

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

Report Run Date: 31-Jan-2021

Data Lock Date: 28-Jan-2021 19:00:04

ALL UK spontaneous reports received between 9/12/20 and 24/01/21 for mRNA Pfizer- BioNTech vaccine analysis print

Case Series Drug Analysis Print

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

Report Run Date: 31-Jan-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 28-Jan-2021 19:00:04
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	1	0
<i>Lymphatic system disorders NEC</i>		
Lymph node pain	151	0
Lymphadenitis	18	0
Lymphadenopathy	969	0
Lymphatic disorder	1	0
Pseudolymphoma	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Pancytopenia	1	0
<i>Neutropenias</i>		
Neutropenia	2	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	1	0
Thrombocytopenia	4	0
<i>Thrombocytoses</i>		
Thrombocytosis	1	0
Blood disorders SOC TOTAL	1152	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	1	0
<i>Cardiac signs and symptoms NEC</i>		
Palpitations	254	0
<i>Heart failures NEC</i>		
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute myocardial infarction	4	0
Angina pectoris	4	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	7	0
Bradycardia	11	0
Cardiac flutter	8	0
Extrasystoles	7	0
Postural orthostatic tachycardia syndrome	1	0
Tachycardia	193	0
<i>Supraventricular arrhythmias</i>		
Arrhythmia supraventricular	2	0
Atrial fibrillation	24	1
Atrial tachycardia	1	0
Sinus bradycardia	1	0
Sinus tachycardia	18	0
Supraventricular tachycardia	7	0
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	16	7
Pulseless electrical activity	1	0
Ventricular extrasystoles	2	0
Ventricular fibrillation	2	0
Ventricular tachycardia	1	0
Cardiac disorders SOC TOTAL	590	12

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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	9	0
Ear disorder	1	0
Ear pain	98	0
Ear pruritus	1	0
Ear swelling	1	0
<i>Hearing losses</i>		
Deafness	5	0
Hypoacusis	13	0
Sudden hearing loss	1	0
<i>Hyperacusia</i>		
Hyperacusis	5	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	1	0
Inner ear disorder	1	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	9	0
Tinnitus	72	0
Vertigo	105	0
Vertigo labyrinthine	2	0
Vertigo positional	6	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
Ear disorders SOC TOTAL	334	0

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Reaction Name	Total	Fatal
Endocrine disorders		
<i>Endocrine abnormalities of puberty</i>		
Premature menarche	1	0
<i>Thyroid disorders NEC</i>		
Goitre	1	0
Endocrine disorders SOC TOTAL	2	0

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Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	1	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Vitreous floaters	4	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	6	0
<i>Corneal infections, oedemas and inflammations</i>		
Ulcerative keratitis	1	0
<i>Eyelid movement disorders</i>		
Blepharospasm	8	0
Eyelid ptosis	1	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Iridocyclitis	3	0
Uveitis	1	0
<i>Lacrimation disorders</i>		
Dry eye	10	0
Lacrimation increased	17	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	1	0
Erythema of eyelid	1	0
Eyelid irritation	1	0
Eyelid margin crusting	1	0
Eyelid rash	2	0
Swelling of eyelid	15	0
<i>Lid, lash and lacrimal structural disorders</i>		
Eyelid exfoliation	1	0
<i>Ocular disorders NEC</i>		
Eye disorder	9	0
Eye oedema	2	0
Eye pain	122	0
Eye swelling	56	0
Eye ulcer	1	0
Eyelid pain	1	0
Eyelids pruritus	1	0
Ocular discomfort	4	0
Periorbital oedema	3	0
Periorbital pain	1	0
Periorbital swelling	13	0
<i>Ocular infections, inflammations and associated manifestations</i>		
Eye allergy	1	0
Eye discharge	3	0
Eye inflammation	2	0
Eye irritation	13	0
Eye pruritus	32	0
Ocular hyperaemia	25	0
<i>Ocular nerve and muscle disorders</i>		
Binocular eye movement disorder	1	0
Eye movement disorder	4	0
Ophthalmoplegia	1	0
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	4	0
Asthenopia	22	0

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Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Eye paraesthesia	1	0
Foreign body sensation in eyes	5	0
Hypoaesthesia eye	1	0
Photophobia	50	0
Optic disc abnormalities NEC		
Papilloedema	1	0
Pupil disorders		
Miosis	1	0
Mydriasis	2	0
Pupils unequal	2	0
Retinal structural change, deposit and degeneration		
Maculopathy	1	0
Scleral infections, irritations and inflammations		
Episcleritis	1	0
Visual disorders NEC		
Diplopia	12	0
Halo vision	2	0
Metamorphopsia	2	0
Oscillopsia	1	0
Photopsia	10	0
Vision blurred	106	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	31	0
Eye disorders SOC TOTAL	634	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Gastrointestinal sounds abnormal	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>		
Anorectal discomfort	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	1	0
<i>Colitis (excl infective)</i>		
Colitis	1	0
Crohn's disease	1	0
<i>Dental disorders NEC</i>		
Teething	1	0
<i>Dental pain and sensation disorders</i>		
Hyperaesthesia teeth	3	0
Toothache	8	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	732	1
Diarrhoea haemorrhagic	2	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	34	0
Epigastric discomfort	1	0
Eructation	7	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	21	0
Aerophagia	2	0
Flatulence	20	0
<i>Gastritis (excl infective)</i>		
Gastritis	4	0
Reflux gastritis	2	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal pain	156	0
Abdominal pain lower	8	0
Abdominal pain upper	214	0
Abdominal tenderness	2	0
Gastrointestinal pain	10	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	12	0
Duodenogastric reflux	1	0
Gastrooesophageal reflux disease	13	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	2	0
Gastric disorder	2	0
Gastrointestinal disorder	1	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
<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	66	0
Anal incontinence	2	0
Breath odour	5	0
Dysphagia	27	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	2	0
Frequent bowel movements	8	0
Irritable bowel syndrome	6	0
Oesophageal spasm	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	2	0
Gingival discomfort	1	0
Gingival pain	9	0
Gingival swelling	2	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	1	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	4	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Haemorrhoids	2	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	1	0
Rectal haemorrhage	7	0
<i>Malabsorption syndromes</i>		
Steatorrhoea	1	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	2	0
Nausea	2365	0
Regurgitation	1	0
Retching	14	0
Vomiting	616	2
Vomiting projectile	10	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	2	0
Haematemesis	9	2
Haematochezia	2	0
Melaena	2	0
Upper gastrointestinal haemorrhage	2	0
<i>Oesophagitis (excl infective)</i>		
Oesophagitis	1	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	1	0
Dry mouth	76	0
Lip dry	5	0

