

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

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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 |
|----------------------------------------------------------|-------------|----------|
| 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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|-------------------------------------------------------|------------|----------|
| 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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|-------------------------------------------|----------|----------|
| 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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|----------------------------------------------------------------|------------|----------|
| 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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| 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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|--------------------------------------------------------------|-------|-------|
| 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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|-----------------------------------------------------------|-------|-------|
| 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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| 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 |

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 |
|---------------------------------------------------|--------------|-----------|
| 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 |

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 |
|------------------------------------------------|----------|----------|
| 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 |

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 |
|-----------------------------------------------------------------------------|------------|----------|
| 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 |

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 | | |
| <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
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 | | |
| 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
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 Injuries cont'd | | |
| Product dose omission issue | 1 | 0 |
| <i>Product preparation errors and issues</i> | | |
| Product preparation issue | 3 | 0 |
| <i>Radiation injuries</i> | | |
| Sunburn | 1 | 0 |
| <i>Site specific injuries NEC</i> | | |
| Face crushing | 1 | 0 |
| Head injury | 1 | 0 |
| Limb injury | 1 | 0 |
| <i>Skin injuries NEC</i> | | |
| Contusion | 47 | 0 |
| Scar | 1 | 0 |
| Skin abrasion | 2 | 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> | | |
| Burns second degree | 1 | 0 |
| Thermal burn | 2 | 0 |
| <i>Vaccination related complications</i> | | |
| 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

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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 |
|-----------------------------------------------------------|------------|----------|
| 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

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

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MedDRA Version: MedDRA 23.1

| 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

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

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MedDRA Version: MedDRA 23.1

| 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

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 |
|--------------------------------------|----------|----------|
| 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

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 |
|--------------------------------------------------------------------------|-------|-------|
| 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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Report Run Date: 31-Jan-2021
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MedDRA Version: MedDRA 23.1

| 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

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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

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| 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

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| 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

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| Reaction Name | Total | Fatal |
|--------------------------------------------------------------------------|------------|----------|
| Psychiatric disorders <small>Psychiatric disorders cont'd</small> | | |
| <i>Mental disorders NEC</i> | | |
| Mental disorder | 1 | 0 |
| <i>Mood alterations with depressive symptoms</i> | | |
| Decreased interest | 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

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| 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 |

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| Reaction Name | Total | Fatal |
|-------------------------------------------------------------|-------|-------|
| Reproductive & breast disorders | | |
| <i>Benign and malignant breast neoplasms</i> | | |
| Breast cyst | 1 | 0 |
| <i>Breast disorders NEC</i> | | |
| Breast mass | 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 |

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

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| 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 |

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| 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

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 |
|----------------------------------------|-------------|----------|
| 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

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 |
|----------------------------------------------|-------|-------|
| 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

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 |
|------------------------------------------------------------------------|-------|-------|
| 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

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 |
|---------------------------------------------|-------------|----------|
| 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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Earliest Reaction Date: 19-Jan-2001

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

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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 |