	0
<i>Product administration errors and issues</i>		
Accidental overdose	1	0
Contraindicated product administered	1	0
Inappropriate schedule of product administration	9	0
Incomplete course of vaccination	1	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	3	0
<i>Product preparation errors and issues</i>		
Product preparation issue	3	0
<i>Radiation injuries</i>		
Sunburn	3	0
<i>Site specific injuries NEC</i>		
Face crushing	1	0
Head injury	1	0
Limb injury	5	0
<i>Skin injuries NEC</i>		
Contusion	114	0
Nail avulsion	1	0
Scar	2	0
Scratch	1	0
Skin abrasion	3	0
<i>Stoma complications</i>		
Gastrointestinal stoma complication	1	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
<i>Thermal burns</i>		
Airway burns	1	0
Burn oesophageal	1	0

Case Series Drug Analysis Print

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

Report Run Date: 04-Mar-2021

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

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Burn of internal organs	1	0
Burns second degree	2	0
Thermal burn	3	0
Thermal burns of eye	1	0
<i>Underdoses NEC</i>		
Underdose	1	0
<i>Vaccination related complications</i>		
Vaccination complication	13	0
Vaccination failure	1	0
Injuries SOC TOTAL	393	1

Case Series Drug Analysis Print

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

Report Run Date: 04-Mar-2021
Earliest Reaction Date: 19-Jan-2001

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

Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Cortisol decreased	1	0
<i>Autoimmunity analyses</i>		
Rheumatoid factor	1	0
<i>Blood gas and acid base analyses</i>		
Blood lactic acid	1	0
Blood lactic acid increased	2	0
Blood pH	1	0
Blood pH increased	3	0
Oxygen consumption decreased	1	0
Oxygen saturation	4	0
Oxygen saturation decreased	22	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	2	0
Blood glucose abnormal	2	0
Blood glucose decreased	5	0
Blood glucose fluctuation	2	0
Blood glucose increased	32	0
Glycosylated haemoglobin increased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	1	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	4	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	2	0
International normalised ratio abnormal	1	0
International normalised ratio decreased	6	0
International normalised ratio increased	21	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	1	0
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	2	0
<i>Heart rate and pulse investigations</i>		
Heart rate	48	0
Heart rate abnormal	4	0
Heart rate decreased	9	0
Heart rate increased	152	0
Heart rate irregular	19	0
Pulse abnormal	6	0
Radial pulse abnormal	1	0
<i>Immunology analyses NEC</i>		
Antibody test	1	0
Antibody test abnormal	1	0

Case Series Drug Analysis Print

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

Report Run Date: 04-Mar-2021

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

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Immunology test	3	0
Immunology skin tests NEC		
Skin test positive	1	0
Investigations NEC		
Blood test abnormal	2	0
Polymerase chain reaction positive	14	0
Systemic lupus erythematosus disease activity index increased	1	0
Liver function analyses		
Alanine aminotransferase increased	3	0
Gamma-glutamyltransferase increased	1	0
Hepatic enzyme increased	1	0
Liver function test abnormal	2	0
Liver function test increased	5	0
Transaminases increased	1	0
Metabolism tests NEC		
Blood ketone body	1	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	1	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
Ophthalmic function diagnostic procedures		
Intraocular pressure increased	1	0
Physical examination procedures and organ system status		
Body temperature	83	0
Body temperature abnormal	19	0
Body temperature decreased	11	0
Body temperature fluctuation	8	0
Body temperature increased	160	0
Body temperature normal	1	0
Breath sounds abnormal	1	0
Grip strength	2	0
Grip strength decreased	2	0
Lymph node palpable	8	0
Product residue present	1	0
Respiratory rate	2	0
Respiratory rate decreased	2	0
Respiratory rate increased	14	0
Skin temperature	12	0
Temperature difference of extremities	1	0
Weight	1	0
Weight decreased	8	0
Weight increased	1	0
Pituitary analyses anterior		
Blood growth hormone	2	0

