

COVID-19 mRNA Pfizer- BioNTech vaccine analysis print

All UK spontaneous reports received between 9/12/20 and 25/08/21 for mRNA Pfizer/BioNTech vaccine analysis print.

A report of a suspected ADR to the Yellow Card scheme does not necessarily mean that it was caused by the vaccine, only that the reporter has a suspicion it may have. Underlying or previously undiagnosed illness unrelated to vaccination can also be factors in such reports. The relative number and nature of reports should therefore not be used to compare the safety of the different vaccines. All reports are kept under continual review in order to identify possible new risks.

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders		
<i>Anaemia deficiencies</i>		
Anaemia folate deficiency	1	0
Anaemia vitamin B12 deficiency	2	0
Deficiency anaemia	1	0
Iron deficiency anaemia	6	0
<i>Anaemias NEC</i>		
Anaemia	86	0
Anaemia macrocytic	1	0
Anaemia megaloblastic	1	0
Autoimmune anaemia	2	0
Blood loss anaemia	1	0
Microcytic anaemia	1	0
<i>Anaemias haemolytic NEC</i>		
Coombs negative haemolytic anaemia	1	0
Haemolytic anaemia	6	0
<i>Anaemias haemolytic immune</i>		
Autoimmune haemolytic anaemia	9	0
<i>Anaemias haemolytic mechanical factor</i>		
Microangiopathic haemolytic anaemia	1	0
<i>Bleeding tendencies</i>		
Haemorrhagic diathesis	1	0
Increased tendency to bruise	33	0
Spontaneous haematoma	2	0
<i>Coagulation factor deficiencies</i>		
Acquired haemophilia	2	0
<i>Coagulopathies</i>		
Abnormal clotting factor	3	0
Antiphospholipid syndrome	5	0
Coagulopathy	17	1
Disseminated intravascular coagulation	2	0
Hypercoagulation	3	0
Thrombotic microangiopathy	2	0
<i>Eosinophilic disorders</i>		
Eosinophilia	12	0
<i>Haematological disorders</i>		
Blood disorder	3	0
Hypergammaglobulinaemia	1	0
Hyperviscosity syndrome	1	0
Mast cell activation syndrome	6	0
Methaemoglobinaemia	1	0
<i>Haemolyses NEC</i>		
Haemolysis	6	0
Intravascular haemolysis	1	0
<i>Leukocytoses NEC</i>		
Leukocytosis	1	0
Lymphocytosis	6	0
Neutrophilia	8	0
<i>Leukopenias NEC</i>		
Leukopenia	4	1
Lymphopenia	4	0
<i>Lymphatic system disorders NEC</i>		
Abdominal lymphadenopathy	1	0
Hilar lymphadenopathy	2	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Blood disorders Blood disorders cont'd		
Lymph node pain	1317	0
Lymph node ulcer	1	0
Lymphadenitis	110	0
Lymphadenopathy	8540	0
Lymphatic disorder	1	0
Necrotic lymphadenopathy	3	0
Pseudolymphoma	10	0
Retroperitoneal lymphadenopathy	1	0
<i>Marrow depression and hypoplastic anaemias</i>		
Aplasia pure red cell	2	0
Hypoplastic anaemia	1	0
Myelosuppression	2	0
Pancytopenia	6	0
<i>Neutropenias</i>		
Autoimmune neutropenia	2	0
Neutropenia	37	0
<i>Platelet disorders NEC</i>		
Platelet anisocytosis	1	0
Platelet disorder	2	0
<i>Polycythaemia (excl rubra vera)</i>		
Polycythaemia	1	0
<i>Purpuras (excl thrombocytopenic)</i>		
Purpura non-thrombocytopenic	1	0
<i>Red blood cell abnormal findings NEC</i>		
Polychromasia	2	0
Red blood cell abnormality	2	0
<i>Spleen disorders</i>		
Spleen atrophy	1	0
Splenic infarction	2	0
Splenic thrombosis	1	0
Splenic vein thrombosis	1	0
Splenomegaly	10	0
<i>Thrombocytopenias</i>		
Immune thrombocytopenia	70	0
Thrombocytopenia	170	1
Thrombocytopenic purpura	4	0
Thrombotic thrombocytopenic purpura	5	0
<i>Thrombocytoses</i>		
Thrombocytosis	5	0
Blood disorders SOC TOTAL	10557	3

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Cardiac disorders		
<i>Cardiac conduction disorders</i>		
Atrioventricular block	9	1
Atrioventricular block complete	2	1
Atrioventricular block first degree	1	0
Atrioventricular block second degree	2	0
Bundle branch block	2	0
Bundle branch block right	1	0
<i>Cardiac disorders NEC</i>		
Acute cardiac event	3	0
Cardiac disorder	41	0
Cardiac dysfunction	1	0
Cardiovascular deconditioning	1	0
Cardiovascular disorder	5	0
Intracardiac thrombus	4	0
<i>Cardiac hypertensive complications</i>		
Hypertensive heart disease	2	0
<i>Cardiac infections and inflammations NEC</i>		
Carditis	3	0
<i>Cardiac signs and symptoms NEC</i>		
Cardiac discomfort	10	0
Cardiovascular symptom	1	0
Palpitations	2424	0
<i>Cardiac valve disorders NEC</i>		
Cardiac valve disease	1	0
Heart valve incompetence	1	0
<i>Cardiomyopathies</i>		
Cardiomyopathy	4	0
Congestive cardiomyopathy	5	0
Stress cardiomyopathy	2	0
<i>Coronary artery disorders NEC</i>		
Coronary artery disease	5	2
Coronary artery occlusion	2	0
Coronary artery thrombosis	1	1
<i>Endocarditis NEC</i>		
Endocarditis noninfective	1	1
<i>Heart failures NEC</i>		
Cardiac failure	54	8
Cardiac failure acute	2	0
Cardiac failure chronic	2	0
Cardiac failure congestive	3	1
Cardiogenic shock	4	1
Cardiopulmonary failure	1	1
<i>Ischaemic coronary artery disorders</i>		
Acute coronary syndrome	3	0
Acute myocardial infarction	17	1
Angina pectoris	141	0
Angina unstable	2	0
Arteriospasm coronary	1	0
Microvascular coronary artery disease	2	0
Myocardial infarction	172	30
Myocardial ischaemia	6	2
<i>Left ventricular failures</i>		
Acute left ventricular failure	1	1

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
Left ventricular failure	6	2
Mitral valvular disorders		
Mitral valve incompetence	4	0
Mitral valve prolapse	2	0
Myocardial disorders NEC		
Cardiac amyloidosis	1	0
Cardiomegaly	18	1
Left atrial dilatation	1	0
Left ventricular dysfunction	5	0
Left ventricular enlargement	1	0
Left ventricular hypertrophy	1	0
Myocardial fibrosis	1	0
Myocardial haemorrhage	1	0
Myocardial oedema	3	0
Myocardial rupture	1	0
Right ventricular enlargement	1	0
Ventricular hypertrophy	2	0
Noninfectious myocarditis		
Myocarditis	223	2
Noninfectious pericarditis		
Pericarditis	182	1
Pericardial disorders NEC		
Pericardial effusion	21	0
Pericardial haemorrhage	3	3
Pericardial rub	1	0
Rate and rhythm disorders NEC		
Arrhythmia	91	0
Bradycardia	50	0
Bradycardia foetal	2	1
Cardiac flutter	300	0
Extrasystoles	113	0
Paroxysmal arrhythmia	1	0
Postural orthostatic tachycardia syndrome	15	0
Tachyarrhythmia	1	0
Tachycardia	612	0
Tachycardia paroxysmal	1	0
Right ventricular failures		
Cor pulmonale	1	0
Supraventricular arrhythmias		
Arrhythmia supraventricular	9	0
Atrial fibrillation	154	0
Atrial flutter	13	0
Atrial tachycardia	5	0
Nodal arrhythmia	1	0
Sinus arrest	1	0
Sinus arrhythmia	2	0
Sinus bradycardia	7	0
Sinus node dysfunction	1	0
Sinus tachycardia	42	0
Supraventricular extrasystoles	2	0
Supraventricular tachycardia	32	0
Tricuspid valvular disorders		
Tricuspid valve incompetence	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021

Data Lock Date: 25-Aug-2021 18:30:56

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Cardiac disorders Cardiac disorders cont'd		
<i>Ventricular arrhythmias and cardiac arrest</i>		
Cardiac arrest	85	31
Cardio-respiratory arrest	1	1
Pulseless electrical activity	3	0
Ventricular arrhythmia	4	0
Ventricular extrasystoles	14	0
Ventricular fibrillation	6	1
Ventricular tachycardia	10	0
Cardiac disorders SOC TOTAL	5003	94

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Congenital disorders		
<i>Cardiac disorders congenital NEC</i>		
Heart disease congenital	12	0
<i>Cardiac septal defects congenital</i>		
Hypertrophic cardiomyopathy	1	0
<i>Central nervous system disorders congenital NEC</i>		
Spina bifida	1	0
<i>Cerebellar disorders congenital</i>		
Arnold-Chiari malformation	1	0
Hereditary ataxia	1	0
<i>Cerebral disorders congenital</i>		
Anencephaly	2	0
Cerebral palsy	2	0
<i>Chemically-induced congenital syndromes</i>		
Foetal warfarin syndrome	1	0
<i>Coagulation disorders congenital</i>		
Haemophilia	1	0
<i>Congenital disorders NEC</i>		
Foetal malformation	1	0
Young's syndrome	1	0
<i>Connective tissue disorders congenital</i>		
Ehlers-Danlos syndrome	2	0
<i>External ear disorders congenital</i>		
Anotia	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
Neonatal alloimmune thrombocytopenia	1	0
<i>Haemoglobinopathies congenital</i>		
Congenital methaemoglobinaemia	1	0
<i>Lymphatic system disorders congenital</i>		
Cystic lymphangioma	3	0
<i>Male reproductive tract disorders congenital</i>		
Cryptorchism	1	0
Micropenis	2	0
Phimosis	1	0
<i>Musculoskeletal and connective tissue disorders of limbs congenital</i>		
Developmental hip dysplasia	1	0
<i>Musculoskeletal and connective tissue disorders of spine congenital</i>		
Brachyolmia	1	0
<i>Musculoskeletal disorders congenital NEC</i>		
Congenital multiplex arthrogyposis	1	0
<i>Neurological disorders congenital NEC</i>		
Familial hemiplegic migraine	2	0
Familial periodic paralysis	1	0
Moebius II syndrome	1	0
Tourette's disorder	2	0
<i>Ocular disorders congenital NEC</i>		
Colour blindness	3	0
<i>Palate disorders congenital</i>		
Cleft lip and palate	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021

Data Lock Date: 25-Aug-2021 18:30:56

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Congenital disorders Congenital disorders cont'd		
<i>Peripheral nervous system disorders congenital NEC</i>		
Hereditary neuropathy with liability to pressure palsies	1	0
Paroxysmal extreme pain disorder	1	0
<i>Pulmonary and bronchial disorders congenital</i>		
Congenital cystic lung	1	0
<i>Retinal disorders congenital</i>		
Retinitis pigmentosa	1	0
<i>Skin and subcutaneous tissue disorders congenital NEC</i>		
Acral peeling skin syndrome	1	0
<i>Tongue disorders congenital</i>		
Ankyloglossia congenital	1	0
Congenital disorders SOC TOTAL	58	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Ear disorders		
<i>Ear disorders NEC</i>		
Ear canal erythema	1	0
Ear congestion	27	0
Ear discomfort	81	0
Ear disorder	14	0
Ear haemorrhage	9	0
Ear pain	779	0
Ear pruritus	9	0
Ear swelling	29	0
Otorrhoea	3	0
<i>Eustachian tube disorders</i>		
Eustachian tube disorder	4	0
Eustachian tube dysfunction	8	0
Eustachian tube obstruction	4	0
<i>External ear disorders NEC</i>		
Auricular swelling	1	0
Excessive cerumen production	7	0
External ear pain	2	0
Red ear syndrome	2	0
<i>External ear infections and inflammations</i>		
External ear inflammation	2	0
<i>Hearing disorders NEC</i>		
Auditory disorder	7	0
Diplacusis	2	0
<i>Hearing losses</i>		
Conductive deafness	1	0
Deafness	189	0
Deafness bilateral	6	0
Deafness neurosensory	13	0
Deafness transitory	6	0
Deafness unilateral	25	0
Hypoacusis	144	0
Sudden hearing loss	32	0
<i>Hyperacusia</i>		
Hyperacusis	43	0
Misophonia	3	0
<i>Inner ear disorders NEC</i>		
Acute vestibular syndrome	1	0
Inner ear disorder	9	0
Meniere's disease	9	0
Vestibular disorder	8	0
<i>Inner ear infections and inflammations</i>		
Inner ear inflammation	7	0
<i>Inner ear signs and symptoms</i>		
Motion sickness	43	0
Tinnitus	1539	0
Vertigo	1092	0
Vertigo labyrinthine	9	0
Vertigo positional	62	0
<i>Mastoid disorders</i>		
Mastoid effusion	1	0
<i>Middle ear disorders NEC</i>		
Middle ear disorder	3	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021

Data Lock Date: 25-Aug-2021 18:30:56

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Ear disorders Ear disorders cont'd		
Middle ear effusion	1	0
<i>Middle ear infections and inflammations</i>		
Middle ear inflammation	1	0
<i>Tympanic membrane disorders (excl infections)</i>		
Tympanic membrane perforation	3	0
Ear disorders SOC TOTAL	4241	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Endocrine disorders		
<i>Acute and chronic thyroiditis</i>		
Autoimmune thyroiditis	1	0
Thyroiditis	12	0
Thyroiditis acute	2	0
Thyroiditis subacute	3	0
<i>Adrenal cortical hypofunctions</i>		
Addison's disease	2	0
Adrenocortical insufficiency acute	10	0
<i>Adrenal gland disorders NEC</i>		
Adrenal haemorrhage	2	0
<i>Anterior pituitary hyperfunction</i>		
Pituitary-dependent Cushing's syndrome	1	0
<i>Anterior pituitary hypofunction</i>		
Hypopituitarism	1	0
<i>Endocrine abnormalities of gonadal function NEC</i>		
Oestrogen deficiency	1	0
<i>Endocrine abnormalities of puberty</i>		
Delayed menarche	3	0
Premature menarche	14	0
<i>Female gonadal function disorders</i>		
Anovulatory cycle	33	0
Ovulation delayed	23	0
<i>Thyroid disorders NEC</i>		
Autoimmune thyroid disorder	1	0
Goitre	11	0
Thyroid disorder	6	0
Thyroid mass	1	0
Thyroid pain	4	0
<i>Thyroid hyperfunction disorders</i>		
Basedow's disease	8	0
Hyperthyroidism	25	0
Thyrotoxic crisis	3	0
<i>Thyroid hypofunction disorders</i>		
Autoimmune hypothyroidism	1	0
Hypothyroidism	22	0
Myxoedema	1	0
Endocrine disorders SOC TOTAL	191	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Eye disorders		
<i>Amblyopic vision impairment</i>		
Amblyopia	6	0
<i>Cataract conditions</i>		
Cataract	10	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	17	0
Vitreous floaters	62	0
<i>Colour blindness (incl acquired)</i>		
Dyschromatopsia	6	0
<i>Conjunctival and corneal bleeding and vascular disorders</i>		
Conjunctival haemorrhage	33	0
<i>Conjunctival infections, irritations and inflammations</i>		
Conjunctival hyperaemia	2	0
Conjunctival irritation	1	0
Conjunctival oedema	3	0
Conjunctivitis allergic	1	0
<i>Corneal infections, oedemas and inflammations</i>		
Corneal oedema	1	0
Keratitis	6	0
Ulcerative keratitis	4	0
<i>Eyelid movement disorders</i>		
Blepharospasm	115	0
Excessive eye blinking	4	0
Eyelid function disorder	3	0
Eyelid myokymia	4	0
Eyelid ptosis	38	0
Paralytic lagophthalmos	2	0
<i>Glaucomas (excl congenital)</i>		
Angle closure glaucoma	2	0
Glaucoma	5	0
<i>Iris and ciliary body structural change, deposit and degeneration</i>		
Eye colour change	2	0
<i>Iris and uveal tract infections, irritations and inflammations</i>		
Autoimmune uveitis	1	0
Iridocyclitis	9	0
Iritis	5	0
Uveitis	37	0
<i>Lacrimation disorders</i>		
Dry eye	118	0
Lacrimation increased	107	0
<i>Lid bleeding and vascular disorders</i>		
Eyelid bleeding	1	0
<i>Lid, lash and lacrimal infections, irritations and inflammations</i>		
Blepharitis	10	0
Chalazion	6	0
Eczema eyelids	4	0
Erythema of eyelid	7	0
Eyelid cyst	4	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Eyelid irritation	2	0
Eyelid margin crusting	3	0
Eyelid oedema	3	0
Eyelid rash	13	0
Swelling of eyelid	105	0
Lid, lash and lacrimal structural disorders		
Dermatochalasis	1	0
Eyelash changes	1	0
Eyelid exfoliation	2	0
Eyelid skin dryness	2	0
Eyelid thickening	1	0
Floppy eyelid syndrome	1	0
Growth of eyelashes	3	0
Lagophthalmos	2	0
Ocular bleeding and vascular disorders NEC		
Eye haematoma	4	0
Eye haemorrhage	22	0
Ocular vascular disorder	1	0
Ophthalmic vein thrombosis	1	0
Ocular disorders NEC		
Dark circles under eyes	6	0
Eye disorder	28	0
Eye oedema	12	0
Eye pain	847	0
Eye swelling	403	0
Eye symptom	8	0
Eye ulcer	3	0
Eyelid disorder	11	0
Eyelid pain	10	0
Eyelids pruritus	5	0
Ocular discomfort	26	0
Periorbital oedema	16	0
Periorbital pain	1	0
Periorbital swelling	102	0
Retinal disorder	2	0
Vitreous disorder	1	0
Ocular infections, inflammations and associated manifestations		
Eye allergy	11	0
Eye discharge	21	0
Eye inflammation	20	0
Eye irritation	80	0
Eye pruritus	198	0
Limbal swelling	2	0
Ocular hyperaemia	174	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	27	0
Gaze palsy	1	0
Ocular myasthenia	1	0
Ophthalmoplegia	3	0
Strabismus	5	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
<i>Ocular sensation disorders</i>		
Abnormal sensation in eye	14	0
Asthenopia	126	0
Eye paraesthesia	2	0
Foreign body sensation in eyes	16	0
Hypoaesthesia eye	14	0
Photophobia	350	0
<i>Optic disc abnormalities NEC</i>		
Papilloedema	4	0
<i>Optic nerve bleeding and vascular disorders</i>		
Optic disc haemorrhage	1	0
Optic ischaemic neuropathy	2	0
<i>Orbital infections, inflammations and irritations</i>		
Parophthalmia	1	0
<i>Orbital structural change, deposit and degeneration</i>		
Orbital oedema	2	0
<i>Pupil disorders</i>		
Miosis	2	0
Mydriasis	19	0
Pupil fixed	2	0
Pupils unequal	10	0
<i>Refractive and accommodative disorders</i>		
Accommodation disorder	1	0
Altered visual depth perception	2	0
Astigmatism	1	0
Hypermetropia	1	0
Myopia	1	0
<i>Retinal bleeding and vascular disorders (excl retinopathy)</i>		
Retinal artery occlusion	9	0
Retinal artery thrombosis	1	0
Retinal haemorrhage	5	0
Retinal vascular thrombosis	1	0
Retinal vein occlusion	28	0
Retinal vein thrombosis	2	0
<i>Retinal structural change, deposit and degeneration</i>		
Macular degeneration	3	0
Macular hole	2	0
Macular rupture	1	0
Maculopathy	1	0
Neovascular age-related macular degeneration	2	0
Retinal detachment	3	0
Retinal tear	2	0
Retinal toxicity	3	0
<i>Retinal, choroid and vitreous infections and inflammations</i>		
Birdshot chorioretinopathy	1	0
Cystoid macular oedema	1	0
Macular oedema	3	0
Retinal vasculitis	3	0
<i>Retinopathies NEC</i>		
Acute macular outer retinopathy	1	0
Retinal exudates	2	0
Retinopathy	1	0
<i>Scleral infections, irritations and inflammations</i>		