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Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Salivary hypersecretion	6	0
Oral soft tissue disorders NEC		
Chapped lips	3	0
Cheilitis	5	0
Enlarged uvula	2	0
Lip blister	5	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	3	0
Oral soft tissue signs and symptoms		
Hypoaesthesia oral	81	0
Lip discolouration	1	0
Lip erythema	1	0
Lip pain	8	0
Lip pruritus	2	0
Lip scab	1	0
Odynophagia	2	0
Oral discomfort	6	0
Oral mucosal blistering	6	0
Oral mucosal eruption	3	0
Oral mucosal exfoliation	2	0
Oral pain	18	0
Oral pruritus	4	0
Paraesthesia oral	255	0
Oral soft tissue swelling and oedema		
Lip oedema	1	0
Lip swelling	113	0
Mouth swelling	9	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
Salivary gland disorders NEC		
Salivary gland pain	2	0
Salivary gland enlargements		
Parotid gland enlargement	1	0
Submaxillary gland enlargement	3	0
Stomatitis and ulceration		
Aphthous ulcer	7	0
Lip ulceration	2	0
Mouth ulceration	46	0
Oral mucosa erosion	1	0
Stomatitis	6	0
Tongue disorders		
Glossitis	2	0
Plicated tongue	2	0

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Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Tongue disorder	4	0
Tongue haemorrhage	1	0
Tongue ulceration	7	0
<i>Tongue signs and symptoms</i>		
Glossodynia	31	0
Stiff tongue	1	0
Swollen tongue	88	0
Tongue blistering	2	0
Tongue coated	1	0
Tongue discolouration	1	0
Tongue discomfort	6	0
Tongue dry	4	0
Tongue eruption	3	0
Tongue erythema	1	0
Tongue movement disturbance	1	0
Tongue oedema	2	0
Tongue spasm	2	0
Gastrointestinal disorders SOC TOTAL	5314	5

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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	3	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	1	0
<i>Application and instillation site reactions</i>		
Application site bruise	1	0
Application site erythema	1	0
Application site pain	1	0
Instillation site warmth	1	0
<i>Asthenic conditions</i>		
Asthenia	223	0
Chronic fatigue syndrome	1	0
Fatigue	3230	0
Malaise	779	0
Sluggishness	2	0
<i>Body temperature altered</i>		
Hypothermia	8	0
Temperature regulation disorder	3	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	59	53
Sudden death	7	7
<i>Febrile disorders</i>		
Hyperpyrexia	2	0
Pyrexia	3173	0
<i>Feelings and sensations NEC</i>		
Chills	1994	0
Feeling abnormal	144	0
Feeling cold	191	0
Feeling drunk	10	0
Feeling hot	233	0
Feeling jittery	5	0
Feeling of body temperature change	66	0
Hangover	5	0
Hunger	3	0
Sensation of foreign body	10	0
Temperature intolerance	1	0
Thirst	37	0
<i>Gait disturbances</i>		
Gait disturbance	15	0
Gait inability	10	0
Loss of control of legs	1	0

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Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>General signs and symptoms NEC</i>		
Condition aggravated	14	0
Crying	4	0
Disease recurrence	1	0
Exercise tolerance decreased	2	0
General physical health deterioration	1	0
Glassy eyes	2	0
Illness	203	0
Induration	2	0
Influenza like illness	412	0
Local reaction	25	0
Peripheral swelling	380	0
Pre-existing condition improved	1	0
Screaming	1	0
Secretion discharge	2	0
Swelling	328	0
Swelling face	102	0
<i>Inflamations</i>		
Inflammation	35	0
Systemic inflammatory response syndrome	1	0
<i>Infusion site reactions</i>		
Infusion site erythema	1	0
Infusion site joint pain	2	0
Infusion site pain	1	0
<i>Injection site reactions</i>		
Injected limb mobility decreased	7	0
Injection site bruising	10	0
Injection site discolouration	1	0
Injection site discomfort	2	0
Injection site erythema	96	0
Injection site haemorrhage	2	0
Injection site hypoaesthesia	4	0
Injection site induration	1	0
Injection site inflammation	6	0
Injection site joint pain	3	0
Injection site mass	63	0
Injection site oedema	4	0
Injection site pain	699	0
Injection site paraesthesia	2	0
Injection site pruritus	39	0
Injection site rash	13	0
Injection site reaction	5	0
Injection site scab	1	0
Injection site scar	2	0
Injection site swelling	85	0
Injection site urticaria	4	0
Injection site vesicles	2	0
Injection site warmth	29	0
<i>Interactions</i>		
Alcohol interaction	2	0
Drug interaction	2	0
<i>Mass conditions NEC</i>		