Case Series Drug Analysis Print

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

Report Run Date: 04-Mar-2021

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

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Blood thyroid stimulating hormone increased	1	0
Platelet analyses		
Platelet count decreased	3	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	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	1	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	1	0
Tissue enzyme analyses NEC		
Blood alkaline phosphatase increased	1	0
Urinalysis NEC		
Blood urine present	5	0
Glucose urine present	1	0
pH urine	2	0
pH urine increased	1	0
Urinary tract function analyses NEC		
Urine output	4	0
Urine output decreased	3	0
Urine output increased	1	0
Vascular tests NEC (incl blood pressure)		
Blood pressure abnormal	3	0
Blood pressure decreased	10	0
Blood pressure increased	70	0
Blood pressure measurement	7	0
Blood pressure systolic decreased	1	0
Blood pressure systolic increased	1	0
Virus identification and serology		
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	12	0
SARS-CoV-2 antibody test positive	1	0
SARS-CoV-2 test	11	0
SARS-CoV-2 test false positive	1	0
SARS-CoV-2 test negative	2	0

Case Series Drug Analysis Print

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

Report Run Date: 04-Mar-2021

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

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
SARS-CoV-2 test positive	35	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	965	0

Case Series Drug Analysis Print

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

Report Run Date: 04-Mar-2021
Earliest Reaction Date: 19-Jan-2001

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

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	1	0
Decreased appetite	354	0
Eating disorder symptom	1	0
Food craving	2	0
Food refusal	4	0
Hypophagia	4	0
Increased appetite	3	0
Salt craving	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	1	0
Diabetes mellitus inadequate control	3	1
Type 1 diabetes mellitus	3	0
<i>Diabetic complications NEC</i>		
Diabetic complication	1	0
Diabetic ketoacidosis	3	0
<i>Disorders of purine metabolism</i>		
Gout	17	0
<i>Electrolyte imbalance NEC</i>		
Fluid imbalance	1	0
<i>Fluid intake increased</i>		
Polydipsia	2	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Gluten sensitivity	1	0
Histamine intolerance	1	0
<i>General nutritional disorders NEC</i>		
Abnormal weight gain	4	0
Feeding disorder	10	0
Food aversion	2	0
Overweight	1	0
Poor feeding infant	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	18	0
Insulin resistance	1	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	27	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	3	0
Metabolic acidosis	2	0
<i>Mixed acid-base disorders</i>		
Acidosis	2	0
<i>Potassium imbalance</i>		
Hyperkalaemia	1	0
Hypokalaemic syndrome	1	0
<i>Sodium imbalance</i>		
Hyponatraemia	3	0
<i>Total fluid volume decreased</i>		
Dehydration	41	0
<i>Total fluid volume increased</i>		
Fluid retention	3	0

Case Series Drug Analysis Print

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

Report Run Date: 04-Mar-2021

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

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Metabolic disorders SOC TOTAL	525	1

Case Series Drug Analysis Print

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

Report Run Date: 04-Mar-2021
 Earliest Reaction Date: 19-Jan-2001

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	46	0
Arthropathy	4	0
Polyarthritis	1	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	78	0
Bone swelling	1	0
Coccydynia	1	0
Pain in jaw	76	0
Spinal pain	9	0
<i>Bursal disorders</i>		
Bursitis	7	0
<i>Cartilage disorders</i>		
Costochondritis	9	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	4	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 lock	1	0
Periarthritis	9	0
Temporomandibular joint syndrome	1	0
<i>Joint related signs and symptoms</i>		
Arthralgia	2412	0
Jaw clicking	2	0
Joint effusion	4	0
Joint noise	4	0
Joint range of motion decreased	2	0
Joint stiffness	51	0
Joint swelling	70	0
Joint vibration	1	0
Joint warmth	3	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	2	0
<i>Muscle infections and inflammations</i>		
Antisynthetase syndrome	1	0
Myositis	3	0
Polymyositis	1	0
<i>Muscle pains</i>		
Fibromyalgia	14	0
Myalgia	3549	0
Myofascial pain syndrome	5	0