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Eye disorders Eye disorders cont'd		
Episcleritis	7	0
Scleritis	3	0
<i>Scleral structural change, deposit and degeneration</i>		
Scleral discolouration	2	0
<i>Visual colour distortions</i>		
Chloropsia	3	0
Cyanopsia	1	0
Erythropsia	2	0
Xanthopsia	1	0
<i>Visual disorders NEC</i>		
Charles Bonnet syndrome	1	0
Diplopia	132	0
Glare	1	0
Halo vision	7	0
Heteronymous diplopia	1	0
Metamorphopsia	15	0
Oscillopsia	2	0
Photopsia	101	0
Scintillating scotoma	4	0
Vision blurred	954	0
Visual brightness	3	0
Visual snow syndrome	6	0
<i>Visual field disorders</i>		
Visual field defect	18	0
<i>Visual impairment and blindness (excl colour blindness)</i>		
Amaurosis fugax	2	0
Blindness	101	0
Blindness transient	10	0
Blindness unilateral	11	0
Central vision loss	3	0
Sudden visual loss	3	0
Visual acuity reduced	18	0
Visual acuity reduced transiently	1	0
Visual impairment	265	0
<i>Visual pathway disorders</i>		
Optic nerve disorder	1	0
Eye disorders SOC TOTAL	5162	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Abdominal findings abnormal</i>		
Abdominal mass	1	0
Gastrointestinal sounds abnormal	16	0
<i>Abdominal hernias NEC</i>		
Abdominal hernia	2	0
<i>Abdominal wall conditions NEC</i>		
Abdominal wall haematoma	1	0
<i>Acute and chronic pancreatitis</i>		
Alcoholic pancreatitis	1	0
Obstructive pancreatitis	1	0
Pancreatitis	11	0
Pancreatitis acute	11	0
Pancreatitis necrotising	1	0
<i>Anal and rectal disorders NEC</i>		
Anal fissure	2	0
Anal sphincter atony	1	0
<i>Anal and rectal pains</i>		
Proctalgia	9	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
Rectal tenesmus	1	0
<i>Benign oral cavity neoplasms</i>		
Mouth cyst	5	0
Tongue cyst	4	0
<i>Colitis (excl infective)</i>		
Autoimmune colitis	1	0
Colitis	32	1
Colitis ischaemic	1	0
Colitis microscopic	1	0
Colitis ulcerative	59	0
Crohn's disease	39	0
Eosinophilic colitis	1	0
Inflammatory bowel disease	4	0
<i>Dental and periodontal infections and inflammations</i>		
Dental caries	1	0
<i>Dental disorders NEC</i>		
Loose tooth	1	0
Teeth brittle	3	0
Teething	5	0
Tooth disorder	2	0
Tooth socket haemorrhage	1	0
<i>Dental pain and sensation disorders</i>		
Dental discomfort	6	0
Dental paraesthesia	10	0
Hyperaesthesia teeth	32	0
Toothache	129	0
<i>Dental surface disorders</i>		
Tooth discolouration	9	0
<i>Diaphragmatic hernias</i>		

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Hiatus hernia	5	0
<i>Diarrhoea (excl infective)</i>		
Diarrhoea	4173	2
Diarrhoea haemorrhagic	20	0
<i>Diverticula</i>		
Diverticulum	4	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	3	0
<i>Dyspeptic signs and symptoms</i>		
Dyspepsia	326	0
Epigastric discomfort	13	0
Eructation	38	0
<i>Faecal abnormalities NEC</i>		
Abnormal faeces	16	0
Faecaloma	3	0
Faeces discoloured	48	0
Faeces hard	2	0
Faeces pale	3	0
Faeces soft	10	0
Mucous stools	7	0
<i>Flatulence, bloating and distension</i>		
Abdominal distension	390	0
Aerophagia	3	0
Flatulence	142	0
<i>Gastric and oesophageal haemorrhages</i>		
Gastric haemorrhage	5	1
Mallory-Weiss syndrome	1	0
Oesophageal varices haemorrhage	1	0
<i>Gastric ulcers and perforation</i>		
Gastric ulcer	6	0
<i>Gastritis (excl infective)</i>		
Chronic gastritis	2	0
Gastritis	37	0
Reflux gastritis	4	0
<i>Gastrointestinal and abdominal pains (excl oral and throat)</i>		
Abdominal migraine	2	0
Abdominal pain	1097	0
Abdominal pain lower	99	0
Abdominal pain upper	1830	0
Abdominal rigidity	18	0
Abdominal tenderness	9	0
Gastrointestinal pain	103	0
Oesophageal pain	5	0
<i>Gastrointestinal atonic and hypomotility disorders NEC</i>		
Constipation	193	0
Duodenogastric reflux	3	0
Gastric dilatation	7	0
Gastrooesophageal reflux disease	110	0
Impaired gastric emptying	6	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Infrequent bowel movements	3	0
Intestinal dilatation	1	0
Intestinal pseudo-obstruction	2	0
<i>Gastrointestinal disorders NEC</i>		
Food poisoning	4	0
Functional gastrointestinal disorder	7	0
Gastric disorder	6	0
Gastrointestinal disorder	17	0
Stomach mass	4	0
<i>Gastrointestinal dyskinetic disorders</i>		
Bowel movement irregularity	2	0
Change of bowel habit	5	0
Dyschezia	2	0
Gastrointestinal motility disorder	1	0
Oesophageal achalasia	1	0
<i>Gastrointestinal fistulae</i>		
Diverticular fistula	1	0
<i>Gastrointestinal inflammatory disorders NEC</i>		
Duodenitis	1	0
Enteritis	5	0
Epiploic appendagitis	2	0
Gastrointestinal inflammation	3	0
Intestinal angioedema	2	0
<i>Gastrointestinal mucosal dystrophies and secretion disorders</i>		
Hyperchlorhydria	4	0
<i>Gastrointestinal signs and symptoms NEC</i>		
Abdominal discomfort	492	0
Abdominal symptom	1	0
Acute abdomen	4	0
Anal incontinence	18	0
Breath odour	15	0
Dysphagia	160	1
Odynophagia	27	0
<i>Gastrointestinal spastic and hypermotility disorders</i>		
Cardiospasm	1	0
Defaecation urgency	8	0
Frequent bowel movements	22	0
Irritable bowel syndrome	68	0
Oesophageal spasm	3	0
Pylorospasm	1	0
<i>Gastrointestinal stenosis and obstruction NEC</i>		
Intestinal obstruction	2	0
Neonatal intestinal obstruction	1	0
<i>Gastrointestinal vascular malformations</i>		
Gastric antral vascular ectasia	6	0
<i>Gastrointestinal vascular occlusion and infarction</i>		
Intestinal ischaemia	5	2
Mesenteric vein thrombosis	6	0
Omental infarction	1	0
Thrombosis mesenteric vessel	1	0
Visceral venous thrombosis	1	0
<i>Gingival disorders, signs and symptoms NEC</i>		
Gingival blister	11	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Gingival discomfort	3	0
Gingival disorder	3	0
Gingival erythema	2	0
Gingival hypertrophy	1	0
Gingival oedema	1	0
Gingival pain	88	0
Gingival pruritus	1	0
Gingival swelling	30	0
Gingival ulceration	1	0
Gingivitis ulcerative	1	0
Noninfective gingivitis	6	0
<i>Gingival haemorrhages</i>		
Gingival bleeding	51	0
<i>Haemorrhoids and gastrointestinal varices (excl oesophageal)</i>		
Gastric varices	1	0
Haemorrhoidal haemorrhage	1	0
Haemorrhoids	23	0
Haemorrhoids thrombosed	1	0
<i>Intestinal haemorrhages</i>		
Anal haemorrhage	15	1
Intestinal haemorrhage	1	0
Mesenteric haemorrhage	1	0
Rectal haemorrhage	53	0
Small intestinal haemorrhage	6	0
<i>Intestinal ulcers and perforation NEC</i>		
Intestinal perforation	5	2
Large intestinal ulcer	1	0
Large intestine perforation	1	0
<i>Malabsorption syndromes</i>		
Bile acid malabsorption	2	0
Coeliac disease	8	0
Malabsorption	1	0
Steatorrhoea	4	0
<i>Nausea and vomiting symptoms</i>		
Discoloured vomit	10	0
Infantile vomiting	5	0
Nausea	11019	0
Regurgitation	1	0
Retching	83	0
Vomiting	3291	0
Vomiting projectile	46	0
<i>Non-mechanical ileus</i>		
Ileus paralytic	1	0
<i>Non-site specific gastrointestinal haemorrhages</i>		
Gastrointestinal haemorrhage	13	1
Haematemesis	26	2
Haematochezia	45	0
Melaena	8	0
Upper gastrointestinal haemorrhage	6	0
<i>Oesophageal stenosis and obstruction</i>		
Oesophageal stenosis	3	0
<i>Oesophagitis (excl infective)</i>		
Eosinophilic oesophagitis	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Oesophagitis	3	0
<i>Oral dryness and saliva altered</i>		
Aptyalism	2	0
Dry mouth	408	0
Lip dry	34	0
Saliva altered	4	0
Salivary hypersecretion	42	0
<i>Oral soft tissue disorders NEC</i>		
Angina bullosa haemorrhagica	1	0
Chapped lips	18	0
Cheilitis	21	0
Enlarged uvula	13	0
Leukoplakia oral	2	0
Lip blister	24	0
Lip disorder	4	0
Oral disorder	11	0
Oral lichen planus	8	0
Oral mucosal hypertrophy	1	0
Oral papule	1	0
Uvulitis	2	0
<i>Oral soft tissue haemorrhages</i>		
Mouth haemorrhage	11	0
Oral blood blister	10	0
Oral purpura	2	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	5	0
Coating in mouth	1	0
Hypoaesthesia oral	396	0
Lip discolouration	7	0
Lip erythema	2	0
Lip exfoliation	5	0
Lip pain	44	0
Lip pruritus	13	0
Lip scab	1	0
Oral discomfort	66	0
Oral dysaesthesia	1	0
Oral mucosal blistering	13	0
Oral mucosal discolouration	1	0
Oral mucosal eruption	11	0
Oral mucosal erythema	5	0
Oral mucosal exfoliation	8	0
Oral mucosal roughening	3	0
Oral pain	140	0
Oral pruritus	20	0
Paraesthesia oral	789	0
Pigmentation lip	1	0
<i>Oral soft tissue swelling and oedema</i>		
Lip oedema	4	0
Lip swelling	578	0
Mouth swelling	73	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
<i>Gastrointestinal disorders cont'd</i>		
Oedema mouth	4	0
Palatal oedema	2	0
Palatal swelling	2	0
<i>Pancreatic disorders NEC</i>		
Pancreatic mass	1	0
<i>Peptic ulcers and perforation</i>		
Peptic ulcer	1	0
Peptic ulcer haemorrhage	9	0
<i>Peritoneal and retroperitoneal disorders</i>		
Ascites	1	0
<i>Peritoneal and retroperitoneal fibrosis and adhesions</i>		
Abdominal adhesions	1	0
<i>Peritoneal and retroperitoneal haemorrhages</i>		
Haemoperitoneum	1	0
Retroperitoneal haemorrhage	1	1
<i>Rectal inflammations NEC</i>		
Proctitis	2	0
Proctitis ulcerative	1	0
<i>Salivary gland disorders NEC</i>		
Salivary gland disorder	1	0
Salivary gland pain	12	0
<i>Salivary gland enlargements</i>		
Parotid gland enlargement	9	0
Salivary gland enlargement	5	0
Submaxillary gland enlargement	6	0
<i>Salivary gland infections and inflammations</i>		
Noninfective sialoadenitis	1	0
<i>Stomatitis and ulceration</i>		
Aphthous ulcer	36	0
Lip ulceration	16	0
Mouth ulceration	361	0
Oral mucosa erosion	1	0
Palatal ulcer	1	0
Stomatitis	53	0
<i>Tongue disorders</i>		
Glossitis	14	0
Hypertrophy of tongue papillae	1	0
Plicated tongue	3	0
Tongue disorder	30	0
Tongue geographic	1	0
Tongue haemorrhage	2	0
Tongue ulceration	26	0
Trichoglossia	4	0
<i>Tongue signs and symptoms</i>		
Glossodynia	167	0
Scalloped tongue	5	0
Stiff tongue	3	0
Swollen tongue	396	0
Tongue blistering	15	0
Tongue coated	15	0
Tongue discolouration	31	0
Tongue discomfort	36	0
Tongue dry	13	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021

Data Lock Date: 25-Aug-2021 18:30:56

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Gastrointestinal disorders cont'd		
Tongue eruption	9	0
Tongue erythema	7	0
Tongue exfoliation	1	0
Tongue movement disturbance	5	0
Tongue oedema	19	0
Tongue pruritus	2	0
Tongue rough	3	0
Tongue spasm	8	0
<i>Tooth missing</i>		
Tooth loss	5	0
Gastrointestinal disorders SOC TOTAL	29115	14

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders		
<i>Administration site reactions NEC</i>		
Administration site bruise	5	0
Administration site erythema	3	0
Administration site extravasation	3	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 nerve damage	1	0
Administration site pain	13	0
Administration site rash	3	0
Administration site reaction	1	0
Administration site swelling	2	0
Administration site urticaria	1	0
Administration site warmth	2	0
Puncture site bruise	26	0
Puncture site pain	6	0
Puncture site reaction	1	0
Puncture site swelling	2	0
Vessel puncture site bruise	2	0
Vessel puncture site erythema	1	0
Vessel puncture site pain	1	0
<i>Adverse effect absent</i>		
No adverse event	12	0
<i>Application and instillation site reactions</i>		
Application site acne	2	0
Application site bruise	7	0
Application site burn	1	0
Application site erythema	11	0
Application site haemorrhage	1	0
Application site hypoaesthesia	1	0
Application site irritation	1	0
Application site joint erythema	1	0
Application site joint pain	1	0
Application site mass	1	0
Application site odour	2	0
Application site pain	12	0
Application site pruritus	4	0
Application site rash	2	0
Application site reaction	1	0
Application site swelling	2	0
Application site vesicles	5	0
Application site warmth	1	0
Instillation site warmth	5	0
<i>Asthenic conditions</i>		
Asthenia	1398	1
Chronic fatigue syndrome	62	0
Decreased activity	7	0
Fatigue	17573	0
Malaise	3917	0
Sluggishness	12	0
<i>Body temperature altered</i>		

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Hyperthermia	5	0
Hypothermia	20	0
Temperature regulation disorder	10	0
Breast complications associated with device		
Capsular contracture associated with breast implant	1	0
Cardiac complications associated with device		
Prosthetic cardiac valve thrombosis	2	0
Complications associated with device NEC		
Capsular contracture associated with implant	1	0
Complication of device removal	3	0
Injury associated with device	3	0
Medical device pain	1	0
Medical device site swelling	1	0
Phantom shocks	1	0
Death and sudden death		
Brain death	3	3
Clinical death	1	1
Death	137	137
Drowning	2	0
Sudden death	27	27
Febrile disorders		
Hyperpyrexia	7	0
Pyrexia	11435	0
Feelings and sensations NEC		
Chills	7329	0
Feeling abnormal	1221	0
Feeling cold	892	0
Feeling drunk	67	0
Feeling hot	899	0
Feeling jittery	19	0
Feeling of body temperature change	252	0
Feeling of relaxation	3	0
Hangover	70	0
Hunger	33	0
Sensation of blood flow	3	0
Sensation of foreign body	41	0
Temperature intolerance	34	0
Thirst	269	0
Fibrosis NEC		
Fibrosis	2	0
Gait disturbances		
Gait disturbance	164	0
Gait inability	54	0
Loss of control of legs	13	0
General signs and symptoms NEC		
Adhesion	1	0
Chronic disease	1	0
Condition aggravated	154	0
Crepitations	1	0
Crying	120	0
Deformity	2	0
Discharge	10	0
Disease progression	2	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Disease recurrence	24	0
Effusion	2	0
Energy increased	17	0
Exercise tolerance decreased	15	0
Foaming at mouth	1	0
General physical health deterioration	14	1
General symptom	2	0
Glassy eyes	3	0
High-pitched crying	2	0
Illness	1374	0
Induration	13	0
Influenza like illness	1794	0
Irritability postvaccinal	2	0
Local reaction	68	0
Moaning	3	0
Multiple organ dysfunction syndrome	7	4
Nonspecific reaction	1	0
Organ failure	1	1
Perforation	2	0
Peripheral swelling	2676	0
Pre-existing condition improved	8	0
Prolapse	1	0
Screaming	18	0
Secretion discharge	15	0
Swelling	2176	0
Swelling face	632	0
Symptom recurrence	1	0
Terminal state	1	0
Implant and catheter site reactions		
Implant site discolouration	2	0
Implant site pain	1	0
Implant site rash	1	0
Implant site swelling	1	0
Implant site urticaria	1	0
Implant site warmth	3	0
Inflamations		
Granuloma	1	0
Inflammation	326	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 mass	1	0
Infusion site nerve damage	1	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	25	0
Injection site bruising	55	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Injection site coldness	1	0
Injection site cyst	2	0
Injection site discolouration	5	0
Injection site discomfort	9	0
Injection site eczema	1	0
Injection site erythema	299	0
Injection site haemorrhage	6	0
Injection site hypersensitivity	2	0
Injection site hypoaesthesia	8	0
Injection site indentation	9	0
Injection site induration	3	0
Injection site inflammation	29	0
Injection site joint discomfort	1	0
Injection site joint erythema	1	0
Injection site joint movement impairment	1	0
Injection site joint pain	12	0
Injection site lymphadenopathy	1	0
Injection site macule	1	0
Injection site mass	398	0
Injection site movement impairment	1	0
Injection site necrosis	3	0
Injection site nerve damage	1	0
Injection site oedema	12	0
Injection site pain	2361	0
Injection site paraesthesia	11	0
Injection site pruritus	145	0
Injection site rash	125	0
Injection site reaction	21	0
Injection site scab	2	0
Injection site scar	5	0
Injection site swelling	241	0
Injection site urticaria	24	0
Injection site vesicles	9	0
Injection site warmth	154	0
Interactions		
Alcohol interaction	2	0
Drug interaction	22	0
Inhibitory drug interaction	3	0
Mass conditions NEC		
Cyst	30	0
Mass	55	0
Nodule	30	0
Mucosal findings abnormal		
Mucosa vesicle	1	0
Mucosal dryness	1	0
Mucosal haemorrhage	9	0
Mucosal inflammation	2	0
Oedema mucosal	1	0
Polyp	2	0
Necrosis NEC		
Fat necrosis	2	0
Necrosis	3	0
Oedema NEC		