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General disorders General disorders cont'd		
Cyst	1	0
Mass	3	0
Nodule	3	0
Oedema NEC		
Face oedema	4	0
Localised oedema	6	0
Oedema	5	0
Oedema peripheral	9	0
Pain and discomfort NEC		
Axillary pain	145	0
Chest discomfort	190	0
Chest pain	242	0
Discomfort	20	0
Facial discomfort	3	0
Facial pain	28	0
Non-cardiac chest pain	2	0
Pain	1176	0
Tenderness	93	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	599	0
Adverse event	5	0
Adverse reaction	4	0
Drug ineffective	58	0
Immediate post-injection reaction	1	0
No reaction on previous exposure to drug	4	0
Therapeutic product effect delayed	1	0
Therapeutic response unexpected	4	0
Treatment failure	1	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	1	0
Shoulder injury related to vaccine administration	1	0
Vaccination site bruising	26	0
Vaccination site discolouration	4	0
Vaccination site discomfort	11	0
Vaccination site eczema	1	0
Vaccination site erythema	151	0
Vaccination site haemorrhage	4	0
Vaccination site hypoaesthesia	1	0
Vaccination site induration	23	0
Vaccination site inflammation	24	0
Vaccination site irritation	3	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	3	0
Vaccination site joint movement impairment	8	0
Vaccination site joint pain	18	0
Vaccination site joint swelling	2	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	1	0
Vaccination site mass	37	0
Vaccination site movement impairment	10	0
Vaccination site oedema	3	0
Vaccination site pain	624	0

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General disorders General disorders cont'd		
Vaccination site paraesthesia	4	0
Vaccination site pruritus	43	0
Vaccination site rash	21	0
Vaccination site reaction	9	0
Vaccination site swelling	171	0
Vaccination site ulcer	1	0
Vaccination site urticaria	4	0
Vaccination site vesicles	1	0
Vaccination site warmth	91	0
General disorders SOC TOTAL	16749	61

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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	4	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Hepatitis	1	0
Liver injury	1	0
Hepatic disorders SOC TOTAL	8	0

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Reaction Name	Total	Fatal
Immune system disorders		
<i>Allergic conditions NEC</i>		
Allergic oedema	2	0
Hypersensitivity	121	0
Type IV hypersensitivity reaction	1	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergy to vaccine	12	0
Drug hypersensitivity	2	0
Reaction to preservatives	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	91	0
Anaphylactic shock	2	0
Anaphylactoid reaction	6	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	2	0
Immune system disorder	1	0
Immune-mediated adverse reaction	1	0
Immune system disorders SOC TOTAL	248	0

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Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	2	0
Gastroenteritis	3	0
<i>Bacterial infections NEC</i>		
Bacterial diarrhoea	1	0
Cellulitis	35	0
Injection site cellulitis	1	0
Tonsillitis bacterial	1	0
Vaccination site cellulitis	6	0
<i>Breast infections</i>		
Breast abscess	1	0
Mastitis	3	0
<i>Candida infections</i>		
Candida infection	2	0
Oral candidiasis	5	0
Vulvovaginal candidiasis	4	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	4	0
COVID-19	217	10
COVID-19 pneumonia	2	1
Coronavirus infection	5	0
Severe acute respiratory syndrome	1	0
Suspected COVID-19	15	0
<i>Coxiella infections</i>		
Q fever	4	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	1	0
Gingivitis	1	0
Parotitis	4	0
<i>Ear infections</i>		
Ear infection	5	0
Labyrinthitis	9	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	10	0
Eye abscess	1	0
Eye infection	1	0
Hordeolum	2	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	1	0
Herpes simplex	1	0
Herpes simplex reactivation	1	0
Herpes virus infection	3	0
Herpes zoster	70	0
Herpes zoster oticus	1	0

Case Series Drug Analysis Print

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

Report Run Date: 31-Jan-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 28-Jan-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Oral herpes	30	0
<i>Infections NEC</i>		
Abscess	3	0
Infection	56	0
Injection site infection	1	0
Localised infection	2	0
Lymph gland infection	2	0
Vaccination site abscess	1	0
Vaccination site infection	6	0
<i>Influenza viral infections</i>		
Influenza	192	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	1	0
Lower respiratory tract infection	14	4
Pneumonia	8	2
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	3	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	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	90	0
Pharyngitis	4	0
Rhinitis	10	0
Sinusitis	4	0
Tonsillitis	11	0
Tracheitis	1	0
<i>Urinary tract infections</i>		
Cystitis	4	0
Kidney infection	2	0
Pyelonephritis	1	0
Urinary tract infection	11	0
<i>Vascular infections</i>		
Haematoma infection	1	0
<i>Viral infections NEC</i>		
Conjunctivitis viral	1	0

Case Series Drug Analysis Print

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

Report Run Date: 31-Jan-2021

Data Lock Date: 28-Jan-2021 19:00:04

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Infections Infections cont'd		
Eye infection viral	1	0
Gastroenteritis viral	3	0
Post viral fatigue syndrome	4	0
Sweating fever	21	0
Vestibular neuronitis	3	0
Viral infection	1	0
Viral labyrinthitis	2	0
Viral pharyngitis	3	0
Viral rash	6	0
Viral tonsillitis	1	0
Infections SOC TOTAL	948	17

