

COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

Report Run Date: 06-May-2021

Data Lock Date: 05-May-2021 18:30:08

All UK spontaneous reports received between 9/12/20 and 05/05/21 for mRNA
Pfizer/BioNTech vaccine analysis print

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia vitamin B12 deficiency	2	0
Deficiency anaemia	1	0
Iron deficiency anaemia	1	0
<i>Anaemias NEC</i>		
Anaemia	21	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	1	0
<i>Anaemias haemolytic NEC</i>		
Haemolytic anaemia	2	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	5	1
<i>Bleeding tendencies</i>		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	13	0
<i>Coagulation factor deficiencies</i>		
Acquired haemophilia	2	0
<i>Coagulopathies</i>		
Abnormal clotting factor	1	0
Antiphospholipid syndrome	2	0
Coagulopathy	3	0
Disseminated intravascular coagulation	1	0
Hypercoagulation	1	0
Thrombotic microangiopathy	1	0
<i>Eosinophilic disorders</i>		
Eosinophilia	5	0
<i>Haematological disorders</i>		
Mast cell activation syndrome	1	0
<i>Haemolyses NEC</i>		
Haemolysis	4	0
Intravascular haemolysis	1	0
<i>Leukocytoses NEC</i>		
Lymphocytosis	4	0
Neutrophilia	2	0
<i>Leukopenias NEC</i>		
Leukopenia	2	0
Lymphopenia	2	0
<i>Lymphatic system disorders NEC</i>		
Abdominal lymphadenopathy	2	0
Lymph node pain	665	0
Lymphadenitis	92	0
Lymphadenopathy	4483	0
Lymphatic disorder	1	0
Necrotic lymphadenopathy	1	0
Pseudolymphoma	4	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplasia pure red cell	1	0
Myelosuppression	1	0
Pancytopenia	3	0
<i>Neutropenias</i>		
Autoimmune neutropenia	2	0
Neutropenia	26	0
<i>Platelet disorders NEC</i>		

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021

Data Lock Date: 05-May-2021 18:30:08

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Platelet anisocytosis	1	0
Spleen disorders		
Spleen atrophy	1	0
Splenic vein thrombosis	1	0
Splenomegaly	4	0
Thrombocytopenias		
Immune thrombocytopenia	44	0
Thrombocytopenia	76	1
Thrombocytopenic purpura	3	0
Thrombotic thrombocytopenic purpura	5	0
Thrombocytoses		
Thrombocytosis	2	0
Blood disorders SOC TOTAL	5498	2

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	3	0
Atrioventricular block complete	1	0
Atrioventricular block second degree	1	0
Bundle branch block	1	0
Bundle branch block right	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	2	0
Cardiac disorder	8	0
Cardiac dysfunction	1	0
Cardiovascular disorder	1	0
<i>Cardiac hypertensive complications</i>		
Hypertensive heart disease	1	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	2	0
Palpitations	948	0
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	1	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	2	0
Congestive cardiomyopathy	1	0
Stress cardiomyopathy	2	0
<i>Coronary artery disorders NEC</i>		
Coronary artery disease	3	1
<i>Heart failures NEC</i>		
Cardiac failure	20	2
Cardiac failure acute	2	0
Cardiac failure chronic	1	0
Cardiac failure congestive	2	1
Cardiogenic shock	2	0
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	3	0
Acute myocardial infarction	14	1
Angina pectoris	37	0
Angina unstable	1	0
Arteriospasm coronary	1	0
Microvascular coronary artery disease	2	0
Myocardial infarction	85	17
Myocardial ischaemia	4	2
<i>Left ventricular failures</i>		
Left ventricular failure	2	1
<i>Mitral valvular disorders</i>		
Mitral valve incompetence	1	0
Mitral valve prolapse	1	0
<i>Myocardial disorders NEC</i>		
Cardiac amyloidosis	1	0
Cardiomegaly	1	0
Left ventricular dysfunction	2	0
Myocardial fibrosis	1	0
Myocardial haemorrhage	1	0
Myocardial oedema	2	0
Right ventricular enlargement	1	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Ventricular hypertrophy	2	0
Noninfectious myocarditis		
Myocarditis	20	0
Noninfectious pericarditis		
Pericarditis	17	1
Pericardial disorders NEC		
Pericardial effusion	7	0
Pericardial haemorrhage	2	2
Rate and rhythm disorders NEC		
Arrhythmia	30	0
Bradycardia	27	0
Cardiac flutter	54	0
Extrasystoles	34	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	4	0
Tachycardia	433	0
Right ventricular failures		
Cor pulmonale	1	0
Supraventricular arrhythmias		
Arrhythmia supraventricular	7	0
Atrial fibrillation	95	0
Atrial flutter	9	0
Atrial tachycardia	3	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus bradycardia	3	0
Sinus tachycardia	31	0
Supraventricular tachycardia	17	0
Tricuspid valvular disorders		
Tricuspid valve incompetence	1	0
Ventricular arrhythmias and cardiac arrest		
Cardiac arrest	58	21
Cardio-respiratory arrest	1	1
Pulseless electrical activity	2	0
Ventricular arrhythmia	3	0
Ventricular extrasystoles	6	0
Ventricular fibrillation	5	1
Ventricular tachycardia	6	0
Cardiac disorders SOC TOTAL	2048	52

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	2	0
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	1	0
<i>Coagulation disorders congenital</i>		
Haemophilia	1	0
<i>Congenital disorders NEC</i>		
Foetal malformation	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	1	0
<i>Gastrointestinal tract disorders congenital NEC</i>		
Gastroschisis	1	0
<i>Great vessel disorders congenital</i>		
Transposition of the great vessels	1	0
<i>Haematological disorders congenital NEC</i>		
Amegakaryocytic thrombocytopenia	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital multiplex arthrogyposis	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	1	0
Familial periodic paralysis	1	0
<i>Peripheral nervous system disorders congenital NEC</i>		
Hereditary neuropathy with liability to pressure palsies	1	0
<i>Pulmonary and bronchial disorders congenital</i>		
Congenital cystic lung	1	0
<i>Retinal disorders congenital</i>		
Retinitis pigmentosa	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
Congenital disorders SOC TOTAL	16	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	7	0
Ear discomfort	29	0
Ear disorder	9	0
Ear haemorrhage	3	0
Ear pain	399	0
Ear pruritus	5	0
Ear swelling	10	0
Otorrhoea	1	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	1	0
Eustachian tube dysfunction	5	0
Eustachian tube obstruction	1	0
<i>External ear disorders NEC</i>		
Excessive cerumen production	1	0
External ear pain	2	0
Red ear syndrome	2	0
<i>External ear infections and inflammations</i>		
External ear inflammation	1	0
<i>Hearing disorders NEC</i>		
Auditory disorder	3	0
<i>Hearing losses</i>		
Deafness	82	0
Deafness bilateral	3	0
Deafness neurosensory	9	0
Deafness transitory	3	0
Deafness unilateral	14	0
Hypoacusis	56	0
Sudden hearing loss	14	0
<i>Hyperacusia</i>		
Hyperacusis	15	0
Misophonia	2	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	1	0
Inner ear disorder	4	0
Meniere's disease	5	0
Vestibular disorder	3	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	2	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	25	0
Tinnitus	650	0
Vertigo	541	0
Vertigo labyrinthine	6	0
Vertigo positional	44	0
<i>Middle ear disorders NEC</i>		
Middle ear disorder	1	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
Ear disorders SOC TOTAL	1961	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Thyroiditis	2	0
Thyroiditis subacute	2	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	1	0
Adrenocortical insufficiency acute	7	0
<i>Endocrine abnormalities of puberty</i>		
Premature menarche	2	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	2	0
<i>Thyroid disorders NEC</i>		
Goitre	5	0
Thyroid disorder	1	0
Thyroid pain	1	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	1	0
Hyperthyroidism	6	0
<i>Thyroid hypofunction disorders</i>		
Hypothyroidism	9	0
Endocrine disorders SOC TOTAL	39	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	3	0
<i>Cataract conditions</i>		
Cataract	3	0
<i>Choroid and vitreous haemorrhages and vascular disorders</i>		
Choroidal haemorrhage	1	0
Choroidal neovascularisation	1	0
Vitreous haemorrhage	3	0
<i>Choroid and vitreous structural change, deposit and degeneration</i>		
Chorioretinopathy	2	0
Vitreous detachment	13	0
Vitreous floaters	27	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	1	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	19	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	2	0
<i>Corneal infections, oedemas and inflammations</i>		
Keratitis	4	0
Ulcerative keratitis	4	0
<i>Eyelid movement disorders</i>		
Blepharospasm	49	0
Excessive eye blinking	1	0
Eyelid myokymia	1	0
Eyelid ptosis	18	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	1	0
Glaucoma	3	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	1	0
Iridocyclitis	6	0
Iritis	3	0
Uveitis	14	0
<i>Lacrimation disorders</i>		
Dry eye	59	0
Lacrimation increased	64	0
<i>Lid bleeding and vascular disorders</i>		
Eyelid bleeding	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	5	0
Chalazion	2	0
Eczema eyelids	2	0
Erythema of eyelid	2	0
Eyelid cyst	2	0
Eyelid irritation	2	0
Eyelid margin crusting	2	0
Eyelid oedema	3	0
Eyelid rash	6	0
Swelling of eyelid	54	0
<i>Lid, lash and lacrimal structural disorders</i>		

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Dermatochalasis	1	0
Eyelash changes	1	0
Eyelid exfoliation	2	0
Eyelid skin dryness	1	0
Growth of eyelashes	1	0
Lagophthalmos	2	0
Ocular bleeding and vascular disorders NEC		
Eye haematoma	1	0
Eye haemorrhage	7	0
Ophthalmic vein thrombosis	1	0
Ocular disorders NEC		
Dark circles under eyes	3	0
Eye disorder	13	0
Eye oedema	7	0
Eye pain	440	0
Eye swelling	214	0
Eye ulcer	1	0
Eyelid disorder	2	0
Eyelid pain	8	0
Eyelids pruritus	3	0
Ocular discomfort	14	0
Periorbital oedema	14	0
Periorbital pain	1	0
Periorbital swelling	52	0
Retinal disorder	1	0
Vitreous disorder	1	0
Ocular infections, inflammations and associated manifestations		
Eye allergy	2	0
Eye discharge	11	0
Eye inflammation	10	0
Eye irritation	44	0
Eye pruritus	123	0
Limbal swelling	2	0
Ocular hyperaemia	97	0
Ocular nerve and muscle disorders		
Binocular eye movement disorder	1	0
Extraocular muscle disorder	1	0
Extraocular muscle paresis	1	0
Eye movement disorder	10	0
Ocular myasthenia	1	0
Ophthalmoplegia	2	0
Strabismus	2	0
Ocular sensation disorders		
Abnormal sensation in eye	9	0
Asthenopia	68	0
Eye paraesthesia	1	0
Foreign body sensation in eyes	13	0
Hypoaesthesia eye	5	0
Photophobia	174	0
Optic disc abnormalities NEC		
Papilloedema	1	0
Optic nerve bleeding and vascular disorders		
Optic disc haemorrhage	1	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Optic ischaemic neuropathy	2	0
Orbital infections, inflammations and irritations		
Parophthalmia	1	0
Orbital structural change, deposit and degeneration		
Orbital oedema	1	0
Pupil disorders		
Miosis	2	0
Mydriasis	7	0
Pupil fixed	1	0
Pupils unequal	3	0
Retinal bleeding and vascular disorders (excl retinopathy)		
Retinal artery occlusion	2	0
Retinal artery thrombosis	1	0
Retinal haemorrhage	2	0
Retinal vein occlusion	9	0
Retinal vein thrombosis	1	0
Retinal structural change, deposit and degeneration		
Macular degeneration	1	0
Macular hole	1	0
Macular rupture	1	0
Maculopathy	1	0
Retinal detachment	1	0
Retinal tear	1	0
Retinal toxicity	1	0
Retinal, choroid and vitreous infections and inflammations		
Macular oedema	2	0
Retinal vasculitis	1	0
Retinopathies NEC		
Retinal exudates	2	0
Retinopathy	1	0
Scleral infections, irritations and inflammations		
Episcleritis	4	0
Scleritis	2	0
Scleral structural change, deposit and degeneration		
Scleral discolouration	2	0
Visual colour distortions		
Chloropsia	2	0
Cyanopsia	1	0
Erythroopsia	2	0
Visual disorders NEC		
Diplopia	66	0
Halo vision	4	0
Metamorphopsia	7	0
Oscillopsia	2	0
Photopsia	54	0
Scintillating scotoma	3	0
Vision blurred	401	0
Visual brightness	1	0
Visual snow syndrome	1	0
Visual field disorders		
Visual field defect	7	0
Visual impairment and blindness (excl colour blindness)		
Amaurosis fugax	1	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021