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Face oedema	25	0
Generalised oedema	2	0
Localised oedema	15	0
Oedema	51	0
Oedema peripheral	69	0
<i>Pain and discomfort NEC</i>		
Axillary pain	2220	0
Chest discomfort	1220	0
Chest pain	2763	0
Discomfort	350	0
Facial discomfort	16	0
Facial pain	172	0
Inflammatory pain	9	0
Non-cardiac chest pain	23	0
Pain	6703	0
Suprapubic pain	1	0
Tenderness	517	0
Visceral pain	1	0
<i>Therapeutic and nontherapeutic responses</i>		
Adverse drug reaction	23	0
Adverse event	1	0
Adverse food reaction	1	0
Drug ineffective	213	1
Drug intolerance	2	0
Immediate post-injection reaction	2	0
Inadequate analgesia	8	0
No reaction on previous exposure to drug	37	0
Product intolerance	1	0
Therapeutic product effect decreased	1	0
Therapeutic product effect delayed	2	0
Therapeutic product effect increased	1	0
Therapeutic product ineffective	2	0
Therapeutic response decreased	2	0
Therapeutic response unexpected	64	0
Therapy non-responder	1	0
Treatment failure	6	0
Vaccination failure	16	0
<i>Trophic disorders</i>		
Atrophy	1	0
Calcinosis	1	0
Hyperplasia	1	0
<i>Ulcers NEC</i>		
Ulcer	22	0
Ulcer haemorrhage	1	0
<i>Vaccination site reactions</i>		
Extensive swelling of vaccinated limb	10	0
Shoulder injury related to vaccine administration	20	0
Vaccination site bruising	95	0
Vaccination site coldness	2	0
Vaccination site cyst	5	0
Vaccination site dermatitis	1	0
Vaccination site discolouration	12	0
Vaccination site discomfort	40	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
General disorders General disorders cont'd		
Vaccination site dryness	1	0
Vaccination site eczema	1	0
Vaccination site erythema	480	0
Vaccination site granuloma	1	0
Vaccination site haematoma	1	0
Vaccination site haemorrhage	16	0
Vaccination site hypersensitivity	2	0
Vaccination site hypoaesthesia	14	0
Vaccination site induration	68	0
Vaccination site inflammation	48	0
Vaccination site irritation	12	0
Vaccination site joint discomfort	2	0
Vaccination site joint erythema	7	0
Vaccination site joint inflammation	1	0
Vaccination site joint movement impairment	18	0
Vaccination site joint pain	27	0
Vaccination site joint swelling	3	0
Vaccination site joint warmth	1	0
Vaccination site lymphadenopathy	4	0
Vaccination site macule	1	0
Vaccination site mass	210	0
Vaccination site movement impairment	67	0
Vaccination site nerve damage	1	0
Vaccination site nodule	2	0
Vaccination site oedema	3	0
Vaccination site pain	1805	0
Vaccination site paraesthesia	6	0
Vaccination site phlebitis	1	0
Vaccination site pruritus	124	0
Vaccination site rash	107	0
Vaccination site reaction	28	0
Vaccination site scab	2	0
Vaccination site scar	1	0
Vaccination site swelling	454	0
Vaccination site ulcer	1	0
Vaccination site urticaria	11	0
Vaccination site vesicles	6	0
Vaccination site warmth	227	0
<i>Vascular complications associated with device</i>		
Vascular stent thrombosis	1	0
<i>Withdrawal and rebound effects</i>		
Drug withdrawal syndrome	5	0
Withdrawal syndrome	30	0
General disorders SOC TOTAL	78357	176

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Hepatic disorders		
<i>Bile duct infections and inflammations</i>		
Biliary colic	11	0
Cholangitis	1	0
<i>Cholecystitis and cholelithiasis</i>		
Cholecystitis	2	0
Cholecystitis acute	2	0
Cholelithiasis	8	0
<i>Cholestasis and jaundice</i>		
Cholestasis	2	0
Jaundice	18	0
Jaundice cholestatic	10	0
Ocular icterus	2	0
<i>Gallbladder disorders NEC</i>		
Gallbladder disorder	1	0
<i>Hepatic and hepatobiliary disorders NEC</i>		
Liver disorder	10	0
<i>Hepatic enzymes and function abnormalities</i>		
Hepatic function abnormal	2	0
<i>Hepatic failure and associated disorders</i>		
Acute hepatic failure	1	0
Hepatic failure	2	1
<i>Hepatic fibrosis and cirrhosis</i>		
Hepatic cirrhosis	1	0
<i>Hepatic vascular disorders</i>		
Congestive hepatopathy	2	0
Hepatic artery embolism	1	0
Hepatic haemorrhage	2	0
Hepatic vein thrombosis	5	0
Portal vein thrombosis	6	0
<i>Hepatobiliary signs and symptoms</i>		
Hepatic pain	21	0
Hepatomegaly	1	0
Liver tenderness	3	0
<i>Hepatocellular damage and hepatitis NEC</i>		
Autoimmune hepatitis	5	0
Drug-induced liver injury	2	0
Hepatitis	9	0
Immune-mediated hepatic disorder	1	0
Liver injury	9	0
Hepatic disorders SOC TOTAL	140	1

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Immune system disorders		
<i>Acute and chronic sarcoidosis</i>		
Sarcoidosis	10	0
<i>Allergic conditions NEC</i>		
Allergic oedema	12	0
Allergy to animal	1	0
Allergy to arthropod bite	5	0
Allergy to arthropod sting	1	0
Allergy to metals	1	0
Allergy to sting	1	0
Hypersensitivity	753	0
Infusion related hypersensitivity reaction	2	0
Mite allergy	2	0
Multiple allergies	6	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	6	0
<i>Allergies to foods, food additives, drugs and other chemicals</i>		
Allergic reaction to excipient	5	0
Allergy to chemicals	2	0
Allergy to vaccine	34	0
Contrast media reaction	2	0
Drug hypersensitivity	19	0
Food allergy	21	0
Oral allergy syndrome	2	0
Reaction to colouring	1	0
Reaction to excipient	8	0
Reaction to preservatives	5	0
Rubber sensitivity	1	0
Smoke sensitivity	1	0
<i>Anaphylactic and anaphylactoid responses</i>		
Anaphylactic reaction	406	2
Anaphylactic shock	43	0
Anaphylactoid reaction	19	0
Anaphylactoid shock	4	0
<i>Atopic disorders</i>		
Atopy	1	0
Seasonal allergy	91	0
<i>Autoimmune disorders NEC</i>		
Autoimmune disorder	32	0
<i>Immune and associated conditions NEC</i>		
Bacille Calmette-Guerin scar reactivation	41	0
Graft versus host disease	1	0
Immune system disorder	17	0
Immune-mediated adverse reaction	6	0
Immunisation reaction	1	0
Sensitisation	4	0
Systemic immune activation	2	0
<i>Immunodeficiency disorders NEC</i>		
Hypogammaglobulinaemia	1	0
Immunodeficiency	1	0
Immunosuppression	3	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021

Data Lock Date: 25-Aug-2021 18:30:56

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Immune system disorders		
<i>Immune system disorders cont'd</i>		
<i>Transplant rejections</i>		
Corneal graft rejection	5	0
Kidney transplant rejection	1	0
Solid organ transplant rejection	1	0
Transplant rejection	1	0
Immune system disorders SOC TOTAL	1589	2

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections		
<i>Abdominal and gastrointestinal infections</i>		
Abdominal abscess	1	0
Abdominal infection	1	0
Anal abscess	3	0
Appendicitis	28	0
Appendicitis perforated	3	0
Diverticulitis	10	0
Dysentery	1	0
Gastric infection	2	0
Gastroenteritis	22	0
Mesenteric abscess	1	0
Peritonitis	1	1
Rectal abscess	1	0
<i>Adenoviral infections</i>		
Adenoviral conjunctivitis	1	0
<i>Aspergillus infections</i>		
Bronchopulmonary aspergillosis	1	0
<i>Bacterial infections NEC</i>		
Abscess bacterial	1	0
Arthritis bacterial	3	0
Bacterial colitis	1	0
Bacterial diarrhoea	1	0
Bacterial infection	12	0
Cellulitis	141	0
Conjunctivitis bacterial	1	0
Ear infection bacterial	1	0
Folliculitis	13	0
Gangrene	1	0
Injection site cellulitis	2	0
Meningitis bacterial	3	0
Paronychia	3	0
Perichondritis	1	0
Periorbital cellulitis	1	0
Sinusitis bacterial	1	0
Skin bacterial infection	2	0
Tonsillitis bacterial	3	0
Urinary tract infection bacterial	1	0
Vaccination site cellulitis	18	0
Zoonotic bacterial infection	1	1
<i>Bartonella infections</i>		
Cat scratch disease	1	0
<i>Bone and joint infections</i>		
Abscess jaw	1	0
Arthritis infective	1	0
Osteomyelitis	1	0
<i>Borrelial infections</i>		
Lyme disease	2	0
Relapsing fever	1	0
<i>Breast infections</i>		
Breast abscess	2	0
Mastitis	63	0
<i>Caliciviral infections</i>		
Gastroenteritis norovirus	2	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Campylobacter infections</i>		
Campylobacter gastroenteritis	1	0
Campylobacter infection	1	0
<i>Candida infections</i>		
Anal candidiasis	3	0
Balanitis candida	1	0
Candida infection	52	0
Oral candidiasis	35	0
Respiratory moniliasis	1	0
Skin candida	1	0
Systemic candida	1	0
Vulvovaginal candidiasis	38	0
<i>Cardiac infections</i>		
Pericarditis infective	1	0
<i>Central nervous system and spinal infections</i>		
Brain abscess	1	0
CNS ventriculitis	1	0
Cavernous sinus thrombosis	1	0
Encephalitis	14	0
Meningitis	6	0
Meningitis aseptic	1	0
Myelitis	5	0
Subdural abscess	1	0
<i>Clostridia infections</i>		
Clostridium difficile infection	2	0
<i>Coronavirus infections</i>		
Asymptomatic COVID-19	12	0
COVID-19	990	36
COVID-19 pneumonia	39	13
Coronavirus infection	7	0
Post-acute COVID-19 syndrome	1	0
Severe acute respiratory syndrome	2	0
Suspected COVID-19	48	1
<i>Coxiella infections</i>		
Q fever	9	0
<i>Cytomegaloviral infections</i>		
Cytomegalovirus infection	2	0
Cytomegalovirus syndrome	1	0
<i>Dental and oral soft tissue infections</i>		
Abscess oral	4	0
Gingivitis	10	0
Oral infection	1	0
Parotitis	9	0
Pulpitis dental	1	0
Sialoadenitis	3	0
Tooth abscess	8	0
Tooth infection	8	0
<i>Ear infections</i>		
Ear infection	67	0
Labyrinthitis	75	0
Mastoiditis	1	0
Otitis externa	1	0
Otitis media	4	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021

Data Lock Date: 25-Aug-2021 18:30:56

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Otitis media acute	1	0
<i>Ectoparasitic infestations</i>		
Acarodermatitis	4	0
Bed bug infestation	1	0
<i>Epstein-Barr viral infections</i>		
Epstein-Barr virus infection	3	0
Infectious mononucleosis	22	0
<i>Eye and eyelid infections</i>		
Conjunctivitis	60	0
Eye abscess	1	0
Eye infection	16	0
Eyelid boil	1	0
Eyelid infection	2	0
Hordeolum	21	0
Periorbital infection	2	0
<i>Female reproductive tract infections</i>		
Bartholin's abscess	1	0
Bartholinitis	1	0
Endometritis	3	0
Funisitis	1	0
Pelvic inflammatory disease	1	0
Vaginal infection	1	0
Vulval abscess	1	0
Vulvitis	1	0
<i>Fungal infections NEC</i>		
Fungal infection	11	0
Fungal skin infection	4	0
Onychomycosis	1	0
Oral fungal infection	2	0
Pneumonia fungal	2	0
Vulvovaginal mycotic infection	6	0
<i>Hepatitis virus infections</i>		
Hepatitis A	1	0
Hepatitis E	1	0
<i>Hepatobiliary and spleen infections</i>		
Biliary sepsis	2	0
Cholecystitis infective	1	0
<i>Herpes viral infections</i>		
Disseminated varicella zoster virus infection	1	0
Eczema herpeticum	2	0
Genital herpes	70	0
Genital herpes simplex	6	0
Herpes ophthalmic	3	0
Herpes simplex	22	0
Herpes simplex encephalitis	1	1
Herpes simplex reactivation	2	0
Herpes virus infection	9	0
Herpes zoster	1175	0
Herpes zoster meningoencephalitis	1	0
Herpes zoster oticus	12	0
Herpes zoster reactivation	1	0
Nasal herpes	3	0
Ophthalmic herpes zoster	3	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Oral herpes	253	0
Varicella	21	0
Varicella zoster virus infection	1	0
<i>Infections NEC</i>		
Abscess	33	0
Abscess limb	6	0
Abscess soft tissue	1	0
Genital abscess	2	0
Infected bite	3	0
Infected cyst	2	0
Infection	190	0
Infection susceptibility increased	1	0
Injection site abscess	1	0
Injection site infection	5	0
Localised infection	21	0
Lymph gland infection	7	0
Lymph node abscess	5	0
Opportunistic infection	1	0
Pathogen resistance	1	0
Purulent discharge	1	0
Respiratory tract infection	9	0
Vaccination site abscess	6	0
Vaccination site infection	13	0
Vaccine breakthrough infection	23	0
Vestibulitis	3	0
Wound infection	1	0
<i>Infectious transmissions</i>		
Secondary transmission	9	0
Vaccine virus shedding	1	0
<i>Influenza viral infections</i>		
Influenza	1193	0
<i>Klebsiella infections</i>		
Klebsiella infection	1	0
<i>Lower respiratory tract and lung infections</i>		
Bronchitis	19	0
Infectious pleural effusion	1	0
Lower respiratory tract infection	163	7
Pneumonia	100	11
Sputum purulent	1	0
<i>Male reproductive tract infections</i>		
Epididymitis	5	0
Orchitis	4	0
Prostate infection	2	0
<i>Mumps viral infections</i>		
Mumps	6	0
<i>Muscle and soft tissue infections</i>		
Abscess neck	1	0
Infective tenosynovitis	1	0
Necrotising fasciitis	2	0
Soft tissue infection	1	0
<i>Neisseria infections</i>		
Gonorrhoea	1	0
<i>Plasmodia infections</i>		

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021

Data Lock Date: 25-Aug-2021 18:30:56

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Malaria	1	0
<i>Pneumocystis infections</i>		
Pneumocystis jirovecii pneumonia	2	0
<i>Prion-associated disorders</i>		
Creutzfeldt-Jakob disease	1	0
<i>Retroviral infections</i>		
Acquired immunodeficiency syndrome	1	0
HIV infection	1	0
<i>Rotaviral infections</i>		
Gastroenteritis rotavirus	1	0
<i>Rubeola viral infections</i>		
Measles	4	0
<i>Sepsis, bacteraemia, viraemia and fungaemia NEC</i>		
Bacteraemia	1	0
Neutropenic sepsis	3	1
Sepsis	40	5
Sepsis syndrome	1	0
Septic rash	1	0
Septic shock	5	1
Urosepsis	5	0
<i>Skin structures and soft tissue infections</i>		
Abscess sweat gland	1	0
Acne pustular	1	0
Blister infected	1	0
Dermatitis infected	2	0
Impetigo	8	0
Infected skin ulcer	1	0
Injection site pustule	1	0
Nail infection	1	0
Pustule	12	0
Rash pustular	9	0
Skin infection	26	0
Subcutaneous abscess	6	0
Sweat gland infection	1	0
Vaccination site pustule	4	0
<i>Staphylococcal infections</i>		
Furuncle	32	0
Pneumonia staphylococcal	1	0
Staphylococcal abscess	1	0
Staphylococcal infection	3	0
Staphylococcal sepsis	1	0
<i>Streptococcal infections</i>		
Meningitis pneumococcal	1	0
Pharyngitis streptococcal	5	0
Streptococcal abscess	1	0
Streptococcal endocarditis	1	0
Streptococcal infection	1	0
Streptococcal sepsis	1	0
<i>Tinea infections</i>		
Body tinea	1	0
Tinea infection	1	0
Tinea pedis	2	0
Tinea versicolour	2	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
<i>Treponema infections</i>		
Syphilis	2	0
<i>Trypanosomal infections</i>		
African trypanosomiasis	2	0
<i>Tuberculous infections</i>		
Latent tuberculosis	1	0
Lymph node tuberculosis	1	0
Pulmonary tuberculosis	1	0
Tuberculosis	1	0
Tuberculosis of central nervous system	1	0
<i>Upper respiratory tract infections</i>		
Acute sinusitis	4	0
Chronic sinusitis	1	0
Croup infectious	1	0
Epiglottitis	1	0
Laryngitis	24	0
Nasopharyngitis	788	0
Peritonsillar abscess	2	0
Pharyngitis	27	0
Rhinitis	36	0
Sinusitis	123	0
Tonsillitis	90	0
Tracheitis	4	0
Tracheostomy infection	1	0
Upper respiratory tract infection	6	0
<i>Urinary tract infections</i>		
Cystitis	61	0
Kidney infection	34	0
Pyelonephritis	2	0
Urinary tract infection	154	0
<i>Vascular infections</i>		
Haematoma infection	1	0
Infected lymphocele	1	0
Infusion site infection	1	0
Lymphangitis	7	0
<i>Viral infections NEC</i>		
Arthritis viral	1	0
Conjunctivitis viral	2	0
Encephalitis viral	4	1
Eye infection viral	2	0
Gastroenteritis viral	21	0
Hepatitis viral	2	0
Meningitis viral	8	0
Meningoencephalitis viral	1	0
Oral viral infection	1	0
Pleurisy viral	1	0
Pneumonia viral	2	1
Post viral fatigue syndrome	37	0
Sweating fever	77	0
Vestibular neuronitis	23	0
Viral diarrhoea	2	0
Viral infection	40	0
Viral labyrinthitis	3	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021

Data Lock Date: 25-Aug-2021 18:30:56

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Infections Infections cont'd		
Viral myocarditis	1	0
Viral pericarditis	4	0
Viral pharyngitis	13	0
Viral rash	41	0
Viral sinusitis	1	0
Viral tonsillitis	1	0
Infections SOC TOTAL	7299	80

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries		
<i>Abdominal and gastrointestinal injuries NEC</i>		
Mouth injury	3	0
Oral contusion	3	0
Palate injury	1	0
Rectal injury	1	0
Splenic rupture	6	0
Tongue injury	2	0
Tooth fracture	1	0
Tooth injury	1	0
<i>Accidental exposures to product</i>		
Accidental exposure to product	16	0
<i>Anaesthetic and allied procedural complications</i>		
Airway complication of anaesthesia	1	0
Delayed recovery from anaesthesia	2	0
Sedation complication	1	0
<i>Atmospheric pressure injuries</i>		
Barotitis media	1	0
Hypobarism	1	0
<i>Bone and joint injuries NEC</i>		
Bursa injury	1	0
Joint injury	7	0
<i>Cardiovascular injuries</i>		
Heart injury	4	0
Vascular injury	5	0
<i>Cerebral injuries NEC</i>		
Brain contusion	1	0
Brain herniation	1	0
Concussion	2	0
Cranio-cerebral injury	1	0
Subarachnoid haematoma	1	0
Subdural haematoma	5	0
Subdural haemorrhage	5	0
Traumatic intracranial haemorrhage	1	1
<i>Chemical injuries</i>		
Chemical burn of skin	1	0
Chemical cystitis	1	0
<i>Chest and respiratory tract injuries NEC</i>		
Chest crushing	8	0
Foreign body in throat	1	0
<i>Conditions caused by cold</i>		
Chillblains	49	0
<i>Cranial nerve injuries</i>		
Vth nerve injury	1	0
<i>Ear injuries NEC</i>		
Ear injury	1	0
<i>Exposures associated with pregnancy, delivery and lactation</i>		
Exposure during pregnancy	9	0
Exposure via breast milk	38	0
Foetal exposure during pregnancy	30	0
Maternal exposure before pregnancy	2	0
Maternal exposure during breast feeding	1275	0
Maternal exposure during pregnancy	658	0
Maternal exposure timing unspecified	2	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Paternal exposure before pregnancy	2	0
Paternal exposure during pregnancy	1	0
Exposures to agents or circumstances NEC		
Exposure to SARS-CoV-2	2	0
Exposure to vaccinated person	3	0
Eye and ear procedural complications		
Toxic anterior segment syndrome	1	0
Eye injuries NEC		
Eye contusion	13	0
Eye injury	15	0
Foreign body in eye	3	0
Injury corneal	1	0
Periorbital haematoma	1	0
Retinal injury	2	0
Superficial injury of eye	1	0
Foetal and neonatal conditions associated with product exposure		
Intoxication by breast feeding	1	0
Fractures and dislocations NEC		
Bone fragmentation	1	0
Fracture	2	0
Joint dislocation	2	0
Multiple fractures	1	0
Gastrointestinal and hepatobiliary procedural complications		
Post procedural constipation	1	0
Postoperative ileus	1	0
Procedural nausea	7	0
Procedural vomiting	1	0
Heat injuries (excl thermal burns)		
Heat cramps	2	0
Heat exhaustion	3	0
Heat illness	1	0
Heat oedema	7	0
Heat stroke	3	0
Intentional product use issues		
Intentional dose omission	1	0
Intentional product use issue	1	0
Limb fractures and dislocations		
Atypical femur fracture	1	0
Clavicle fracture	22	0
Femoral neck fracture	1	0
Femur fracture	1	0
Fibula fracture	1	0
Hip fracture	1	0
Tibia fracture	1	0
Upper limb fracture	1	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
Inadequate aseptic technique in use of product	1	0
Medication error	18	0
Prescription drug used without a prescription	2	0
Product use complaint	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021