Case Series Drug Analysis Print

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

Report Run Date: 31-Jan-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 28-Jan-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>Conditions caused by cold</i>		
Chillblains	4	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	5	0
Maternal exposure during breast feeding	8	0
Maternal exposure during pregnancy	10	0
<i>Eye injuries NEC</i>		
Eye contusion	2	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	1	0
Heat stroke	1	0
<i>Medication errors, product use errors and issues NEC</i>		
Medication error	1	0
<i>Muscle, tendon and ligament injuries</i>		
Muscle strain	2	0
<i>Nerve injuries NEC</i>		
Nerve injury	2	0
<i>Neurological and psychiatric procedural complications</i>		
Procedural dizziness	2	0
<i>Non-site specific injuries NEC</i>		
Bite	1	0
Electric shock	2	0
Fall	18	0
Wound complication	1	0
<i>Non-site specific procedural complications</i>		
Incision site pain	1	0
Infusion related reaction	2	0
Injection related reaction	7	0
<i>Off label uses</i>		
Off label use	1	0
<i>Overdoses NEC</i>		
Overdose	6	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	4	0
Product administered at inappropriate site	3	0
Product administered to patient of inappropriate age	1	0
Product administration error	1	0

Case Series Drug Analysis Print

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

Report Run Date: 31-Jan-2021
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Data Lock Date: 28-Jan-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
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	47	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	1	0
Thermal burn	2	0
Vaccination related complications		
Vaccination complication	9	0
Injuries SOC TOTAL	172	0

Case Series Drug Analysis Print

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

Report Run Date: 31-Jan-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 28-Jan-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Cortisol decreased	1	0
<i>Blood gas and acid base analyses</i>		
Blood lactic acid increased	2	0
Blood pH increased	1	0
Oxygen consumption decreased	1	0
Oxygen saturation decreased	16	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose decreased	4	0
Blood glucose increased	13	0
Glycosylated haemoglobin increased	1	0
<i>Cardiac function diagnostic procedures</i>		
Central venous pressure	1	0
<i>Chemistry analyses NEC</i>		
Inflammatory marker increased	1	0
<i>Coagulation and bleeding analyses</i>		
Fibrin D dimer increased	1	0
International normalised ratio decreased	1	0
International normalised ratio increased	8	0
<i>ECG investigations</i>		
Electrocardiogram ST segment elevation	1	0
<i>Haematological analyses NEC</i>		
Red blood cell sedimentation rate increased	1	0
<i>Heart rate and pulse investigations</i>		
Heart rate	16	0
Heart rate abnormal	2	0
Heart rate decreased	5	0
Heart rate increased	98	0
Heart rate irregular	8	0
Pulse abnormal	5	0
<i>Immunology analyses NEC</i>		
Immunology test	1	0
<i>Investigations NEC</i>		
Blood test abnormal	2	0
Polymerase chain reaction positive	3	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	1	0
Gamma-glutamyltransferase increased	1	0
Hepatic enzyme increased	1	0
Liver function test increased	1	0
Transaminases increased	1	0
<i>Metabolism tests NEC</i>		
Blood ketone body increased	1	0
<i>Microbiology and serology tests NEC</i>		
Culture negative	1	0
<i>Mineral and electrolyte analyses</i>		
Blood potassium abnormal	1	0
<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>		

Case Series Drug Analysis Print

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

Report Run Date: 31-Jan-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 28-Jan-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
Body temperature	59	0
Body temperature abnormal	17	0
Body temperature decreased	6	0
Body temperature fluctuation	4	0
Body temperature increased	120	0
Body temperature normal	1	0
Breath sounds abnormal	1	0
Grip strength	1	0
Grip strength decreased	2	0
Lymph node palpable	3	0
Respiratory rate decreased	1	0
Respiratory rate increased	11	0
Skin temperature	4	0
Weight decreased	3	0
<i>Pituitary analyses anterior</i>		
Blood growth hormone	1	0
<i>Protein analyses NEC</i>		
C-reactive protein increased	2	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
<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>Urinalysis NEC</i>		
Blood urine present	4	0
pH urine	1	0
<i>Urinary tract function analyses NEC</i>		
Urine output	2	0
Urine output decreased	3	0
Urine output increased	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	2	0
Blood pressure decreased	9	0
Blood pressure increased	37	0
Blood pressure measurement	5	0
Blood pressure systolic decreased	1	0
Blood pressure systolic increased	1	0
<i>Virus identification and serology</i>		
SARS-CoV-2 test	1	0
SARS-CoV-2 test false positive	1	0
SARS-CoV-2 test positive	20	0
<i>White blood cell analyses</i>		
White blood cell count decreased	1	0
Investigations SOC TOTAL	538	0

Case Series Drug Analysis Print

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

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Earliest Reaction Date: 19-Jan-2001

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	1	0
Decreased appetite	210	0
Eating disorder symptom	1	0
Food craving	1	0
Food refusal	1	0
Hypophagia	2	0
Increased appetite	1	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus inadequate control	2	1
Type 1 diabetes mellitus	1	0
<i>Diabetic complications NEC</i>		
Diabetic complication	1	0
Diabetic ketoacidosis	3	0
<i>Disorders of purine metabolism</i>		
Gout	4	0
<i>Electrolyte imbalance NEC</i>		
Fluid imbalance	1	0
<i>Fluid intake decreased</i>		
Fluid intake reduced	1	0
<i>Fluid intake increased</i>		
Polydipsia	1	0
<i>General nutritional disorders NEC</i>		
Abnormal weight gain	1	0
Feeding disorder	5	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	11	0
<i>Hypoglycaemic conditions NEC</i>		
Hypoglycaemia	14	0
<i>Lipid metabolism and deposit disorders NEC</i>		
Body fat disorder	1	0
<i>Metabolic acidoses (excl diabetic acidoses)</i>		
Ketoacidosis	1	0
<i>Mixed acid-base disorders</i>		
Acidosis	2	0
<i>Sodium imbalance</i>		
Hyponatraemia	2	0
<i>Total fluid volume decreased</i>		
Dehydration	20	0
<i>Total fluid volume increased</i>		
Fluid retention	2	0
Metabolic disorders SOC TOTAL	290	1