Case Series Drug Analysis Print

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

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
<i>Muscle related signs and symptoms NEC</i>		
Muscle atrophy	1	0
Muscle discomfort	1	0
Muscle disorder	2	0
Muscle fatigue	95	0
Muscle spasms	166	0
Muscle swelling	8	0
Muscle tightness	19	0
Muscle twitching	65	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	7	0
Nuchal rigidity	4	0
Torticollis	2	0
Trismus	8	0
<i>Muscle weakness conditions</i>		
Muscular weakness	181	0
<i>Musculoskeletal and connective tissue conditions NEC</i>		
Limb mass	2	0
Mandibular mass	1	0
Mastication disorder	1	0
Mobility decreased	17	0
Musculoskeletal disorder	3	0
Musculoskeletal stiffness	273	0
Posture abnormal	1	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	516	0
Flank pain	7	0
Limb discomfort	373	0
Musculoskeletal chest pain	33	0
Musculoskeletal discomfort	20	0
Musculoskeletal pain	16	0
Neck pain	427	0
Pain in extremity	2819	0
Rheumatic disorder	1	0
<i>Myopathies</i>		
Rhabdomyolysis	3	0
<i>Osteoarthropathies</i>		
Osteoarthritis	6	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	2	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	14	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	36	0
Groin pain	23	0
Neck mass	7	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	2	0
Arthritis reactive	6	0
<i>Synovial disorders</i>		

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Synovial cyst	3	0
Synovitis	3	0
<i>Tendon disorders</i>		
Tendon pain	2	0
Tendonitis	3	0
Tenosynovitis	1	0
Tenosynovitis stenosaurs	1	0
<i>Trunk deformities</i>		
Drooping shoulder syndrome	1	0
Muscle & tissue disorders SOC TOTAL	11565	0

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Reaction Name	Total	Fatal
Neoplasms		
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	4	0
<i>Metastases to specified sites</i>		
Metastases to lymph nodes	2	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>Soft tissue neoplasms benign NEC</i>		
Lipoma	1	0
<i>Soft tissue sarcomas histology unspecified</i>		
Sarcoma	1	0
Neoplasms SOC TOTAL	20	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Extensor plantar response	1	0
Hyperreflexia	1	0
Hyporeflexia	4	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	2	0
<i>Absence seizures</i>		
Petit mal epilepsy	5	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	3	0
<i>Autonomic nervous system disorders</i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	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	2	0
Cerebral artery occlusion	1	0
Cerebral haemorrhage	10	3
Cerebral infarction	7	0
Cerebrovascular accident	48	3
Embolic stroke	1	0
Haemorrhage intracranial	2	0
Haemorrhagic stroke	1	1
Ischaemic cerebral infarction	1	0
Ischaemic stroke	10	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>Cervical spinal cord and nerve root disorders</i>		
Cervicobrachial syndrome	1	0
<i>Choreiform movements</i>		
Chorea	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	1	0
Balance disorder	77	0
Coordination abnormal	10	0
Dysstasia	13	0
<i>Cortical dysfunction NEC</i>		
Aphasia	13	0
Neurologic neglect syndrome	1	0
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	2	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	3	0
Dementia with Lewy bodies	1	0
<i>Demyelinating disorders NEC</i>		