Data Lock Date: 25-Aug-2021 18:30:56

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Product use issue	18	0
Vaccination error	6	0
Wrong dose	3	0
Wrong drug	11	0
Wrong technique in product usage process	4	0
Muscle, tendon and ligament injuries		
Epicondylitis	17	0
Ligament injury	2	0
Ligament sprain	8	0
Mallet finger	1	0
Muscle injury	15	0
Muscle rupture	6	0
Muscle strain	24	0
Post-traumatic neck syndrome	1	0
Tendon injury	5	0
Tendon rupture	11	0
Musculoskeletal procedural complications		
Periprosthetic osteolysis	2	0
Post laminectomy syndrome	1	0
Nerve injuries NEC		
Nerve injury	65	0
Neurological and psychiatric procedural complications		
Post procedural stroke	1	0
Procedural dizziness	11	0
Non-occupational environmental exposures		
Exposure to extreme temperature	1	0
Non-site specific injuries NEC		
Arthropod bite	4	0
Arthropod sting	4	0
Bite	1	0
Electric shock	16	0
Fall	137	0
Foreign body	2	0
Injury	9	0
Multiple injuries	1	0
Nervous system injury	1	0
Post concussion syndrome	1	0
Traumatic haematoma	1	0
Wound	5	0
Wound complication	8	0
Wound haematoma	1	0
Wound haemorrhage	2	0
Wound secretion	4	0
Non-site specific procedural complications		
Incision site pain	3	0
Infusion related reaction	6	0
Injection related reaction	37	0
Post procedural complication	3	0
Procedural pain	2	0
Seroma	1	0
Occupational exposures		
Occupational exposure to SARS-CoV-2	1	0
Occupational exposure to product	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Off label uses		
Off label use	52	0
Overdoses NEC		
Overdose	47	0
Pathways and sources of exposure		
Exposure via unknown route	1	0
Pelvic fractures and dislocations		
Pelvic fracture	1	0
Peripheral nerve injuries		
Brachial plexus injury	1	0
Ulnar nerve injury	4	0
Poisoning and toxicity		
Alcohol poisoning	1	0
Poisoning	10	0
Toxicity to various agents	2	0
Product administration errors and issues		
Accidental overdose	6	0
Contraindicated product administered	1	0
Expired product administered	10	0
Inappropriate schedule of product administration	412	0
Incomplete course of vaccination	1	0
Incorrect dose administered	51	0
Incorrect drug administration rate	1	0
Incorrect product formulation administered	2	0
Incorrect route of product administration	4	0
Poor quality product administered	3	0
Product administered at inappropriate site	11	0
Product administered to patient of inappropriate age	1	0
Product administration error	6	0
Product dose omission issue	8	0
Wrong product administered	19	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	2	0
Product preparation issue	5	0
Product prescribing errors and issues		
Contraindicated product prescribed	2	0
Product prescribing error	1	0
Product selection errors and issues		
Product selection error	2	0
Radiation injuries		
Sunburn	19	0
Renal and urinary tract injuries NEC		
Foreign body in urogenital tract	1	0
Site specific injuries NEC		
Face crushing	1	0
Face injury	1	0
Head injury	32	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Injuries Injuries cont'd		
Limb crushing injury	2	0
Limb injury	81	0
Nasal injury	1	0
Neck crushing	1	0
Neck injury	1	0
<i>Skin injuries NEC</i>		
Contusion	925	0
Nail avulsion	1	0
Scar	16	0
Scratch	7	0
Skin abrasion	6	0
Skin injury	4	0
Skin laceration	2	0
Skin wound	3	0
Subcutaneous haematoma	2	0
<i>Skin procedural complications</i>		
Recall phenomenon	1	0
<i>Skull fractures, facial bone fractures and dislocations</i>		
Facial bones fracture	1	0
Fractured skull depressed	1	0
<i>Spinal cord injuries NEC</i>		
Spinal cord injury cervical	1	0
<i>Spinal fractures and dislocations</i>		
Spinal fracture	3	0
<i>Stoma complications</i>		
Gastrointestinal stoma complication	1	0
Stoma site discharge	1	0
Stoma site extravasation	1	0
Stoma site haemorrhage	1	0
<i>Thermal burns</i>		
Airway burns	1	0
Burn oesophageal	2	0
Burn of internal organs	2	0
Burn oral cavity	3	0
Burns second degree	4	0
Thermal burn	17	0
Thermal burns of eye	10	0
<i>Underdoses NEC</i>		
Underdose	6	0
<i>Vaccination related complications</i>		
Vaccination complication	41	0
Injuries SOC TOTAL	4623	1

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations		
Adrenal cortex tests		
Cortisol decreased	3	0
Adrenal medulla tests		
Epinephrine abnormal	1	0
Epinephrine increased	1	0
Auditory and vestibular diagnostic procedures		
Acoustic stimulation tests	5	0
Audiogram abnormal	1	0
Autoimmunity analyses		
Antinuclear antibody	1	0
Antinuclear antibody increased	1	0
Antinuclear antibody positive	2	0
Rheumatoid factor	3	0
Bacteria identification and serology (excl mycobacteria)		
Klebsiella test positive	1	0
Blood counts NEC		
Blood count	5	0
Blood count abnormal	2	0
Blood gas and acid base analyses		
Acid base balance abnormal	2	0
Blood lactic acid	4	0
Blood lactic acid decreased	1	0
Blood lactic acid increased	4	0
Blood pH	6	0
Blood pH increased	6	0
Oxygen consumption decreased	2	0
Oxygen saturation	8	0
Oxygen saturation decreased	54	0
PO2 decreased	1	0
Bone marrow and immune tissue histopathology procedures		
Aspiration bone marrow	1	0
Biopsy lymph gland	1	0
Bone marrow and immune tissue imaging procedures		
Lymph nodes scan abnormal	1	0
Scan lymph nodes	4	0
Carbohydrate tolerance analyses (incl diabetes)		
Blood glucose	7	0
Blood glucose abnormal	10	0
Blood glucose decreased	27	0
Blood glucose fluctuation	14	0
Blood glucose increased	84	0
Blood glucose normal	1	0
Glycosylated haemoglobin increased	1	0
Cardiac auscultatory investigations		
Cardiac murmur	25	0
Heart sounds	4	0
Heart sounds abnormal	4	0
Cardiac function diagnostic procedures		
Cardiac monitoring	1	0
Cardiac output	1	0
Central venous pressure	1	0
Echocardiogram	1	0
Myocardial strain	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Stroke volume decreased	1	0
Cardiac imaging procedures		
Magnetic resonance imaging heart	1	0
Scan myocardial perfusion abnormal	1	0
Cell marker analyses		
HLA-B*27 positive	1	0
Prostatic specific antigen increased	2	0
Central nervous system imaging procedures		
Computerised tomogram head	5	0
Magnetic resonance imaging head	12	0
Magnetic resonance imaging head abnormal	1	0
Cerebrospinal fluid tests (excl microbiology)		
CSF pressure	1	0
Chemistry analyses NEC		
Histamine abnormal	1	0
Histamine level increased	1	0
Inflammatory marker increased	3	0
Renin	1	0
Cholesterol analyses		
Blood cholesterol increased	6	0
Remnant-like lipoprotein particles	3	0
Coagulation and bleeding analyses		
Activated partial thromboplastin time prolonged	15	0
Activated partial thromboplastin time shortened	1	0
Bleeding time	1	0
Bleeding time abnormal	1	0
Bleeding time prolonged	5	0
Blood thromboplastin	1	0
Clot retraction	1	1
Coagulation factor VIII level decreased	1	0
Coagulation time prolonged	9	0
Coagulation time shortened	4	0
Fibrin D dimer increased	7	0
International normalised ratio abnormal	5	0
International normalised ratio decreased	19	0
International normalised ratio fluctuation	2	0
International normalised ratio increased	48	0
Prothrombin time shortened	1	0
Digestive enzymes		
Amylase increased	1	0
ECG investigations		
Electrocardiogram	2	0
Electrocardiogram QRS complex prolonged	1	0
Electrocardiogram QT prolonged	3	0
Electrocardiogram ST segment depression	1	0
Electrocardiogram ST segment elevation	6	0
Electrocardiogram ST-T segment abnormal	1	0
Electrocardiogram T wave inversion	4	0
Electrocardiogram abnormal	13	0
Electrocardiogram change	1	0
Electrocardiogram normal	2	0
Electrocardiogram repolarisation abnormality	1	0
QRS axis abnormal	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Endocrine analyses and imaging NEC</i>		
Hormone level abnormal	35	0
<i>Faecal analyses NEC</i>		
Faecal calprotectin	2	0
Faecal calprotectin increased	4	0
<i>Fertility analyses</i>		
Infertility tests	1	0
Semen analysis abnormal	1	0
<i>Foetal and neonatal diagnostic procedures</i>		
Foetal heart rate abnormal	2	2
Foetal heart rate increased	1	0
Foetal monitoring	1	0
Foetal non-stress test	1	0
<i>Gastrointestinal and abdominal imaging procedures</i>		
Computerised tomogram abdomen	1	0
Sigmoidoscopy abnormal	1	0
X-ray with contrast upper gastrointestinal tract	1	0
<i>Gastrointestinal function diagnostic procedures</i>		
Gastric pH decreased	1	0
<i>Gastrointestinal, pancreatic and APUD hormone analyses</i>		
Blood insulin	1	0
Blood insulin decreased	1	0
<i>Haematological analyses NEC</i>		
Blood viscosity abnormal	1	0
Plasma viscosity	1	0
Red blood cell sedimentation rate increased	5	0
<i>Heart rate and pulse investigations</i>		
Carotid pulse	1	0
Heart rate	338	0
Heart rate abnormal	46	0
Heart rate decreased	55	0
Heart rate increased	667	0
Heart rate irregular	126	0
Heart rate normal	1	0
Maximum heart rate	2	0
Pulse abnormal	14	0
Pulse pressure increased	1	0
Radial pulse abnormal	1	0
Sinus rhythm	5	0
<i>Imaging procedures NEC</i>		
Computerised tomogram	3	0
Magnetic resonance imaging	3	0
Magnetic resonance imaging abnormal	1	0
Scan	2	0
X-ray	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	4	0
Immunology test	9	0
<i>Immunology skin tests NEC</i>		

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021

Data Lock Date: 25-Aug-2021 18:30:56

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Skin test positive	1	0
Investigations NEC		
Blood test	20	0
Blood test abnormal	45	0
False positive investigation result	1	0
Laboratory test	1	0
Polymerase chain reaction positive	33	0
Quality of life decreased	2	0
Systemic lupus erythematosus disease activity index increased	1	0
Liver function analyses		
Alanine aminotransferase increased	19	0
Aspartate aminotransferase	1	0
Aspartate aminotransferase increased	2	0
Blood bilirubin increased	3	0
Gamma-glutamyltransferase increased	4	0
Hepatic enzyme increased	6	0
Liver function test	1	0
Liver function test abnormal	24	0
Liver function test increased	19	0
Transaminases increased	4	0
Metabolism tests NEC		
Blood ketone body	3	0
Blood ketone body increased	1	0
Blood ketone body present	1	0
Blood uric acid increased	2	0
Brain natriuretic peptide increased	1	0
Ubiquinone	1	0
Urine ketone body present	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 iron decreased	8	0
Blood magnesium decreased	1	0
Blood phosphorus decreased	1	0
Blood phosphorus increased	1	0
Blood potassium abnormal	1	0
Blood potassium decreased	4	0
Blood potassium increased	2	0
Blood sodium decreased	8	0
Serum ferritin	1	0
Serum ferritin decreased	4	0
Serum ferritin increased	1	0
Sweat test	1	0
Urine copper	1	0
Musculoskeletal and soft tissue imaging procedures		
Skull X-ray	6	0
Musculoskeletal and soft tissue tests NEC		
Swollen joint count increased	1	0
Mycobacteria identification and serology		
Tuberculin test positive	1	0
Neurologic diagnostic procedures		

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Coma scale abnormal	3	0
Hoover's sign of leg paresis	1	0
Joint position sense decreased	1	0
Lumbar puncture	5	0
Temperature perception test abnormal	1	0
Temperature perception test increased	1	0
<i>Ophthalmic function diagnostic procedures</i>		
Corneal reflex decreased	1	0
Intraocular pressure increased	7	0
Intraocular pressure test	1	0
<i>Physical examination procedures and organ system status</i>		
Body temperature	211	0
Body temperature abnormal	36	0
Body temperature decreased	34	0
Body temperature fluctuation	36	0
Body temperature increased	337	0
Body temperature normal	1	0
Breath sounds abnormal	1	0
General physical condition abnormal	1	0
Grip strength	2	0
Grip strength decreased	15	0
Head lag	5	0
Lymph node palpable	34	0
Menstruation normal	2	0
Muscle strength abnormal	1	0
Ophthalmological examination	2	0
Orthopaedic examination	1	0
Palpatory finding abnormal	2	0
Product residue present	2	0
Psoriasis area severity index decreased	1	0
Respiratory rate	8	0
Respiratory rate decreased	15	0
Respiratory rate increased	31	0
Skin temperature	32	0
Temperature difference of extremities	7	0
Weight	1	0
Weight decreased	81	0
Weight increased	25	0
<i>Pituitary analyses anterior</i>		
Blood corticotrophin	1	0
Blood follicle stimulating hormone	1	0
Blood growth hormone	3	0
Blood prolactin	2	0
Blood prolactin increased	2	0
Blood thyroid stimulating hormone decreased	1	0
Blood thyroid stimulating hormone increased	3	0
<i>Platelet analyses</i>		
Mean platelet volume decreased	1	0
Mean platelet volume increased	1	0
Platelet count	3	0
Platelet count decreased	59	0
Platelet count increased	2	0
<i>Protein analyses NEC</i>		

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
Alpha 1 globulin decreased	1	0
Alpha 2 globulin decreased	1	0
C-reactive protein increased	16	0
Red blood cell analyses		
Haematocrit	1	0
Haematocrit increased	1	0
Haemoglobin	1	0
Haemoglobin decreased	10	0
Haemoglobin increased	1	0
Renal function analyses		
Blood creatinine increased	1	0
Glomerular filtration rate decreased	2	0
Reproductive hormone analyses		
Anti-Muellerian hormone level decreased	1	0
Blood testosterone increased	1	0
False negative pregnancy test	7	0
Female sex hormone level	2	0
Pregnancy test	18	0
Pregnancy test false positive	1	0
Pregnancy test positive	1	0
Reproductive organ and breast histopathology procedures		
Biopsy endometrium	1	0
Smear cervix	1	0
Reproductive organ and breast imaging procedures		
Hysteroscopy	2	0
Respiratory and pulmonary function diagnostic procedures		
Forced expiratory volume increased	2	0
Maximal voluntary ventilation	1	0
Peak expiratory flow rate	1	0
Peak expiratory flow rate decreased	4	0
Pulmonary function test	2	0
Total lung capacity decreased	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	18	0
Chest X-ray abnormal	1	0
Chest X-ray normal	1	0
Chest scan	1	0
Computerised tomogram thorax	1	0
Skeletal and cardiac muscle analyses		
Blood creatine phosphokinase increased	4	0
Myocardial necrosis marker	1	0
Troponin	1	0
Troponin T increased	1	0
Troponin increased	10	0
Therapeutic drug monitoring analyses		
Analgesic drug level	4	0
Anticoagulation drug level above therapeutic	1	0
Anticoagulation drug level below therapeutic	5	0
Anticoagulation drug level increased	1	0
Drug level decreased	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
<i>Thyroid analyses</i>		
Anti-thyroid antibody	1	0
Thyroid function test abnormal	4	0
Thyroxine free increased	2	0
Tri-iodothyronine	1	0
Tri-iodothyronine decreased	4	0
<i>Tissue enzyme analyses NEC</i>		
Blood alkaline phosphatase increased	2	0
Enzyme level increased	1	0
<i>Toxicology laboratory analyses</i>		
Blood caffeine decreased	1	0
Blood lead	1	0
Drug screen positive	2	0
Opiates	1	0
<i>Urinalysis NEC</i>		
Blood urine	13	0
Blood urine present	40	0
Cells in urine	1	0
Glucose urine present	1	0
Protein urine absent	1	0
Urine analysis abnormal	5	0
Urine uric acid increased	1	0
pH urine	5	0
pH urine increased	2	0
<i>Urinary tract function analyses NEC</i>		
Urine output	12	0
Urine output decreased	8	0
Urine output increased	6	0
<i>Urinary tract imaging procedures</i>		
Cystoscopy	2	0
<i>Vascular imaging procedures NEC</i>		
Venogram	1	0
<i>Vascular tests NEC (incl blood pressure)</i>		
Blood pressure abnormal	6	0
Blood pressure decreased	58	0
Blood pressure diastolic	1	0
Blood pressure diastolic decreased	1	0
Blood pressure diastolic increased	2	0
Blood pressure increased	181	0
Blood pressure measurement	30	0
Blood pressure normal	2	0
Blood pressure systolic	1	0
Blood pressure systolic decreased	3	0
Blood pressure systolic increased	1	0
<i>Virus identification and serology</i>		
Coronavirus test	11	0
Coronavirus test positive	3	0
HIV test	1	0
SARS-CoV-1 test	1	0
SARS-CoV-1 test positive	1	0
SARS-CoV-2 antibody test	9	0
SARS-CoV-2 antibody test negative	13	0
SARS-CoV-2 antibody test positive	2	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021

Data Lock Date: 25-Aug-2021 18:30:56

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Investigations Investigations cont'd		
SARS-CoV-2 test	26	0
SARS-CoV-2 test false negative	1	0
SARS-CoV-2 test false positive	2	0
SARS-CoV-2 test negative	7	0
SARS-CoV-2 test positive	90	0
Viral test	4	0
<i>Vitamin analyses</i>		
Blood folate decreased	4	0
Vitamin B12	1	0
Vitamin B12 abnormal	1	0
Vitamin B12 decreased	1	0
Vitamin D	2	0
Vitamin D decreased	3	0
<i>Water and electrolyte analyses NEC</i>		
Urine osmolarity	1	0
Volume blood	1	0
<i>White blood cell analyses</i>		
Eosinophil count	1	0
Eosinophil count increased	3	0
Lymphocyte count	1	0
Lymphocyte count decreased	2	0
Neutrophil count	3	0
Neutrophil count decreased	8	0
White blood cell count	2	0
White blood cell count decreased	10	0
White blood cell count increased	6	0
Investigations SOC TOTAL	3873	3