Case Series Drug Analysis Print

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

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	18	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	44	0
Bone swelling	2	0
Coccydynia	1	0
Pain in jaw	42	0
Spinal pain	6	0
<i>Bursal disorders</i>		
Bursitis	2	0
<i>Cartilage disorders</i>		
Costochondritis	2	0
<i>Connective tissue disorders NEC</i>		
Polymyalgia rheumatica	2	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	1414	0
Jaw clicking	2	0
Joint effusion	3	0
Joint noise	2	0
Joint range of motion decreased	1	0
Joint stiffness	25	0
Joint swelling	31	0
Joint warmth	1	0
<i>Lupus erythematosus (incl subtypes)</i>		
Systemic lupus erythematosus	1	0
<i>Muscle infections and inflammations</i>		
Myositis	2	0
<i>Muscle pains</i>		
Fibromyalgia	6	0
Myalgia	2280	0
Myofascial pain syndrome	2	0
<i>Muscle related signs and symptoms NEC</i>		
Muscle discomfort	1	0
Muscle disorder	2	0
Muscle fatigue	47	0
Muscle spasms	87	0
Muscle swelling	5	0
Muscle tightness	6	0
Muscle twitching	28	0
<i>Muscle tone abnormalities</i>		
Muscle rigidity	5	0

Case Series Drug Analysis Print

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

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Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Nuchal rigidity	2	0
Torticollis	1	0
Trismus	2	0
<i>Muscle weakness conditions</i>		
Muscular weakness	101	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	149	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	304	0
Flank pain	6	0
Limb discomfort	193	0
Musculoskeletal chest pain	16	0
Musculoskeletal discomfort	12	0
Musculoskeletal pain	10	0
Neck pain	260	0
Pain in extremity	1530	0
<i>Myopathies</i>		
Rhabdomyolysis	3	0
<i>Osteoarthropathies</i>		
Osteoarthritis	1	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	1	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	5	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	22	0
Groin pain	13	0
Neck mass	5	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	1	0
Arthritis reactive	3	0
<i>Synovial disorders</i>		
Synovial cyst	1	0
Synovitis	2	0
<i>Tendon disorders</i>		
Tendon pain	1	0
Tendonitis	1	0
Muscle & tissue disorders SOC TOTAL	6746	0

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Neoplasms		
<i>Lymphomas unspecified NEC</i>		
Lymphoma	1	0
<i>Metastases to specified sites</i>		
Metastases to lymph nodes	1	0
Neoplasms SOC TOTAL	2	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>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	4	1
Cerebral infarction	4	0
Cerebrovascular accident	21	1
Haemorrhage intracranial	2	0
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>		
Balance disorder	38	0
Coordination abnormal	7	0
Dysstasia	9	0
<i>Cortical dysfunction NEC</i>		
Aphasia	7	0
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	1	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	1	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	3	0
Consciousness fluctuating	1	0
Depressed level of consciousness	4	0
Lethargy	390	0
Loss of consciousness	42	0
Sedation	2	0
Somnolence	105	0
Stupor	1	0
Syncope	151	0
<i>Dyskinesias and movement disorders NEC</i>		
Bradykinesia	2	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Dyskinesia	1	0
Fine motor skill dysfunction	1	0
Hypokinesia	2	0
Motor dysfunction	1	0
Movement disorder	5	0
Psychomotor hyperactivity	3	0
Dystonias		
Dystonia	5	0
Writer's cramp	1	0
Encephalopathies NEC		
Posterior reversible encephalopathy syndrome	1	0
Eye movement disorders		
Vlth nerve paralysis	1	0
Facial cranial nerve disorders		
Facial nerve disorder	1	0
Facial paralysis	58	0
Facial paresis	11	0
Facial spasm	6	0
Generalised tonic-clonic seizures		
Generalised tonic-clonic seizure	4	0
Headaches NEC		
Cervicogenic headache	1	0
Cluster headache	29	0
Cold-stimulus headache	1	0
Exertional headache	3	0
Headache	4570	0
Medication overuse headache	2	0
New daily persistent headache	1	0
Ophthalmoplegic migraine	1	0
Primary cough headache	1	0
Primary headache associated with sexual activity	1	0
Sinus headache	55	0
Tension headache	79	0
Thunderclap headache	1	0
Lumbar spinal cord and nerve root disorders		
Sciatica	7	0
Memory loss (excl dementia)		
Amnesia	7	0
Memory impairment	14	0
Mental impairment (excl dementia and memory loss)		
Cognitive disorder	6	0
Disturbance in attention	37	0
Mental impairment	5	0
Migraine headaches		
Migraine	308	0
Migraine with aura	21	0
Retinal migraine	2	0
Typical aura without headache	1	0
Vestibular migraine	1	0
Mononeuropathies		
Carpal tunnel syndrome	1	0
Mononeuropathy	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Nervous system disorders Nervous system disorders cont'd		
Nerve compression	2	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	1	0
Multiple sclerosis relapse	2	0
Muscle tone abnormal		
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	14	0
Narcolepsy	1	0
Nervous system disorders NEC		
Nervous system disorder	2	0
Neurologic visual problems NEC		
Tunnel vision	3	0
Visual field defect	1	0
Neurological signs and symptoms NEC		
Dizziness	1278	0
Dizziness exertional	3	0
Dizziness postural	117	0
Head discomfort	29	0
Hyporesponsive to stimuli	1	0
Myoclonus	1	0
Neurological symptom	2	0
Persistent postural-perceptual dizziness	1	0
Presyncope	95	0
Slow response to stimuli	1	0
Unresponsive to stimuli	12	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	4	0
Neuromuscular junction dysfunction		
Myasthenia gravis	1	0
Olfactory nerve disorders		
Anosmia	38	0
Hyposmia	4	0
Parosmia	20	0
Optic nerve disorders NEC		
Optic neuritis	1	0
Paraesthesias and dysaesthesias		
Burning sensation	51	0
Dysaesthesia	1	0
Formication	3	0
Hemiparaesthesia	1	0
Hyperaesthesia	13	0
Hypoaesthesia	259	0
Paraesthesia	394	0
Paralysis and paresis (excl cranial nerve)		
Hemiparesis	10	0
Hemiplegia	1	0
Locked-in syndrome	1	0