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Reaction Name	Total	Fatal
Nervous system disorders		
Nervous system disorders cont'd		
Demyelination	1	0
Disturbances in consciousness NEC		
Altered state of consciousness	4	0
Consciousness fluctuating	2	0
Depressed level of consciousness	6	0
Lethargy	676	0
Loss of consciousness	78	0
Sedation	3	0
Somnolence	210	0
Stupor	1	0
Syncope	278	0
Dyskinesias and movement disorders NEC		
Akathisia	1	0
Bradykinesia	3	0
Dyskinesia	5	0
Extrapyramidal disorder	1	0
Fine motor skill dysfunction	2	0
Hypokinesia	4	0
Motor dysfunction	1	0
Movement disorder	8	0
Psychomotor hyperactivity	4	0
Dystonias		
Dystonia	5	0
Writer's cramp	1	0
Encephalopathies NEC		
Encephalopathy	1	0
Posterior reversible encephalopathy syndrome	1	0
Eye movement disorders		
IIIrd nerve paralysis	2	0
VIth nerve paralysis	3	0
Facial cranial nerve disorders		
Facial nerve disorder	1	0
Facial paralysis	135	0
Facial paresis	24	0
Facial spasm	10	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	5	0
Headaches NEC		
Cervicogenic headache	1	0
Cluster headache	48	0
Cold-stimulus headache	2	0
Exertional headache	3	0
Headache	7776	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	101	0
Tension headache	126	0
Thunderclap headache	1	0
Vascular headache	3	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	8	0
<i>Memory loss (excl dementia)</i>		
Amnesia	11	0
Memory impairment	27	0
Transient global amnesia	1	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	9	0
Disturbance in attention	57	0
Mental impairment	7	0
<i>Migraine headaches</i>		
Hemiplegic migraine	3	0
Migraine	529	0
Migraine with aura	30	0
Retinal migraine	8	0
Typical aura without headache	1	0
Vestibular migraine	1	0
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	2	0
Mononeuropathy	1	0
Nerve compression	3	0
Peroneal nerve palsy	2	0
<i>Multiple sclerosis acute and progressive</i>		
Multiple sclerosis	5	0
Multiple sclerosis relapse	6	0
<i>Muscle tone abnormal</i>		
Hypotonia	4	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	7	0
<i>Narcolepsy and hypersomnia</i>		
Hypersomnia	21	0
Narcolepsy	1	0
<i>Nervous system disorders NEC</i>		
Nervous system disorder	1	0
<i>Neurologic visual problems NEC</i>		
Tunnel vision	4	0
Visual field defect	3	0
<i>Neurological signs and symptoms NEC</i>		
Dizziness	2240	0
Dizziness exertional	11	0
Dizziness postural	192	0
Drooling	2	0
Head discomfort	53	0
Hyporesponsive to stimuli	1	0
Inability to crawl	1	0
Myoclonus	4	0
Neurological symptom	4	0
Persistent postural-perceptual dizziness	3	0
Presyncope	141	0
Slow response to stimuli	2	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Unresponsive to stimuli	15	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	5	0
Muscle spasticity	2	0
Neuromuscular pain	1	0
Neuromuscular junction dysfunction		
Myasthenia gravis	2	0
Olfactory nerve disorders		
Anosmia	61	0
Hyposmia	5	0
Parosmia	48	0
Optic nerve disorders NEC		
Optic neuritis	4	0
Paraesthesias and dysaesthesias		
Burning sensation	89	0
Dysaesthesia	3	0
Formication	8	0
Hemiparaesthesia	1	0
Hyperaesthesia	21	0
Hypoaesthesia	499	0
Paraesthesia	739	0
Synaesthesia	1	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	1	1
Hemiparesis	12	0
Hemiplegia	3	0
Locked-in syndrome	1	0
Monoparesis	16	0
Monoplegia	11	0
Paralysis	17	0
Paraparesis	1	0
Paresis	1	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	3	0
Parkinsonian gait	1	0
Parkinsonism	3	0
Partial complex seizures		
Dreamy state	1	0
Temporal lobe epilepsy	1	0
Peripheral neuropathies NEC		
Neuritis	2	0
Neuropathy peripheral	15	0
Peripheral sensory neuropathy	3	0
Seizures and seizure disorders NEC		
Clonic convulsion	1	0
Epilepsy	21	0
Febrile convulsion	1	0
Partial seizures	2	0
Psychogenic seizure	3	0
Seizure	85	1
Seizure cluster	1	0
Status epilepticus	2	0
Tonic convulsion	5	0

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Sensory abnormalities NEC</i>		
Ageusia	127	0
Allodynia	3	0
Aura	7	0
Dysgeusia	334	0
Hypergeusia	1	0
Neuralgia	76	0
Phantom limb syndrome	1	0
Post herpetic neuralgia	2	0
Restless legs syndrome	22	0
Sensory disturbance	11	0
Sensory loss	10	0
Taste disorder	66	0
<i>Sleep disturbances NEC</i>		
Poor quality sleep	45	0
Sleep deficit	2	0
<i>Speech and language abnormalities</i>		
Dysarthria	28	0
Incoherent	1	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	18	0
<i>Tremor (excl congenital)</i>		
Essential tremor	1	0
Resting tremor	1	0
Tremor	412	0
<i>Trigeminal disorders</i>		
Facial neuralgia	9	0
Numb chin syndrome	1	0
Trigeminal nerve disorder	1	0
Trigeminal neuralgia	9	0
Nervous system disorders SOC TOTAL	16107	14