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Metabolic disorders		
<i>Appetite disorders</i>		
Appetite disorder	13	0
Decreased appetite	947	0
Diet refusal	1	0
Eating disorder symptom	2	0
Food craving	9	0
Food refusal	10	0
Hyperphagia	11	0
Hypophagia	16	0
Increased appetite	26	0
Salt craving	2	0
<i>Calcium metabolism disorders</i>		
Hypocalcaemia	3	0
Tetany	3	0
<i>Diabetes mellitus (incl subtypes)</i>		
Diabetes mellitus	35	0
Diabetes mellitus inadequate control	12	1
Increased insulin requirement	1	0
Insulin resistant diabetes	1	0
Latent autoimmune diabetes in adults	2	0
Type 1 diabetes mellitus	14	0
Type 2 diabetes mellitus	3	0
<i>Diabetic complications NEC</i>		
Diabetic complication	2	0
Diabetic ketoacidosis	11	0
Diabetic ketosis	1	0
<i>Disorders of purine metabolism</i>		
Gout	77	0
<i>Electrolyte imbalance NEC</i>		
Fluid imbalance	1	0
<i>Fat soluble vitamin deficiencies and disorders</i>		
Vitamin D deficiency	2	0
<i>Fluid intake increased</i>		
Polydipsia	5	0
<i>Food malabsorption and intolerance syndromes (excl sugar intolerance)</i>		
Alcohol intolerance	3	0
Dairy intolerance	1	0
Food intolerance	10	0
Gluten sensitivity	6	0
Histamine intolerance	3	0
<i>General nutritional disorders NEC</i>		
Abnormal loss of weight	13	0
Abnormal weight gain	14	0
Cachexia	1	0
Feeding disorder	54	0
Food aversion	7	0
Malnutrition	1	0
Neonatal insufficient breast milk syndrome	4	0
Overweight	1	0
Poor feeding infant	12	0
Weight loss poor	2	0
<i>Hyperglycaemic conditions NEC</i>		
Glucose tolerance impaired	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Metabolic disorders Metabolic disorders cont'd		
Hyperglycaemia	59	0
Insulin resistance	4	0
Hypoglycaemic conditions NEC		
Glycopenia	1	0
Hypoglycaemia	71	0
Hypoglycaemia unawareness	1	0
Postprandial hypoglycaemia	1	0
Iron deficiencies		
Iron deficiency	11	0
Iron excess		
Haemochromatosis	1	0
Iron overload	1	0
Lipid metabolism and deposit disorders NEC		
Body fat disorder	1	0
Metabolic acidoses (excl diabetic acidoses)		
Ketoacidosis	4	0
Lactic acidosis	2	0
Metabolic acidosis	2	0
Metabolic disorders NEC		
Metabolic disorder	1	0
Mixed acid-base disorders		
Acidosis	3	0
Potassium imbalance		
Hyperkalaemia	3	0
Hypokalaemia	3	0
Hypokalaemic syndrome	1	0
Sodium imbalance		
Hyponatraemia	7	0
Hyponatraemic syndrome	3	0
Salt intoxication	1	0
Sugar intolerance (excl glucose intolerance)		
Lactose intolerance	1	0
Total fluid volume decreased		
Dehydration	156	0
Total fluid volume increased		
Fluid overload	1	0
Fluid retention	42	0
Hypervolaemia	1	0
Vitamin deficiencies NEC		
Hypovitaminosis	4	0
Water soluble vitamin deficiencies		
Folate deficiency	3	0
Vitamin B12 deficiency	3	0
Metabolic disorders SOC TOTAL	1735	1

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Arthropathies NEC</i>		
Arthritis	207	0
Arthropathy	23	0
Autoimmune arthritis	5	0
Haemarthrosis	5	0
Joint microhaemorrhage	1	0
Palindromic rheumatism	1	0
Polyarthritis	13	0
Rheumatic fever	1	0
Sacroiliitis	4	0
Seronegative arthritis	2	0
<i>Bone disorders NEC</i>		
Bone cyst	1	0
Jaw disorder	3	0
Medial tibial stress syndrome	4	0
Osteitis	5	0
Osteonecrosis	1	0
Osteonecrosis of jaw	3	0
Spinal disorder	1	0
<i>Bone related signs and symptoms</i>		
Bone pain	287	0
Bone swelling	7	0
Coccydynia	3	0
Metatarsalgia	1	0
Pain in jaw	284	0
Pubic pain	2	0
Spinal pain	59	0
<i>Bursal disorders</i>		
Bursitis	52	0
<i>Cartilage disorders</i>		
Chondritis	1	0
Costochondritis	59	0
Osteochondritis	1	0
Polychondritis	3	0
<i>Connective tissue disorders NEC</i>		
Connective tissue disorder	1	0
Polymyalgia rheumatica	47	0
Reynold's syndrome	1	0
Sjogren's syndrome	5	0
<i>Crystal arthropathic disorders</i>		
Chondrocalcinosis pyrophosphate	2	0
Crystal arthropathy	1	0
<i>Epiphyseal disorders</i>		
Epiphyses premature fusion	1	0
<i>Extremity deformities</i>		
Bone deformity	1	0
Finger deformity	1	0
Foot deformity	1	0
Hand deformity	2	0
Knee deformity	1	0
Limb deformity	4	0
Musculoskeletal deformity	1	0
<i>Intervertebral disc disorders NEC</i>		

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Intervertebral disc protrusion	3	0
Joint related disorders NEC		
Chondromalacia	1	0
Hypermobility syndrome	1	0
Joint deposit	1	0
Joint destruction	1	0
Joint laxity	3	0
Joint lock	21	0
Patellofemoral pain syndrome	1	0
Periarthritis	114	0
Rotator cuff syndrome	19	0
Temporomandibular joint syndrome	7	0
Joint related signs and symptoms		
Arthralgia	6994	0
Jaw clicking	4	0
Joint effusion	14	0
Joint noise	29	0
Joint range of motion decreased	24	0
Joint stiffness	185	0
Joint swelling	399	0
Joint vibration	2	0
Joint warmth	12	0
Loose body in joint	1	0
Ligament disorders		
Ligament pain	1	0
Symphysiolysis	1	0
Lupus erythematosus (incl subtypes)		
Lupus-like syndrome	1	0
Systemic lupus erythematosus	17	0
Metabolic bone disorders		
Osteopenia	2	0
Osteoporosis	2	0
Muscle infections and inflammations		
Antisynthetase syndrome	3	0
Immune-mediated myositis	1	0
Myositis	23	0
Polymyositis	5	0
Muscle pains		
Fibromyalgia	75	0
Myalgia	8664	0
Myalgia intercostal	1	0
Myofascial pain syndrome	10	0
Muscle related signs and symptoms NEC		
Haematoma muscle	1	0
Muscle atrophy	15	0
Muscle discomfort	2	0
Muscle disorder	4	0
Muscle fatigue	282	0
Muscle haemorrhage	1	0
Muscle mass	4	0
Muscle oedema	1	0
Muscle spasms	1550	0
Muscle swelling	22	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Muscle & tissue disorders cont'd		
Muscle tightness	71	0
Muscle twitching	353	0
Muscle tone abnormalities		
Muscle rigidity	13	0
Nuchal rigidity	10	0
Torticollis	4	0
Trismus	28	0
Muscle weakness conditions		
Muscular weakness	691	0
Musculoskeletal and connective tissue conditions NEC		
Back disorder	2	0
Growth disorder	1	0
Limb mass	19	0
Mandibular mass	2	0
Mastication disorder	3	0
Mobility decreased	77	0
Musculoskeletal disorder	10	0
Musculoskeletal stiffness	995	0
Posture abnormal	1	0
Sacroiliac joint dysfunction	1	0
Weight bearing difficulty	1	0
Musculoskeletal and connective tissue deformities of skull, face and buccal cavity		
Head deformity	2	0
Musculoskeletal and connective tissue infections and inflammations NEC		
Dactylitis	2	0
Dupuytren's contracture	1	0
Fasciitis	1	0
Plantar fasciitis	6	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	1820	0
Flank pain	46	0
Limb discomfort	1208	0
Musculoskeletal chest pain	162	0
Musculoskeletal discomfort	75	0
Musculoskeletal pain	36	0
Neck pain	1461	0
Pain in extremity	10001	0
Rheumatic disorder	9	0
Myopathies		
Myopathy	4	0
Rhabdomyolysis	9	0
Osteoarthropathies		
Nodal osteoarthritis	1	0
Osteoarthritis	33	0
Spinal osteoarthritis	1	0
Psoriatic arthropathies		
Psoriatic arthropathy	15	0
Rheumatoid arthropathies		
Rheumatoid arthritis	92	0
Soft tissue disorders NEC		
Axillary mass	182	0
Fluctuance	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021

Data Lock Date: 25-Aug-2021 18:30:56

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Muscle & tissue disorders		
<i>Muscle & tissue disorders cont'd</i>		
Groin pain	88	0
Neck mass	25	0
Purple glove syndrome	1	0
Soft tissue disorder	2	0
Soft tissue swelling	4	0
Spine and neck deformities		
Kyphosis	2	0
Lordosis	1	0
Neck deformity	1	0
Scoliosis	1	0
Spinal stenosis	1	0
Spondyloarthropathies		
Ankylosing spondylitis	6	0
Arthritis reactive	33	0
Spondylitis	2	0
Synovial disorders		
Synovial cyst	18	0
Synovitis	5	0
Tendon disorders		
Enthesopathy	1	0
Tendon disorder	2	0
Tendon pain	18	0
Tendonitis	30	0
Tenosynovitis	2	0
Tenosynovitis stenosaurs	2	0
Trigger finger	21	0
Trunk deformities		
Drooping shoulder syndrome	1	0
Shoulder deformity	2	0
Muscle & tissue disorders SOC TOTAL	37351	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Neoplasms		
<i>B-cell lymphomas NEC</i>		
B-cell lymphoma	1	1
Follicular lymphoma	3	0
<i>Bone neoplasms unspecified malignancy</i>		
Bone neoplasm	2	0
<i>Breast and nipple neoplasms benign</i>		
Benign breast neoplasm	1	0
<i>Breast and nipple neoplasms malignant</i>		
Breast cancer	29	0
Breast cancer female	1	0
Breast cancer male	1	0
Breast cancer stage I	1	0
Breast cancer stage III	2	0
Invasive ductal breast carcinoma	1	0
Triple negative breast cancer	2	0
<i>Cardiovascular neoplasms benign</i>		
Pericardial lipoma	1	0
<i>Colorectal neoplasms malignant</i>		
Colon cancer	1	0
Colorectal cancer	1	0
Rectal cancer	1	0
<i>Endocrine neoplasms malignant and unspecified NEC</i>		
Neuroendocrine tumour	1	0
Thyroid neoplasm	1	0
<i>Endometrial neoplasms malignant</i>		
Endometrial cancer	2	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	3	0
<i>Hodgkin's disease NEC</i>		
Hodgkin's disease	3	0
<i>Islet cell neoplasms and APUDoma NEC</i>		
Pancreatic neuroendocrine tumour	1	0
<i>Leukaemias NEC</i>		
Leukaemia	2	1
<i>Leukaemias acute NEC</i>		
Acute leukaemia	1	0
<i>Leukaemias chronic NEC</i>		
Chronic leukaemia	1	0
<i>Leukaemias chronic lymphocytic</i>		
Chronic lymphocytic leukaemia	2	0
<i>Lip and oral cavity neoplasms malignant</i>		
Lip and/or oral cavity cancer recurrent	1	0
<i>Lymphomas unspecified NEC</i>		
Lymphoma	24	1
<i>Metastases to specified sites</i>		
Metastases to liver	1	0
Metastases to lymph nodes	5	0
<i>Metastases to unknown and unspecified sites</i>		
Metastasis	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
<i>Myelodysplastic syndromes</i>		
Myelodysplastic syndrome	2	0
<i>Myeloproliferative disorders (excl leukaemias)</i>		
Essential thrombocythaemia	1	0
<i>Neoplasms benign site unspecified NEC</i>		
Adenoma benign	1	0
<i>Neoplasms malignant site unspecified NEC</i>		
Adenocarcinoma metastatic	1	0
Metastatic neoplasm	1	0
Neoplasm malignant	7	0
Second primary malignancy	1	0
Squamous cell carcinoma	4	0
<i>Neoplasms unspecified malignancy and site unspecified NEC</i>		
Neoplasm	2	0
Neoplasm recurrence	1	0
<i>Nervous system neoplasms benign NEC</i>		
Cranial nerve neoplasm benign	1	0
Neurilemmoma benign	1	0
<i>Nervous system neoplasms unspecified malignancy NEC</i>		
Brain neoplasm	2	0
Spinal cord neoplasm	1	0
<i>Neuromas</i>		
Acoustic neuroma	2	0
<i>Non-Hodgkin's lymphomas NEC</i>		
Non-Hodgkin's lymphoma	3	0
<i>Oesophageal neoplasms malignant</i>		
Oesophageal cancer metastatic	4	0
<i>Oncologic complications and emergencies</i>		
Cancer pain	1	0
<i>Oropharyngeal, nasopharyngeal and tonsillar neoplasms malignant and unspecified</i>		
Tonsil cancer	3	0
<i>Pancreatic neoplasms malignant (excl islet cell and carcinoid)</i>		
Pancreatic carcinoma	4	0
<i>Plasma cell myelomas</i>		
POEMS syndrome	1	0
Plasma cell myeloma	1	0
<i>Plasma cell neoplasms NEC</i>		
TEMPI syndrome	1	0
<i>Prostatic neoplasms malignant</i>		
Prostate cancer	3	0
<i>Renal neoplasms malignant</i>		
Renal cancer	2	0
<i>Respiratory tract and pleural neoplasms malignant cell type unspecified NEC</i>		
Bronchial carcinoma	1	0
Lung neoplasm malignant	8	0
<i>Skin melanomas (excl ocular)</i>		
Malignant melanoma	1	0
<i>Skin neoplasms benign</i>		
Acrochordon	2	0
Anogenital warts	6	0
Haemangioma of skin	3	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021

Data Lock Date: 25-Aug-2021 18:30:56

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Neoplasms Neoplasms cont'd		
Melanocytic naevus	4	0
Pyogenic granuloma	1	0
Skin papilloma	13	0
<i>Skin neoplasms malignant and unspecified (excl melanoma)</i>		
Basal cell carcinoma	2	0
Bowen's disease	1	0
Neoplasm skin	2	0
Squamous cell carcinoma of skin	1	0
<i>Soft tissue neoplasms benign NEC</i>		
Lipoma	6	0
Lymphangioma	1	0
<i>Soft tissue sarcomas histology unspecified</i>		
Sarcoma	1	0
<i>Thyroid neoplasms malignant</i>		
Papillary thyroid cancer	2	0
Thyroid cancer	1	0
<i>Uterine neoplasms benign</i>		
Uterine leiomyoma	9	0
Neoplasms SOC TOTAL	215	4

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Abnormal reflexes</i>		
Areflexia	5	0
Extensor plantar response	2	0
Hyperreflexia	4	0
Hyporeflexia	7	0
<i>Abnormal sleep-related events</i>		
Sleep paralysis	22	0
<i>Absence seizures</i>		
Petit mal epilepsy	22	0
<i>Acute polyneuropathies</i>		
Acute motor axonal neuropathy	1	0
Guillain-Barre syndrome	44	1
Subacute inflammatory demyelinating polyneuropathy	1	0
<i>Autonomic nervous system disorders</i>		
Anticholinergic syndrome	1	0
Autonomic nervous system imbalance	8	0
Autonomic neuropathy	2	0
Horner's syndrome	1	0
<i>Central nervous system aneurysms and dissections</i>		
Carotid artery dissection	1	0
Intracranial aneurysm	2	1
<i>Central nervous system haemorrhages and cerebrovascular accidents</i>		
Brain stem infarction	1	1
Brain stem stroke	1	0
Carotid artery thrombosis	3	0
Cerebellar haemorrhage	2	0
Cerebellar infarction	2	0
Cerebellar ischaemia	1	0
Cerebellar stroke	6	0
Cerebral artery embolism	3	1
Cerebral artery occlusion	1	0
Cerebral artery thrombosis	3	0
Cerebral haemorrhage	41	8
Cerebral infarction	23	1
Cerebral thrombosis	11	0
Cerebrovascular accident	322	13
Embolic stroke	6	0
Haemorrhage intracranial	9	2
Haemorrhagic cerebral infarction	1	0
Haemorrhagic stroke	9	3
Internal capsule infarction	1	0
Intracranial haematoma	1	0
Ischaemic cerebral infarction	1	0
Ischaemic stroke	33	1
Lacunar infarction	2	0
Lacunar stroke	3	0
Lateral medullary syndrome	1	0
Pseudostroke	1	0
Subarachnoid haemorrhage	15	6
Thalamic infarction	1	0
Thrombotic stroke	3	1
<i>Central nervous system inflammatory disorders NEC</i>		
Gliosis	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Central nervous system vascular disorders NEC		
Brain hypoxia	1	1
Central nervous system vasculitis	1	0
Cerebral amyloid angiopathy	1	0
Cerebral congestion	2	0
Cerebral small vessel ischaemic disease	1	0
Cerebrovascular disorder	1	0
Post cardiac arrest syndrome	1	0
Reversible cerebral vasoconstriction syndrome	1	0
Cerebrovascular venous and sinus thrombosis		
Cerebral venous sinus thrombosis	38	3
Cerebral venous thrombosis	4	0
Superior sagittal sinus thrombosis	3	0
Transverse sinus thrombosis	1	0
Cervical spinal cord and nerve root disorders		
Cervical radiculopathy	1	0
Cervicobrachial syndrome	3	0
Choreiform movements		
Chorea	2	0
Chronic polyneuropathies		
Demyelinating polyneuropathy	1	0
Coma states		
Coma	10	0
Diabetic coma	1	0
Hypoglycaemic coma	1	0
Coordination and balance disturbances		
Ataxia	9	0
Balance disorder	300	0
Coordination abnormal	43	0
Dysdiadochokinesis	1	0
Dysstasia	44	0
Nystagmus	10	0
Cortical dysfunction NEC		
Alexia	2	0
Aphasia	63	0
Apraxia	1	0
Dyslexia	1	0
Dyspraxia	1	0
Neurologic neglect syndrome	1	0
Sensory processing disorder	2	0
Visuospatial deficit	1	0
Cranial nerve disorders NEC		
Cranial nerve disorder	2	0
Dementia (excl Alzheimer's type)		
Dementia	12	0
Dementia with Lewy bodies	1	0
Senile dementia	1	0
Demyelinating disorders NEC		
Acute disseminated encephalomyelitis	4	0
Clinically isolated syndrome	1	0
Demyelination	8	0
Neuromyelitis optica spectrum disorder	3	0
Disturbances in consciousness NEC		