Data Lock Date: 05-May-2021 18:30:08

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Blindness	33	0
Blindness transient	5	0
Blindness unilateral	7	0
Central vision loss	2	0
Sudden visual loss	2	0
Visual acuity reduced	9	0
Visual impairment	133	0
<i>Visual pathway disorders</i>		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	2554	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
Gastrointestinal sounds abnormal	7	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	1	0
<i>Acute and chronic pancreatitis</i>		
Obstructive pancreatitis	1	0
Pancreatitis	3	0
Pancreatitis acute	4	0
Pancreatitis necrotising	1	0
<i>Anal and rectal disorders NEC</i>		
Anal sphincter atony	1	0
<i>Anal and rectal pains</i>		
Proctalgia	5	0
<i>Anal and rectal signs and symptoms</i>		
Anal hypoaesthesia	1	0
Anal spasm	1	0
Anorectal discomfort	3	0
Anorectal swelling	1	0
Rectal discharge	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	3	0
Tongue cyst	1	0
<i>Colitis (excl infective)</i>		
Colitis	17	1
Colitis ischaemic	1	0
Colitis microscopic	1	0
Colitis ulcerative	22	0
Crohn's disease	15	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Teething	3	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	2	0
Dental paraesthesia	2	0
Hyperaesthesia teeth	11	0
Toothache	49	0
<i>Diaphragmatic hernias</i>		
Hiatus hernia	2	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	2351	3
Diarrhoea haemorrhagic	11	0
<i>Diverticula</i>		
Diverticulum	2	0
Diverticulum intestinal	1	0
<i>Duodenal and small intestinal stenosis and obstruction</i>		
Small intestinal obstruction	1	0
<i>Duodenal ulcers and perforation</i>		
Duodenal ulcer haemorrhage	1	0
Duodenal ulcer perforation	1	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	139	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Epigastric discomfort	8	0
Eructation	23	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	6	0
Faecaloma	1	0
Faeces discoloured	19	0
Faeces hard	1	0
Faeces pale	2	0
Faeces soft	6	0
Mucous stools	1	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	106	0
Aerophagia	2	0
Flatulence	73	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	2	1
Oesophageal varices haemorrhage	1	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	3	0
<i>Gastritis (excl infective)</i>		
Chronic gastritis	1	0
Gastritis	23	0
Reflux gastritis	4	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	2	0
Abdominal pain	519	0
Abdominal pain lower	33	0
Abdominal pain upper	838	0
Abdominal rigidity	3	0
Abdominal tenderness	5	0
Gastrointestinal pain	49	0
Oesophageal pain	1	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	104	0
Duodenogastric reflux	2	0
Gastric dilatation	3	0
Gastrooesophageal reflux disease	47	0
Impaired gastric emptying	3	0
Infrequent bowel movements	2	0
Intestinal pseudo-obstruction	2	0
<i>Gastrointestinal disorders NEC</i>		
Functional gastrointestinal disorder	5	0
Gastric disorder	3	0
Gastrointestinal disorder	5	0
Stomach mass	1	0
<i>Gastrointestinal dyskinetic disorders</i>		
Change of bowel habit	3	0
Dyschezia	1	0
Gastrointestinal motility disorder	1	0
<i>Gastrointestinal fistulae</i>		
Diverticular fistula	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Duodenitis	1	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Enteritis	3	0
Intestinal angioedema	1	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	2	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	275	0
Abdominal symptom	1	0
Acute abdomen	3	0
Anal incontinence	9	0
Breath odour	8	0
Dysphagia	82	1
Odynophagia	9	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Defaecation urgency	4	0
Frequent bowel movements	12	0
Irritable bowel syndrome	32	0
Oesophageal spasm	2	0
Pylorospasm	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	2	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	3	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	3	2
Mesenteric vein thrombosis	4	0
Visceral venous thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	7	0
Gingival discomfort	2	0
Gingival disorder	2	0
Gingival pain	43	0
Gingival pruritus	1	0
Gingival swelling	12	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	3	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	19	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Gastric varices	1	0
Haemorrhoids	11	0
Haemorrhoids thrombosed	1	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	7	0
Rectal haemorrhage	30	0
Small intestinal haemorrhage	3	0
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	4	2
Large intestine perforation	1	0
<i>Malabsorption syndromes</i>		
Bile acid malabsorption	1	0
Coeliac disease	7	0
Steatorrhoea	1	0
<i>Nausea and vomiting symptoms</i>		

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Discoloured vomit	7	0
Nausea	6717	1
Regurgitation	1	0
Retching	46	0
Vomiting	1899	2
Vomiting projectile	30	0
<i>Non-mechanical ileus</i>		
Ileus paralytic	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	7	0
Haematemesis	16	2
Haematochezia	16	0
Melaena	6	0
Upper gastrointestinal haemorrhage	2	0
<i>Oesophageal stenosis and obstruction</i>		
Oesophageal stenosis	1	0
<i>Oesophagitis (excl infective)</i>		
Oesophagitis	1	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	1	0
Dry mouth	264	0
Lip dry	26	0
Saliva altered	1	0
Salivary hypersecretion	20	0
<i>Oral soft tissue disorders NEC</i>		
Angina bullosa haemorrhagica	1	0
Chapped lips	10	0
Cheilitis	14	0
Enlarged uvula	7	0
Lip blister	14	0
Lip disorder	3	0
Oral disorder	6	0
Oral lichen planus	3	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	1	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	3	0
Oral blood blister	6	0
Oral purpura	1	0
<i>Oral soft tissue infections</i>		
Angular cheilitis	1	0
<i>Oral soft tissue signs and symptoms</i>		
Anaesthesia oral	1	0
Burning mouth syndrome	3	0
Coating in mouth	1	0
Hypoaesthesia oral	230	0
Lip discolouration	2	0
Lip erythema	1	0
Lip exfoliation	5	0
Lip pain	30	0
Lip pruritus	5	0
Lip scab	1	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Oral discomfort	39	0
Oral dysaesthesia	1	0
Oral mucosal blistering	8	0
Oral mucosal eruption	10	0
Oral mucosal erythema	3	0
Oral mucosal exfoliation	4	0
Oral mucosal roughening	3	0
Oral pain	85	0
Oral pruritus	14	0
Paraesthesia oral	570	0
Pigmentation lip	1	0
Oral soft tissue swelling and oedema		
Lip oedema	3	0
Lip swelling	345	0
Mouth swelling	43	0
Oedema mouth	3	0
Palatal oedema	2	0
Palatal swelling	1	0
Peptic ulcers and perforation		
Peptic ulcer haemorrhage	3	0
Peritoneal and retroperitoneal disorders		
Ascites	1	0
Peritoneal and retroperitoneal fibrosis and adhesions		
Abdominal adhesions	1	0
Peritoneal and retroperitoneal haemorrhages		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	1
Rectal inflammations NEC		
Proctitis	1	0
Proctitis ulcerative	1	0
Salivary gland disorders NEC		
Salivary gland pain	6	0
Salivary gland enlargements		
Parotid gland enlargement	4	0
Salivary gland enlargement	2	0
Submaxillary gland enlargement	5	0
Salivary gland infections and inflammations		
Noninfective sialoadenitis	1	0
Stomatitis and ulceration		
Aphthous ulcer	21	0
Lip ulceration	4	0
Mouth ulceration	185	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	29	0
Tongue disorders		
Glossitis	7	0
Plicated tongue	2	0
Tongue disorder	18	0
Tongue haemorrhage	1	0
Tongue ulceration	12	0
Trichoglossia	1	0
Tongue signs and symptoms		

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Glossodynia	107	0
Scalloped tongue	2	0
Stiff tongue	1	0
Swollen tongue	250	0
Tongue blistering	8	0
Tongue coated	5	0
Tongue discolouration	14	0
Tongue discomfort	25	0
Tongue dry	8	0
Tongue eruption	7	0
Tongue erythema	3	0
Tongue movement disturbance	3	0
Tongue oedema	16	0
Tongue rough	2	0
Tongue spasm	6	0
Gastrointestinal disorders SOC TOTAL	16512	16

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	3	0
Administration site erythema	1	0
Administration site extravasation	2	0
Administration site haematoma	3	0
Administration site inflammation	1	0
Administration site irritation	1	0
Administration site joint discomfort	1	0
Administration site joint movement impairment	1	0
Administration site pain	9	0
Administration site swelling	2	0
Administration site warmth	1	0
Puncture site bruise	14	0
Puncture site pain	4	0
Puncture site swelling	1	0
Vessel puncture site bruise	1	0
Vessel puncture site erythema	1	0
Vessel puncture site pain	1	0
<i>Adverse effect absent</i>		
No adverse event	15	0
<i>Application and instillation site reactions</i>		
Application site acne	1	0
Application site bruise	2	0
Application site burn	1	0
Application site erythema	5	0
Application site haemorrhage	1	0
Application site hypoaesthesia	1	0
Application site joint pain	1	0
Application site mass	1	0
Application site odour	1	0
Application site pain	6	0
Application site pruritus	3	0
Application site rash	1	0
Application site reaction	1	0
Application site vesicles	3	0
Instillation site warmth	1	0
<i>Asthenic conditions</i>		
Asthenia	703	1
Chronic fatigue syndrome	27	0
Decreased activity	2	0
Fatigue	10206	0
Malaise	2401	0
Sluggishness	4	0
<i>Body temperature altered</i>		
Hyperthermia	4	0
Hypothermia	17	0
Temperature regulation disorder	5	0
<i>Breast complications associated with device</i>		
Capsular contracture associated with breast implant	1	0
<i>Complications associated with device NEC</i>		
Injury associated with device	1	0
Medical device pain	1	0
Medical device site swelling	1	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
<i>Death and sudden death</i>		
Clinical death	1	1
Death	118	118
Sudden death	19	19
<i>Febrile disorders</i>		
Hyperpyrexia	5	0
Pyrexia	7467	1
<i>Feelings and sensations NEC</i>		
Chills	5058	0
Feeling abnormal	524	0
Feeling cold	582	0
Feeling drunk	26	0
Feeling hot	514	0
Feeling jittery	11	0
Feeling of body temperature change	150	0
Hangover	23	0
Hunger	6	0
Sensation of foreign body	26	0
Temperature intolerance	13	0
Thirst	138	0
<i>Gait disturbances</i>		
Gait disturbance	65	0
Gait inability	29	0
Loss of control of legs	8	0
<i>General signs and symptoms NEC</i>		
Adhesion	1	0
Condition aggravated	63	0
Crepitations	1	0
Crying	38	0
Discharge	1	0
Disease progression	1	0
Disease recurrence	8	0
Effusion	2	0
Energy increased	7	0
Exercise tolerance decreased	3	0
Foaming at mouth	1	0
General physical health deterioration	8	1
General symptom	1	0
Glassy eyes	2	0
High-pitched crying	2	0
Illness	736	0
Induration	2	0
Influenza like illness	1247	0
Irritability postvaccinal	1	0
Local reaction	62	0
Moaning	1	0
Multiple organ dysfunction syndrome	3	1
Nonspecific reaction	1	0
Peripheral swelling	1451	0
Pre-existing condition improved	7	0
Prolapse	2	0
Screaming	6	0
Secretion discharge	6	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Swelling	1101	0
Swelling face	388	0
Implant and catheter site reactions		
Implant site pain	1	0
Implant site rash	1	0
Implant site swelling	1	0
Inflamations		
Granuloma	1	0
Inflammation	137	0
Papillitis	1	0
Serositis	1	0
Systemic inflammatory response syndrome	1	0
Infusion site reactions		
Infusion site coldness	1	0
Infusion site joint pain	2	0
Infusion site pain	1	0
Infusion site swelling	1	0
Infusion site urticaria	1	0
Infusion site warmth	1	0
Injection site reactions		
Injected limb mobility decreased	17	0
Injection site bruising	26	0
Injection site coldness	1	0
Injection site cyst	2	0
Injection site discolouration	3	0
Injection site discomfort	8	0
Injection site erythema	193	0
Injection site haemorrhage	4	0
Injection site hypoaesthesia	6	0
Injection site indentation	2	0
Injection site induration	2	0
Injection site inflammation	18	0
Injection site joint movement impairment	1	0
Injection site joint pain	11	0
Injection site lymphadenopathy	1	0
Injection site mass	231	0
Injection site necrosis	3	0
Injection site oedema	11	0
Injection site pain	1554	0
Injection site paraesthesia	5	0
Injection site pruritus	88	0
Injection site rash	75	0
Injection site reaction	17	0
Injection site scab	2	0
Injection site scar	2	0
Injection site swelling	167	0
Injection site urticaria	15	0
Injection site vesicles	3	0
Injection site warmth	83	0
Interactions		
Alcohol interaction	2	0
Drug interaction	10	0
Mass conditions NEC		