Case Series Drug Analysis Print

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Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Monoparesis	4	0
Monoplegia	4	0
Paralysis	14	0
<i>Parkinson's disease and parkinsonism</i>		
Freezing phenomenon	1	0
Parkinsonian gait	1	0
Parkinsonism	1	0
<i>Partial complex seizures</i>		
Dreamy state	1	0
<i>Peripheral neuropathies NEC</i>		
Neuropathy peripheral	8	0
Peripheral sensory neuropathy	2	0
<i>Seizures and seizure disorders NEC</i>		
Epilepsy	4	0
Febrile convulsion	1	0
Partial seizures	1	0
Seizure	34	0
Tonic convulsion	2	0
<i>Sensory abnormalities NEC</i>		
Ageusia	82	0
Allodynia	3	0
Aura	6	0
Dysgeusia	205	0
Neuralgia	31	0
Restless legs syndrome	13	0
Sensory disturbance	10	0
Sensory loss	3	0
Taste disorder	38	0
<i>Sleep disturbances NEC</i>		
Poor quality sleep	20	0
<i>Speech and language abnormalities</i>		
Dysarthria	14	0
Repetitive speech	1	0
Speech disorder	5	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculopathy	1	0
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	11	0
<i>Tremor (excl congenital)</i>		
Essential tremor	1	0
Resting tremor	1	0
Tremor	221	0
<i>Trigeminal disorders</i>		
Facial neuralgia	2	0
Trigeminal nerve disorder	1	0
Trigeminal neuralgia	3	0
Nervous system disorders SOC TOTAL	9204	5

Case Series Drug Analysis Print

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

Report Run Date: 31-Jan-2021

Data Lock Date: 28-Jan-2021 19:00:04

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions spontaneous</i>		
Abortion spontaneous	4	0
<i>Maternal complications of pregnancy NEC</i>		
Morning sickness	1	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	3	0
Pregnancy conditions SOC TOTAL	8	0

Case Series Drug Analysis Print

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

Report Run Date: 31-Jan-2021

Data Lock Date: 28-Jan-2021 19:00:04

Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
<i>Device malfunction events NEC</i>		
Device stimulation issue	1	0
Oversensing	4	0
<i>Product contamination and sterility issues</i>		
Product contamination physical	1	0
null SOC TOTAL	6	0

Case Series Drug Analysis Print

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

Report Run Date: 31-Jan-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 28-Jan-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Anxiety symptoms</i>		
Agitation	18	0
Anxiety	55	0
Nervousness	30	0
Tension	12	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	18	0
<i>Communications disorders</i>		
Communication disorder	1	0
<i>Confusion and disorientation</i>		
Confusional state	86	0
Disorientation	26	0
<i>Deliria</i>		
Delirium	21	0
<i>Depressive disorders</i>		
Depression	9	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	2	0
Dissociation	3	0
Dissociative amnesia	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	3	0
Insomnia	129	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	15	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	1	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	31	0
Hallucination, auditory	2	0
Hallucination, olfactory	1	0
Hallucination, tactile	1	0
Hallucination, visual	4	0
<i>Increased physical activity levels</i>		
Restlessness	18	0

Case Series Drug Analysis Print

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

Report Run Date: 31-Jan-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 28-Jan-2021 19:00:04
MedDRA Version: MedDRA 23.1

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	2	0
Depressed mood	21	0
Negative thoughts	1	0
Tearfulness	2	0
<i>Mood disorders NEC</i>		
Apathy	1	0
Laziness	1	0
Listless	1	0
<i>Narcolepsy and associated conditions</i>		
Sleep attacks	2	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive symptom	1	0
<i>Panic attacks and disorders</i>		
Panic attack	11	0
Panic disorder	1	0
Panic reaction	3	0
<i>Parasomnias</i>		
Abnormal dreams	25	0
Nightmare	23	0
Sleep terror	1	0
<i>Perception disturbances NEC</i>		
Autoscopy	1	0
Derealisation	2	0
Illusion	1	0
<i>Psychiatric elimination disorders</i>		
Enuresis	4	0
<i>Psychiatric symptoms NEC</i>		
Trance	1	0
<i>Psychotic disorder NEC</i>		
Psychotic behaviour	1	0
<i>Sleep disorders NEC</i>		
Sleep disorder	23	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>Stereotypies and automatisms</i>		
Head banging	2	0
Stereotypy	1	0
<i>Suicidal and self-injurious behaviour</i>		
Intentional self-injury	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	7	0
Thinking abnormal	3	0
Psychiatric disorders SOC TOTAL	665	0