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021

Data Lock Date: 25-Aug-2021 18:30:56

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>		
Altered state of consciousness	10	0
Consciousness fluctuating	2	0
Depressed level of consciousness	37	0
Infant sedation	1	0
Lethargy	1799	0
Loss of consciousness	489	0
Postictal state	4	0
Sedation	8	0
Somnolence	821	0
Stupor	4	0
Syncope	1611	0
<i>Disturbances in sleep phase rhythm</i>		
Circadian rhythm sleep disorder	1	0
Irregular sleep phase	2	0
Irregular sleep wake rhythm disorder	1	0
<i>Dyskinesias and movement disorders NEC</i>		
Akathisia	4	0
Bradykinesia	15	0
Clumsiness	16	0
Dyskinesia	53	0
Extrapyramidal disorder	2	0
Fine motor skill dysfunction	9	0
Foetal movement disorder	1	0
Hyperkinesia	3	0
Hypokinesia	55	0
Motor dysfunction	2	0
Movement disorder	43	0
Psychomotor hyperactivity	19	0
Synkinesis	2	0
Tardive dyskinesia	2	0
<i>Dystonias</i>		
Dystonia	15	0
Writer's cramp	1	0
<i>Encephalitis NEC</i>		
Encephalitis autoimmune	1	0
Limbic encephalitis	1	0
Noninfective encephalitis	4	0
<i>Encephalopathies NEC</i>		
Encephalopathy	3	0
Hashimoto's encephalopathy	1	0
Posterior reversible encephalopathy syndrome	1	0
<i>Eye movement disorders</i>		
IIIrd nerve disorder	1	0
IIIrd nerve paralysis	5	0
IVth nerve paralysis	1	0
Microvascular cranial nerve palsy	1	0
VIth nerve paralysis	10	0
<i>Facial cranial nerve disorders</i>		
Bell's palsy	402	0
Facial nerve disorder	8	0
Facial paralysis	312	0
Facial paresis	79	0
Facial spasm	36	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders <small>Nervous system disorders cont'd</small>		
<i>Generalised tonic-clonic seizures</i>		
Generalised tonic-clonic seizure	40	0
<i>Headaches NEC</i>		
Cervicogenic headache	3	0
Cluster headache	178	0
Cold-stimulus headache	17	0
Drug withdrawal headache	2	0
Exertional headache	8	0
External compression headache	2	0
Headache	21061	0
Medication overuse headache	2	0
New daily persistent headache	4	0
Occipital neuralgia	10	0
Ophthalmoplegic migraine	1	0
Primary cough headache	4	0
Primary headache associated with sexual activity	5	0
Sinus headache	291	0
Tension headache	448	0
Thunderclap headache	7	0
Vascular headache	13	0
<i>Hydrocephalic conditions</i>		
Hydrocephalus	2	0
<i>Hypoglossal nerve disorders</i>		
Tongue paralysis	1	0
<i>Increased intracranial pressure disorders</i>		
Brain compression	1	0
Brain oedema	5	1
Idiopathic intracranial hypertension	6	0
Intracranial pressure increased	1	0
<i>Intellectual disabilities</i>		
Intellectual disability	3	0
<i>Lumbar spinal cord and nerve root disorders</i>		
Sciatica	66	0
<i>Memory loss (excl dementia)</i>		
Amnesia	133	0
Memory impairment	143	0
Transient global amnesia	7	0
<i>Mental impairment (excl dementia and memory loss)</i>		
Cognitive disorder	70	0
Cognitive linguistic deficit	1	0
Disturbance in attention	252	0
Mental impairment	40	0
<i>Migraine headaches</i>		
Hemiplegic migraine	25	0
Migraine	2301	0
Migraine with aura	151	0
Migraine without aura	15	0
Ophthalmic migraine	5	0
Retinal migraine	27	0
Typical aura without headache	7	0
Vestibular migraine	16	0
<i>Mixed cranial nerve disorders</i>		
Bulbar palsy	2	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
<i>Mononeuropathies</i>		
Carpal tunnel syndrome	17	0
Cubital tunnel syndrome	2	0
Meralgia paraesthetica	1	0
Mononeuritis	2	0
Mononeuropathy	2	0
Nerve compression	19	0
Peripheral nerve lesion	1	0
Peroneal nerve palsy	12	0
Sciatic nerve neuropathy	2	0
Ulnar nerve palsy	2	0
Ulnar neuritis	1	0
Ulnar tunnel syndrome	1	0
<i>Motor neurone diseases</i>		
Lower motor neurone lesion	1	0
Motor neurone disease	1	0
<i>Multiple sclerosis acute and progressive</i>		
Band sensation	1	0
Multiple sclerosis	25	0
Multiple sclerosis relapse	20	0
Tumefactive multiple sclerosis	1	1
<i>Muscle tone abnormal</i>		
Drop attacks	1	0
Hypertonia	2	0
Hypotonia	14	0
Muscle tone disorder	1	0
Serotonin syndrome	1	0
Stiff leg syndrome	1	0
<i>Myelitis (incl infective)</i>		
Myelitis transverse	26	0
<i>Narcolepsy and hypersomnia</i>		
Cataplexy	1	0
Hypersomnia	91	0
Narcolepsy	6	0
<i>Nervous system disorders NEC</i>		
Central nervous system lesion	2	0
Cerebral disorder	1	0
Nervous system disorder	10	0
Neurotoxicity	2	0
<i>Neurologic visual problems NEC</i>		
Hemianopia	1	0
Hemianopia homonymous	2	0
Quadrantanopia	1	0
Tunnel vision	15	0
<i>Neurological signs and symptoms NEC</i>		
Agitation neonatal	1	0
Clonus	3	0
Decerebrate posture	1	0
Dizziness	7887	0
Dizziness exertional	38	0
Dizziness postural	602	0
Drooling	21	0
Fontanelle bulging	2	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Head discomfort	263	0
Hyporesponsive to stimuli	2	0
Inability to crawl	2	0
Infant irritability	6	0
Myoclonus	20	0
Neurological symptom	39	0
Patient elopement	1	0
Persistent postural-perceptual dizziness	12	0
Presyncope	498	0
Sensory overload	3	0
Slow response to stimuli	3	0
Tongue biting	4	0
Unresponsive to stimuli	37	0
Neuromuscular disorders NEC		
Muscle contractions involuntary	16	0
Muscle spasticity	10	0
Neuromuscular pain	3	0
Neuromuscular junction dysfunction		
Myasthenia gravis	7	0
Myasthenia gravis crisis	2	0
Olfactory nerve disorders		
Anosmia	208	0
Hyposmia	14	0
Parosmia	199	0
Optic nerve disorders NEC		
Optic neuritis	24	0
Paraesthesias and dysaesthesias		
Burning feet syndrome	7	0
Burning sensation	416	0
Burning sensation mucosal	2	0
Dysaesthesia	5	0
Formication	33	0
Hand-arm vibration syndrome	3	0
Hemianaesthesia	1	0
Hemiparaesthesia	2	0
Hyperaesthesia	73	0
Hypoaesthesia	2336	0
Paraesthesia	3215	0
Reversed hot-cold sensation	4	0
Synaesthesia	1	0
Paralysis and paresis (excl cranial nerve)		
Diplegia	11	0
Hemiparesis	38	0
Hemiplegia	34	0
Locked-in syndrome	1	0
Monoparesis	46	0
Monoplegia	60	0
Paralysis	104	0
Paraparesis	3	0
Paresis	6	0
Quadriparesis	1	0
Quadriplegia	1	0
Parkinson's disease and parkinsonism		

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Freezing phenomenon	8	0
Parkinson's disease	3	0
Parkinsonian gait	1	0
Parkinsonian rest tremor	1	0
Parkinsonism	4	0
Reduced facial expression	8	0
Partial complex seizures		
Dreamy state	6	0
Focal dyscognitive seizures	3	0
Temporal lobe epilepsy	2	0
Partial simple seizures NEC		
Autonomic seizure	1	0
Peripheral neuropathies NEC		
Axonal neuropathy	2	0
Neuralgic amyotrophy	2	0
Neuritis	7	0
Neuropathy peripheral	77	0
Peripheral sensorimotor neuropathy	1	0
Peripheral sensory neuropathy	10	0
Polyneuropathy	2	0
Thoracic outlet syndrome	1	0
Seizures and seizure disorders NEC		
Atonic seizures	5	0
Change in seizure presentation	2	0
Clonic convulsion	3	0
Convulsions local	1	0
Epilepsy	134	0
Epileptic aura	2	0
Epileptic encephalopathy	1	0
Febrile convulsion	14	0
Partial seizures	17	0
Post stroke seizure	1	0
Psychogenic seizure	7	0
Seizure	479	0
Seizure anoxic	1	0
Seizure cluster	5	0
Seizure like phenomena	2	0
Status epilepticus	37	0
Tonic clonic movements	2	0
Tonic convulsion	20	0
Tonic posturing	1	0
Sensory abnormalities NEC		
Ageusia	419	0
Allodynia	19	0
Aura	16	0
Complex regional pain syndrome	4	0
Dysgeusia	1001	0
Electric shock sensation	32	0
Hypergeusia	1	0
Hypogeusia	6	0
Intercostal neuralgia	1	0
Loss of proprioception	3	0
Morton's neuralgia	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Nervous system disorders		
<i>Nervous system disorders cont'd</i>		
Neuralgia	415	0
Persistent genital arousal disorder	1	0
Phantom limb syndrome	4	0
Post herpetic neuralgia	14	0
Restless arm syndrome	2	0
Restless legs syndrome	104	0
Sensory disturbance	81	0
Sensory loss	62	0
Taste disorder	217	0
Visual perseveration	3	0
Sleep disturbances NEC		
Sleep deficit	5	0
Sudden onset of sleep	1	0
Speech and language abnormalities		
Dysarthria	153	0
Incoherent	9	0
Language disorder	1	0
Repetitive speech	3	0
Slow speech	12	0
Speech disorder	54	0
Spinal cord and nerve root disorders NEC		
Radiculitis brachial	8	0
Radiculopathy	5	0
Structural brain disorders NEC		
Brain injury	6	2
Hyperintensity in brain deep nuclei	1	0
Transient cerebrovascular events		
Transient ischaemic attack	128	3
Tremor (excl congenital)		
Action tremor	1	0
Essential tremor	3	0
Head titubation	9	0
Resting tremor	3	0
Tremor	1303	0
Trigeminal disorders		
Facial neuralgia	15	0
Numb chin syndrome	2	0
Trigeminal nerve disorder	3	0
Trigeminal neuralgia	36	0
Vagus nerve disorders		
Vocal cord paralysis	1	0
Vertigos NEC		
Cervicogenic vertigo	1	0
Vertigo CNS origin	2	0
Nervous system disorders SOC TOTAL	54154	50

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Pregnancy conditions		
<i>Abortion related conditions and complications</i>		
Anembryonic gestation	1	0
<i>Abortions not specified as induced or spontaneous</i>		
Abortion	1	0
Abortion missed	3	1
<i>Abortions spontaneous</i>		
Abortion spontaneous	294	0
Abortion threatened	2	0
<i>Amniotic fluid and cavity disorders of pregnancy NEC</i>		
Amniorrhoea	1	0
<i>Foetal complications NEC</i>		
Foetal disorder	1	0
Foetal hypokinesia	5	0
<i>Foetal growth complications</i>		
Foetal growth restriction	2	0
<i>Foetal position and presentation abnormalities</i>		
Oblique presentation	1	0
<i>Gestational age and weight conditions</i>		
Premature baby	2	1
Term baby	1	0
<i>Haemorrhagic complications of pregnancy</i>		
Haemorrhage in pregnancy	1	0
Premature separation of placenta	2	0
Subchorionic haematoma	2	0
Subchorionic haemorrhage	1	0
<i>Hypertension associated disorders of pregnancy</i>		
Pre-eclampsia	1	0
<i>Labour onset and length abnormalities</i>		
Premature delivery	1	0
Premature labour	3	0
Premature rupture of membranes	1	0
Threatened labour	1	0
<i>Maternal complications of labour NEC</i>		
Uterine contractions abnormal	1	0
Uterine hypertonus	7	0
<i>Maternal complications of pregnancy NEC</i>		
Decidual cast	4	0
Ectopic pregnancy	4	0
Morning sickness	13	0
Preterm premature rupture of membranes	3	0
Somatic symptom disorder of pregnancy	3	0
<i>Neonatal hepatobiliary disorders</i>		
Jaundice neonatal	1	0
<i>Newborn complications NEC</i>		
Neonatal disorder	1	0
<i>Normal newborn status</i>		
Normal newborn	1	0
<i>Normal pregnancy, labour and delivery</i>		
Labour pain	1	0
Live birth	2	0
Pregnancy	51	0
Uterine contractions during pregnancy	2	0
<i>Placental abnormalities (excl neoplasms)</i>		

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Pregnancy conditions <small>Pregnancy conditions cont'd</small>		
Placental disorder	1	0
Postpartum complications NEC		
Postpartum haemorrhage	4	0
Pregnancy complicated by maternal disorders		
Gestational diabetes	2	0
Peripartum cardiomyopathy	1	0
Stillbirth and foetal death		
Foetal death	3	3
Stillbirth	3	3
Unintended pregnancies		
Pregnancy after post coital contraception	2	0
Pregnancy on contraceptive	2	0
Pregnancy on oral contraceptive	2	0
Pregnancy with contraceptive device	1	0
Unintended pregnancy	1	0
Pregnancy conditions SOC TOTAL	443	8

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021

Data Lock Date: 25-Aug-2021 18:30:56

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
<i>Device issues NEC</i>		
Device connection issue	1	0
Device failure	1	0
Device issue	2	0
<i>Device malfunction events NEC</i>		
Device infusion issue	1	0
Device malfunction	1	0
Device pacing issue	1	0
Device stimulation issue	1	0
Oversensing	15	0
Thrombosis in device	9	0
<i>Device physical property and chemical issues</i>		
Device breakage	1	0
Device defective	7	0
Device kink	1	0
Needle issue	2	0
<i>Product contamination and sterility issues</i>		
Product contamination	10	0
Product contamination physical	4	0
<i>Product packaging issues</i>		
Product closure issue	1	0
<i>Product physical issues</i>		
Liquid product physical issue	7	0
Product odour abnormal	1	0
Product physical issue	2	0
Product taste abnormal	9	0
<i>Product quality issues NEC</i>		
Product complaint	1	0
Product origin unknown	6	0
<i>Product supply and availability issues</i>		
Product availability issue	1	0
null SOC TOTAL	85	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Psychiatric disorders		
<i>Abnormal behaviour NEC</i>		
Abnormal behaviour	23	0
Behaviour disorder	1	0
Breath holding	6	0
Sexually inappropriate behaviour	1	0
Staring	6	0
<i>Adjustment disorders</i>		
Adjustment disorder with depressed mood	2	0
<i>Affect alterations NEC</i>		
Affect lability	10	0
Constricted affect	3	0
Flat affect	5	0
Inappropriate affect	16	0
<i>Amnesic symptoms</i>		
Paramnesia	5	0
<i>Anxiety disorders NEC</i>		
Anxiety disorder	1	0
Generalised anxiety disorder	1	0
Neurosis	1	0
<i>Anxiety symptoms</i>		
Agitation	63	0
Anxiety	650	0
Immunisation anxiety related reaction	2	0
Nervousness	139	0
Stress	77	0
Tension	34	0
<i>Attention deficit and disruptive behaviour disorders</i>		
Attention deficit hyperactivity disorder	5	0
<i>Behaviour and socialisation disturbances</i>		
Aggression	11	0
Aversion	1	0
Disinhibition	2	0
Indifference	6	0
Paranoia	22	0
Personality change	4	0
Social avoidant behaviour	5	0
Soliloquy	2	0
Suspiciousness	1	0
<i>Bipolar disorders</i>		
Bipolar I disorder	2	0
Bipolar disorder	4	0
<i>Cognitive and attention disorders and disturbances NEC</i>		
Daydreaming	7	0
Distractibility	1	0
Mental fatigue	178	0
<i>Communications disorders</i>		
Communication disorder	5	0
Mutism	2	0
<i>Confusion and disorientation</i>		
Confusional state	716	0
Disorientation	230	0
<i>Decreased physical activity levels</i>		
Catatonia	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Deliria</i>		
Delirium	85	0
<i>Delusional symptoms</i>		
Delusion	9	0
<i>Depressive disorders</i>		
Agitated depression	3	0
Depression	264	0
Depression suicidal	10	0
Major depression	6	0
Mixed anxiety and depressive disorder	3	0
<i>Dissociative states</i>		
Depersonalisation/derealisation disorder	8	0
Dissociation	23	0
Dissociative amnesia	2	0
Dissociative disorder	2	0
<i>Disturbances in initiating and maintaining sleep</i>		
Initial insomnia	17	0
Insomnia	1086	0
Middle insomnia	23	0
Terminal insomnia	29	0
<i>Dyssomnias</i>		
Dyssomnia	1	0
Poor quality sleep	172	0
<i>Eating disorders NEC</i>		
Bulimia nervosa	1	0
Eating disorder	10	0
Selective eating disorder	1	0
<i>Emotional and mood disturbances NEC</i>		
Anger	27	0
Dysphoria	2	0
Emotional disorder	45	0
Emotional distress	33	0
Emotional poverty	1	0
Euphoric mood	39	0
Frustration tolerance decreased	3	0
Irritability	166	0
Mood altered	49	0
<i>Factitious disorders</i>		
Factitious disorder	4	0
<i>Fear symptoms and phobic disorders (incl social phobia)</i>		
Agoraphobia	1	0
Fear	17	0
Fear of death	1	0
Fear of falling	3	0
Fear of injection	6	0
Osmophobia	1	0
Phobia	3	0
Phonophobia	2	0
Social anxiety disorder	1	0
Social fear	1	0
<i>Fluctuating mood symptoms</i>		
Mood swings	105	0
<i>Hallucinations (excl sleep-related)</i>		