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Cyst	8	0
Mass	16	0
Nodule	16	0
Mucosal findings abnormal		
Mucosal dryness	1	0
Mucosal haemorrhage	3	0
Oedema mucosal	1	0
Necrosis NEC		
Fat necrosis	1	0
Necrosis	1	0
Oedema NEC		
Face oedema	18	0
Generalised oedema	1	0
Localised oedema	13	0
Oedema	26	0
Oedema peripheral	39	0
Pain and discomfort NEC		
Axillary pain	989	0
Chest discomfort	583	0
Chest pain	951	0
Discomfort	106	0
Facial discomfort	8	0
Facial pain	96	0
Inflammatory pain	2	0
Non-cardiac chest pain	9	0
Pain	3305	0
Suprapubic pain	1	0
Tenderness	314	0
Visceral pain	1	0
Therapeutic and nontherapeutic responses		
Adverse drug reaction	90	0
Adverse event	4	0
Adverse reaction	4	0
Drug ineffective	114	1
Immediate post-injection reaction	2	0
Inadequate analgesia	2	0
No reaction on previous exposure to drug	27	0
Therapeutic product effect delayed	2	0
Therapeutic product effect increased	1	0
Therapeutic product ineffective	1	0
Therapeutic response decreased	1	0
Therapeutic response unexpected	24	0
Treatment failure	5	0
Vaccination failure	4	0
Trophic disorders		
Calcinosis	1	0
Ulcers NEC		
Ulcer	9	0
Vaccination site reactions		
Extensive swelling of vaccinated limb	6	0
Shoulder injury related to vaccine administration	7	0
Vaccination site bruising	56	0
Vaccination site cyst	1	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021

Data Lock Date: 05-May-2021 18:30:08

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site dermatitis	1	0
Vaccination site discolouration	7	0
Vaccination site discomfort	27	0
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	323	0
Vaccination site granuloma	1	0
Vaccination site haemorrhage	9	0
Vaccination site hypersensitivity	2	0
Vaccination site hypoaesthesia	7	0
Vaccination site induration	51	0
Vaccination site inflammation	33	0
Vaccination site irritation	5	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	6	0
Vaccination site joint movement impairment	12	0
Vaccination site joint pain	20	0
Vaccination site joint swelling	2	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	3	0
Vaccination site macule	1	0
Vaccination site mass	105	0
Vaccination site movement impairment	36	0
Vaccination site oedema	3	0
Vaccination site pain	1123	0
Vaccination site paraesthesia	4	0
Vaccination site pruritus	67	0
Vaccination site rash	56	0
Vaccination site reaction	19	0
Vaccination site scab	1	0
Vaccination site swelling	327	0
Vaccination site ulcer	1	0
Vaccination site urticaria	7	0
Vaccination site vesicles	2	0
Vaccination site warmth	163	0
Withdrawal and rebound effects		
Drug withdrawal syndrome	4	0
Withdrawal syndrome	9	0
General disorders SOC TOTAL	45426	143

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	2	0
Cholangitis	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholelithiasis	4	0
<i>Cholestasis and jaundice</i>		
Cholestasis	1	0
Cholestasis of pregnancy	1	0
Jaundice	12	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	2	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	1	0
<i>Hepatic failure and associated disorders</i>		
Hepatic failure	1	0
<i>Hepatic vascular disorders</i>		
Congestive hepatopathy	1	0
Hepatic artery embolism	1	0
Hepatic haemorrhage	1	0
Hepatic vein thrombosis	3	0
Portal vein thrombosis	2	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	9	0
Liver tenderness	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Drug-induced liver injury	1	0
Hepatitis	7	0
Immune-mediated hepatic disorder	1	0
Liver injury	5	0
Hepatic disorders SOC TOTAL	60	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	8	0
<i>Allergic conditions NEC</i>		
Allergic oedema	10	0
Allergy to arthropod bite	1	0
Allergy to arthropod sting	1	0
Allergy to metals	1	0
Hypersensitivity	420	0
Mite allergy	1	0
Multiple allergies	3	0
Serum sickness	2	0
Serum sickness-like reaction	3	0
Type I hypersensitivity	1	0
Type III immune complex mediated reaction	1	0
Type IV hypersensitivity reaction	5	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	4	0
Allergy to chemicals	2	0
Allergy to vaccine	23	0
Contrast media reaction	1	0
Drug hypersensitivity	12	0
Food allergy	8	0
Oral allergy syndrome	1	0
Reaction to colouring	1	0
Reaction to excipient	4	0
Reaction to preservatives	3	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	253	1
Anaphylactic shock	19	0
Anaphylactoid reaction	15	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	1	0
Seasonal allergy	17	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	14	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	12	0
Graft versus host disease	1	0
Immune system disorder	10	0
Immune-mediated adverse reaction	2	0
Immunisation reaction	1	0
Sensitisation	2	0
Systemic immune activation	2	0
<i>Transplant rejections</i>		
Corneal graft rejection	1	0
Kidney transplant rejection	1	0
Immune system disorders SOC TOTAL	871	1

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Appendicitis	10	0
Diverticulitis	3	0
Dysentery	1	0
Gastroenteritis	17	0
Mesenteric abscess	1	0
Peritonitis	1	1
Rectal abscess	1	0
<i>Aspergillus infections</i>		
Bronchopulmonary aspergillosis	1	0
<i>Bacterial infections NEC</i>		
Arthritis bacterial	1	0
Bacterial diarrhoea	1	0
Bacterial infection	2	0
Cellulitis	102	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
Folliculitis	5	0
Injection site cellulitis	2	0
Meningitis bacterial	1	0
Paronychia	1	0
Periorbital cellulitis	1	0
Tonsillitis bacterial	2	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	12	0
<i>Bone and joint infections</i>		
Abscess jaw	1	0
<i>Borrelial infections</i>		
Relapsing fever	1	0
<i>Breast infections</i>		
Breast abscess	2	0
Mastitis	17	0
<i>Caliciviral infections</i>		
Gastroenteritis norovirus	1	0
<i>Candida infections</i>		
Anal candidiasis	2	0
Candida infection	14	0
Oral candidiasis	20	0
Systemic candida	1	0
Vulvovaginal candidiasis	13	0
<i>Central nervous system and spinal infections</i>		
Cavernous sinus thrombosis	1	0
Encephalitis	9	0
Meningitis	4	0
Meningitis aseptic	1	0
Myelitis	2	0
<i>Clostridia infections</i>		
Clostridium difficile infection	2	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	10	0
COVID-19	611	33
COVID-19 pneumonia	22	9
Coronavirus infection	6	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Severe acute respiratory syndrome	1	0
Suspected COVID-19	34	1
<i>Coxiella infections</i>		
Q fever	6	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	3	0
Gingivitis	4	0
Parotitis	6	0
Pulpitis dental	1	0
Sialoadenitis	2	0
Tooth abscess	3	0
Tooth infection	2	0
<i>Ear infections</i>		
Ear infection	32	0
Labyrinthitis	45	0
Mastoiditis	1	0
Otitis media	1	0
Otitis media acute	1	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	2	0
Bed bug infestation	1	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	1	0
Infectious mononucleosis	7	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	35	0
Eye abscess	1	0
Eye infection	9	0
Eyelid infection	1	0
Hordeolum	9	0
Periorbital infection	2	0
<i>Female reproductive tract infections</i>		
Bartholinitis	1	0
Endometritis	1	0
Vulval abscess	1	0
<i>Fungal infections NEC</i>		
Fungal infection	2	0
Fungal skin infection	1	0
Pneumonia fungal	1	0
<i>Hepatitis virus infections</i>		
Hepatitis A	1	0
Hepatitis E	1	0
<i>Hepatobiliary and spleen infections</i>		
Biliary sepsis	1	0
<i>Herpes viral infections</i>		
Disseminated varicella zoster virus infection	1	0
Eczema herpeticum	2	0
Genital herpes	26	0
Genital herpes simplex	5	0
Herpes ophthalmic	2	0
Herpes simplex	11	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	2	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
Infections cont'd		
Herpes virus infection	3	0
Herpes zoster	678	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	5	0
Herpes zoster reactivation	1	0
Nasal herpes	2	0
Ophthalmic herpes zoster	1	0
Oral herpes	155	0
Varicella	12	0
Varicella zoster virus infection	1	0
Infections NEC		
Abscess	16	0
Abscess limb	1	0
Abscess soft tissue	1	0
Infected bite	1	0
Infected cyst	1	0
Infection	110	0
Injection site abscess	1	0
Injection site infection	4	0
Localised infection	13	0
Lymph gland infection	5	0
Lymph node abscess	1	0
Respiratory tract infection	3	0
Vaccination site abscess	2	0
Vaccination site infection	11	0
Vaccine breakthrough infection	22	0
Vestibulitis	2	0
Infectious transmissions		
Secondary transmission	1	0
Influenza viral infections		
Influenza	730	0
Lower respiratory tract and lung infections		
Bronchitis	4	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	81	7
Pneumonia	49	7
Sputum purulent	1	0
Male reproductive tract infections		
Epididymitis	2	0
Orchitis	2	0
Mumps viral infections		
Mumps	4	0
Muscle and soft tissue infections		
Infective tenosynovitis	1	0
Necrotising fasciitis	1	0
Soft tissue infection	1	0
Neisseria infections		
Gonorrhoea	1	0
Retroviral infections		
HIV infection	1	0
Rotaviral infections		
Gastroenteritis rotavirus	1	0
Rubeola viral infections		

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Measles	2	0
Sepsis, bacteraemia, viraemia and fungaemia NEC		
Bacteraemia	1	0
Neutropenic sepsis	2	0
Sepsis	23	3
Sepsis syndrome	1	0
Septic shock	4	1
Urosepsis	2	0
Skin structures and soft tissue infections		
Abscess sweat gland	1	0
Acne pustular	1	0
Dermatitis infected	1	0
Impetigo	1	0
Injection site pustule	1	0
Pustule	5	0
Rash pustular	6	0
Skin infection	14	0
Subcutaneous abscess	5	0
Vaccination site pustule	2	0
Staphylococcal infections		
Furuncle	20	0
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	2	0
Staphylococcal sepsis	1	0
Streptococcal infections		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	3	0
Streptococcal abscess	1	0
Streptococcal sepsis	1	0
Tinea infections		
Body tinea	1	0
Treponema infections		
Syphilis	1	0
Trypanosomal infections		
African trypanosomiasis	1	0
Tuberculous infections		
Pulmonary tuberculosis	1	0
Upper respiratory tract infections		
Epiglottitis	1	0
Laryngitis	7	0
Nasopharyngitis	353	0
Pharyngitis	8	0
Rhinitis	23	0
Sinusitis	47	0
Tonsillitis	35	0
Tracheitis	2	0
Upper respiratory tract infection	3	0
Urinary tract infections		
Cystitis	29	0
Kidney infection	9	0
Pyelonephritis	1	0
Urinary tract infection	57	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Vascular infections</i>		
Haematoma infection	1	0
Lymphangitis	5	0
<i>Viral infections NEC</i>		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Encephalitis viral	1	0
Eye infection viral	2	0
Gastroenteritis viral	9	0
Hepatitis viral	2	0
Meningitis viral	3	0
Oral viral infection	1	0
Pneumonia viral	1	1
Post viral fatigue syndrome	24	0
Sweating fever	56	0
Vestibular neuronitis	11	0
Viral infection	20	0
Viral labyrinthitis	3	0
Viral pericarditis	1	0
Viral pharyngitis	6	0
Viral rash	23	0
Viral tonsillitis	1	0
Infections SOC TOTAL	3967	64