Case Series Drug Analysis Print

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

Report Run Date: 31-Jan-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 28-Jan-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	1	0
Dysuria	6	0
Incontinence	4	0
Micturition disorder	1	0
Micturition urgency	1	0
Pollakiuria	6	0
Urinary incontinence	8	0
Urinary retention	8	0
<i>Bladder disorders NEC</i>		
Bladder disorder	3	0
<i>Genital and urinary tract disorders NEC</i>		
Urinary tract disorder	1	0
<i>Myoneurogenic bladder disorders</i>		
Hypertonic bladder	1	0
Loss of bladder sensation	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	3	0
Renal failure	2	0
<i>Urinary abnormalities</i>		
Chromaturia	11	0
Haematuria	3	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	29	0
Renal & urinary disorders SOC TOTAL	98	0

Case Series Drug Analysis Print

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Data Lock Date: 28-Jan-2021 19:00:04
MedDRA Version: MedDRA 23.1

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	3	0
<i>Breast signs and symptoms</i>		
Breast discomfort	1	0
Breast pain	22	0
Breast swelling	8	0
Breast tenderness	2	0
Nipple pain	3	0
Nipple swelling	2	0
<i>Erection and ejaculation conditions and disorders</i>		
Erectile dysfunction	3	0
<i>Menopausal effects NEC</i>		
Menopausal symptoms	2	0
<i>Menstruation and uterine bleeding NEC</i>		
Dysmenorrhoea	9	0
Menstrual disorder	5	0
Menstruation irregular	7	0
Metrorrhagia	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	1	0
Hypomenorrhoea	2	0
Menstruation delayed	7	0
<i>Menstruation with increased bleeding</i>		
Menorrhagia	15	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	1	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 signs and symptoms NEC</i>		
Pelvic discomfort	1	0
Pelvic pain	2	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>Testicular and epididymal disorders NEC</i>		
Testicular pain	2	0
Testicular swelling	1	0
<i>Uterine tone disorders</i>		
Uterine spasm	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	16	0
Vulval ulceration	2	0

Case Series Drug Analysis Print

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

Report Run Date: 31-Jan-2021

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Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Vulvovaginal signs and symptoms</i>		
Vulvovaginal pruritus	1	0
Reproductive & breast disorders SOC TOTAL	135	0

Case Series Drug Analysis Print

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

Report Run Date: 31-Jan-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 28-Jan-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Dyspnoea	415	0
Dyspnoea exertional	6	1
Hyperventilation	5	0
Hypopnoea	6	0
Irregular breathing	1	0
Mouth breathing	1	0
Orthopnoea	2	0
Respiration abnormal	7	0
Respiratory arrest	2	0
Respiratory distress	1	0
Tachypnoea	11	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	1	0
<i>Bronchospasm and obstruction</i>		
Asthma	37	0
Bronchospasm	3	0
Obstructive airways disorder	1	0
Wheezing	55	0
<i>Conditions associated with abnormal gas exchange</i>		
Hypoxia	4	1
<i>Coughing and associated symptoms</i>		
Cough	325	0
Haemoptysis	5	0
Productive cough	18	0
Sputum discoloured	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Epiglottic oedema	1	0
Stridor	1	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Hypersensitivity pneumonitis	1	0
Pneumonia aspiration	2	2
Pneumonitis	3	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	2	0
Pleuritic pain	4	0
Pulmonary pain	9	0
Rales	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	27	0
Rhinitis allergic	2	0
<i>Nasal disorders NEC</i>		
Epistaxis	80	0
Intranasal hypoaesthesia	1	0
Intranasal paraesthesia	1	0
Nasal disorder	1	0
Nasal dryness	3	0
Nasal odour	1	0
Nasal oedema	1	0
Nasal pruritus	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Sinonasal obstruction	2	0

Case Series Drug Analysis Print

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

Report Run Date: 31-Jan-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 28-Jan-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders Respiratory disorders cont'd		
Sinus congestion	6	0
Sinus disorder	1	0
Sinusitis noninfective	1	0
Parenchymal lung disorders NEC		
Atelectasis	1	0
Pharyngeal disorders (excl infections and neoplasms)		
Pharyngeal erythema	3	0
Pharyngeal haemorrhage	1	0
Pharyngeal hypoaesthesia	7	0
Pharyngeal inflammation	1	0
Pharyngeal oedema	3	0
Pharyngeal paraesthesia	16	0
Pharyngeal swelling	37	0
Pharyngeal ulceration	2	0
Tonsillar hypertrophy	9	0
Tonsillar inflammation	1	0
Pleural infections and inflammations		
Pleurisy	1	0
Pneumothorax and pleural effusions NEC		
Pleural effusion	1	0
Pulmonary oedemas		
Pulmonary congestion	1	0
Pulmonary oedema	2	0
Pulmonary thrombotic and embolic conditions		
Pulmonary embolism	2	0
Pulmonary infarction	1	0
Respiratory failures (excl neonatal)		
Acute respiratory failure	1	1
Respiratory signs and symptoms NEC		
Painful respiration	2	0
Respiratory symptom	1	0
Respiratory tract disorders NEC		
Aspiration	1	0
Respiratory disorder	1	0
Respiratory tract irritation	1	0
Respiratory tract oedema	1	0
Upper respiratory tract neoplasms		
Tonsillar cyst	1	0
Upper respiratory tract signs and symptoms		
Aphonia	10	0
Catarrh	3	0
Choking	2	0
Dry throat	26	0
Dysphonia	21	0
Increased upper airway secretion	3	0
Increased viscosity of upper respiratory secretion	2	0
Nasal discharge discolouration	1	0
Nasal discomfort	5	0
Nasal obstruction	2	0
Oropharyngeal blistering	5	0
Oropharyngeal discomfort	10	0
Oropharyngeal pain	386	0