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Hallucination	153	0
Hallucination, auditory	12	0
Hallucination, olfactory	10	0
Hallucination, tactile	1	0
Hallucination, visual	23	0
Hallucinations, mixed	2	0
Increased physical activity levels		
Restlessness	125	0
Infancy, childhood and adolescence psychiatric disorders NEC		
Social (pragmatic) communication disorder	1	0
Learning disorders		
Learning disability	1	0
Learning disorder	1	0
Mental disorders NEC		
Mental disorder	14	0
Mental status changes	1	0
Psychological factor affecting medical condition	1	0
Mood alterations with depressive symptoms		
Anhedonia	3	0
Decreased interest	9	0
Depressed mood	294	0
Depressive symptom	1	0
Feeling guilty	1	0
Feeling of despair	4	0
Feelings of worthlessness	1	0
Negative thoughts	1	0
Psychomotor retardation	2	0
Sense of a foreshortened future	2	0
Tearfulness	32	0
Mood alterations with manic symptoms		
Hypomania	2	0
Mania	9	0
Mood disorders NEC		
Affective disorder	2	0
Apathy	23	0
Boredom	1	0
Laziness	1	0
Listless	16	0
Mood disorder due to a general medical condition	1	0
Narcolepsy and associated conditions		
Hypnagogic hallucination	3	0
Hypnopompic hallucination	2	0
Sleep attacks	3	0
Obsessive-compulsive disorders and symptoms		
Obsessive-compulsive symptom	1	0
Orgasmic disorders and disturbances		
Anorgasmia	4	0
Female orgasmic disorder	2	0
Orgasm abnormal	4	0
Orgasmic sensation decreased	1	0
Premature ejaculation	1	0
Panic attacks and disorders		
Panic attack	151	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
Panic disorder	3	0
Panic reaction	23	0
Paraphilias and paraphilic disorders		
Transvestism	1	0
Parasomnias		
Abnormal dreams	148	0
Abnormal sleep-related event	1	0
Confusional arousal	1	0
Exploding head syndrome	2	0
Nightmare	166	0
Parasomnia	1	0
Sleep inertia	1	0
Sleep talking	6	0
Sleep terror	17	0
Somnambulism	4	0
Perception disturbances NEC		
Autoscopy	15	0
Deja vu	2	0
Derealisation	7	0
Flashback	3	0
Illusion	1	0
Near death experience	1	0
Time perception altered	2	0
Personality disorders NEC		
Personality disorder	1	0
Pervasive developmental disorders NEC		
Autism spectrum disorder	3	0
Psychiatric elimination disorders		
Enuresis	18	0
Psychiatric symptoms NEC		
Hypervigilance	9	0
Psychiatric symptom	3	0
Psychological trauma	2	0
Trance	1	0
Psychotic disorder NEC		
Psychotic behaviour	1	0
Psychotic disorder	18	0
Schizophrenia NEC		
Schizophrenia	1	0
Sexual arousal disorders		
Disturbance in sexual arousal	2	0
Sexual desire disorders		
Libido decreased	9	0
Libido increased	4	0
Loss of libido	13	0
Sleep disorders NEC		
Sleep disorder	164	0
Sleep disorder due to general medical condition, insomnia type	2	0
Somatic symptom disorders		
Conversion disorder	17	0
Habit cough	14	0
Somatic symptom disorder	1	0
Vomiting psychogenic	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Psychiatric disorders <small>Psychiatric disorders cont'd</small>		
<i>Speech and language usage disturbances</i>		
Disorganised speech	7	0
Logorrhoea	2	0
<i>Speech articulation and rhythm disturbances</i>		
Dysphemia	22	0
Lack of spontaneous speech	1	0
Pressure of speech	1	0
<i>Stereotypies and automatisms</i>		
Bruxism	10	0
Head banging	7	0
Stereotypy	1	0
<i>Stress disorders</i>		
Burnout syndrome	2	0
Post-traumatic stress disorder	2	0
<i>Substance related and addictive disorders</i>		
Alcohol problem	1	0
Alcoholic hangover	1	0
Alcoholism	2	0
Nicotine dependence	1	0
<i>Suicidal and self-injurious behaviour</i>		
Completed suicide	1	1
Intentional self-injury	6	0
Self-injurious ideation	2	0
Suicidal ideation	30	1
Suicide attempt	14	0
Suicide threat	1	0
<i>Thinking disturbances</i>		
Bradyphrenia	35	0
Intrusive thoughts	4	0
Morbid thoughts	1	0
Tachyphrenia	5	0
Thinking abnormal	16	0
Thought blocking	1	0
<i>Tic disorders</i>		
Tic	9	0
Psychiatric disorders SOC TOTAL	6312	2

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Renal & urinary disorders		
<i>Bladder and urethral symptoms</i>		
Bladder discomfort	2	0
Bladder irritation	6	0
Bladder pain	23	0
Bladder spasm	1	0
Dysuria	41	0
Incontinence	21	0
Lower urinary tract symptoms	2	0
Micturition disorder	1	0
Micturition urgency	33	0
Pollakiuria	94	0
Stress urinary incontinence	1	0
Urethral pain	6	0
Urge incontinence	1	0
Urinary hesitation	1	0
Urinary incontinence	45	0
Urinary retention	32	0
Urine flow decreased	9	0
<i>Bladder disorders NEC</i>		
Bladder disorder	6	0
Bladder fibrosis	1	0
Urinary bladder haemorrhage	2	0
<i>Bladder infections and inflammations</i>		
Cystitis interstitial	4	0
<i>Genital and urinary tract disorders NEC</i>		
Genitourinary symptom	1	0
Urinary tract disorder	4	0
<i>Glomerulonephritis and nephrotic syndrome</i>		
Glomerulonephritis minimal lesion	5	0
Glomerulonephritis rapidly progressive	1	0
IgA nephropathy	1	0
Nephrotic syndrome	15	0
<i>Myoneurogenic bladder disorders</i>		
Bladder dysfunction	5	0
Hypertonic bladder	1	0
Hypotonic urinary bladder	1	0
Loss of bladder sensation	1	0
Neurogenic bladder	2	0
<i>Nephritis NEC</i>		
Lupus nephritis	1	0
Nephritis	2	0
Tubulointerstitial nephritis	2	0
<i>Nephropathies and tubular disorders NEC</i>		
Nephropathy	1	0
<i>Renal disorders NEC</i>		
Renal disorder	4	1
Renal haemorrhage	1	0
Renal mass	1	0
<i>Renal failure and impairment</i>		
Acute kidney injury	40	4
Anuria	3	0
Chronic kidney disease	4	0
Oliguria	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Renal & urinary disorders		
Renal & urinary disorders cont'd		
Renal failure	15	1
Renal impairment	17	0
Renal injury	1	0
Renal lithiasis		
Nephrolithiasis	6	0
Renal neoplasms		
Renal cyst	1	0
Renal obstructive disorders		
Hydronephrosis	2	0
Renal structural abnormalities and trauma		
Kidney small	1	0
Renal vascular and ischaemic conditions		
Renal infarct	1	0
Renal tubular necrosis	1	0
Renal vasculitis	1	1
Structural and obstructive urethral disorders (excl congenital)		
Urethral stenosis	1	0
Ureteric disorders NEC		
Ureteric stenosis	1	0
Urinary abnormalities		
Albuminuria	1	0
Chromaturia	42	0
Haematuria	29	0
Ketonuria	1	0
Myoglobinuria	1	0
Proteinuria	8	0
Urine abnormality	8	0
Urine odour abnormal	5	0
Urinary tract lithiasis (excl renal)		
Calculus urinary	1	0
Urinary tract signs and symptoms NEC		
Costovertebral angle tenderness	1	0
Cystitis-like symptom	1	0
Haemorrhage urinary tract	18	0
Nocturia	3	0
Polyuria	6	0
Renal colic	4	0
Renal pain	218	0
Urinary tract discomfort	1	0
Urinary tract pain	4	0
Renal & urinary disorders SOC TOTAL	829	7

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Benign and malignant breast neoplasms</i>		
Breast cyst	9	0
<i>Breast disorders NEC</i>		
Breast disorder	1	0
Breast enlargement	20	0
Breast mass	91	0
Gynaecomastia	3	0
Mastoptosis	1	0
<i>Breast infections and inflammations</i>		
Breast inflammation	1	0
Nipple inflammation	1	0
<i>Breast signs and symptoms</i>		
Breast discharge	3	0
Breast discomfort	8	0
Breast engorgement	7	0
Breast haematoma	1	0
Breast oedema	4	0
Breast pain	473	0
Breast swelling	98	0
Breast tenderness	53	0
Nipple pain	27	1
Nipple swelling	3	0
<i>Cervix disorders NEC</i>		
Cervical dysplasia	2	0
Cervix disorder	1	0
Cervix haemorrhage uterine	2	0
Ectropion of cervix	2	0
<i>Cervix neoplasms</i>		
Cervical polyp	1	0
<i>Erection and ejaculation conditions and disorders</i>		
Ejaculation disorder	2	0
Ejaculation failure	2	0
Erectile dysfunction	37	0
Erection increased	2	0
Organic erectile dysfunction	12	0
Painful ejaculation	1	0
Spontaneous ejaculation	1	0
<i>Fallopian tube and ovary infections and inflammations</i>		
Noninfective oophoritis	2	0
<i>Lactation disorders</i>		
Breast milk discolouration	3	0
Breast milk odour abnormal	1	0
Galactorrhoea	5	0
Galactostasis	1	0
Lactation disorder	6	0
Lactation puerperal increased	4	0
Suppressed lactation	18	0
<i>Menopausal effects NEC</i>		
Artificial menopause	1	0
Menopausal symptoms	13	0
Menopause delayed	1	0
Premature menopause	12	0
<i>Menopausal effects on the genitourinary tract</i>		

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
Atrophic vulvovaginitis	1	0
Postmenopausal haemorrhage	68	0
Menstruation and uterine bleeding NEC		
Abnormal uterine bleeding	5	0
Dysmenorrhoea	1999	0
Intermenstrual bleeding	780	0
Menstrual discomfort	17	0
Menstrual disorder	1204	0
Menstruation irregular	2106	0
Premenstrual dysphoric disorder	7	0
Premenstrual headache	5	0
Premenstrual pain	76	0
Premenstrual syndrome	89	0
Retrograde menstruation	1	0
Withdrawal bleed	12	0
Menstruation with decreased bleeding		
Amenorrhoea	413	0
Hypomenorrhoea	474	0
Menstruation delayed	3383	0
Oligomenorrhoea	99	0
Menstruation with increased bleeding		
Heavy menstrual bleeding	3823	0
Menometrorrhagia	15	0
Polymenorrhoea	556	0
Ovarian and fallopian tube cysts and neoplasms		
Ovarian cyst	8	0
Polycystic ovaries	34	0
Ovarian and fallopian tube disorders NEC		
Adnexal torsion	1	0
Hydrosalpinx	2	0
Ovarian haemorrhage	4	0
Ovulation disorder	1	0
Ovulation pain	41	0
Premature ovulation	4	0
Pelvis and broad ligament disorders NEC		
Adnexa uteri mass	1	0
Adnexa uteri pain	39	0
Pelvic congestion	1	0
Pelvic floor muscle weakness	1	0
Pelvic haemorrhage	15	0
Penile and scrotal infections and inflammations		
Balanoposthitis	2	0
Penile disorders NEC (excl erection and ejaculation)		
Penile discomfort	1	0
Penile erythema	1	0
Penile haemorrhage	2	0
Penile pain	1	0
Penile size reduced	2	0
Penile swelling	4	0
Penis disorder	8	0
Prostate and seminal vesicles infections and inflammations		
Prostatitis	3	0
Prostatic signs, symptoms and disorders NEC		

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
Prostatic pain	1	0
Prostatomegaly	3	0
Reproductive tract disorders NEC (excl neoplasms)		
Genital haemorrhage	16	0
Genital hypoaesthesia	1	0
Genital lesion	1	0
Genital paraesthesia	1	0
Genital ulceration	5	0
Perineal ulceration	1	0
Reproductive tract infections and inflammations NEC		
Genital tract inflammation	1	0
Reproductive tract signs and symptoms NEC		
Genital burning sensation	2	0
Genital pain	3	0
Genital rash	3	0
Genital swelling	2	0
Pelvic discomfort	5	0
Pelvic pain	77	0
Perineal pain	2	0
Perineal rash	1	0
Pruritus genital	3	0
Scrotal disorders NEC		
Acquired hydrocele	1	0
Scrotal angiokeratoma	1	0
Scrotal discomfort	1	0
Scrotal erythema	1	0
Scrotal exfoliation	1	0
Scrotal pain	12	0
Scrotal swelling	4	0
Varicocele	1	0
Sexual function and fertility disorders NEC		
Dyspareunia	4	0
Infertility	4	0
Sexual dysfunction	4	0
Spermatogenesis and semen disorders		
Aspermia	1	0
Haematospermia	6	0
Semen discolouration	1	0
Testicular and epididymal disorders NEC		
Testicular disorder	2	0
Testicular pain	39	0
Testicular swelling	6	0
Testis discomfort	1	0
Uterine disorders NEC		
Adenomyosis	7	0
Endometrial thickening	2	0
Endometriosis	69	0
Uterine haemorrhage	23	0
Uterine pain	13	0
Uterine infections and inflammations (excl cervix)		
Uterine inflammation	1	0
Uterine neoplasms		
Uterine polyp	4	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021

Data Lock Date: 25-Aug-2021 18:30:56

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Reproductive & breast disorders		
<i>Reproductive & breast disorders cont'd</i>		
<i>Uterine tone disorders</i>		
Uterine spasm	24	0
<i>Vulvovaginal cysts and neoplasms</i>		
Bartholin's cyst	1	0
Vaginal cyst	5	0
Vaginal polyp	1	0
<i>Vulvovaginal disorders NEC</i>		
Vaginal haemorrhage	1044	0
Vaginal mucosal blistering	1	0
Vaginal ulceration	1	0
Vulval disorder	1	0
Vulval haemorrhage	17	0
Vulval ulceration	5	0
Vulvovaginal ulceration	3	0
<i>Vulvovaginal signs and symptoms</i>		
Clitoral engorgement	1	0
Coital bleeding	2	0
Labia enlarged	1	0
Vaginal discharge	56	0
Vaginal lesion	1	0
Vaginal odour	1	0
Vulval oedema	1	0
Vulvovaginal burning sensation	3	0
Vulvovaginal dryness	3	0
Vulvovaginal erythema	1	0
Vulvovaginal pain	21	0
Vulvovaginal pruritus	6	0
Vulvovaginal rash	2	0
Vulvovaginal swelling	2	0
Reproductive & breast disorders SOC TOTAL	17786	1

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders		
<i>Breathing abnormalities</i>		
Apnoea	5	0
Apnoeic attack	1	0
Dyspnoea	3387	6
Dyspnoea at rest	9	0
Dyspnoea exertional	31	1
Hyperventilation	40	0
Hypopnoea	84	0
Hypoventilation	1	0
Irregular breathing	18	0
Mouth breathing	3	0
Nocturnal dyspnoea	2	0
Orthopnoea	3	0
Respiration abnormal	42	0
Respiratory arrest	14	0
Respiratory depression	1	0
Respiratory distress	16	0
Sleep apnoea syndrome	10	0
Tachypnoea	23	0
<i>Bronchial conditions NEC</i>		
Bronchial secretion retention	2	0
Bronchiectasis	11	0
<i>Bronchospasm and obstruction</i>		
Asthma	274	0
Asthma late onset	2	0
Bronchospasm	15	0
Chronic obstructive pulmonary disease	14	1
Cough variant asthma	4	0
Obstructive airways disorder	8	0
Reversible airways obstruction	1	0
Wheezing	323	0
<i>Conditions associated with abnormal gas exchange</i>		
Asphyxia	1	0
Cyanosis central	1	0
Hyperoxia	1	0
Hypoxia	22	1
Respiratory acidosis	2	0
<i>Coughing and associated symptoms</i>		
Allergic cough	5	0
Cough	1901	2
Cough decreased	2	0
Haemoptysis	45	0
Productive cough	127	0
Sputum discoloured	5	0
Sputum increased	2	0
<i>Diaphragmatic disorders</i>		
Diaphragm muscle weakness	1	0
<i>Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)</i>		
Laryngeal disorder	1	0
Reflux laryngitis	1	0
Vocal cord disorder	1	0
Vocal cord dysfunction	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
<i>Laryngeal spasm, oedema and obstruction</i>		
Epiglottic oedema	1	0
Laryngeal obstruction	1	0
Laryngeal oedema	2	0
Laryngospasm	1	0
Stridor	20	0
<i>Lower respiratory tract inflammatory and immunologic conditions</i>		
Alveolitis	1	0
Hypersensitivity pneumonitis	1	0
Lower respiratory tract inflammation	1	0
Pneumonia aspiration	8	5
Pneumonitis	25	1
Pulmonary sarcoidosis	2	0
<i>Lower respiratory tract signs and symptoms</i>		
Hiccups	25	0
Increased bronchial secretion	1	0
Lung opacity	2	0
Pleuritic pain	15	0
Pulmonary haemorrhage	1	0
Pulmonary pain	71	0
Rales	4	0
Respiratory fremitus	1	0
<i>Mediastinal disorders</i>		
Mediastinal mass	1	0
<i>Nasal congestion and inflammations</i>		
Nasal congestion	230	0
Nasal inflammation	2	0
Rhinitis allergic	16	0
<i>Nasal disorders NEC</i>		
Epistaxis	738	0
Intranasal hyposensitivity	1	0
Intranasal paraesthesia	1	0
Nasal crusting	1	0
Nasal disorder	3	0
Nasal dryness	29	0
Nasal mucosal discolouration	1	0
Nasal odour	6	0
Nasal oedema	5	0
Nasal polyps	1	0
Nasal pruritus	9	0
<i>Neonatal hypoxic conditions</i>		
Dry lung syndrome	1	0
Gasping syndrome	1	0
Infantile apnoea	1	0
<i>Paranasal sinus disorders (excl infections and neoplasms)</i>		
Allergic sinusitis	1	0
Paranasal sinus inflammation	2	0
Sinonasal obstruction	9	0
Sinus congestion	47	0
Sinus disorder	5	0
<i>Parenchymal lung disorders NEC</i>		
Atelectasis	1	0
Combined pulmonary fibrosis and emphysema	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Emphysema	2	0
Interstitial lung disease	9	0
Lung consolidation	1	0
Lung infiltration	1	0
Pulmonary alveolar haemorrhage	1	0
Pulmonary cavitation	1	0
Pulmonary fibrosis	4	0
<i>Pharyngeal disorders (excl infections and neoplasms)</i>		
Pharyngeal enanthema	1	0
Pharyngeal erythema	6	0
Pharyngeal haemorrhage	2	0
Pharyngeal hypoaesthesia	31	0
Pharyngeal inflammation	4	0
Pharyngeal oedema	12	0
Pharyngeal paraesthesia	50	0
Pharyngeal swelling	204	0
Pharyngeal ulceration	14	0
Tonsillar erythema	8	0
Tonsillar haemorrhage	1	0
Tonsillar hypertrophy	64	0
Tonsillar inflammation	3	0
Tonsillar ulcer	1	0
Tonsillolith	1	0
<i>Pleural infections and inflammations</i>		
Pleurisy	27	0
<i>Pneumothorax and pleural effusions NEC</i>		
Pleural effusion	18	0
Pneumothorax	7	0
Pneumothorax spontaneous	2	0
<i>Pulmonary hypertensions</i>		
Pulmonary hypertension	2	0
<i>Pulmonary oedemas</i>		
Acute respiratory distress syndrome	2	1
Pulmonary congestion	11	0
Pulmonary oedema	18	1
<i>Pulmonary thrombotic and embolic conditions</i>		
Pulmonary embolism	370	24
Pulmonary infarction	4	0
Pulmonary thrombosis	6	1
<i>Respiratory failures (excl neonatal)</i>		
Acute respiratory failure	2	1
Respiratory failure	10	2
<i>Respiratory signs and symptoms NEC</i>		
Allergic respiratory symptom	5	0
Diaphragmalgia	5	0
Nasal flaring	1	0
Painful respiration	8	1
Pleural rub	1	0
Respiratory symptom	14	0
Suffocation feeling	2	0
<i>Respiratory tract disorders NEC</i>		
Aspiration	3	0
Lung disorder	3	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Respiratory disorders <small>Respiratory disorders cont'd</small>		
Pulmonary mass	4	0
Respiratory disorder	10	0
Respiratory tract congestion	3	0
Respiratory tract haemorrhage	1	0
Respiratory tract inflammation	2	0
Respiratory tract irritation	5	0
Respiratory tract oedema	3	0
<i>Thoracic musculoskeletal disorders</i>		
Respiratory muscle weakness	2	0
<i>Tracheal disorders (excl infections and neoplasms)</i>		
Tracheal disorder	1	0
Tracheal pain	1	0
<i>Upper respiratory tract neoplasms</i>		
Tonsillar cyst	1	0
<i>Upper respiratory tract signs and symptoms</i>		
Aphonia	90	0
Catarrh	17	0
Choking	13	0
Choking sensation	3	0
Dry throat	138	0
Dysphonia	135	0
Increased upper airway secretion	5	0
Increased viscosity of upper respiratory secretion	26	0
Nasal discharge discolouration	3	0
Nasal discomfort	42	0
Nasal obstruction	2	0
Oropharyngeal blistering	10	0
Oropharyngeal discomfort	50	0
Oropharyngeal pain	2322	0
Oropharyngeal plaque	2	0
Paranasal sinus discomfort	37	0
Rhinalgia	11	0
Rhinorrhoea	717	0
Sinus pain	170	0
Sneezing	298	0
Snoring	7	0
Throat clearing	8	0
Throat irritation	200	0
Throat tightness	211	0
Upper airway obstruction	2	0
Upper respiratory tract irritation	1	0
Upper-airway cough syndrome	7	0
Yawning	22	0
<i>Vascular pulmonary disorders NEC</i>		
Acute chest syndrome	1	0
Respiratory disorders SOC TOTAL	13284	48