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Mouth injury	1	0
Oral contusion	1	0
Rectal injury	1	0
Splenic rupture	2	0
Tongue injury	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	11	0
<i>Anaesthetic and allied procedural complications</i>		
Delayed recovery from anaesthesia	2	0
Sedation complication	1	0
<i>Atmospheric pressure injuries</i>		
Hypobarism	1	0
<i>Bone and joint injuries NEC</i>		
Joint injury	2	0
<i>Cardiovascular injuries</i>		
Heart injury	2	0
Vascular injury	2	0
<i>Cerebral injuries NEC</i>		
Subdural haematoma	3	0
Subdural haemorrhage	2	0
Traumatic intracranial haemorrhage	1	1
<i>Chemical injuries</i>		
Chemical cystitis	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	4	0
<i>Conditions caused by cold</i>		
Chillblains	28	0
<i>Cranial nerve injuries</i>		
Vth nerve injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	6	0
Exposure via breast milk	15	0
Foetal exposure during pregnancy	5	0
Maternal exposure before pregnancy	1	0
Maternal exposure during breast feeding	182	0
Maternal exposure during pregnancy	108	0
Paternal exposure before pregnancy	1	0
Paternal exposure during pregnancy	2	0
<i>Exposures to agents or circumstances NEC</i>		
Exposure to SARS-CoV-2	1	0
<i>Eye and ear procedural complications</i>		
Toxic anterior segment syndrome	1	0
<i>Eye injuries NEC</i>		
Eye contusion	9	0
Eye injury	6	0
Injury corneal	1	0
Periorbital haematoma	1	0
Retinal injury	2	0
<i>Fractures and dislocations NEC</i>		
Joint dislocation	1	0
<i>Gastrointestinal and hepatobiliary procedural complications</i>		
Post procedural constipation	1	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Postoperative ileus	1	0
Procedural nausea	4	0
Procedural vomiting	1	0
Heat injuries (excl thermal burns)		
Heat illness	1	0
Heat oedema	6	0
Heat stroke	2	0
Limb fractures and dislocations		
Atypical femur fracture	1	0
Clavicle fracture	12	0
Wrist fracture	1	0
Medication errors, product use errors and issues NEC		
Circumstance or information capable of leading to medication error	1	0
Dose calculation error	1	0
Medication error	9	0
Prescription drug used without a prescription	1	0
Product use complaint	1	0
Product use issue	7	0
Vaccination error	2	0
Wrong drug	5	0
Wrong technique in product usage process	3	0
Muscle, tendon and ligament injuries		
Epicondylitis	6	0
Ligament sprain	4	0
Mallet finger	1	0
Muscle injury	2	0
Muscle rupture	2	0
Muscle strain	11	0
Tendon injury	2	0
Tendon rupture	1	0
Musculoskeletal procedural complications		
Periprosthetic osteolysis	1	0
Post laminectomy syndrome	1	0
Nerve injuries NEC		
Nerve injury	16	0
Neurological and psychiatric procedural complications		
Procedural dizziness	7	0
Non-occupational environmental exposures		
Exposure to extreme temperature	1	0
Non-site specific injuries NEC		
Arthropod sting	1	0
Bite	1	0
Electric shock	8	0
Fall	72	1
Foreign body	1	0
Injury	4	0
Wound	4	0
Wound complication	4	0
Wound haemorrhage	1	0
Wound secretion	2	0
Non-site specific procedural complications		
Incision site pain	2	0
Infusion related reaction	6	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries		
Injuries cont'd		
Injection related reaction	32	0
Post procedural complication	3	0
Occupational exposures		
Occupational exposure to SARS-CoV-2	1	0
Occupational exposure to product	1	0
Off label uses		
Off label use	16	0
Overdoses NEC		
Overdose	6	0
Pathways and sources of exposure		
Exposure via unknown route	1	0
Peripheral nerve injuries		
Brachial plexus injury	1	0
Ulnar nerve injury	4	0
Poisoning and toxicity		
Poisoning	3	0
Toxicity to various agents	1	0
Product administration errors and issues		
Accidental overdose	2	0
Contraindicated product administered	1	0
Expired product administered	6	0
Inappropriate schedule of product administration	18	0
Incomplete course of vaccination	1	0
Incorrect dose administered	1	0
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	1	0
Product administered at inappropriate site	6	0
Product administered to patient of inappropriate age	1	0
Product administration error	2	0
Product dose omission issue	3	0
Wrong product administered	9	0
Product confusion errors and issues		
Product label confusion	1	0
Product dispensing errors and issues		
Product dispensing error	3	0
Product monitoring errors and issues		
Drug monitoring procedure incorrectly performed	1	0
Product preparation errors and issues		
Product preparation error	1	0
Product preparation issue	2	0
Product prescribing errors and issues		
Contraindicated product prescribed	2	0
Radiation injuries		
Sunburn	6	0
Renal and urinary tract injuries NEC		
Foreign body in urogenital tract	1	0
Site specific injuries NEC		
Face crushing	1	0
Head injury	9	0
Limb crushing injury	2	0
Limb injury	25	0
Skin injuries NEC		

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Contusion	373	0
Nail avulsion	1	0
Scar	3	0
Scratch	1	0
Skin abrasion	4	0
Skin injury	1	0
Skin wound	1	0
Subcutaneous haematoma	1	0
Skull fractures, facial bone fractures and dislocations		
Fractured skull depressed	1	0
Spinal fractures and dislocations		
Spinal fracture	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		
Airway burns	1	0
Burn oesophageal	1	0
Burn of internal organs	1	0
Burn oral cavity	1	0
Burns second degree	3	0
Thermal burn	7	0
Thermal burns of eye	6	0
Underdoses NEC		
Underdose	2	0
Vaccination related complications		
Vaccination complication	34	0
Injuries SOC TOTAL	1255	2

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations		
<i>Adrenal cortex tests</i>		
Cortisol decreased	2	0
<i>Auditory and vestibular diagnostic procedures</i>		
Acoustic stimulation tests	4	0
<i>Autoimmunity analyses</i>		
Antinuclear antibody	1	0
Rheumatoid factor	2	0
<i>Blood counts NEC</i>		
Blood count	3	0
Blood count abnormal	2	0
<i>Blood gas and acid base analyses</i>		
Blood lactic acid	2	0
Blood lactic acid increased	2	0
Blood pH	4	0
Blood pH increased	5	0
Oxygen consumption decreased	1	0
Oxygen saturation	5	0
Oxygen saturation decreased	36	0
<i>Bone marrow and immune tissue histopathology procedures</i>		
Biopsy lymph gland	1	0
<i>Bone marrow and immune tissue imaging procedures</i>		
Lymph nodes scan abnormal	1	0
<i>Carbohydrate tolerance analyses (incl diabetes)</i>		
Blood glucose	6	0
Blood glucose abnormal	6	0
Blood glucose decreased	15	0
Blood glucose fluctuation	11	0
Blood glucose increased	61	0
Glycosylated haemoglobin increased	1	0
<i>Cardiac auscultatory investigations</i>		
Cardiac murmur	7	0
Heart sounds abnormal	2	0
<i>Cardiac function diagnostic procedures</i>		
Cardiac output	1	0
Central venous pressure	1	0
<i>Central nervous system imaging procedures</i>		
Computerised tomogram head	2	0
Magnetic resonance imaging head	10	0
Magnetic resonance imaging head abnormal	1	0
<i>Chemistry analyses NEC</i>		
Inflammatory marker increased	3	0
<i>Cholesterol analyses</i>		
Blood cholesterol increased	2	0
<i>Coagulation and bleeding analyses</i>		
Activated partial thromboplastin time prolonged	10	0
Bleeding time abnormal	1	0
Blood thromboplastin	1	0
Clot retraction	1	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	2	0
Fibrin D dimer increased	3	0
International normalised ratio abnormal	3	0
International normalised ratio decreased	16	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
International normalised ratio increased	37	0
<i>ECG investigations</i>		
Electrocardiogram ST segment elevation	2	0
Electrocardiogram T wave inversion	1	0
Electrocardiogram abnormal	3	0
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	3	0
<i>Faecal analyses NEC</i>		
Faecal calprotectin	2	0
Faecal calprotectin increased	3	0
<i>Gastrointestinal and abdominal imaging procedures</i>		
Sigmoidoscopy abnormal	1	0
<i>Haematological analyses NEC</i>		
Plasma viscosity	1	0
Red blood cell sedimentation rate increased	4	0
<i>Heart rate and pulse investigations</i>		
Heart rate	121	0
Heart rate abnormal	7	0
Heart rate decreased	18	0
Heart rate increased	279	0
Heart rate irregular	43	0
Pulse abnormal	8	0
Radial pulse abnormal	1	0
<i>Imaging procedures NEC</i>		
Computerised tomogram	1	0
Magnetic resonance imaging	1	0
Magnetic resonance imaging abnormal	1	0
<i>Immunoglobulin analyses</i>		
Blood immunoglobulin G increased	1	0
Blood immunoglobulin M	1	0
Blood immunoglobulin M increased	1	0
<i>Immunology analyses NEC</i>		
Antibody test	1	0
Immunology test	5	0
<i>Immunology skin tests NEC</i>		
Skin test positive	1	0
<i>Investigations NEC</i>		
Blood test	5	0
Blood test abnormal	10	0
False positive investigation result	1	0
Polymerase chain reaction positive	33	0
Systemic lupus erythematosus disease activity index increased	1	0
<i>Liver function analyses</i>		
Alanine aminotransferase increased	8	0
Aspartate aminotransferase increased	1	0
Gamma-glutamyltransferase increased	2	0
Hepatic enzyme increased	3	0
Liver function test abnormal	12	0
Liver function test increased	10	0
Transaminases increased	1	0
<i>Metabolism tests NEC</i>		
Blood ketone body	2	0
Blood ketone body increased	1	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021

Data Lock Date: 05-May-2021 18:30:08

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Ubiquinone	1	0
Microbiology and serology tests NEC		
Culture negative	1	0
Mineral and electrolyte analyses		
Blood copper increased	1	0
Blood iron	1	0
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	3	0
Blood potassium increased	1	0
Blood sodium decreased	3	0
Serum ferritin increased	1	0
Musculoskeletal and soft tissue tests NEC		
Swollen joint count increased	1	0
Neurologic diagnostic procedures		
Coma scale abnormal	2	0
Temperature perception test increased	1	0
Ophthalmic function diagnostic procedures		
Corneal reflex decreased	1	0
Intraocular pressure increased	2	0
Physical examination procedures and organ system status		
Body temperature	141	0
Body temperature abnormal	22	0
Body temperature decreased	19	0
Body temperature fluctuation	16	0
Body temperature increased	232	0
Body temperature normal	1	0
Breath sounds abnormal	1	0
General physical condition abnormal	1	0
Grip strength	2	0
Grip strength decreased	8	0
Lymph node palpable	20	0
Ophthalmological examination	1	0
Palpatory finding abnormal	1	0
Product residue present	2	0
Psoriasis area severity index decreased	1	0
Respiratory rate	3	0
Respiratory rate decreased	4	0
Respiratory rate increased	20	0
Skin temperature	21	0
Temperature difference of extremities	6	0
Weight	1	0
Weight decreased	26	0
Weight increased	4	0
Pituitary analyses anterior		
Blood growth hormone	2	0
Blood thyroid stimulating hormone increased	2	0
Platelet analyses		
Mean platelet volume decreased	1	0
Platelet count decreased	29	0
Platelet count increased	1	0
Protein analyses NEC		

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
C-reactive protein increased	7	0
Red blood cell analyses		
Haematocrit	1	0
Haemoglobin decreased	6	0
Reproductive hormone analyses		
False negative pregnancy test	1	0
Pregnancy test	1	0
Pregnancy test false positive	1	0
Pregnancy test positive	1	0
Reproductive organ and breast histopathology procedures		
Smear cervix	1	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume increased	2	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	4	0
Pulmonary function test	2	0
Vital capacity	1	0
Respiratory tract and thoracic histopathology procedures		
Sputum abnormal	3	0
Respiratory tract and thoracic imaging procedures		
Chest X-ray	8	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	3	0
Troponin increased	4	0
Therapeutic drug monitoring analyses		
Analgesic drug level	1	0
Anticoagulation drug level below therapeutic	5	0
Anticoagulation drug level increased	1	0
Drug level decreased	1	0
Thyroid analyses		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	1	0
Thyroxine free increased	2	0
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	2	0
Tissue enzyme analyses NEC		
Blood alkaline phosphatase increased	2	0
Toxicology laboratory analyses		
Opiates	1	0
Urinalysis NEC		
Blood urine	7	0
Blood urine present	15	0
Cells in urine	1	0
Glucose urine present	1	0
Urine analysis abnormal	2	0
pH urine	4	0
pH urine increased	1	0
Urinary tract function analyses NEC		
Urine output	6	0
Urine output decreased	5	0
Urine output increased	3	0
Urinary tract imaging procedures		
Cystoscopy	2	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations		
Investigations cont'd		
<i>Vascular imaging procedures NEC</i>		
Venogram	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	3	0
Blood pressure decreased	25	0
Blood pressure diastolic	1	0
Blood pressure diastolic increased	1	0
Blood pressure increased	116	0
Blood pressure measurement	17	0
Blood pressure systolic decreased	2	0
Blood pressure systolic increased	1	0
<i>Virus identification and serology</i>		
Coronavirus test	5	0
Coronavirus test positive	2	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	4	0
SARS-CoV-2 antibody test negative	10	0
SARS-CoV-2 antibody test positive	1	0
SARS-CoV-2 test	20	0
SARS-CoV-2 test false negative	1	0
SARS-CoV-2 test false positive	1	0
SARS-CoV-2 test negative	4	0
SARS-CoV-2 test positive	49	0
Viral test	3	0
<i>Vitamin analyses</i>		
Blood folate decreased	2	0
Vitamin D	2	0
<i>Water and electrolyte analyses NEC</i>		
Volume blood	1	0
<i>White blood cell analyses</i>		
Lymphocyte count	1	0
Lymphocyte count decreased	1	0
Neutrophil count decreased	1	0
White blood cell count	1	0
White blood cell count decreased	5	0
White blood cell count increased	2	0
Investigations SOC TOTAL	1881	1