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Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	16	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	4	0
Preterm premature rupture of membranes	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	5	0
Pregnancy conditions SOC TOTAL	29	1

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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	5	0
<i>Product physical issues</i>		
Product odour abnormal	1	0
Product taste abnormal	2	0
<i>Product quality issues NEC</i>		
Product origin unknown	1	0
null SOC TOTAL	12	0

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Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Affect alterations NEC</i>		
Flat affect	1	0
<i>Anxiety symptoms</i>		
Agitation	24	0
Anxiety	107	0
Nervousness	51	0
Stress	1	0
Tension	11	0
<i>Behaviour and socialisation disturbances</i>		
Indifference	2	0
Paranoia	6	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	1	0
Mental fatigue	36	0
<i>Communications disorders</i>		
Communication disorder	2	0
<i>Confusion and disorientation</i>		
Confusional state	171	0
Disorientation	57	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	34	0
<i>Delusional symptoms</i>		
Delusion	1	0
<i>Depressive disorders</i>		
Depression	28	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	2	0
Dissociation	4	0
Dissociative amnesia	1	0
Dissociative disorder	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	3	0
Insomnia	231	0
Middle insomnia	6	0
Terminal insomnia	1	0
<i>Dyssomnias</i>		
Dyssomnia	1	0
<i>Eating disorders NEC</i>		
Eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	3	0
Dysphoria	1	0
Emotional disorder	6	0
Emotional distress	6	0
Euphoric mood	5	0
Irritability	42	0
Mood altered	7	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear of falling	1	0
Phonophobia	1	0
Social fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	5	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	50	0
Hallucination, auditory	3	0
Hallucination, olfactory	1	0
Hallucination, tactile	1	0
Hallucination, visual	5	0
Hallucinations, mixed	1	0
<i>Increased physical activity levels</i>		
Restlessness	25	0
<i>Mental disorders NEC</i>		
Mental disorder	2	0
<i>Mental disorders due to a general medical condition NEC</i>		
Neuropsychiatric symptoms	1	0
<i>Mood alterations with depressive symptoms</i>		
Decreased interest	3	0
Depressed mood	49	0
Feeling of despair	1	0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Sense of a foreshortened future	2	0
Tearfulness	4	0
<i>Mood alterations with manic symptoms</i>		
Hypomania	1	0
<i>Mood disorders NEC</i>		
Apathy	4	0
Laziness	1	0
Listless	4	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	24	0
Panic disorder	2	0
Panic reaction	5	0
<i>Parasomnias</i>		
Abnormal dreams	43	0
Confusional arousal	1	0
Nightmare	35	0
Sleep terror	2	0
<i>Perception disturbances NEC</i>		
Autoscopy	2	0
Derealisation	3	0
Flashback	1	0
Illusion	1	0

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Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<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	4	0
<i>Sexual desire disorders</i>		
Loss of libido	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	38	0
<i>Somatic symptom disorders</i>		
Habit cough	5	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
Pressure of speech	1	0
<i>Stereotypies and automatisms</i>		
Bruxism	3	0
Head banging	2	0
Stereotypy	1	0
<i>Suicidal and self-injurious behaviour</i>		
Intentional self-injury	2	0
Suicidal ideation	1	0
Suicide attempt	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	10	0
Tachyphrenia	1	0
Thinking abnormal	3	0
Psychiatric disorders SOC TOTAL	1235	0

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Earliest Reaction Date: 19-Jan-2001