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders		
<i>Acnes</i>		
Acne	145	0
Acne cystic	13	0
Dermatitis acneiform	8	0
<i>Alopecias</i>		
Alopecia	175	0
Alopecia areata	28	0
Alopecia totalis	2	0
Androgenetic alopecia	1	0
Diffuse alopecia	2	0
Hypotrichosis	1	0
Madarosis	3	0
<i>Angioedemas</i>		
Angioedema	166	0
Circumoral swelling	1	0
<i>Apocrine and eccrine gland disorders</i>		
Anhidrosis	1	0
Bromhidrosis	1	0
Cold sweat	601	0
Hidradenitis	2	0
Hyperhidrosis	1739	0
Hypohidrosis	1	0
Milia	2	0
Miliaria	75	0
Night sweats	476	0
<i>Bullous conditions</i>		
Blister	371	0
Blister rupture	1	0
Blood blister	22	0
Dermatitis bullous	10	0
Erythema multiforme	32	0
Fracture blisters	1	0
Herpes gestationis	1	0
Pemphigoid	21	0
Pemphigus	5	0
Stevens-Johnson syndrome	4	0
Toxic epidermal necrolysis	2	1
<i>Connective tissue disorders</i>		
Cutaneous lupus erythematosus	1	0
Dermatomyositis	4	0
Subacute cutaneous lupus erythematosus	1	0
<i>Dermal and epidermal conditions NEC</i>		
Acute febrile neutrophilic dermatosis	1	0
Dermatosis	1	0
Dry skin	175	0
Macule	4	0
Neutrophilic dermatosis	1	0
Pain of skin	217	0
Papule	94	0
Pathergy reaction	1	0
Peau d'orange	2	0
Scab	17	0
Scar pain	12	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Sensitive skin	138	0
Skin burning sensation	176	0
Skin degenerative disorder	1	0
Skin discolouration	104	0
Skin discomfort	3	0
Skin disorder	15	0
Skin fissures	8	0
Skin indentation	2	0
Skin induration	3	0
Skin lesion	35	0
Skin lesion inflammation	1	0
Skin necrosis	1	0
Skin odour abnormal	15	0
Skin plaque	2	0
Skin reaction	116	0
Skin sensitisation	28	0
Skin swelling	69	0
Skin texture abnormal	1	0
Skin tightness	24	0
Skin warm	237	0
Skin weeping	9	0
Sticky skin	1	0
Target skin lesion	2	0
Transient acantholytic dermatosis	1	0
Yellow skin	20	0
<i>Dermatitis and eczema</i>		
Dermatitis	93	0
Dermatitis allergic	186	0
Dermatitis atopic	26	0
Dermatitis contact	13	0
Dermatitis diaper	3	0
Dyshidrotic eczema	21	0
Eczema	225	0
Eczema asteatotic	7	0
Eczema infantile	1	0
Eczema nummular	4	0
Eczema weeping	1	0
Hand dermatitis	1	0
Intertrigo	1	0
Perioral dermatitis	1	0
Seborrhoeic dermatitis	3	0
Skin irritation	92	0
<i>Dermatitis ascribed to specific agent</i>		
Drug eruption	27	0
Drug reaction with eosinophilia and systemic symptoms	1	0
Fixed eruption	2	0
Toxic skin eruption	2	0
<i>Erythemas</i>		
Erythema	1741	0
Palmar erythema	4	0
Red man syndrome	2	0
<i>Exfoliative conditions</i>		
Dermatitis exfoliative	2	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Dermatitis exfoliative generalised	4	0
Exfoliative rash	18	0
Keratolysis exfoliativa acquired	2	0
Skin exfoliation	88	0
<i>Granulomatous and deep cutaneous inflammatory conditions</i>		
Cutaneous sarcoidosis	1	0
Granuloma annulare	2	0
<i>Hyperkeratoses</i>		
Hyperkeratosis	1	0
Keratosis pilaris	3	0
Lichenoid keratosis	3	0
<i>Hyperpigmentation disorders</i>		
Argyria	1	0
Chloasma	1	0
Ephelides	1	0
Skin hyperpigmentation	3	0
Solar lentigo	2	0
<i>Hypertrichoses</i>		
Hirsutism	1	0
<i>Hypopigmentation disorders</i>		
Skin depigmentation	4	0
Skin hypopigmentation	1	0
Vitiligo	9	0
<i>Lipodystrophies</i>		
Lipoatrophy	4	0
Lipodystrophy acquired	1	0
<i>Nail and nail bed conditions (excl infections and infestations)</i>		
Nail discolouration	8	0
Nail disorder	3	0
Nail pigmentation	2	0
Nail ridging	2	0
Onychalgia	7	0
Onychoclasia	4	0
Onychomadesis	2	0
Splinter haemorrhages	3	0
<i>Panniculitides</i>		
Erythema nodosum	21	0
Panniculitis	1	0
<i>Papulosquamous conditions</i>		
Erythema annulare	2	0
Lichen planus	14	0
Lichen sclerosus	7	0
Parapsoriasis	2	0
Pityriasis rosea	86	0
<i>Photosensitivity and photodermatosis conditions</i>		
Photosensitivity reaction	53	0
Polymorphic light eruption	2	0
Solar dermatitis	1	0
<i>Pigmentation changes NEC</i>		
Haemosiderin stain	1	0
Pigmentation disorder	10	0
<i>Pilar disorders NEC</i>		
Hair colour changes	8	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Hair disorder	1	0
Hair growth abnormal	4	0
Hair texture abnormal	5	0
Piloerection	23	0
Pseudofolliculitis	2	0
Trichorrhexis	2	0
Pruritus NEC		
Itching scar	5	0
Pruritus	4186	0
Psoriatic conditions		
Dermatitis psoriasiform	2	0
Guttate psoriasis	13	0
Nail psoriasis	1	0
Palmoplantar pustulosis	2	0
Psoriasis	131	0
Pustular psoriasis	2	0
Purpura and related conditions		
Henoch-Schonlein purpura	5	0
Petechiae	115	0
Purpura	41	0
Pustular conditions		
Acute generalised exanthematous pustulosis	1	0
Rashes, eruptions and exanthems NEC		
Butterfly rash	4	0
Rash	4481	0
Rash erythematous	942	0
Rash macular	418	0
Rash maculo-papular	48	0
Rash morbilliform	36	0
Rash papular	276	0
Rash pruritic	944	0
Rash vesicular	56	0
Systemic lupus erythematosus rash	6	0
Rosaceas		
Rosacea	24	0
Scaly conditions		
Dandruff	4	0
Pityriasis	19	0
Sebaceous gland disorders		
Seborrhoea	9	0
Skin and subcutaneous conditions NEC		
Cutaneous symptom	4	0
Reactive perforating collagenosis	1	0
Skin mass	16	0
Skin and subcutaneous tissue ulcerations		
Mucocutaneous ulceration	1	0
Scleroderma associated digital ulcer	1	0
Skin erosion	19	0
Skin ulcer	13	0
Skin cysts and polyps		
Dermal cyst	10	0
Skin dystrophies		
Keloid scar	3	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Skin disorders Skin disorders cont'd		
Skin wrinkling	2	0
Skin haemorrhages		
Haemorrhage subcutaneous	6	0
Skin haemorrhage	14	0
Skin hyperplasias and hypertrophies		
Skin hypertrophy	2	0
Skin hypoplasias and atrophies		
Skin atrophy	1	0
Skin striae	7	0
Skin injuries and mechanical dermatoses		
Decubitus ulcer	2	0
Needle track marks	2	0
Skin preneoplastic conditions NEC		
Actinic keratosis	1	0
Skin vascular conditions NEC		
Skin oedema	4	0
Skin vasculitides		
Capillaritis	2	0
Cutaneous vasculitis	10	0
Hypersensitivity vasculitis	1	0
Vasculitic rash	18	0
Skin vasomotor conditions		
Livedo reticularis	19	0
Telangiectasia and related conditions		
Spider naevus	1	0
Telangiectasia	1	0
Urticarias		
Chronic spontaneous urticaria	3	0
Cold urticaria	4	0
Idiopathic urticaria	1	0
Mechanical urticaria	5	0
Solar urticaria	2	0
Urticaria	1434	0
Urticaria cholinergic	1	0
Urticaria chronic	14	0
Urticaria contact	1	0
Urticaria papular	3	0
Urticaria thermal	4	0
Urticularial vasculitis	3	0
Skin disorders SOC TOTAL	21748	1

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Social circumstances		
<i>Age related issues</i>		
Infant	2	0
Menopause	23	0
Postmenopause	3	0
<i>Criminal activity</i>		
Verbal abuse	1	0
<i>Dependents</i>		
Sick relative	4	0
<i>Dietary and nutritional issues</i>		
Feeding tube user	1	0
<i>Disability issues</i>		
Bedridden	20	0
Breast prosthesis user	3	0
Disability	2	0
Hearing disability	1	0
Housebound	1	0
Immobile	12	0
Impaired driving ability	4	0
Impaired work ability	7	0
Loss of personal independence in daily activities	35	0
Physical disability	3	0
Sight disability	8	0
Sitting disability	1	0
Walking disability	1	0
Wheelchair user	1	0
<i>Economic circumstances</i>		
High income	1	0
Low income	1	0
<i>Employment issues</i>		
Retirement	4	0
Stress at work	1	0
<i>Family and partner issues</i>		
Bed sharing	1	0
<i>Non-occupational and unspecified environmental problems</i>		
Flooding	1	0
Water pollution	2	0
<i>Pregnancy related circumstances</i>		
Breast feeding	15	0
Multigravida	1	0
Parity	1	0
<i>Social issues NEC</i>		
Hair dye user	2	0
Impaired quality of life	1	0
<i>Tobacco use</i>		
Ex-tobacco user	1	0
Non-tobacco user	4	0
Tobacco user	1	0
Social circumstances SOC TOTAL	170	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Anaesthesia and allied procedures</i>		
Local anaesthesia	2	0
Nerve block	4	0
<i>Analgesia supportive care</i>		
Analgesic therapy	1	0
<i>Antiinfective therapies</i>		
COVID-19 treatment	3	0
<i>Arterial therapeutic procedures (excl aortic)</i>		
Splenic artery embolisation	1	0
<i>Autonomic nerve therapeutic procedures</i>		
Vagotomy	1	0
<i>Blood and blood product treatment</i>		
Transfusion	2	0
<i>Breast therapeutic procedures NEC</i>		
Axillary lymphadenectomy	3	0
Mammoplasty	1	0
<i>Bronchial and pulmonary therapeutic procedures</i>		
Airway secretion clearance therapy	1	0
<i>Cardiac therapeutic procedures NEC</i>		
Cardiac operation	1	0
<i>Contraceptive methods female</i>		
Contraception	1	0
Contraceptive implant	2	0
Oral contraception	1	0
<i>Contraceptive methods male</i>		
Condom	1	0
<i>Dietary and nutritional therapies</i>		
Medical diet	8	0
Nothing by mouth order	5	0
Wheat-free diet	1	0
<i>External ear therapeutic procedures</i>		
Ear irrigation	1	0
<i>Fertility and fertilisation interventions female</i>		
Endometrial scratching	1	0
<i>Gastrointestinal therapeutic procedures NEC</i>		
Intestinal anastomosis	1	0
Prophylaxis of nausea and vomiting	13	0
<i>Gynaecological therapeutic procedures NEC</i>		
Menstrual cycle management	8	0
<i>Haematological therapeutic procedures NEC</i>		
Anticoagulant therapy	1	0
<i>Head, neck and oral cavity therapeutic procedures NEC</i>		
Neck lift	1	0
<i>Hernia repairs</i>		
Hernia repair	1	0
<i>Hormonal therapeutic procedures NEC</i>		
Hormone replacement therapy	1	0
Hormone therapy	7	0
<i>Immunisations</i>		
COVID-19 immunisation	77	0
Immunisation	52	0
<i>Joint therapeutic procedures</i>		
Joint surgery	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Surgical & medical procedures		
<i>Surgical & medical procedures cont'd</i>		
Knee arthroplasty	1	0
Large intestine therapeutic procedures		
Appendectomy	2	0
Limb therapeutic procedures		
Leg amputation	1	0
Limb immobilisation	7	0
Limb operation	5	0
Lymphoid tissue therapeutic procedures		
Lymphadenectomy	1	0
Splenectomy	1	0
Mastectomies		
Breast conserving surgery	3	0
Nail therapeutic procedures		
Nail operation	3	0
Nervous system therapeutic procedures NEC		
Multiple sclerosis relapse prophylaxis	2	0
Orbit and globe therapeutic procedures		
Strabismus correction	1	0
Peripheral nerve therapeutic procedures		
Neurolysis	1	0
Peripheral nerve neurostimulation	1	0
Phototherapies		
UV light therapy	1	0
Prophylactic procedures NEC		
Anaphylaxis prophylaxis	2	0
Immune tolerance induction	1	0
Prophylaxis against transplant rejection	1	0
Reproductive system disorder prophylaxis	1	0
Psychiatric therapies		
Electroconvulsive therapy	1	0
Renal therapeutic procedures		
Dialysis	1	0
Respiratory tract therapeutic procedures NEC		
Asthma prophylaxis	3	0
Retinal therapeutic procedures		
Retinopexy	1	0
Skin and subcutaneous tissue therapeutic procedures NEC		
Dermal filler injection	4	0
Skull and brain therapeutic procedures		
Posterior fossa decompression	1	0
Therapeutic bladder catheterisation		
Bladder catheterisation	1	0
Therapeutic procedures NEC		
Abscess drainage	1	0
Anaphylaxis treatment	4	0
Bed rest	2	0
Fatigue management	1	0
Hospitalisation	10	0
Injection	41	0
Interchange of vaccine products	4	0
Localised alternating hot and cold therapy	1	0
Magnetic therapy	1	0
Mass excision	2	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021

Data Lock Date: 25-Aug-2021 18:30:56

Earliest Reaction Date: 13-Apr-1968

MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Surgical & medical procedures		
Surgical & medical procedures cont'd		
Medical procedure	1	0
Medication dilution	2	0
Physical fitness training	1	0
Product used for unknown indication	2	0
Specialist consultation	1	0
Therapeutic procedure	1	0
Therapy change	1	0
Tracheal therapeutic procedures		
Tracheostomy	1	0
Uterine therapeutic procedures		
Endometrial ablation	1	0
Surgical & medical procedures SOC TOTAL	329	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders		
<i>Accelerated and malignant hypertension</i>		
Hypertensive crisis	10	0
Hypertensive urgency	1	0
Malignant hypertension	3	0
<i>Aneurysms and dissections non-site specific</i>		
Aneurysm	1	0
Artery dissection	1	0
<i>Aortic aneurysms and dissections</i>		
Acute aortic syndrome	1	0
Aortic aneurysm rupture	1	1
Aortic dissection	1	0
<i>Aortic embolism and thrombosis</i>		
Aortic embolus	5	0
Aortic thrombosis	2	0
<i>Arterial infections and inflammations</i>		
Arteritis	1	0
Giant cell arteritis	10	0
<i>Blood pressure disorders NEC</i>		
Blood pressure fluctuation	10	0
Labile blood pressure	3	0
<i>Bruising, ecchymosis and purpura</i>		
Achenbach syndrome	3	0
<i>Circulatory collapse and shock</i>		
CT hypotension complex	2	0
Circulatory collapse	58	0
Hypoperfusion	1	0
Hypovolaemic shock	1	1
Neurogenic shock	21	0
Peripheral circulatory failure	5	0
Shock	18	0
<i>Haemorrhages NEC</i>		
Bloody discharge	17	0
Haematoma	36	0
Haemorrhage	885	2
Internal haemorrhage	6	0
Venous haemorrhage	2	0
<i>Lymphangiopathies</i>		
Lymphangiopathy	1	0
Lymphocele	4	0
<i>Lymphoedemas</i>		
Lymphoedema	155	0
<i>Non-site specific embolism and thrombosis</i>		
Arterial thrombosis	3	0
Embolism	60	0
Embolism venous	5	0
Microembolism	1	0
Thrombosis	365	7
Venous thrombosis	6	0
<i>Non-site specific necrosis and vascular insufficiency NEC</i>		
Arterial occlusive disease	2	0
Arterial spasm	1	0
Arteriosclerosis	1	0
Haemorrhagic infarction	1	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders Vascular disorders cont'd		
Infarction	3	0
Ischaemia	7	0
Vasospasm	1	0
Non-site specific vascular disorders NEC		
Capillary disorder	1	0
Capillary fragility	1	0
Superficial vein prominence	1	0
Vascular pain	24	0
Vasodilatation	29	0
Vein discolouration	5	0
Vein disorder	6	0
Vein rupture	4	0
Peripheral embolism and thrombosis		
Axillary vein thrombosis	1	0
Blue toe syndrome	22	0
Deep vein thrombosis	246	1
Femoral artery embolism	1	0
Jugular vein thrombosis	3	0
Pelvic venous thrombosis	4	0
Peripheral artery thrombosis	1	0
Peripheral embolism	1	0
Subclavian vein thrombosis	3	0
Thrombophlebitis	18	0
Thrombophlebitis superficial	10	0
Peripheral vascular disorders NEC		
Cyanosis	36	0
Erythromelalgia	1	0
Flushing	357	0
Hot flush	923	0
Peripheral vascular disorder	1	0
Peripheral vasoconstriction, necrosis and vascular insufficiency		
Claudication of jaw muscles	1	0
Extremity necrosis	2	0
Intermittent claudication	2	0
Ischaemic limb pain	1	0
Jugular vein occlusion	1	0
Peripheral arterial occlusive disease	2	0
Peripheral artery occlusion	1	0
Peripheral coldness	260	0
Peripheral ischaemia	12	0
Poor peripheral circulation	12	0
Raynaud's phenomenon	47	0
Vasoconstriction	2	0
Phlebitis NEC		
Phlebitis	25	0
Phlebitis superficial	6	0
Site specific vascular disorders NEC		
Inferior vena cava dilatation	1	0
Pallor	277	0
Varicose veins NEC		
Spider vein	5	0
Varicophlebitis	4	0
Varicose vein	20	0

Case Series Drug Analysis Print

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

Report Run Date: 26-Aug-2021
 Earliest Reaction Date: 13-Apr-1968

Data Lock Date: 25-Aug-2021 18:30:56
 MedDRA Version: MedDRA 24.0

Reaction Name	Total	Fatal
Vascular disorders <small>Vascular disorders cont'd</small>		
<i>Vascular hypertensive disorders NEC</i>		
Diastolic hypertension	2	0
Essential hypertension	3	0
Hypertension	454	1
Labile hypertension	1	0
Orthostatic hypertension	1	0
Secondary hypertension	1	0
Systolic hypertension	5	0
White coat hypertension	1	0
<i>Vascular hypotensive disorders</i>		
Hypotension	316	0
Orthostatic hypotension	28	0
<i>Vasculitides NEC</i>		
Behcet's syndrome	4	0
Diffuse vasculitis	1	0
Granulomatosis with polyangiitis	1	0
MAGIC syndrome	1	0
Thromboangiitis obliterans	1	0
Vasculitis	40	0
<i>Vena caval embolism and thrombosis</i>		
Vena cava embolism	1	0
Vena cava thrombosis	1	0
Vascular disorders SOC TOTAL	4963	13
TOTAL REACTIONS FOR DRUG	309612	509
TOTAL REPORTS	109660	
TOTAL FATAL OUTCOME REPORTS		509