Case Series Drug Analysis Print

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Report Run Date: 31-Jan-2021

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Earliest Reaction Date: 19-Jan-2001

MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Respiratory disorders		
Respiratory disorders cont'd		
Paranasal sinus discomfort	4	0
Rhinalgia	4	0
Rhinorrhoea	77	0
Sinus pain	25	0
Sneezing	45	0
Snoring	2	0
Throat clearing	2	0
Throat irritation	37	0
Throat tightness	51	0
Respiratory disorders SOC TOTAL	1880	5

Case Series Drug Analysis Print

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Report Run Date: 31-Jan-2021
Earliest Reaction Date: 19-Jan-2001

Data Lock Date: 28-Jan-2021 19:00:04
MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	4	0
<i>Alopecias</i>		
Alopecia	4	0
<i>Angioedemas</i>		
Angioedema	27	0
Circumoral swelling	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	102	0
Hyperhidrosis	251	0
Miliaria	8	0
Night sweats	104	0
<i>Bullous conditions</i>		
Blister	26	0
Blood blister	1	0
Dermatitis bullous	3	0
Erythema multiforme	3	0
Stevens-Johnson syndrome	1	0
Toxic epidermal necrolysis	1	1
<i>Dermal and epidermal conditions NEC</i>		
Dermatosis	1	0
Dry skin	20	0
Macule	1	0
Pain of skin	45	0
Papule	11	0
Peau d'orange	2	0
Scar pain	3	0
Sensitive skin	27	0
Skin burning sensation	24	0
Skin discolouration	17	0
Skin disorder	1	0
Skin induration	1	0
Skin lesion	3	0
Skin odour abnormal	2	0
Skin reaction	17	0
Skin sensitisation	4	0
Skin swelling	10	0
Skin tightness	11	0
Skin warm	45	0
Sticky skin	1	0
Yellow skin	3	0
<i>Dermatitis and eczema</i>		
Dermatitis	15	0
Dermatitis allergic	29	0
Dyshidrotic eczema	1	0
Eczema	7	0
Skin irritation	11	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	2	0
Fixed eruption	1	0
Toxic skin eruption	1	0
<i>Erythemas</i>		

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Erythema	371	0
Exfoliative conditions		
Skin exfoliation	9	0
Hyperpigmentation disorders		
Ephelides	1	0
Nail and nail bed conditions (excl infections and infestations)		
Nail discolouration	2	0
Nail disorder	1	0
Onychalgia	1	0
Panniculitides		
Erythema nodosum	1	0
Papulosquamous conditions		
Lichen planus	1	0
Pityriasis rosea	7	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	6	0
Pigmentation changes NEC		
Pigmentation disorder	1	0
Pilar disorders NEC		
Piloerection	3	0
Pruritus NEC		
Itching scar	3	0
Pruritus	612	0
Psoriatic conditions		
Psoriasis	4	0
Purpura and related conditions		
Petechiae	15	0
Purpura	6	0
Rashes, eruptions and exanthems NEC		
Rash	648	0
Rash erythematous	132	0
Rash macular	69	0
Rash maculo-papular	12	0
Rash morbilliform	4	0
Rash papular	42	0
Rash pruritic	102	0
Rash vesicular	4	0
Rosaceas		
Rosacea	1	0
Scaly conditions		
Pityriasis	3	0
Skin and subcutaneous conditions NEC		
Skin mass	3	0
Skin and subcutaneous tissue ulcerations		
Skin erosion	3	0
Skin ulcer	1	0
Skin cysts and polyps		
Dermal cyst	1	0
Skin haemorrhages		
Haemorrhage subcutaneous	1	0
Skin haemorrhage	1	0
Skin hyperplasias and hypertrophies		

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin hypertrophy	1	0
Skin vasculitides		
Vasculitic rash	1	0
Skin vasomotor conditions		
Livedo reticularis	8	0
Urticarias		
Cold urticaria	1	0
Mechanical urticaria	1	0
Urticaria	217	0
Urticaria papular	1	0
Urticaria thermal	1	0
Skin disorders SOC TOTAL	3154	1

Case Series Drug Analysis Print

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MedDRA Version: MedDRA 23.1

Reaction Name	Total	Fatal
Social circumstances		
<i>Disability issues</i>		
Bedridden	5	0
Breast prosthesis user	1	0
Immobile	2	0
Impaired work ability	1	0
Social circumstances SOC TOTAL	9	0

Case Series Drug Analysis Print

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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	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	1	0
<i>Respiratory tract therapeutic procedures NEC</i>		
Asthma prophylaxis	1	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	15	0

Case Series Drug Analysis Print

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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	21	0
Neurogenic shock	6	0
Peripheral circulatory failure	2	0
<i>Haemorrhages NEC</i>		
Haematoma	3	0
Haemorrhage	5	0
<i>Lymphoedemas</i>		
Lymphoedema	17	0
<i>Non-site specific embolism and thrombosis</i>		
Thrombosis	6	0
<i>Non-site specific vascular disorders NEC</i>		
Superficial vein prominence	1	0
Vasodilatation	1	0
Vein discolouration	1	0
Vein disorder	2	0
Vein rupture	1	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	1	0
Deep vein thrombosis	5	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	8	0
Flushing	106	0
Hot flush	152	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Peripheral coldness	43	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	32	0
<i>Vascular hypertensive disorders NEC</i>		
Hypertension	78	0
<i>Vascular hypotensive disorders</i>		
Hypotension	62	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	570	0
TOTAL REACTIONS FOR DRUG	49472	107
TOTAL REPORTS	16756	
TOTAL FATAL OUTCOME REPORTS		107