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Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	1	0
Dysuria	9	0
Incontinence	8	0
Micturition disorder	1	0
Micturition urgency	6	0
Pollakiuria	15	0
Urethral pain	1	0
Urinary incontinence	15	0
Urinary retention	14	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>Glomerulonephritis and nephrotic syndrome</i>		
Glomerulonephritis minimal lesion	1	0
Nephrotic syndrome	2	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	10	0
Anuria	1	0
Chronic kidney disease	1	0
Renal failure	3	0
<i>Urinary abnormalities</i>		
Chromaturia	12	0
Haematuria	6	0
Proteinuria	2	0
Urine abnormality	4	0
Urine odour abnormal	2	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0
Haemorrhage urinary tract	4	0
Nocturia	1	0
Polyuria	1	0
Renal pain	53	0
Urinary tract pain	1	0
Renal & urinary disorders SOC TOTAL	187	0

Case Series Drug Analysis Print

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

Report Run Date: 04-Mar-2021

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

Earliest Reaction Date: 19-Jan-2001

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	7	0
Gynaecomastia	1	0
<i>Breast signs and symptoms</i>		
Breast discomfort	2	0
Breast oedema	1	0
Breast pain	46	0
Breast swelling	10	0
Breast tenderness	6	0
Nipple pain	5	0
Nipple swelling	2	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	7	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	18	0
Menstrual disorder	19	0
Menstruation irregular	17	0
Metrorrhagia	8	0
Premenstrual pain	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	7	0
Hypomenorrhoea	11	0
Menstruation delayed	32	0
Oligomenorrhoea	1	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	38	0
Polymenorrhoea	5	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovulation pain	3	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	3	0
Pelvic haemorrhage	1	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile swelling	3	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatomegaly	1	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital haemorrhage	1	0
Genital ulceration	2	0
<i>Reproductive tract infections and inflammations NEC</i>		
Genital tract inflammation	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital pain	2	0
Pelvic discomfort	2	0
Pelvic pain	7	0
Perineal pain	1	0
<i>Scrotal disorders NEC</i>		

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Reaction Name	Total	Fatal
Reproductive & breast disorders		
Scrotal erythema	1	0
Scrotal exfoliation	1	0
Scrotal pain	3	0
Scrotal swelling	3	0
<i>Sexual function and fertility disorders NEC</i>		
Infertility	1	0
<i>Spermatogenesis and semen disorders</i>		
Haematospermia	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular pain	5	0
Testicular swelling	3	0
<i>Uterine disorders NEC</i>		
Endometriosis	2	0
Uterine pain	1	0
<i>Uterine tone disorders</i>		
Uterine spasm	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	34	0
Vulval ulceration	2	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	1	0
Vulval oedema	1	0
Vulvovaginal pruritus	1	0
Reproductive & breast disorders SOC TOTAL	338	0

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Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	1	0
Dyspnoea	816	2
Dyspnoea at rest	1	0
Dyspnoea exertional	7	1
Hyperventilation	9	0
Hypopnoea	14	0
Irregular breathing	6	0
Mouth breathing	2	0
Orthopnoea	2	0
Respiration abnormal	16	0
Respiratory arrest	5	0
Respiratory distress	4	0
Sleep apnoea syndrome	1	0
Tachypnoea	14	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	1	0
Bronchiectasis	3	0
<i>Bronchospasm and obstruction</i>		
Asthma	76	0
Asthma late onset	1	0
Bronchospasm	6	0
Chronic obstructive pulmonary disease	5	0
Obstructive airways disorder	1	0
Reversible airways obstruction	1	0
Wheezing	101	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	9	1
<i>Coughing and associated symptoms</i>		
Allergic cough	1	0
Cough	594	0
Haemoptysis	7	0
Productive cough	36	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	8	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Hypersensitivity pneumonitis	1	0
Pneumonia aspiration	3	2
Pneumonitis	8	3
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	3	0
Increased bronchial secretion	1	0
Pleuritic pain	4	0
Pulmonary pain	25	0
Rales	2	0
<i>Nasal congestion and inflammations</i>		