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	4	0
Decreased appetite	587	0
Eating disorder symptom	1	0
Food craving	4	0
Food refusal	4	0
Hyperphagia	1	0
Hypophagia	8	0
Increased appetite	5	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	3	0
Tetany	2	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	21	0
Diabetes mellitus inadequate control	6	1
Increased insulin requirement	1	0
Latent autoimmune diabetes in adults	1	0
Type 1 diabetes mellitus	10	0
Type 2 diabetes mellitus	1	0
<i>Diabetic complications NEC</i>		
Diabetic complication	2	0
Diabetic ketoacidosis	6	0
Diabetic ketosis	1	0
<i>Disorders of purine metabolism</i>		
Gout	40	0
<i>Electrolyte imbalance NEC</i>		
Fluid imbalance	1	0
<i>Fluid intake increased</i>		
Polydipsia	4	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	2	0
Dairy intolerance	1	0
Food intolerance	4	0
Gluten sensitivity	1	0
Histamine intolerance	2	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	5	0
Abnormal weight gain	5	0
Cachexia	1	0
Feeding disorder	22	0
Food aversion	5	0
Overweight	1	0
Poor feeding infant	3	0
Weight loss poor	1	0
<i>Hyperglycaemic conditions NEC</i>		
Hyperglycaemia	53	0
Insulin resistance	4	0
<i>Hypoglycaemic conditions NEC</i>		
Glycopenia	1	0
Hypoglycaemia	50	0
Postprandial hypoglycaemia	1	0
<i>Iron deficiencies</i>		

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021

Data Lock Date: 05-May-2021 18:30:08

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Iron deficiency	1	0
Lipid metabolism and deposit disorders NEC		
Body fat disorder	1	0
Metabolic acidoses (excl diabetic acidoses)		
Ketoacidosis	4	0
Metabolic acidosis	2	0
Mixed acid-base disorders		
Acidosis	3	0
Potassium imbalance		
Hyperkalaemia	2	0
Hypokalaemia	2	0
Hypokalaemic syndrome	1	0
Sodium imbalance		
Hyponatraemia	5	0
Hyponatraemic syndrome	2	0
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	1	0
Total fluid volume decreased		
Dehydration	71	0
Total fluid volume increased		
Fluid retention	17	0
Hypervolaemia	1	0
Vitamin deficiencies NEC		
Hypovitaminosis	2	0
Metabolic disorders SOC TOTAL	992	1

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	116	0
Arthropathy	13	0
Haemarthrosis	3	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	1	0
Polyarthritis	9	0
Sacroiliitis	3	0
Seronegative arthritis	1	0
<i>Bone disorders NEC</i>		
Medial tibial stress syndrome	2	0
Osteitis	1	0
Osteonecrosis of jaw	2	0
Spinal disorder	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	173	0
Bone swelling	3	0
Coccydynia	1	0
Pain in jaw	145	0
Spinal pain	24	0
<i>Bursal disorders</i>		
Bursitis	23	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	22	0
Osteochondritis	1	0
Polychondritis	2	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	1	0
Polymyalgia rheumatica	26	0
Sjogren's syndrome	3	0
<i>Crystal arthropathic disorders</i>		
Crystal arthropathy	1	0
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		
Bone deformity	1	0
Foot deformity	1	0
Hand deformity	1	0
Knee deformity	1	0
Musculoskeletal deformity	1	0
<i>Joint related disorders NEC</i>		
Joint destruction	1	0
Joint laxity	2	0
Joint lock	8	0
Patellofemoral pain syndrome	1	0
Periarthritis	48	0
Rotator cuff syndrome	4	0
Temporomandibular joint syndrome	2	0
<i>Joint related signs and symptoms</i>		
Arthralgia	4358	0
Jaw clicking	4	0
Joint effusion	11	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Joint noise	10	0
Joint range of motion decreased	3	0
Joint stiffness	99	0
Joint swelling	202	0
Joint vibration	1	0
Joint warmth	7	0
Loose body in joint	1	0
Ligament disorders		
Symphysiolysis	1	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	8	0
Metabolic bone disorders		
Osteopenia	1	0
Osteoporosis	1	0
Muscle infections and inflammations		
Antisynthetase syndrome	1	0
Myositis	12	0
Polymyositis	2	0
Muscle pains		
Fibromyalgia	37	0
Myalgia	5764	0
Myalgia intercostal	1	0
Myofascial pain syndrome	6	0
Muscle related signs and symptoms NEC		
Haematoma muscle	1	0
Muscle atrophy	6	0
Muscle discomfort	2	0
Muscle disorder	2	0
Muscle fatigue	175	0
Muscle mass	2	0
Muscle spasms	338	0
Muscle swelling	11	0
Muscle tightness	26	0
Muscle twitching	131	0
Muscle tone abnormalities		
Muscle rigidity	7	0
Nuchal rigidity	6	0
Torticollis	3	0
Trismus	12	0
Muscle weakness conditions		
Muscular weakness	383	0
Musculoskeletal and connective tissue conditions NEC		
Limb mass	5	0
Mandibular mass	2	0
Mastication disorder	1	0
Mobility decreased	31	0
Musculoskeletal disorder	4	0
Musculoskeletal stiffness	519	0
Posture abnormal	1	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Dupuytren's contracture	1	0
Fasciitis	1	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Plantar fasciitis	4	0
<i>Musculoskeletal and connective tissue pain and discomfort</i>		
Back pain	986	0
Flank pain	17	0
Limb discomfort	610	0
Musculoskeletal chest pain	71	0
Musculoskeletal discomfort	35	0
Musculoskeletal pain	27	0
Neck pain	804	0
Pain in extremity	5116	0
Rheumatic disorder	3	0
<i>Myopathies</i>		
Myopathy	2	0
Rhabdomyolysis	3	0
<i>Osteoarthropathies</i>		
Nodal osteoarthritis	1	0
Osteoarthritis	14	0
<i>Psoriatic arthropathies</i>		
Psoriatic arthropathy	9	0
<i>Rheumatoid arthropathies</i>		
Rheumatoid arthritis	59	0
<i>Soft tissue disorders NEC</i>		
Axillary mass	123	0
Fluctuance	1	0
Groin pain	46	0
Neck mass	12	0
Purple glove syndrome	1	0
Soft tissue swelling	3	0
<i>Spine and neck deformities</i>		
Kyphosis	1	0
Neck deformity	1	0
<i>Spondyloarthropathies</i>		
Ankylosing spondylitis	4	0
Arthritis reactive	17	0
Spondylitis	1	0
<i>Synovial disorders</i>		
Synovial cyst	9	0
Synovitis	4	0
<i>Tendon disorders</i>		
Enthesopathy	1	0
Tendon pain	3	0
Tendonitis	13	0
Tenosynovitis	1	0
Tenosynovitis stenosaurs	1	0
Trigger finger	7	0
<i>Trunk deformities</i>		
Drooping shoulder syndrome	1	0
Muscle & tissue disorders SOC TOTAL	20863	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Neoplasms		
<i>B-cell lymphomas NEC</i>		
Follicular lymphoma	3	0
<i>Bone neoplasms unspecified malignancy</i>		
Bone neoplasm	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	15	0
Breast cancer stage III	1	0
Triple negative breast cancer	2	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	1	0
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Thyroid neoplasm	1	0
<i>Follicular lymphomas</i>		
Primary gastrointestinal follicular lymphoma	1	0
<i>Gastric neoplasms malignant</i>		
Gastric cancer	1	1
<i>Gastrointestinal neoplasms malignant NEC</i>		
Gastrointestinal carcinoma	1	0
<i>Islet cell neoplasms and APUDoma NEC</i>		
Pancreatic neuroendocrine tumour	1	0
<i>Leukaemias acute NEC</i>		
Acute leukaemia	1	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	2	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	9	0
<i>Metastases to specified sites</i>		
Metastases to liver	1	0
Metastases to lymph nodes	4	0
<i>Metastases to unknown and unspecified sites</i>		
Metastasis	1	0
<i>Myeloproliferative disorders (excl leukaemias)</i>		
Essential thrombocythaemia	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Neoplasm malignant	2	0
Second primary malignancy	1	0
Squamous cell carcinoma	2	0
<i>Neoplasms unspecified malignancy and site unspecified NEC</i>		
Neoplasm recurrence	1	0
<i>Nervous system neoplasms benign NEC</i>		
Cranial nerve neoplasm benign	1	0
<i>Nervous system neoplasms unspecified malignancy NEC</i>		
Brain neoplasm	1	0
<i>Non-Hodgkin's lymphomas NEC</i>		
Non-Hodgkin's lymphoma	1	0
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	2	0
<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>		
Pancreatic carcinoma	4	0
<i>Plasma cell myelomas</i>		
Plasma cell myeloma	1	0
<i>Plasma cell neoplasms NEC</i>		

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
TEMPI syndrome	1	0
<i>Prostatic neoplasms malignant</i>		
Prostate cancer	1	0
<i>Renal neoplasms malignant</i>		
Renal cancer	2	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified</i>		
<i>NEC</i>		
Lung neoplasm malignant	4	0
<i>Skin neoplasms benign</i>		
Acrochordon	2	0
Anogenital warts	2	0
Melanocytic naevus	4	0
Skin papilloma	4	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	2	0
Neoplasm skin	1	0
Squamous cell carcinoma of skin	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	1	0
Lymphangioma	1	0
<i>Soft tissue sarcomas histology unspecified</i>		
Sarcoma	1	0
<i>Thyroid neoplasms malignant</i>		
Papillary thyroid cancer	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	4	0
Neoplasms SOC TOTAL	95	1

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	2	0
Extensor plantar response	1	0
Hyperreflexia	1	0
Hyporeflexia	4	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	6	0
<i>Absence seizures</i>		
Petit mal epilepsy	12	0
<i>Acute polyneuropathies</i>		
Guillain-Barre syndrome	29	2
Subacute inflammatory demyelinating polyneuropathy	1	0
<i>Autonomic nervous system disorders</i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	4	0
Horner's syndrome	1	0
<i>Central nervous system aneurysms and dissections</i>		
Intracranial aneurysm	1	0
Vertebral artery dissection	1	0
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	1
Brain stem stroke	1	0
Cerebellar haemorrhage	2	0
Cerebellar infarction	2	0
Cerebellar stroke	3	0
Cerebral artery embolism	3	1
Cerebral artery occlusion	1	0
Cerebral artery thrombosis	2	0
Cerebral haemorrhage	21	6
Cerebral infarction	19	0
Cerebral thrombosis	2	0
Cerebrovascular accident	198	12
Embolic stroke	4	0
Haemorrhage intracranial	4	0
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	6	3
Ischaemic cerebral infarction	1	0
Ischaemic stroke	26	1
Lacunar infarction	2	0
Lacunar stroke	1	0
Lateral medullary syndrome	1	0
Subarachnoid haemorrhage	5	2
Thrombotic stroke	1	0
<i>Central nervous system inflammatory disorders NEC</i>		
Gliosis	1	0
<i>Central nervous system vascular disorders NEC</i>		
Carotid artery disease	1	0
Cerebrovascular disorder	1	0
Reversible cerebral vasoconstriction syndrome	1	0
<i>Cerebrovascular venous and sinus thrombosis</i>		
Cerebral venous sinus thrombosis	15	1
Cerebral venous thrombosis	1	0
Superior sagittal sinus thrombosis	2	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021

Data Lock Date: 05-May-2021 18:30:08

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Cervical spinal cord and nerve root disorders</i>		
Cervicobrachial syndrome	2	0
<i>Choreiform movements</i>		
Chorea	2	0
<i>Coma states</i>		
Coma	4	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
<i>Coordination and balance disturbances</i>		
Ataxia	5	0
Balance disorder	150	0
Coordination abnormal	20	0
Dysdiadochokinesis	1	0
Dysstasia	20	0
Nystagmus	7	0
<i>Cortical dysfunction NEC</i>		
Aphasia	29	0
Apraxia	1	0
Neurologic neglect syndrome	1	0
<i>Cranial nerve disorders NEC</i>		
Cranial nerve disorder	2	0
<i>Dementia (excl Alzheimer's type)</i>		
Dementia	6	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
<i>Demyelinating disorders NEC</i>		
Acute disseminated encephalomyelitis	3	0
Demyelination	5	0
<i>Disturbances in consciousness NEC</i>		
Altered state of consciousness	6	0
Consciousness fluctuating	2	0
Depressed level of consciousness	20	1
Lethargy	1181	0
Loss of consciousness	180	0
Sedation	4	0
Somnolence	397	0
Stupor	2	0
Syncope	520	0
<i>Disturbances in sleep phase rhythm</i>		
Irregular sleep wake rhythm disorder	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	1	0
Bradykinesia	6	0
Clumsiness	6	0
Dyskinesia	25	0
Extrapyramidal disorder	1	0
Fine motor skill dysfunction	4	0
Hyperkinesia	2	0
Hypokinesia	20	1
Motor dysfunction	2	0
Movement disorder	21	0
Psychomotor hyperactivity	8	0
Tardive dyskinesia	2	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021