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Nasal congestion	52	0
Nasal inflammation	1	0
Rhinitis allergic	3	0
<i>Nasal disorders NEC</i>		
Epistaxis	147	0
Intranasal hypoaesthesia	1	0
Intranasal paraesthesia	1	0
Nasal disorder	1	0
Nasal dryness	5	0
Nasal odour	4	0
Nasal oedema	1	0
Nasal pruritus	3	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Allergic sinusitis	1	0
Paranasal sinus inflammation	1	0
Sinonasal obstruction	3	0
Sinus congestion	13	0
Sinus disorder	2	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	1	0
Emphysema	1	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	3	0
Pharyngeal haemorrhage	1	0
Pharyngeal hypoaesthesia	10	0
Pharyngeal inflammation	3	0
Pharyngeal oedema	4	0
Pharyngeal paraesthesia	25	0
Pharyngeal swelling	70	0
Pharyngeal ulceration	5	0
Tonsillar erythema	1	0
Tonsillar hypertrophy	21	0
Tonsillar inflammation	3	0
<i>Pleural infections and inflammations</i>		
Pleurisy	4	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	1	0
Pneumothorax	1	0
<i>Pulmonary oedemas</i>		
Pulmonary congestion	3	0
Pulmonary oedema	2	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	13	1
Pulmonary infarction	1	0
Pulmonary thrombosis	1	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	2	1
<i>Respiratory signs and symptoms NEC</i>		
Painful respiration	3	0
Respiratory symptom	3	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	2	1
Respiratory disorder	2	0

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Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
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	16	0
Catarrh	7	0
Choking	3	0
Dry throat	47	0
Dysphonia	36	0
Increased upper airway secretion	3	0
Increased viscosity of upper respiratory secretion	3	0
Nasal discharge discolouration	1	0
Nasal discomfort	11	0
Nasal obstruction	2	0
Oropharyngeal blistering	6	0
Oropharyngeal discomfort	20	0
Oropharyngeal pain	698	0
Paranasal sinus discomfort	10	0
Rhinalgia	6	0
Rhinorrhoea	182	0
Sinus pain	49	0
Sneezing	90	0
Snoring	2	0
Throat clearing	3	0
Throat irritation	63	0
Throat tightness	81	0
Upper airway obstruction	2	0
Upper-airway cough syndrome	2	0
Yawning	2	0
Respiratory disorders SOC TOTAL	3575	12

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Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	8	0
<i>Alopecias</i>		
Alopecia	13	0
<i>Angioedemas</i>		
Angioedema	54	0
Circumoral swelling	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	173	0
Hyperhidrosis	464	0
Miliaria	18	0
Night sweats	172	0
<i>Bullous conditions</i>		
Blister	63	0
Blood blister	2	0
Dermatitis bullous	4	0
Erythema multiforme	8	0
Fracture blisters	1	0
Pemphigoid	4	0
Pemphigus	2	0
Stevens-Johnson syndrome	2	0
Toxic epidermal necrolysis	2	1
<i>Connective tissue disorders</i>		
Dermatomyositis	1	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	38	0
Macule	2	0
Pain of skin	79	0
Papule	16	0
Pathergy reaction	1	0
Peau d'orange	2	0
Scar pain	4	0
Sensitive skin	45	0
Skin burning sensation	50	0
Skin discolouration	25	0
Skin discomfort	1	0
Skin disorder	1	0
Skin indentation	1	0
Skin induration	2	0
Skin lesion	8	0
Skin necrosis	1	0
Skin odour abnormal	2	0
Skin reaction	31	0
Skin sensitisation	5	0
Skin swelling	18	0
Skin tightness	12	0
Skin warm	85	0
Skin weeping	1	0
Sticky skin	1	0
Yellow skin	5	0
<i>Dermatitis and eczema</i>		

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Dermatitis	27	0
Dermatitis allergic	54	0
Dermatitis atopic	3	0
Dyshidrotic eczema	2	0
Eczema	31	0
Eczema asteatotic	1	0
Eczema nummular	2	0
Eczema weeping	1	0
Perioral dermatitis	1	0
Skin irritation	28	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	11	0
Fixed eruption	1	0
Toxic skin eruption	1	0
<i>Erythemas</i>		
Erythema	654	0
Red man syndrome	1	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	1	0
Exfoliative rash	2	0
Skin exfoliation	20	0
<i>Hyperpigmentation disorders</i>		
Ephelides	1	0
Skin hyperpigmentation	1	0
<i>Hypopigmentation disorders</i>		
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	3	0
<i>Panniculitides</i>		
Erythema nodosum	5	0
<i>Papulosquamous conditions</i>		
Erythema annulare	1	0
Lichen planus	1	0
Pityriasis rosea	18	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	9	0
<i>Pigmentation changes NEC</i>		
Haemosiderin stain	1	0
Pigmentation disorder	2	0
<i>Pilar disorders NEC</i>		
Piloerection	3	0
<i>Pruritus NEC</i>		
Itching scar	4	0
Pruritus	1202	0
<i>Psoriatic conditions</i>		
Psoriasis	15	0
Pustular psoriasis	1	0
<i>Purpura and related conditions</i>		
Petechiae	23	0

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Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Purpura	7	0
Rashes, eruptions and exanthems NEC		
Rash	1224	0
Rash erythematous	276	0
Rash macular	125	0
Rash maculo-papular	19	0
Rash morbilliform	7	0
Rash papular	68	0
Rash pruritic	255	0
Rash vesicular	9	0
Systemic lupus erythematosus rash	1	0
Rosaceas		
Rosacea	3	0
Scaly conditions		
Pityriasis	5	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	9	0
Skin ulcer	1	0
Skin cysts and polyps		
Dermal cyst	1	0
Skin haemorrhages		
Haemorrhage subcutaneous	2	0
Skin haemorrhage	2	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	1	0
Skin vasculitides		
Cutaneous vasculitis	1	0
Vasculitic rash	2	0
Skin vasomotor conditions		
Livedo reticularis	12	0
Urticarias		
Chronic spontaneous urticaria	1	0
Cold urticaria	1	0
Idiopathic urticaria	1	0
Mechanical urticaria	1	0
Urticaria	430	0
Urticaria chronic	1	0
Urticaria papular	2	0
Urticaria thermal	2	0
Skin disorders SOC TOTAL	6042	1

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Reaction Name	Total	Fatal
Social circumstances		
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Disability issues</i>		
Bedridden	8	0
Breast prosthesis user	1	0
Immobile	2	0
Sight disability	1	0
<i>Educational issues</i>		
Illiteracy	1	0
<i>Pregnancy related circumstances</i>		
Breast feeding	1	0
<i>Tobacco use</i>		
Non-tobacco user	1	0
Social circumstances SOC TOTAL	16	0

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Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Bronchial and pulmonary therapeutic procedures</i>		
Airway secretion clearance therapy	1	0
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dietary and nutritional therapies</i>		
Diabetic diet	1	0
Medical diet	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	5	0
<i>Immunisations</i>		
COVID-19 immunisation	13	0
Immunisation	4	0
<i>Joint therapeutic procedures</i>		
Joint surgery	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	2	0
Limb operation	1	0
<i>Mastectomies</i>		
Breast conserving surgery	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	1	0
Bed rest	2	0
Fatigue management	1	0
Hospitalisation	1	0
Injection	2	0
Product used for unknown indication	1	0
Therapy change	1	0
Surgical & medical procedures SOC TOTAL	45	0

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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	2	0
Labile blood pressure	2	0
<i>Circulatory collapse and shock</i>		
CT hypotension complex	2	0
Circulatory collapse	27	0
Neurogenic shock	12	0
Peripheral circulatory failure	2	0
Shock	2	0
<i>Haemorrhages NEC</i>		
Haematoma	10	0
Haemorrhage	18	1
Venous haemorrhage	1	0
<i>Lymphangiopathies</i>		
Lymphocele	1	0
<i>Lymphoedemas</i>		
Lymphoedema	32	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	9	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	2	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	3	0
Deep vein thrombosis	7	0
Thrombophlebitis	2	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	13	0
Flushing	170	0
Hot flush	267	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	70	0
Peripheral ischaemia	1	0
Poor peripheral circulation	1	0
Raynaud's phenomenon	9	0
Vasoconstriction	1	0
<i>Phlebitis NEC</i>		
Phlebitis	2	0
<i>Site specific vascular disorders NEC</i>		

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