Data Lock Date: 05-May-2021 18:30:08

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Dystonias</i>		
Dystonia	9	0
Writer's cramp	1	0
<i>Encephalitis NEC</i>		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	1	0
<i>Encephalopathies NEC</i>		
Encephalopathy	1	0
Posterior reversible encephalopathy syndrome	1	0
<i>Eye movement disorders</i>		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	3	0
IVth nerve paralysis	1	0
VIth nerve paralysis	4	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	228	0
Facial nerve disorder	1	0
Facial paralysis	158	0
Facial paresis	45	0
Facial spasm	18	0
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	16	0
<i>Headaches NEC</i>		
Cervicogenic headache	3	0
Cluster headache	96	0
Cold-stimulus headache	8	0
Drug withdrawal headache	1	0
Exertional headache	5	0
Headache	13180	0
Medication overuse headache	2	0
New daily persistent headache	4	0
Occipital neuralgia	4	0
Ophthalmoplegic migraine	1	0
Primary cough headache	3	0
Primary headache associated with sexual activity	1	0
Sinus headache	177	0
Tension headache	247	0
Thunderclap headache	2	0
Vascular headache	8	0
<i>Hypoglossal nerve disorders</i>		
Tongue paralysis	1	0
<i>Increased intracranial pressure disorders</i>		
Brain oedema	1	0
Idiopathic intracranial hypertension	1	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	25	0
<i>Memory loss (excl dementia)</i>		
Amnesia	54	0
Memory impairment	50	0
Transient global amnesia	6	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	33	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Cognitive linguistic deficit	1	0
Disturbance in attention	119	0
Mental impairment	14	0
Migraine headaches		
Hemiplegic migraine	6	0
Migraine	1150	0
Migraine with aura	77	0
Migraine without aura	8	0
Ophthalmic migraine	3	0
Retinal migraine	15	0
Typical aura without headache	3	0
Vestibular migraine	9	0
Mixed cranial nerve disorders		
Bulbar palsy	1	0
Mononeuropathies		
Carpal tunnel syndrome	7	0
Mononeuropathy	1	0
Nerve compression	8	0
Peroneal nerve palsy	4	0
Sciatic nerve neuropathy	1	0
Ulnar neuritis	1	0
Multiple sclerosis acute and progressive		
Multiple sclerosis	15	0
Multiple sclerosis relapse	10	0
Tumefactive multiple sclerosis	1	1
Muscle tone abnormal		
Hypotonia	6	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
Myelitis (incl infective)		
Myelitis transverse	17	0
Narcolepsy and hypersomnia		
Cataplexy	1	0
Hypersomnia	42	0
Narcolepsy	2	0
Nervous system disorders NEC		
Nervous system disorder	4	0
Neurologic visual problems NEC		
Hemianopia	1	0
Hemianopia homonymous	1	0
Quadrantanopia	1	0
Tunnel vision	5	0
Neurological signs and symptoms NEC		
Dizziness	4030	0
Dizziness exertional	21	0
Dizziness postural	372	0
Drooling	8	0
Fontanelle bulging	1	0
Head discomfort	111	0
Hyporesponsive to stimuli	1	0
Inability to crawl	2	0
Infant irritability	1	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021

Data Lock Date: 05-May-2021 18:30:08

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
Myoclonus	9	0
Neurological symptom	21	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	6	0
Presyncope	227	0
Slow response to stimuli	2	0
Tongue biting	2	0
Unresponsive to stimuli	24	1
Neuromuscular disorders NEC		
Muscle contractions involuntary	10	0
Muscle spasticity	7	0
Neuromuscular pain	2	0
Neuromuscular junction dysfunction		
Myasthenia gravis	5	0
Myasthenia gravis crisis	2	0
Olfactory nerve disorders		
Anosmia	103	0
Hyposmia	9	0
Parosmia	101	0
Optic nerve disorders NEC		
Optic neuritis	13	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	2	0
Burning sensation	200	0
Dysaesthesia	4	0
Formication	19	0
Hand-arm vibration syndrome	2	0
Hemiparaesthesia	1	0
Hyperaesthesia	43	0
Hypoaesthesia	988	0
Paraesthesia	1435	0
Reversed hot-cold sensation	1	0
Synaesthesia	1	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	4	1
Hemiparesis	19	0
Hemiplegia	13	0
Locked-in syndrome	1	0
Monoparesis	29	0
Monoplegia	23	0
Paralysis	43	0
Paraparesis	1	0
Paresis	4	0
Parkinson's disease and parkinsonism		
Freezing phenomenon	6	0
Parkinson's disease	3	0
Parkinsonian gait	1	0
Parkinsonism	4	0
Reduced facial expression	2	0
Partial complex seizures		
Dreamy state	2	0
Focal dyscognitive seizures	1	0
Temporal lobe epilepsy	1	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Peripheral neuropathies NEC</i>		
Neuritis	3	0
Neuropathy peripheral	47	0
Peripheral sensory neuropathy	5	0
<i>Seizures and seizure disorders NEC</i>		
Atonic seizures	4	0
Clonic convulsion	1	0
Epilepsy	77	0
Epileptic aura	2	0
Epileptic encephalopathy	1	0
Febrile convulsion	9	0
Partial seizures	8	0
Post stroke seizure	1	0
Psychogenic seizure	5	0
Seizure	207	0
Seizure anoxic	1	0
Seizure cluster	4	0
Seizure like phenomena	1	0
Status epilepticus	22	0
Tonic clonic movements	2	0
Tonic convulsion	10	0
<i>Sensory abnormalities NEC</i>		
Ageusia	226	0
Allodynia	9	0
Aura	8	0
Dysgeusia	595	0
Electric shock sensation	11	0
Hypergeusia	1	0
Hypogeusia	1	0
Loss of proprioception	2	0
Neuralgia	209	0
Phantom limb syndrome	3	0
Post herpetic neuralgia	10	0
Restless legs syndrome	42	0
Sensory disturbance	31	0
Sensory loss	27	0
Taste disorder	130	0
Visual perseveration	1	0
<i>Sleep disturbances NEC</i>		
Sleep deficit	2	0
Sudden onset of sleep	1	0
<i>Speech and language abnormalities</i>		
Dysarthria	72	0
Incoherent	4	0
Repetitive speech	1	0
Slow speech	3	0
Speech disorder	14	0
<i>Spinal cord and nerve root disorders NEC</i>		
Radiculitis brachial	3	0
Radiculopathy	3	0
<i>Structural brain disorders NEC</i>		
Brain injury	2	2
Hyperintensity in brain deep nuclei	2	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Transient cerebrovascular events</i>		
Transient ischaemic attack	71	0
<i>Tremor (excl congenital)</i>		
Essential tremor	2	0
Head titubation	2	0
Resting tremor	1	0
Tremor	727	0
<i>Trigeminal disorders</i>		
Facial neuralgia	11	0
Numb chin syndrome	1	0
Trigeminal nerve disorder	1	0
Trigeminal neuralgia	24	0
<i>Vertigos NEC</i>		
Vertigo CNS origin	1	0
Nervous system disorders SOC TOTAL	29614	36

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortions not specified as induced or spontaneous</i>		
Abortion missed	2	0
<i>Abortions spontaneous</i>		
Abortion spontaneous	64	2
<i>Foetal complications NEC</i>		
Hydrops foetalis	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	1	1
<i>Labour onset and length abnormalities</i>		
Premature delivery	1	0
Premature labour	1	0
<i>Maternal complications of pregnancy NEC</i>		
Morning sickness	6	0
Preterm premature rupture of membranes	2	0
<i>Normal pregnancy, labour and delivery</i>		
Pregnancy	10	0
<i>Pregnancy complicated by maternal disorders</i>		
Gestational diabetes	2	0
<i>Stillbirth and foetal death</i>		
Foetal death	3	0
Stillbirth	2	0
<i>Unintended pregnancies</i>		
Pregnancy after post coital contraception	1	0
Pregnancy with contraceptive device	2	0
Pregnancy with implant contraceptive	1	0
Unintended pregnancy	1	0
Pregnancy conditions SOC TOTAL	100	3

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021

Data Lock Date: 05-May-2021 18:30:08

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device issue	1	0
<i>Device malfunction events NEC</i>		
Device infusion issue	1	0
Device pacing issue	1	0
Device stimulation issue	1	0
Oversensing	11	0
Thrombosis in device	3	0
<i>Device physical property and chemical issues</i>		
Device defective	1	0
Device kink	1	0
Needle issue	2	0
<i>Product contamination and sterility issues</i>		
Product contamination	1	0
<i>Product physical issues</i>		
Liquid product physical issue	4	0
Product odour abnormal	1	0
Product physical issue	1	0
Product taste abnormal	5	0
<i>Product quality issues NEC</i>		
Product origin unknown	3	0
null SOC TOTAL	37	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	4	0
Behaviour disorder	1	0
Staring	2	0
<i>Adjustment disorders</i>		
Adjustment disorder with depressed mood	1	0
<i>Affect alterations NEC</i>		
Affect lability	2	0
Constricted affect	1	0
Flat affect	4	0
Inappropriate affect	2	0
<i>Amnesic symptoms</i>		
Paramnesia	2	0
<i>Anxiety symptoms</i>		
Agitation	40	0
Anxiety	226	0
Immunisation anxiety related reaction	1	0
Nervousness	90	0
Stress	14	0
Tension	16	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	2	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	4	0
Aversion	1	0
Indifference	4	0
Paranoia	8	0
Personality change	2	0
Social avoidant behaviour	2	0
Soliloquy	1	0
Suspiciousness	1	0
<i>Bipolar disorders</i>		
Bipolar I disorder	1	0
Bipolar disorder	2	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	2	0
Mental fatigue	84	0
<i>Communications disorders</i>		
Communication disorder	4	0
Mutism	1	0
<i>Confusion and disorientation</i>		
Confusional state	372	0
Disorientation	114	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0
<i>Deliria</i>		
Delirium	57	0
<i>Delusional symptoms</i>		
Delusion	4	0
<i>Depressive disorders</i>		
Agitated depression	1	0
Depression	92	0
Depression suicidal	2	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Major depression	3	0
Perinatal depression	1	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	3	0
Dissociation	8	0
Dissociative amnesia	1	0
Dissociative disorder	1	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	6	0
Insomnia	454	0
Middle insomnia	11	0
Terminal insomnia	5	0
<i>Dyssomnias</i>		
Dyssomnia	1	0
Poor quality sleep	84	0
<i>Eating disorders NEC</i>		
Bulimia nervosa	1	0
Eating disorder	5	0
Selective eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	5	0
Dysphoria	2	0
Emotional disorder	14	0
Emotional distress	10	0
Euphoric mood	14	0
Irritability	68	0
Mood altered	18	0
<i>Factitious disorders</i>		
Factitious disorder	1	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Fear	3	0
Fear of falling	2	0
Osmophobia	1	0
Phobia	1	0
Phonophobia	1	0
Social fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	12	0
<i>Hallucinations (excl sleep-related)</i>		
Hallucination	92	0
Hallucination, auditory	6	0
Hallucination, olfactory	4	0
Hallucination, tactile	1	0
Hallucination, visual	9	0
Hallucinations, mixed	1	0
<i>Increased physical activity levels</i>		
Restlessness	57	0
<i>Learning disorders</i>		
Learning disorder	1	0
<i>Mental disorders NEC</i>		
Mental disorder	5	0
<i>Mental disorders due to a general medical condition NEC</i>		
Neuropsychiatric symptoms	1	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Mood alterations with depressive symptoms</i>		
Decreased interest	6	0
Depressed mood	109	0
Feeling of despair	1	0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Sense of a foreshortened future	2	0
Tearfulness	18	0
<i>Mood alterations with manic symptoms</i>		
Hypomania	1	0
Mania	4	0
<i>Mood disorders NEC</i>		
Apathy	9	0
Laziness	1	0
Listless	13	0
<i>Narcolepsy and associated conditions</i>		
Hypnagogic hallucination	2	0
Sleep attacks	3	0
<i>Obsessive-compulsive disorders and symptoms</i>		
Obsessive-compulsive symptom	1	0
<i>Orgasmic disorders and disturbances</i>		
Anorgasmia	2	0
<i>Panic attacks and disorders</i>		
Panic attack	43	0
Panic disorder	3	0
Panic reaction	7	0
<i>Parasomnias</i>		
Abnormal dreams	81	0
Confusional arousal	1	0
Nightmare	84	0
Parasomnia	1	0
Sleep talking	1	0
Sleep terror	10	0
Somnambulism	2	0
<i>Perception disturbances NEC</i>		
Autoscopy	6	0
Deja vu	1	0
Derealisation	6	0
Flashback	2	0
Illusion	1	0
<i>Personality disorders NEC</i>		
Personality disorder	1	0
<i>Pervasive developmental disorders NEC</i>		
Autism spectrum disorder	2	1
<i>Psychiatric elimination disorders</i>		
Enuresis	7	0
<i>Psychiatric symptoms NEC</i>		
Hypervigilance	3	0
Psychiatric symptom	1	0
Psychological trauma	1	0
Trance	1	0
<i>Psychotic disorder NEC</i>		
Psychotic behaviour	1	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Psychotic disorder	10	0
Schizophrenia NEC		
Schizophrenia	1	0
Sexual desire disorders		
Libido decreased	3	0
Libido increased	1	0
Loss of libido	5	0
Sleep disorders NEC		
Sleep disorder	80	0
Somatic symptom disorders		
Conversion disorder	2	0
Habit cough	10	0
Somatic symptom disorder	1	0
Vomiting psychogenic	1	0
Speech and language usage disturbances		
Disorganised speech	3	0
Logorrhoea	2	0
Speech articulation and rhythm disturbances		
Dysphemia	5	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
Stereotypies and automatisms		
Bruxism	7	0
Head banging	4	0
Stereotypy	1	0
Stress disorders		
Post-traumatic stress disorder	2	0
Substance related and addictive disorders		
Alcohol problem	1	0
Alcoholic hangover	1	0
Suicidal and self-injurious behaviour		
Completed suicide	1	0
Intentional self-injury	3	0
Self-injurious ideation	2	0
Suicidal behaviour	1	0
Suicidal ideation	6	0
Suicide attempt	3	0
Thinking disturbances		
Bradyphrenia	17	0
Intrusive thoughts	2	0
Tachyphrenia	2	0
Thinking abnormal	4	0
Tic disorders		
Tic	2	0
Psychiatric disorders SOC TOTAL	2708	1

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	1	0
Bladder irritation	1	0
Bladder pain	10	0
Dysuria	21	0
Incontinence	16	0
Micturition disorder	1	0
Micturition urgency	15	0
Pollakiuria	32	0
Urethral pain	1	0
Urinary hesitation	1	0
Urinary incontinence	30	0
Urinary retention	25	0
Urine flow decreased	4	0
<i>Bladder disorders NEC</i>		
Bladder disorder	3	0
Urinary bladder haemorrhage	1	0
<i>Bladder infections and inflammations</i>		
Cystitis interstitial	2	0
<i>Genital and urinary tract disorders NEC</i>		
Urinary tract disorder	2	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Glomerulonephritis	1	0
Glomerulonephritis minimal lesion	3	0
Glomerulonephritis rapidly progressive	1	0
IgA nephropathy	1	0
Nephrotic syndrome	10	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	3	0
Hypertonic bladder	1	0
Loss of bladder sensation	1	0
Neurogenic bladder	1	0
<i>Nephritis NEC</i>		
Nephritis	2	0
Tubulointerstitial nephritis	1	0
<i>Renal disorders NEC</i>		
Renal disorder	1	0
Renal haemorrhage	1	0
Renal mass	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	24	0
Anuria	3	0
Oliguria	1	0
Renal failure	11	1
Renal impairment	10	0
<i>Renal lithiasis</i>		
Nephrolithiasis	1	0
<i>Renal neoplasms</i>		
Renal cyst	1	0
<i>Renal structural abnormalities and trauma</i>		
Kidney small	1	0
<i>Renal vascular and ischaemic conditions</i>		
Renal vasculitis	1	1

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Renal & urinary disorders cont'd</i>		
<i>Structural and obstructive urethral disorders (excl congenital)</i>		
Urethral stenosis	1	0
<i>Ureteric disorders NEC</i>		
Ureteric stenosis	1	0
<i>Urinary abnormalities</i>		
Albuminuria	1	0
Chromaturia	21	0
Haematuria	21	0
Proteinuria	4	0
Urine abnormality	7	0
Urine odour abnormal	4	0
<i>Urinary tract signs and symptoms NEC</i>		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	8	0
Nocturia	1	0
Polyuria	2	0
Renal pain	112	0
Urinary tract pain	2	0
Renal & urinary disorders SOC TOTAL	434	2

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	4	0
<i>Breast disorders NEC</i>		
Breast mass	30	0
Gynaecomastia	1	0
<i>Breast signs and symptoms</i>		
Breast discharge	1	0
Breast discomfort	4	0
Breast engorgement	1	0
Breast haematoma	1	0
Breast oedema	4	0
Breast pain	165	0
Breast swelling	42	0
Breast tenderness	18	0
Nipple pain	8	0
Nipple swelling	3	0
<i>Cervix disorders NEC</i>		
Cervical dysplasia	2	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation disorder	1	0
Erectile dysfunction	18	0
Erection increased	2	0
Organic erectile dysfunction	1	0
<i>Lactation disorders</i>		
Galactorrhoea	2	0
Suppressed lactation	3	0
<i>Menopausal effects NEC</i>		
Artificial menopause	1	0
Menopausal symptoms	5	0
Premature menopause	2	0
<i>Menopausal effects on the genitourinary tract</i>		
Postmenopausal haemorrhage	10	0
<i>Menstruation and uterine bleeding NEC</i>		
Abnormal uterine bleeding	1	0
Dysmenorrhoea	61	0
Intermenstrual bleeding	43	0
Menstrual discomfort	1	0
Menstrual disorder	78	0
Menstruation irregular	77	0
Premenstrual pain	2	0
<i>Menstruation with decreased bleeding</i>		
Amenorrhoea	42	0
Hypomenorrhoea	25	0
Menstruation delayed	141	0
Oligomenorrhoea	2	0
<i>Menstruation with increased bleeding</i>		
Heavy menstrual bleeding	159	0
Polymenorrhoea	24	0
<i>Ovarian and fallopian tube cysts and neoplasms</i>		
Ovarian cyst	2	0
Polycystic ovaries	2	0
<i>Ovarian and fallopian tube disorders NEC</i>		
Ovulation pain	4	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Premature ovulation	1	0
<i>Pelvis and broad ligament disorders NEC</i>		
Adnexa uteri pain	6	0
Pelvic haemorrhage	3	0
<i>Penile disorders NEC (excl erection and ejaculation)</i>		
Penile erythema	1	0
Penile swelling	3	0
Penis disorder	2	0
<i>Prostate and seminal vesicles infections and inflammations</i>		
Prostatitis	2	0
<i>Prostatic signs, symptoms and disorders NEC</i>		
Prostatomegaly	3	0
<i>Reproductive tract disorders NEC (excl neoplasms)</i>		
Genital haemorrhage	3	0
Genital ulceration	3	0
<i>Reproductive tract infections and inflammations NEC</i>		
Genital tract inflammation	1	0
<i>Reproductive tract signs and symptoms NEC</i>		
Genital pain	2	0
Pelvic discomfort	2	0
Pelvic pain	23	0
Perineal pain	1	0
Pruritus genital	1	0
<i>Scrotal disorders NEC</i>		
Scrotal erythema	1	0
Scrotal exfoliation	1	0
Scrotal pain	3	0
Scrotal swelling	3	0
<i>Sexual function and fertility disorders NEC</i>		
Infertility	1	0
<i>Spermatogenesis and semen disorders</i>		
Haemospermia	2	0
Semen discolouration	1	0
<i>Testicular and epididymal disorders NEC</i>		
Testicular disorder	1	0
Testicular pain	8	0
Testicular swelling	5	0
<i>Uterine disorders NEC</i>		
Adenomyosis	1	0
Endometriosis	6	0
Uterine haemorrhage	4	0
Uterine pain	2	0
<i>Uterine tone disorders</i>		
Uterine spasm	2	0
<i>Vulvovaginal cysts and neoplasms</i>		
Vaginal cyst	2	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	112	0
Vulval haemorrhage	4	0
Vulval ulceration	3	0
Vulvovaginal ulceration	3	0
<i>Vulvovaginal signs and symptoms</i>		
Vaginal discharge	4	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021

Data Lock Date: 05-May-2021 18:30:08

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Reproductive & breast disorders cont'd		
Vulval oedema	1	0
Vulvovaginal burning sensation	2	0
Vulvovaginal dryness	1	0
Vulvovaginal pain	4	0
Vulvovaginal pruritus	2	0
Vulvovaginal swelling	1	0
Reproductive & breast disorders SOC TOTAL	1230	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	2	0
Dyspnoea	1536	6
Dyspnoea at rest	3	0
Dyspnoea exertional	14	1
Hyperventilation	20	0
Hypopnoea	35	0
Irregular breathing	9	0
Mouth breathing	3	0
Orthopnoea	3	0
Respiration abnormal	24	0
Respiratory arrest	7	0
Respiratory depression	1	0
Respiratory distress	10	0
Sleep apnoea syndrome	5	0
Tachypnoea	20	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	1	0
Bronchiectasis	7	0
<i>Bronchospasm and obstruction</i>		
Asthma	139	0
Asthma late onset	2	0
Bronchospasm	11	0
Chronic obstructive pulmonary disease	11	0
Cough variant asthma	2	0
Obstructive airways disorder	2	0
Reversible airways obstruction	1	0
Wheezing	203	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	1	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	16	1
Respiratory acidosis	2	0
<i>Coughing and associated symptoms</i>		
Allergic cough	4	0
Cough	1030	1
Cough decreased	2	0
Haemoptysis	14	0
Productive cough	65	0
Sputum discoloured	3	0
Sputum increased	1	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Laryngeal disorder	1	0
<i>Laryngeal spasm, oedema and obstruction</i>		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngospasm	1	0
Stridor	13	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	1	0
Hypersensitivity pneumonitis	1	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Pneumonia aspiration	6	4
Pneumonitis	15	3
Pulmonary sarcoidosis	1	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	8	0
Increased bronchial secretion	1	0
Lung opacity	1	0
Pleuritic pain	6	0
Pulmonary pain	48	0
Rales	2	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	95	0
Nasal inflammation	1	0
Rhinitis allergic	5	0
<i>Nasal disorders NEC</i>		
Epistaxis	385	0
Intranasal hyposensitivity	1	0
Intranasal paraesthesia	1	0
Nasal crusting	1	0
Nasal disorder	1	0
Nasal dryness	14	0
Nasal odour	6	0
Nasal oedema	2	0
Nasal pruritus	5	0
<i>Neonatal hypoxic conditions</i>		
Dry lung syndrome	1	0
Infantile apnoea	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Allergic sinusitis	1	0
Paranasal sinus inflammation	1	0
Sinonasal obstruction	6	0
Sinus congestion	22	0
Sinus disorder	3	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	1	0
Emphysema	1	0
Interstitial lung disease	2	0
Lung infiltration	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	3	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal erythema	4	0
Pharyngeal haemorrhage	2	0
Pharyngeal hyposensitivity	14	0
Pharyngeal inflammation	4	0
Pharyngeal oedema	6	0
Pharyngeal paraesthesia	32	0
Pharyngeal swelling	113	0
Pharyngeal ulceration	8	0
Tonsillar erythema	1	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	30	0
Tonsillar inflammation	3	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Tonsillar ulcer	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	14	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	11	0
Pneumothorax	1	0
Pneumothorax spontaneous	1	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	2	0
<i>Pulmonary oedemas</i>		
Acute respiratory distress syndrome	1	0
Pulmonary congestion	5	0
Pulmonary oedema	8	0
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	172	13
Pulmonary infarction	1	0
Pulmonary thrombosis	2	0
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	2	1
Respiratory failure	6	1
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	1	0
Diaphragmalgia	3	0
Painful respiration	5	0
Respiratory symptom	5	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	3	2
Lung disorder	2	0
Pulmonary mass	1	0
Respiratory disorder	4	0
Respiratory tract congestion	1	0
Respiratory tract irritation	3	0
Respiratory tract oedema	2	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	1	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal pain	1	0
<i>Upper respiratory tract neoplasms</i>		
Tonsillar cyst	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	34	0
Catarrh	10	0
Choking	7	1
Choking sensation	1	0
Dry throat	85	0
Dysphonia	71	0
Increased upper airway secretion	4	0
Increased viscosity of upper respiratory secretion	7	0
Nasal discharge discolouration	1	0
Nasal discomfort	24	0
Nasal obstruction	2	0
Oropharyngeal blistering	6	0
Oropharyngeal discomfort	29	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Oropharyngeal pain	1231	0
Paranasal sinus discomfort	14	0
Rhinalgia	6	0
Rhinorrhoea	346	0
Sinus pain	85	0
Sneezing	151	0
Snoring	3	0
Throat clearing	4	0
Throat irritation	108	0
Throat tightness	125	0
Upper airway obstruction	2	0
Upper-airway cough syndrome	4	0
Yawning	6	0
Respiratory disorders SOC TOTAL	6723	34

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	25	0
Acne cystic	1	0
Dermatitis acneiform	3	0
<i>Alopecias</i>		
Alopecia	62	0
Alopecia areata	4	0
Alopecia totalis	1	0
Androgenetic alopecia	1	0
Madarosis	1	0
<i>Angioedemas</i>		
Angioedema	106	0
Circumoral swelling	1	0
<i>Apocrine and eccrine gland disorders</i>		
Cold sweat	295	0
Hidradenitis	1	0
Hyperhidrosis	868	0
Miliaria	36	0
Night sweats	304	0
<i>Bullous conditions</i>		
Blister	180	0
Blister rupture	1	0
Blood blister	9	0
Dermatitis bullous	8	0
Erythema multiforme	17	0
Fracture blisters	1	0
Pemphigoid	10	0
Pemphigus	3	0
Stevens-Johnson syndrome	3	0
Toxic epidermal necrolysis	2	1
<i>Connective tissue disorders</i>		
Dermatomyositis	3	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	102	0
Macule	2	0
Pain of skin	133	0
Papule	32	0
Pathergy reaction	1	0
Peau d'orange	2	0
Scab	9	0
Scar pain	8	0
Sensitive skin	71	0
Skin burning sensation	101	0
Skin degenerative disorder	1	0
Skin discolouration	49	0
Skin discomfort	1	0
Skin disorder	5	0
Skin fissures	3	0
Skin indentation	2	0
Skin induration	3	0
Skin lesion	19	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin necrosis	1	0
Skin odour abnormal	6	0
Skin plaque	1	0
Skin reaction	64	0
Skin sensitisation	15	0
Skin swelling	39	0
Skin tightness	17	0
Skin warm	139	0
Skin weeping	3	0
Sticky skin	1	0
Transient acantholytic dermatosis	1	0
Yellow skin	8	0
<i>Dermatitis and eczema</i>		
Dermatitis	53	0
Dermatitis allergic	110	0
Dermatitis atopic	12	0
Dermatitis contact	4	0
Dermatitis diaper	1	0
Dyshidrotic eczema	6	0
Eczema	84	0
Eczema asteatotic	4	0
Eczema nummular	3	0
Eczema weeping	1	0
Perioral dermatitis	1	0
Seborrhoeic dermatitis	1	0
Skin irritation	53	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	16	0
Fixed eruption	1	0
Toxic skin eruption	1	0
<i>Erythemas</i>		
Erythema	1108	0
Palmar erythema	4	0
Red man syndrome	1	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	1	0
Dermatitis exfoliative generalised	2	0
Exfoliative rash	6	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	43	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Cutaneous sarcoidosis	1	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	1	0
Lichenoid keratosis	2	0
<i>Hyperpigmentation disorders</i>		
Argyria	1	0
Chloasma	1	0
Ephelides	1	0
Skin hyperpigmentation	2	0
Solar lentigo	1	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	2	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin hypopigmentation	1	0
Vitiligo	2	0
Lipodystrophies		
Lipoatrophy	2	0
Nail and nail bed conditions (excl infections and infestations)		
Nail discolouration	6	0
Nail disorder	2	0
Nail pigmentation	2	0
Onychalgia	6	0
Onychoclasia	3	0
Splinter haemorrhages	1	0
Panniculitides		
Erythema nodosum	12	0
Papulosquamous conditions		
Erythema annulare	1	0
Lichen planus	4	0
Lichen sclerosus	1	0
Parapsoriasis	1	0
Pityriasis rosea	43	0
Photosensitivity and photodermatosis conditions		
Photosensitivity reaction	18	0
Polymorphic light eruption	1	0
Pigmentation changes NEC		
Haemosiderin stain	1	0
Pigmentation disorder	4	0
Pilar disorders NEC		
Hair colour changes	4	0
Hair disorder	1	0
Hair growth abnormal	1	0
Hair texture abnormal	4	0
Piloerection	10	0
Pseudofolliculitis	1	0
Pruritus NEC		
Itching scar	5	0
Pruritus	2354	0
Psoriatic conditions		
Dermatitis psoriasiform	2	0
Guttate psoriasis	7	0
Psoriasis	66	0
Pustular psoriasis	1	0
Purpura and related conditions		
Henoch-Schonlein purpura	1	0
Petechiae	57	0
Purpura	21	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	2	0
Rash	2442	0
Rash erythematous	542	0
Rash macular	235	0
Rash maculo-papular	36	0
Rash morbilliform	20	0
Rash papular	156	0
Rash pruritic	534	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Rash vesicular	28	0
Systemic lupus erythematosus rash	4	0
Rosaceas		
Rosacea	9	0
Scaly conditions		
Dandruff	1	0
Pityriasis	10	0
Sebaceous gland disorders		
Seborrhoea	1	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	1	0
Reactive perforating collagenosis	1	0
Skin mass	8	0
Skin and subcutaneous tissue ulcerations		
Scleroderma associated digital ulcer	1	0
Skin erosion	14	0
Skin ulcer	4	0
Skin cysts and polyps		
Dermal cyst	3	0
Skin dystrophies		
Skin wrinkling	2	0
Skin haemorrhages		
Haemorrhage subcutaneous	4	0
Skin haemorrhage	5	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	1	0
Skin hypoplasias and atrophies		
Skin striae	3	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	2	0
Skin preneoplastic conditions NEC		
Actinic keratosis	1	0
Skin vasculitides		
Cutaneous vasculitis	4	0
Vasculitic rash	12	0
Skin vasomotor conditions		
Livedo reticularis	17	0
Urticarias		
Chronic spontaneous urticaria	2	0
Cold urticaria	2	0
Idiopathic urticaria	1	0
Mechanical urticaria	2	0
Solar urticaria	2	0
Urticaria	788	0
Urticaria chronic	5	0
Urticaria contact	1	0
Urticaria papular	2	0
Urticaria thermal	3	0
Skin disorders SOC TOTAL	11874	1

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Infant	1	0
Menopause	3	0
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Disability issues</i>		
Bedridden	14	0
Breast prosthesis user	1	0
Hearing disability	1	0
Housebound	1	0
Immobile	7	0
Impaired driving ability	1	0
Impaired work ability	2	0
Loss of personal independence in daily activities	3	0
Physical disability	1	0
Sight disability	2	0
Sitting disability	1	0
Walking aid user	1	0
<i>Economic circumstances</i>		
High income	1	0
Low income	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	2	0
<i>Social issues NEC</i>		
Hair dye user	1	0
<i>Tobacco use</i>		
Ex-tobacco user	1	0
Non-tobacco user	3	0
Social circumstances SOC TOTAL	51	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021

Data Lock Date: 05-May-2021 18:30:08

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Antiinfective therapies</i>		
COVID-19 treatment	2	0
<i>Arterial therapeutic procedures (excl aortic)</i>		
Splenic artery embolisation	1	0
<i>Blood and blood product treatment</i>		
Transfusion	1	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	1	0
<i>Bronchial and pulmonary therapeutic procedures</i>		
Airway secretion clearance therapy	1	0
Antitussive therapy	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Cardiac operation	1	0
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	2	0
Nothing by mouth order	1	0
Wheat-free diet	1	0
<i>Fertility and fertilisation interventions female</i>		
Endometrial scratching	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Prophylaxis of nausea and vomiting	11	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	1	0
<i>Immunisations</i>		
COVID-19 immunisation	44	1
Immunisation	15	0
<i>Joint therapeutic procedures</i>		
Joint surgery	1	0
Knee arthroplasty	1	0
<i>Limb therapeutic procedures</i>		
Limb immobilisation	4	0
Limb operation	3	0
<i>Lymphoid tissue therapeutic procedures</i>		
Lymphadenectomy	1	0
<i>Mastectomies</i>		
Breast conserving surgery	1	0
<i>Nail therapeutic procedures</i>		
Nail operation	1	0
<i>Nervous system therapeutic procedures NEC</i>		
Multiple sclerosis relapse prophylaxis	1	0
<i>Phototherapies</i>		
UV light therapy	1	0
<i>Prophylactic procedures NEC</i>		
Anaphylaxis prophylaxis	2	0
Immune tolerance induction	1	0
<i>Psychiatric therapies</i>		
Electroconvulsive therapy	1	0
<i>Renal therapeutic procedures</i>		
Dialysis	1	0
<i>Respiratory tract therapeutic procedures NEC</i>		
Asthma prophylaxis	2	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021

Data Lock Date: 05-May-2021 18:30:08

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
<i>Skin and subcutaneous tissue therapeutic procedures NEC</i>		
Dermal filler injection	1	0
<i>Therapeutic procedures NEC</i>		
Abscess drainage	1	0
Anaphylaxis treatment	3	0
Bed rest	2	0
Fatigue management	1	0
Hospitalisation	3	0
Injection	8	0
Mass excision	1	0
Medication dilution	1	0
Product used for unknown indication	2	0
Therapeutic procedure	1	0
Therapy change	1	0
Surgical & medical procedures SOC TOTAL	131	1

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	6	0
Hypertensive urgency	1	0
Malignant hypertension	2	0
<i>Aneurysms and dissections non-site specific</i>		
Artery dissection	1	0
<i>Aortic aneurysms and dissections</i>		
Acute aortic syndrome	1	0
Aortic aneurysm rupture	1	0
Aortic dissection	1	0
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	3	0
<i>Aortic necrosis and vascular insufficiency</i>		
Aortic stenosis	1	0
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	5	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	5	0
Labile blood pressure	2	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	1	0
<i>Circulatory collapse and shock</i>		
CT hypotension complex	2	0
Circulatory collapse	36	0
Hypoperfusion	1	0
Neurogenic shock	16	0
Peripheral circulatory failure	3	0
Shock	8	0
Shock symptom	1	0
<i>Haemorrhages NEC</i>		
Bloody discharge	1	0
Haematoma	18	0
Haemorrhage	97	2
Internal haemorrhage	2	0
Venous haemorrhage	1	0
<i>Lymphangiopathies</i>		
Lymphangiopathy	1	0
Lymphocele	3	0
<i>Lymphoedemas</i>		
Lymphoedema	115	0
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	1	0
Embolism	50	0
Embolism venous	1	0
Microembolism	1	0
Thrombosis	117	6
Venous thrombosis	3	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Haemorrhagic infarction	1	0
Infarction	3	0
Ischaemia	2	0
Vasospasm	1	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 05-May-2021 18:30:08
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
<i>Non-site specific vascular disorders NEC</i>		
Superficial vein prominence	1	0
Vascular pain	5	0
Vasodilatation	11	0
Vein discolouration	2	0
Vein disorder	4	0
Vein rupture	2	0
<i>Peripheral embolism and thrombosis</i>		
Blue toe syndrome	12	0
Deep vein thrombosis	112	0
Femoral artery embolism	1	0
Jugular vein thrombosis	2	0
Pelvic venous thrombosis	2	0
Peripheral embolism	1	0
Subclavian vein thrombosis	1	0
Thrombophlebitis	10	0
Thrombophlebitis superficial	6	0
<i>Peripheral vascular disorders NEC</i>		
Cyanosis	22	0
Flushing	278	0
Hot flush	475	0
<i>Peripheral vasoconstriction, necrosis and vascular insufficiency</i>		
Extremity necrosis	1	0
Intermittent claudication	1	0
Peripheral artery occlusion	1	0
Peripheral coldness	146	0
Peripheral ischaemia	7	0
Poor peripheral circulation	5	0
Raynaud's phenomenon	36	0
Vasoconstriction	2	0
<i>Phlebitis NEC</i>		
Phlebitis	15	0
Phlebitis superficial	2	0
<i>Site specific vascular disorders NEC</i>		
Pallor	114	0
<i>Varicose veins NEC</i>		
Spider vein	2	0
Varicose vein	3	0
<i>Vascular hypertensive disorders NEC</i>		
Diastolic hypertension	1	0
Essential hypertension	2	0
Hypertension	251	1
Orthostatic hypertension	1	0
Secondary hypertension	1	0
Systolic hypertension	2	0
<i>Vascular hypotensive disorders</i>		
Hypotension	180	0
Orthostatic hypotension	13	0
<i>Vasculitides NEC</i>		
Behcet's syndrome	2	0
Granulomatosis with polyangiitis	1	0
MAGIC syndrome	1	0
Vasculitis	24	0

Case Series Drug Analysis Print

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

Report Run Date: 06-May-2021

Data Lock Date: 05-May-2021 18:30:08

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
<i>Vena caval embolism and thrombosis</i>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	2279	9
TOTAL REACTIONS FOR DRUG	159219	370
TOTAL REPORTS	55716	
TOTAL FATAL OUTCOME REPORTS		370